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; LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATIONAL HISPANIC MEDICAL ASSOCIATION; PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE; UNITED FARM WORKERS; GREENLATINOS, *Petitioners*, v. MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency; U.S. ENVIRONMENTAL PROTECTION AGENCY, *Respondents.*	No. 19-71979 EPA No. EPA-HQ-OPP-2007-1005

STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF WASHINGTON; STATE OF MARYLAND; STATE OF VERMONT; COMMONWEALTH OF MASSACHUSETTS,
Petitioners,

DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF OREGON,
Intervenors,

v.

MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency; U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

No. 19-71982

EPA No. EPA-HQ-OPP-2007-1005

OPINION

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

Argued and Submitted July 28, 2020
San Francisco, California

Filed April 29, 2021

Before: Jay S. Bybee and Jacqueline H. Nguyen, Circuit Judges, and Jed S. Rakoff,* District Judge.

Opinion by Judge Rakoff;
Dissent by Judge Bybee

SUMMARY**

Environmental Protection Agency

The panel granted petitions for review, vacated the Environmental Protection Agency ("EPA")'s 2017 Order and 2019 Order, and remanded with instructions to the EPA in cases challenging the EPA's regulation of the pesticide chlorpyrifos.

The EPA has recognized that when pregnant mothers are exposed to chlorpyrifos residue, this likely harms infants *in utero*. This proceeding began in 2007, when two environmental non-profit organizations filed a petition asking the EPA to prohibit foods that contain residue of the insecticide chlorpyrifos. The EPA declined to take final action on the 2007 Petition for more than a decade. This Court issued multiple writs of mandamus requiring the EPA to move forward. In 2017, the EPA denied the 2007 Petition, and in 2019 denied all objections to that decision.

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

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

The panel held that the EPA had abdicated its statutory duty under the Federal Food, Drug and Cosmetic Act ("FFDCA"). The panel held that the EPA spent more than a decade assembling a record of chlorpyrifos's ill effects and repeatedly determined, based on that record, that it could not conclude, to the statutorily required standard of reasonable certainty, that the present tolerances caused no harm. Rather than ban the pesticide or reduce the tolerances to levels that the EPA could find were reasonably certain to cause no harm, the EPA sought to evade through delay tactics its plain statutory duty. Because the FFDCA permitted no further delays, the panel ordered the EPA within 60 days after issuance of the mandate either to modify chlorpyrifos's tolerances and concomitantly publish a finding that the modified tolerances are safe, including for infants and children – or to revoke all chlorpyrifos tolerances. The panel also ordered the EPA to correspondingly modify or cancel related Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") regulations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

Specifically, the panel first considered whether the EPA lawfully denied the 2007 Petition. The panel rejected the EPA's argument that it could leave in effect tolerances, without a new safety finding, when the EPA concluded the petition contained insufficient evidence for the EPA to undertake proceedings to revoke or modify tolerances. The panel held, first, once the EPA became aware, through a petition or otherwise, of genuine questions about the safety of an existing tolerance, the EPA had its own continuing duty under the FFDCA to determine whether a tolerance that was once thought to be safe still is. Here, the EPA's own studies and pronouncements still in effect showed that it regarded chlorpyrifos as harmful at levels below the existing tolerances. Second, the 2007 Petition, under the EPA's own

regulations, contained more than sufficient evidence to undertake a safety review, and the EPA recognized as much. The panel held that when the EPA publishes a petition seeking revocation of a tolerance and later takes final action denying that petition, the EPA leaves that tolerance in effect. The EPA can only do so if it finds the tolerance to be safe for the general population and for infants and children. The EPA failed to make such findings, directly contrary to the FFDCA.

The panel held that even if the FFDCA did not require a safety finding here, the EPA's denial of the 2007 Petition was arbitrary and capricious. The panel rejected the EPA's four objections to the data.

The panel held that its remand with specific instructions did not raise due process concerns. On this record, immediate issuance of a final regulation was the only reasonable action, and the panel ordered the EPA to do so. The panel clarified that this was not an open-ended remand, or a remand for further factfinding.

Dissenting, Judge Bybee wrote that the majority opinion erred by misreading the FFDCA, and misallocating the risk of nonpersuasion; overruling the EPA's judgment on the validity and weight to be given technical evidence within the EPA's expertise; and, by its decision to give the EPA 60 days to issue a final decision, likely predetermining EPA's option.

COUNSEL

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OPINION

RAKOFF, District Judge:

This dispute concerning the documented health risks posed by a widely used pesticide, chlorpyrifos, has been before this Court more than a half-dozen times. The Environmental Protection Agency ("EPA" or the "Agency") has recognized that when pregnant mothers are exposed to chlorpyrifos residue, this likely harms infants *in utero*. Nevertheless, in derogation of the statutory mandate to ban pesticides that have not been proven safe, the EPA has failed to act, requesting extension after extension. The Agency's present position is effectively more of the same.

The proceeding began in 2007, when two environmental non-profit organizations – Pesticide Action Network North America ("PANNA") and the Natural Resources Defense Council, Inc. ("NRDC") – filed a petition (the "2007 Petition") asking the EPA to prohibit foods that contain any residue of the insecticide chlorpyrifos. Then, and now, the EPA has permitted distribution of food containing chlorpyrifos residue as long as the residue is less than a limit known as a "tolerance," which varies depending on the food. The 2007 Petition argued that, even at levels beneath these tolerances, chlorpyrifos poses neurodevelopmental risks, especially to infants and children.

The Federal Food, Drug and Cosmetic Act ("FFDCA") provides that the EPA's "Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke

a tolerance if the Administrator determines it is not safe."[1] The statute also requires that the EPA "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue" and "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children."[2]

Since 2007, the evidence of harm has continued to build, primarily through two kinds of studies: experimental studies on live mice and rats and epidemiological studies tracking humans who were exposed to chlorpyrifos *in utero*. Between 2007 and 2016, the EPA published several Human Health Risk Assessments regarding chlorpyrifos and convened its Scientific Advisory Panel ("SAP") several times. Those assessments and SAP reviews increasingly recognized the persuasiveness of the studies showing chlorpyrifos's risks. Nevertheless, the EPA declined to take final action on the 2007 Petition for more than a decade. Eventually, PANNA, NRDC, and others sought judicial relief, and this Court issued multiple writs of mandamus requiring the EPA to move forward. But, *festina lente*, the EPA continued to delay ruling on the 2007 Petition. This, moreover, was despite the fact that in November 2015, the EPA published a Notice of Proposed Rulemaking that proposed to revoke all chlorpyrifos tolerances because the EPA could not find them to be safe. Similarly, in 2016, the EPA issued a Revised Human Health Risk Assessment

[1] 21 U.S.C. § 346a(b)(2)(A)(i).

[2] *Id.* § 346a(b)(2)(C)(i)–(ii).

finding that the present tolerances are "not sufficiently health protective."[3]

In 2017, the EPA, pursuant to a court-set deadline, finally ruled on the 2007 Petition. But in the very face of its own prior acknowledgements of the health risks posed by chlorpyrifos, the EPA denied the 2007 Petition, and in 2019 denied all objections to that decision. In reality, however, this was just one more attempt at delay, because the EPA did not conclude that the tolerances were safe, but simply denied the Petition on the ground that the EPA would forgo further consideration of the question of safety until chlorpyrifos underwent a registration re-review under a separate statute, which could be as late as 2022. As explained below, this delay tactic was a total abdication of the EPA's statutory duty under the FFDCA.

In short, the EPA has spent more than a decade assembling a record of chlorpyrifos's ill effects and has repeatedly determined, based on that record, that it cannot conclude, to the statutorily required standard of reasonable certainty, that the present tolerances are causing no harm. Yet, rather than ban the pesticide or reduce the tolerances to levels that the EPA *can* find are reasonably certain to cause no harm, the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties. The FFDCA permits no further delay. Accordingly, for the reasons that follow, the Court grants the petitions for review and orders the EPA within 60 days after the issuance of the mandate either to modify chlorpyrifos tolerances *and* concomitantly publish a finding that the modified tolerances are safe,

[3] Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (hereinafter "2016 Notice of Data Availability").

including for infants and children – or to revoke all chlorpyrifos tolerances. The Court also orders the EPA to correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

BACKGROUND

I. The EPA's Duty to Regulate Pesticides

Congress requires the EPA to regulate the use of pesticides on food pursuant to the FFDCA. Congress also requires the EPA to regulate the use of pesticides more generally under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). This case principally concerns the FFDCA.

The FFDCA begins with a general rule that food containing pesticide residue is unsafe and prohibited.[4] Congress empowered the EPA to make exceptions to that rule by promulgating "tolerances" for a pesticide – *i.e.*, threshold levels of pesticide residue that the EPA is reasonably certain will cause no harm.[5] If the EPA promulgates a tolerance for a pesticide, then food may contain residue of that pesticide in an amount not exceeding the applicable tolerance.[6]

The EPA's discretion to set such tolerances is circumscribed, however, by an uncompromisable limitation:

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[4] *Id.* §§ 331, 342(a)(2)(B), 346a(a)(1). The FFDCA applies only to food and other products in interstate commerce. *See* 21 U.S.C. § 331.

[5] *Id.* § 346a(b)(1), (b)(2)(A).

[6] *Id.* § 346a(a)(4).

the pesticide must be determined to be safe for human beings. The EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe."[7] Furthermore, following enactment of the Food Quality Protection Act of 1996 ("FQPA"), it is now clear that the EPA must look beyond food to consider all of the ways someone might be exposed to a pesticide, "including all anticipated dietary exposures and all other exposures for which there is reliable information."[8] The EPA can determine that a tolerance is safe only if "there is a *reasonable certainty* that no harm will result from *aggregate* exposure to the pesticide chemical residue."[9]

In addition to requiring this general safety finding, the FFDCA also conditions the EPA's authority to set or leave in effect a tolerance on its determination that the tolerance is safe for infants and children. "In establishing, modifying, leaving in effect, or revoking a tolerance . . . , the Administrator . . . shall . . . ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue," and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children."[10] If a tolerance is not safe – in other words, if the EPA cannot determine that there is a reasonable certainty of no harm across all sources of exposure for infants, children, and adults – then the EPA no longer has discretion. Rather, the

[7] *Id.* § 346a(b)(2)(A)(i) (emphasis added).

[8] *Id.* § 346a(b)(2)(A)(ii).

[9] *Id.* (emphases added).

[10] *Id.* § 346a(b)(2)(C)(ii).

law commands that the EPA "shall modify or revoke [the] tolerance."[11]

The FFDCA authorizes "[a]ny person [to] file . . . a petition proposing the issuance of a regulation establishing, modifying, or revoking a tolerance."[12] The EPA, by regulation, may dictate what a petition seeking revocation of a tolerance must contain.[13] Pursuant to that authority, the EPA requires that a petition state "reasonable grounds for the action sought," including "an assertion of facts."[14] If the EPA determines that a petition has met the threshold requirements, then it must publish the petition within 30 days.[15] "[A]fter giving due consideration to a petition . . . and any other information available to the Administrator," the EPA "shall" do one of three things: "issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance . . . (which final regulation shall be issued without further notice and without further period for public comment)," "issue a proposed regulation . . . and thereafter issue a final regulation," or "issue an order denying the petition."[16] If the EPA denies a petition, "any person may file objections

[11] *Id.* § 346a(b)(2)(A)(i).

[12] *Id.* § 346a(d)(1).

[13] *Id.* § 346a(d)(2)(B).

[14] 40 C.F.R. § 180.32(b).

[15] 21 U.S.C. § 346a(d)(3).

[16] *Id.* § 346a(d)(4)(A).

thereto with the Administrator."[17] The Administrator "shall issue an order stating the action taken upon each . . . objection" "[a]s soon as practicable."[18] Those affected may seek "judicial review . . . in the United States Court of Appeals."[19]

Separately, the EPA also regulates pesticides pursuant to FIFRA. Under FIFRA, pesticides must be registered by the EPA before they can be distributed or sold.[20] To register a pesticide, the EPA must determine, among other things, that it does not have "unreasonable adverse effects on the environment."[21] FIFRA defines "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 standards of the FFDCA.[22] In other words, FIFRA incorporates the FFDCA safety standard for food uses, among other considerations. FIFRA requires the EPA to reevaluate pesticides as part of a registration review every fifteen years.[23]

[17] *Id.* § 346a(g)(2)(A).

[18] *Id.* § 346a(g)(2)(C).

[19] *Id.* § 346a(h)(1).

[20] *See* 7 U.S.C. § 136a(a).

[21] *Id.* § 136a(c)(5)(C)–(D).

[22] *Id.* § 136(bb).

[23] *See id.* §§ 136a(c)(1)(F)(iii), (g)(1)(A), 136a-1(a).

II. This Administrative Proceeding and Related Litigation

This administrative proceeding began with the filing of the 2007 Petition, which sought revocation of all tolerances and registrations for chlorpyrifos. Chlorpyrifos is an organophosphate pesticide. Organophosphates were first developed as toxic nerve agents for potential use in chemical warfare during World War II, and chlorpyrifos was initially registered as a pesticide in the United States in 1965. Since then, farmers have used chlorpyrifos to protect dozens of types of crops. As of 2017, "[b]y pounds of active ingredient, it [was] the most widely used conventional insecticide in the country."[24] Nevertheless, in 2019, California (and the European Union) announced they would ban the sale of chlorpyrifos.[25]

Chlorpyrifos disrupts the functioning of acetylcholinesterase ("AChE"), a crucial enzyme that breaks down the neurotransmitter acetylcholine.[26] In setting

[24] Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16,581, 16,584 (Apr. 5, 2017) (hereinafter "2017 Order").

[25] Press Release, Cal. Env't Prot. Agency & Cal. Dep't of Pesticide Regul., *Agreement Reached to End Sale of Chlorpyrifos in California by February 2020* (Oct. 9, 2019), https://www.cdpr.ca.gov/docs/pressrls/2019/100919.htm; Stephen Gardner, *EU to Ban Chlorpyrifos Pesticide Starting in February*, Bloomberg L. News (Dec. 6, 2019, 6:43 AM), https://news.bloomberglaw.com/environment-and-energy/eu-to-ban-chlorpyrifos-pesticide-starting-in-february.

[26] *See* EPA, Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-01-007, Interim Reregistration Eligibility Determination for Chlorpyrifos 2 (Feb. 2002) ("Chlorpyrifos can cause [AChE] inhibition in humans; that is, it can overstimulate the nervous system causing

chlorpyrifos tolerances, the EPA must determine the greatest exposure amount that poses no risk of harm, which is known as a "point of departure." Since enactment of the FQPA, the EPA has tied the chlorpyrifos point of departure directly to acute AChE inhibition, finding that exposure to chlorpyrifos residue on food would be unsafe if aggregate exposure across all sources caused more than 10% acute AChE inhibition.

However, for decades, the EPA has itself expressed concerns that chlorpyrifos might also be causing harm through a different mechanism: neurotoxic effects that are especially harmful to infants and children.[27] The 2007 Petition was partly based on these concerns. Yet, despite the EPA's expressed concerns, the EPA repeatedly failed to act on the 2007 Petition until this Court compelled it to do so. The following is a chronological summary both of the EPA's assessment of chlorpyrifos's safety and of this dispute.

A. 2000–2006: The EPA Finds Certain Chlorpyrifos Tolerances Safe, Despite Concerns

Between 2000 and 2006, even before the Petition was filed, the EPA began taking steps to reduce exposure to chlorpyrifos as part of its reevaluation of chlorpyrifos's safety, as required by the FQPA. The FQPA imposed the requirements, still included in the FFDCA today, that the

nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.").

[27] This different mechanism of harm might still relate to AChE inhibition; the EPA has considered the possibility that *chronic* AChE inhibition at levels of less than 10% might cause permanent damage. Herein, unless stated otherwise, AChE inhibition means *acute* AChE inhibition of 10% or more.

EPA (1) consider proof of safety as an absolute prerequisite to establishing or leaving in effect a tolerance, without balancing it against other factors; (2) assess a pesticide's cumulative exposure from multiple sources (*e.g.*, drinking water as well as food); and (3) specifically assess the pesticide's potential risks to children. The FQPA also required the EPA to reassess the safety of all then-authorized pesticides using this new standard.

During this period, the EPA began to express concerns that chlorpyrifos might be causing harms through a mechanism other than AChE inhibition. For example, in a 2000 Human Health Risk Assessment, the EPA recognized that studies had preliminarily shown that AChE inhibition might not be the only mechanism of harm.[28]

The EPA also began acting on its concerns about chlorpyrifos safety, in collaboration with the pesticide industry. In 2000, the EPA and the chlorpyrifos technical registrants entered into an agreement regarding chlorpyrifos that eliminated or phased out its use for virtually all residential and termiticide purposes, and on tomatoes and, during the growing season, grapes and apples.[29] In 2002, the

[28] EPA, Office of Pesticide Programs, Human Health Risk Assessment-Chlorpyrifos 4 (June 8, 2000), https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf (discussing live animal studies and explaining that "new data in the literature also gave rise to uncertainties such as the suggestion that the inhibition of [AChE] may not be essential for adverse effects on brain development").

[29] Letter to Aaron Colangelo, NRDC, & Margaret Reeves, PANNA, from Steven Bradbury, EPA, re: Chlorpyrifos Petition Dated September 12, 2007 (hereinafter "2007 Petition"), at 6 (July 16, 2012).

EPA announced certain risk mitigation measures, especially for people exposed to chlorpyrifos through their work.[30]

Subject to these changes, however, the EPA determined in February 2002, based upon the evidence then available, that "[d]ietary exposures from eating food crops treated with chlorpyrifos are below the level of concern for the entire U.S. population, including infants and children," and that "[d]rinking water risk estimates . . . are generally not of concern."[31] The EPA reiterated its safety finding in July 2006, stating that chlorpyrifos tolerances "meet the safety standard under Section 408(b)(2) of the FFDCA."[32]

B. 2007: PANNA and NRDC File a Petition to Revoke Tolerances, Citing Mounting Evidence of Harm

In September 2007, PANNA and NRDC filed an administrative petition with the EPA seeking revocation of all chlorpyrifos tolerances under the FFDCA and the cancellation of all of chlorpyrifos's FIFRA registrations. The 2007 Petition asserted that scientific evidence now available showed that the current chlorpyrifos tolerances were not safe, especially for infants and children; indeed, they argued, "no safe level of early-life exposure to

[30] Interim Reregistration Eligibility Decision for Chlorpyrifos, *supra* note 26.

[31] *Id.* at 2.

[32] EPA, Office of Prevention, Pesticides and Toxic Substances, Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides 2 (July 31, 2006).

chlorpyrifos can be supported."[33] They cited "[m]any studies published since 2001 [that] report that fetal exposure to chlorpyrifos is more damaging than adult exposure."[34]

The 2007 Petition relied in part upon certain experiments performed on live mice and rats. They were exposed *in utero* to levels of chlorpyrifos below those previously known to cause AChE inhibition. The scientists found marked declines in thinking and movement, indicative of neurological effects. The declines were sex-linked, harming males more than females.

The 2007 Petition also relied upon an epidemiological study, known as the "Columbia Study." Researchers worked with a cohort of pregnant women and their children, collecting data on the mothers' organophosphate exposure (including chlorpyrifos) during pregnancy, and then following the development of the children for many years. Some of the participating children were born before the EPA and the registrants agreed to end residential use of chlorpyrifos, and others were born after. Over time, the researchers found a correlation between prenatal chlorpyrifos exposure and several negative outcomes:

- at age three, lower performance in motor and mental development tests and higher incidences of attention-deficit hyperactivity disorder and autism spectrum disorder;

[33] Marc S. Wu et al., NRDC, & Susan E. Kegley, PANNA, Petition to Revoke All Tolerances and Registrations for the Pesticide Chlorpyrifos 5 (Sept. 12, 2007).

[34] *Id.* at 6.

- at age seven, changes in brain morphology and lower IQ scores; and

- at age eleven, a greater likelihood of mild or moderate tremors.

Like the live animal experiments, the Columbia Study found that *in utero* exposures were harmful even beneath the levels thought to cause notable AChE inhibition and that harms were sex-linked, disproportionately affecting boys.

Two other groups of researchers also conducted epidemiological studies similar to the Columbia Study (the "Mount Sinai Study" and the "CHAMACOS Study"; collectively with the Columbia Study, the "Human Cohort Studies"). The Mount Sinai and CHAMACOS Studies looked at exposure to organophosphate pesticides and, like the Columbia Study, found a correlation between prenatal organophosphate exposure and cognitive impairments in early childhood.[35]

C. 2008–2011: The EPA Preliminarily Links Chlorpyrifos to Neurotoxic Harms in Infants and Children

Within a year of the 2007 Petition, the EPA, in August 2008, published a Science Issue Paper, which reviewed existing scientific studies and "preliminarily concluded that chlorpyrifos likely played a role" in the low birth rate and delays in infant mental development observed in the Human

[35] Although the Mount Sinai Study and the CHAMACOS Study were not cited in the 2007 Petition, they later became part of the administrative record.

Cohort Studies.[36] The EPA recognized that some of these studies found these effects despite lesser AChE inhibition, suggesting there was a different mechanism of harm.[37] However, the paper also noted that it was "not a full and complete risk assessment/characterization," and that the EPA "ha[d] not developed any final conclusions regarding updates to the chlorpyrifos hazard assessment."[38]

In September 2008, the EPA convened a committee of experts known as a Scientific Advisory Panel ("SAP") to peer-review its findings. The 2008 SAP considered "the results of the three [Human Cohort Studies] (with an emphasis on the Columbia [S]tudy) . . . along with the findings from experimental studies in animals," and concluded that "maternal chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes in humans."[39] The SAP "agreed with [the EPA's] conclusion that chlorpyrifos likely played a role in the birth and neurodevelopmental outcomes noted in the three [Human Cohort Studies]."[40]

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[36] Health Effects Division, Office of Pesticide Programs, EPA, Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization 52 (Aug. 21, 2008).

[37] *Id*. at 40–41 & fig.5.

[38] *Id*. at 7.

[39] SAP Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos 13 (Sept. 16–18, 2008) (hereinafter "2008 SAP Minutes").

[40] *Id*. at 37.

However, the SAP also posited that the effects might not be entirely attributable to chlorpyrifos; rather, they might also reflect exposure to other AChE-inhibiting insecticides. A majority of SAP members agreed that the adverse outcomes of the Columbia Study were concerning, especially "in light of evidence demonstrating that low levels of exposure to toxicants once thought to have adverse neurodevelopmental effects only at high levels (i.e. lead, mercury, and PCBs) are now known to produce significant effects at lower levels."[41] Nevertheless, the 2008 SAP found that the Human Cohort Studies had "utility for risk characterization, but not as the principal basis for establishing the point of departure."[42]

About three years later, in 2011, the EPA published a Preliminary Human Health Risk Assessment. The EPA discussed the three Human Cohort Studies and noted the 2008 SAP's conclusion that those studies, "in concert with the animal studies[,] indicate that 'maternal chlorpyrifos exposure would likely be associated with adverse

[41] *Id.* at 43–44.

[42] 2007 Petition, *supra* note 29, at 6–7. The Dissent notes that the 2008 SAP expressed "concerns that the Columbia Study—the most robust of the three—did not provide sufficient data to be the sole factor for risk assessment or modifying tolerances and produced uncertainty through its measurement method." Dissent, *infra*, at 91. In fact, although the 2008 SAP recognized that "there were limitations . . . that precluded [the Human Cohort Studies] from being used to directly derive the [point of departure] or the uncertainty factor," it also concluded that the Columbia Study "could be used to determine bounding values for the levels of chlorpyrifos that might cause a measurable effect." 2008 SAP Minutes, *supra* note 39, at 46. Thus, even as early as 2008, the SAP recognized the utility of the Columbia Study for risk assessment.

neurodevelopmental outcomes in humans.'"[43] While the Preliminary Human Health Risk Assessment asserted that the EPA could not yet identify the mechanism of action for neurotoxic harm, nevertheless, it viewed the Human Cohort Studies favorably, describing the Columbia Study as a "natural experiment" since some participants were pregnant before the EPA banned residential use of chlorpyrifos and some were pregnant after the ban.[44] The EPA "intend[ed] to carefully consider the strengths and limitations of the epidemiology studies along with the available empirical data in a full weight of evidence analysis in the final [Human Health Risk Assessment]."[45] Thus, while the EPA continued to use 10% AChE inhibition to set a point of departure, it explained that "ongoing analyses will ensure that [the points of departure] in [its] preliminary assessment are [also] human health protective for neurodevelopmental toxicity that may arise from pre- or postnatal exposure."[46]

[43] Memo from Danette Drew et al. to Tom Myers re: Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review, EPA, at 28 (June 30, 2011).

[44] *Id.* at 31.

[45] *Id.* at 34.

[46] *Id.* at 42.

D. 2012–2015: The EPA Expresses Increasing Certainty That Chlorpyrifos Causes Neurotoxic Effects in Infants and Children

In April 2012, having received no response from the EPA on the pertinent arguments raised in the 2007 Petition,[47] PANNA and NRDC petitioned this Court for a writ of mandamus.

Meanwhile, also in April 2012, the EPA convened another SAP. The 2012 SAP opined with more certainty than the 2008 SAP that multiple "lines of evidence suggest that chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition, and that the use of AChE inhibition data may not be the most appropriate for . . . [assessing] the neurodevelopmental risks of chlorpyrifos."[48] The 2012 SAP paid particular attention to the Human Cohort Studies and identified "nine strengths" of them, including, among others, the longitudinal design, the use of biomarkers of exposure (rather than only self-reported exposure), and "the relative consistency of findings in different populations while using similar standardized exposure and outcome measures."[49] The 2012 SAP also identified some shortcomings of the Human Cohort Studies, such as a relatively small sample size and uncertainty

[47] The 2007 Petition raised several other claims, some of which the EPA addressed at earlier points in time, but here petitioners only press the claims related to neurotoxic effects.

[48] SAP Minutes No. 2012-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects 53 (Apr. 10–12, 2012) (hereinafter "2012 SAP Minutes").

[49] *Id.* at 18.

regarding whether harms could be attributed to chlorpyrifos alone. Overall, though, it found that "[t]he strengths of the three studies support the Panel's conclusion."[50]

Specifically, the 2012 SAP, based on its review of all the evidence available at the time, "concur[red] with the 2008 SAP and the Agency in concluding that chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies."[51] It noted that the Human Cohort Studies showed potentially serious harms to infants and children, including "abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7–9 years, and attention and behavior problems at 3 and 5 years of age."[52]

Despite all this, the EPA, following issuance of the 2012 SAP report, still did not take final action on the 2007 Petition; but it represented in the mandamus proceedings that it had "a concrete timeline for final agency action that would resolve the 2007 Petition by February 2014."[53] In light of that representation, this Court, in July 2013, denied PANNA and NRDC's petition for a writ of mandamus.

February 2014 came and went, but the EPA did not take final action on the 2007 Petition. PANNA and NRDC

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[50] *Id.*

[51] *Id.*

[52] *Id.* at 17.

[53] *PANNA v. EPA* (*In re PANNA*), 532 F. App'x 649, 651 (9th Cir. 2013).

returned to this Court in September 2014 with a second petition for a writ of mandamus.

Shortly thereafter, in December 2014, the EPA published a Revised Human Health Risk Assessment. It expressed greater certainty both that chlorpyrifos was causing the neurotoxic harms seen in the cohort studies and that it was doing so through a mechanism other than AChE inhibition.[54]

Because the EPA concluded that chlorpyrifos could cause harm even if exposure was below the AChE inhibition-related point of departure, the EPA proposed a new method for calculating a point of departure. But with all this, the EPA still did not act on the 2007 Petition.

In August 2015, this Court therefore granted the second mandamus petition.[55] The EPA had offered an "ambiguous plan to possibly issue a proposed rule nearly nine years after receiving the administrative petition," and the Court found this to be "too little, too late."[56] The Court found the EPA's delay "egregious" and ordered the EPA "to issue a full and

[54] Memo from Danette Drew et al. to Tom Myers et al. re: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, EPA (Dec. 29, 2014) (hereinafter "2014 Revised Human Health Risk Assessment"), at 43 ("[C]hlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies."); *id.* at 46 ("[The] EPA believes it is unlikely mothers enrolled in the [Human Cohort Studies] experienced [red blood cell] AChE inhibition"); *see also id.* ("Given the differences across laboratory animal and epidemiology studies, the qualitative similarity in research findings is striking.").

[55] *PANNA v. EPA* (*In re PANNA*), 798 F.3d 809, 811 (9th Cir. 2015).

[56] *Id.*

final response to the petition no later than October 31, 2015."[57]

E. 2015–2016: The EPA Finds That Chlorpyrifos Tolerances Are Unsafe

Once again, this Court's deadline came and went, and the EPA still did not take final action on the 2007 Petition. But in November 2015, the EPA published in the Federal Register a Notice of Proposed Rulemaking "proposing to revoke all tolerances for residues of the insecticide chlorpyrifos."[58] It wrote: "The agency is proposing to revoke all of these tolerances because [the] EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe."[59] Specifically, the EPA found that "contributions to dietary exposures to chlorpyrifos from food and residential exposures are safe," but "when those exposures are combined with estimated exposures from drinking water, as required by the FFDCA, . . . safe levels of chlorpyrifos in the diet may be exceeded for people whose drinking water is derived from certain vulnerable watersheds throughout the United States."[60]

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[57] *Id.*

[58] Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015) (hereinafter "2015 Notice of Proposed Rulemaking").

[59] *Id.*

[60] *Id.*

The EPA adhered to the findings of the 2014 Revised Human Health Risk Assessment. It relied upon "a considerable and still-growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals (rats and mice) indicating that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood."[61] It also relied upon the three Human Cohort Studies:

> [The] EPA has considered the strengths and limitations of these studies, and believes that random or systematic errors in the design, conduct or analysis of these studies were unlikely to fully explain observed positive associations between *in utero* [organophosphate] exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years). [The] EPA believes these are strong studies which support a conclusion that [organophosphates] likely played a role in these outcomes.[62]

The EPA acknowledged "significant uncertainties . . . about the actual exposure levels experienced by mothers and infant participants in the three children's health cohorts," but found that the measured exposures "are likely low enough that they were unlikely to have resulted in AChE inhibition."[63]

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[61] *Id*. at 69,090.

[62] *Id*. at 69,091.

[63] *Id*. at 69,093.

Since, however, the proposed rule did not constitute a final response to the 2007 Petition, this Court, in December 2015, ordered the EPA "to take final action by December 30, 2016 on its proposed revocation rule and its final response to . . . [the] 2007 [P]etition."[64] In other words, this Court, despite the EPA's repeated disregard of this Court's orders, most leniently gave the EPA yet another year to rule on the 2007 Petition.

In April 2016, the EPA convened another SAP, which peer-reviewed the 2014 Revised Human Health Risk Assessment. The 2016 SAP "agree[d] that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell [AChE] inhibition."[65]

However, the 2016 SAP disagreed with the EPA's method for calculating a new point of departure. Specifically, "with the exception of one Panel member, the Panel stated that using [umbilical] cord blood chlorpyrifos concentrations for derivation of the [point of departure] could not be justified by any sound scientific evaluation."[66] "Many Panel members" also objected to the specific threshold of harm that the EPA used to replace 10% AChE inhibition – a 2% decline in working memory – saying that

[64] *PANNA v. EPA* (*In re PANNA*), 808 F.3d 402 (9th Cir. 2015).

[65] SAP Minutes No. 2016-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Chlorpyrifos: Analysis of Biomonitoring Data 18 (Apr. 19–21, 2016) (hereinafter "2016 SAP Minutes").

[66] *Id*. at 26.

such a change in working memory was "of questionable biological significance."[67]

On the other hand, the 2016 SAP explained that, in general, it "support[ed] the use of measured maternal chlorpyrifos blood concentrations as a surrogate for fetal exposure . . . ."[68] And the SAP offered some guidance on how to proceed. "Multiple panel members noted that [physiologically based pharmacokinetic ("PBPK")] modeling is a valuable tool,"[69] and the SAP recommended that the EPA "consider determination and characterization of time-weighted average blood concentrations for different exposure scenarios,"[70] rather than measurements based upon umbilical cord blood concentrations at a single point in time.

The EPA returned to this Court in June 2016, claiming that it once again could not meet the much-extended deadline for final action on the 2007 Petition. In August 2016, the Court denied the EPA's request for an additional six months.[71] The Court did, however, grant the EPA a three-month extension, to March 31, 2017. The Court acknowledged that "evidence may be imperfect . . . [,] the feasibility inquiry is formidable, and . . . premature rulemaking is undesirable," but the Court found that "at this stage, a claim of premature rulemaking has come and

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[67] *Id*. at 27.

[68] *Id*. at 18.

[69] *Id.*

[70] *Id*. at 70.

[71] *NRDC v. EPA* (*In re PANNA*), 840 F.3d 1014, 1015 (9th Cir. 2016).

gone."[72] The Court warned that this was "the final extension" and that the Court would "not grant any further extensions."[73]

In November 2016, the EPA revised its Human Health Risk Assessment again. The 2016 Revised Human Health Risk Assessment remains the EPA's most recent comprehensive assessment of the risks of chlorpyrifos. In the assessment, the EPA "continue[d] to conclude that the [Human Cohort Studies] provide the most robust available epidemiological evidence."[74] The EPA "acknowledge[d] the lack of [an] established" mechanism of action that would explain the neurotoxic effects and also recognized "the inability to make strong causal linkages, and the unknown window(s) of susceptibility."[75] The EPA concluded, nevertheless, that "[t]hese uncertainties do not undermine or reduce the confidence in the findings of the epidemiology studies. The epidemiology studies . . . represent different investigators, locations, points in time, exposure assessment procedures, and outcome measurements."[76] "In summary," the EPA concluded that "the [Columbia Study], with supporting results from the other [two Human Cohort Studies] and the seven additional epidemiological studies

[72] *Id.* (quoting *Public Citizen Health Rsch. Grp. v. Chao*, 314 F.3d 143, 154–55 (3d Cir. 2002)).

[73] *Id.*

[74] Memo from Wade Britton to Dana Friedman re: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, EPA (Nov. 3, 2016) (hereinafter "2016 Revised Human Health Risk Assessment"), at 12.

[75] *Id.*

[76] *Id.*

reviewed in 2015, provides sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition."[77] Based on this finding, the EPA continued to conclude that it was necessary to adopt an approach "protective of both the AChE inhibition and any adverse effects that could occur at lower doses."[78]

The EPA acknowledged that "the 2016 SAP did not support using the [Columbia Study] cord blood" to derive a new point of departure.[79] Responsive to those comments, the EPA adopted a different approach.[80] It accepted the 2016 SAP's statement that the "EPA should use estimated peak blood concentrations or [time-weighted average] blood concentrations within the prenatal period" rather than umbilical cord blood concentrations at the time of delivery.[81] Also, consistent with the 2016 SAP's comments, the EPA

[77] *Id*. at 13.

[78] *Id.*

[79] *Id.*

[80] *Id.* at 4 ("Given that the window(s) of susceptibility are currently not known for the observed neurodevelopmental effects, and the uncertainties associated with quantitatively interpreting the [Columbia Study] cord blood data, the SAP recommended that the agency use a time weighted average . . . blood concentration of chlorpyrifos for the [Columbia] [S]tudy cohort as the [point of departure] for risk assessment. [The] EPA has chosen to follow that advice in this assessment.").

[81] *Id*. at 14.

estimated blood concentrations using a PBPK model devised by a chlorpyrifos registrant.[82]

When the EPA compared the resulting safety thresholds against typical pesticide exposure scenarios, it determined that chlorpyrifos tolerances were not safe – even considering food alone, without aggregating other exposure sources, like drinking water.[83] For example, the EPA found that expected food exposure for children 1–2 years of age was 14,000% of the threshold level of risk concern.[84]

The EPA announced the findings of the 2016 Revised Human Health Risk Assessment through a Notice of Data Availability published in the Federal Register,[85] and it reopened the comment period on its 2015 Notice of Proposed Rulemaking. In the Notice of Data Availability, the EPA reiterated that the present tolerances are "not

[82] *Id.*

[83] *Id.* at 24.

[84] *Id*. at 6.

[85] 2016 Notice of Data Availability, *supra* note 3, 81 Fed. Reg. at 81,050 ("After careful consideration of public comments and the SAP's recommendations, [the] EPA has concluded the most appropriate path for reconciling the SAP's concerns is to follow through on the SAP's recommendation to use a time weighted average approach. The agency agrees with the 2016 FIFRA SAP (and previous SAPs) that there is a potential for neurodevelopmental effects associated with chlorpyrifos exposure to occur at levels below 10% RBC AChE inhibition, and that [the] EPA's existing point of departure (which is based on 10% AChE inhibition), is therefore not sufficiently health protective.").

sufficiently health protective."[86] The Agency explained that its

> revised analyses do not result in a change to the EPA's proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP. The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard under the [FFDCA].

The EPA adhered to its proposal to revoke chlorpyrifos tolerances, rather than modify them, explaining that the "EPA has not identified a set of currently registered uses that meets the FFDCA safety standard because it is likely only a limited number of food uses alone, and in combination with predicted drinking water exposures, would meet the standard."[87] The EPA has never retracted the findings in its 2016 Revised Human Health Risk Assessment.[88]

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[86] *Id.*

[87] *Id.*

[88] Today, the EPA's website continues to warn about chlorpyrifos, citing the 2016 Revised Human Health Risk Assessment:

> What does [the] EPA's revised human health risk assessment show?
>
> This assessment shows dietary and drinking water risks for the current uses of chlorpyrifos. Based on

F. 2017–Present: The EPA Denies the 2007 Petition

Faced with this Court's statement that it would brook no further delays in the EPA's ruling on the 2007 Petition, the EPA finally in April 2017 ruled on the 2007 Petition. Notwithstanding the findings in its own 2016 Revised Human Health Risk Assessment, however, the EPA's order denying the 2007 Petition (the "2017 Order") stated that, "despite several years of study, the science addressing neurodevelopmental effects remains unresolved."[89] Therefore, the EPA concluded that "further evaluation of the science during the remaining time for completion of [FIFRA] registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos."[90]

> current labeled uses, the revised analysis indicates that expected residues of chlorpyrifos on food crops exceed the safety standard under the [FFDCA]. In addition, the majority of estimated drinking water exposure from currently registered uses, including water exposure from non-food uses, continues to exceed safe levels . . . .

EPA, Revised Human Health Risk Assessment on Chlorpyrifos, *available at* https://www.epa.gov/ingredients-used-pesticide-products/revised-human-health-risk-assessment-chlorpyrifos (last accessed Apr. 17, 2021).

[89] 2017 Order, *supra* note 24, 82 Fed. Reg. at 16,583.

[90] *Id.*

The EPA further explained that it was denying the 2007 Petition only because this Court had ordered it to make a decision, but that

> [the] EPA has . . . concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution . . . . Because the [Ninth] Circuit's August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted, [the] EPA is today also denying all remaining petition claims.

PANNA, NRDC, and others objected to the EPA's denial of the 2007 Petition, both by filing objections with the EPA and by seeking relief from this Court. The Court denied mandamus relief on the ground that the EPA had "now complied with our orders" to issue a decision, and "substantive objections must first be made through the administrative process."[91]

But even though the statute required the EPA to rule on petitioners' objections "[a]s soon as practicable after receiving the arguments of the parties," 21 U.S.C. § 346a(g)(2)(C), and even though these objections were simply reiterations of the positions petitioners had consistently taken since 2007, the EPA had still not responded to petitioners' objections *14 months later*, when

[91] *PANNA v. EPA* (*In re PANNA*), 863 F.3d 1131, 1132 (9th Cir. 2017).

the Court heard oral argument on petitioners' petition for review of the 2017 Order.

The EPA objected to this Court's consideration of the merits of the decision on the ground that, until the EPA ruled on petitioners' administrative objections, this Court lacked jurisdiction. A panel of this Court concluded that "the EPA is engaging in yet more delay tactics to avoid our reaching the merits of . . . 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."[92] The panel held that, under these circumstances, the Court had jurisdiction and that, on the merits, "the EPA bears a continuing obligation to revoke tolerances that it can no longer find with a 'reasonable certainty' are safe," and because the Agency could not make such a finding, the tolerance must be revoked.[93] The panel vacated the 2017 Order and remanded to the EPA with instructions to revoke all chlorpyrifos tolerances within 60 days after issuance of the mandate.[94]

Subsequently, however, a majority of nonrecused active judges voted to rehear the case en banc. The en banc Court did not address the jurisdictional question, but instead issued a writ of mandamus requiring the EPA to rule on the objections to the 2017 Order within 90 days.[95] In July 2019,

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[92] *LULAC v. Wheeler*, 899 F.3d 814, 827 (9th Cir. 2018), *vacated on reh'g en banc*, 914 F.3d 1189 (9th Cir. 2019).

[93] *Id.* at 829.

[94] *Id.*

[95] *LULAC v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc).

the EPA issued a final order (the "2019 Order") denying petitioners' objections and thereby completing the administrative denial of the 2007 Petition. The 2019 Order again relied upon the need for greater scientific certainty, but went further and held that "the objections and the underlying Petition are not supported by valid, complete, and reliable evidence sufficient to meet the Petitioners' burden under the FFDCA, as set forth in [the] EPA's implementing regulations."[96]

With the Court's jurisdiction now clear, petitioners petitioned for review of the 2017 and 2019 Orders. Several states moved to intervene. The en banc Court granted the motion to intervene, consolidated the cases, and returned the matter to this panel as a "comeback case."[97]

STANDARD OF REVIEW

The Administrative Procedure Act ("APA") authorizes the Court to "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,"[98] and to "compel agency action unlawfully withheld or unreasonably delayed."[99] Agency action is arbitrary and capricious where the agency has "offered an explanation for

[96] Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555, 35,557 (July 24, 2019) (hereinafter "2019 Order").

[97] *LULAC v. Wheeler*, 940 F.3d 1126, 1126–27 (9th Cir. 2019) (en banc); *see* 9th Cir. Gen. Order 3.6(b).

[98] 5 U.S.C. § 706(2)(A).

[99] *Id.* § 706(1).

its decision that runs counter to the evidence before the agency."[100]

ANALYSIS

I. Merits

The Court first considers whether the EPA lawfully denied the 2007 Petition. Petitioners argue that the EPA's 2017 and 2019 Orders were *ultra vires* under the FFDCA and arbitrary and capricious under the APA.

A. Whether the EPA Left in Effect a Tolerance Without Determining That It Is Safe

As noted above, the FFDCA provides that the EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe."[101] The statute also specifically requires that the EPA "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue" and "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children."[102]

Courts "normally interpret[] a statute in accord with the ordinary public meaning of its terms at the time of its

[100] *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[101] 21 U.S.C. § 346a(b)(2)(A)(i).

[102] *Id.* § 346a(b)(2)(C)(ii)(I)–(II).

enactment."[103] Furthermore, the FFDCA must be "given a liberal construction consistent with the Act's overriding purpose to protect the public health."[104]

The EPA admits that the 2017 and 2019 Orders left in effect tolerances without determining that they are safe, claiming that it could delay this determination for several more years until it had resolved safety-related issues in the 15-year FIFRA registration review. Since, as discussed below, the EPA's duty to engage in a periodic FIFRA registration review is separate from its continuous obligation to ensure safety under the FFDCA, this concession is effectively dispositive in favor of petitioners.

FIFRA aside, the EPA argues that it may leave in effect tolerances, without a new safety finding, "when [the] EPA concludes the petition contains insufficient evidence for [the] EPA to undertake proceedings to revoke or modify tolerances." This argument fails for two reasons. First, once the EPA has become aware, through a petition or otherwise, of genuine questions about the safety of an existing tolerance, the EPA has its own continuing duty under the FFDCA to determine whether a tolerance that was once thought to be safe still is, and here the EPA's own studies and pronouncements still in effect show that it regards chlorpyrifos as harmful at levels below the existing tolerances. Second, in any case, the 2007 Petition, under the EPA's own regulations, contained more than sufficient evidence to undertake a safety review, and the EPA recognized as much, began such a review, and only now,

[103] *Bostock v. Clayton County*, 140 S. Ct. 1731, 1738 (2020).

[104] *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

13 years later, claims for the first time that the 2007 Petition was somehow inadequate.

1. The EPA's Duty to Ensure Human Safety

The FFDCA imposes a continuous duty upon the EPA by permitting it to "leave in effect" a tolerance "only" if it finds it is safe. To "leave" something in effect means "to cause or allow [it] to be or remain in a specified condition."[105] Denying the 2007 Petition caused the chlorpyrifos tolerances to remain in place; as the EPA itself wrote in its brief, it "le[ft] the existing tolerances in place pending . . . registration review." But in so doing, the EPA did not "determine[] that the tolerance is safe."[106] Rather, the EPA's own pronouncements show that it has already concluded that it can no longer be reasonably certain that chlorpyrifos is safe at current tolerances.

It should be noted in this respect that, because of the FQPA, assurance of safety for human health is the primary issue the EPA must consider. Before 1996, when Congress unanimously passed the FQPA, the EPA interpreted the FFDCA to permit the balancing of safety against other considerations, such as economic factors. Congress was

[105] Merriam Webster, "Leave," *available at* https://www.merriam-webster.com/dictionary/leave (last accessed Apr. 17, 2021). The Dissent quibbles with our use of the dictionary, arguing that the phrase "leave in effect" is unambiguous. But then the Dissent ascribes to that term a meaning of the Dissent's own creation: that the EPA leaves in effect a tolerance only when it conducts FIFRA registration review. The statute imposes no such limitation on the phrase.

[106] 21 U.S.C. § 346a(b)(2)(A)(i).

aware of this,[107] and the FQPA largely abrogated that approach.[108] Congress made the explicit decision to prioritize safety over all else. This makes the FFDCA a remedial statute, which, as noted, must be "given a liberal construction consistent with the Act's overriding purpose to protect the public health."[109] Reading the EPA's duty narrowly would undermine the statute's health-protective purpose.

The EPA argues that one of Congress's purposes was to provide the EPA with regulatory discretion. The EPA points to the fifteen-year registration review cycle under FIFRA[110] as evidence that "Congress recognized that [reregistration] would be a complex and potentially burdensome proceeding"; thus, by contrast, Congress must have intended "a different" – and less burdensome – obligation "[w]hen [the] EPA responds to a petition to revoke pesticide tolerances" under the FFDCA. This contention is unpersuasive because of the differences between FIFRA and

[107] H.R. Rep. No. 104-669, pt. 2, at 40 (1996) (noting that under the prior procedure for setting tolerances, the EPA was authorized to consider "factors including the necessity for production of an adequate, wholesome, and economical food supply").

[108] Notwithstanding the safety standard, in certain circumstances the EPA may leave a tolerance in effect if "[u]se of the pesticide chemical . . . is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii)(II). However, this is permitted only where the risk of harm from a "nonthreshold effect," such as cancer, is not significantly greater than would be allowed for threshold effects. *See id.* § 346a(b)(2)(B)(iv). Nonthreshold effects are not at issue here.

[109] *Bacto-Unidisk*, 394 U.S. at 798.

[110] *See* 7 U.S.C. § 136a(g)(1)(A)(iii)–(iv).

the FFDCA. The statutes impose different duties that require different assessments. Under FIFRA, the EPA has a discretionary power to cancel registrations for a variety of reasons.[111] Specifically, FIFRA requires the EPA to balance several factors in determining whether a pesticide should be registered. For example, although FIFRA review includes an assessment of safety under the FFDCA,[112] it also requires a more general assessment of a pesticide's "economic, social, and environmental costs and benefits,"[113] including "the impact of [any proposed] action . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."[114] Given these differences, Congress's decision to give the EPA discretion to set FIFRA priorities does not translate to the FFDCA. The EPA's obligations under the FFDCA are linked to a single issue, safety, but they are mandatory.[115] The whole point of the FQPA would be destroyed if the EPA could exercise unfettered discretion to defer safety considerations until it

[111] 7 U.S.C. § 136d(b).

[112] *See id.* § 136(bb). The Dissent accuses us of "repeatedly miss[ing] this point," Dissent, *infra*, at 83 n.6, but the fact that FIFRA reregistration review includes, as one component, an assessment of safety under the FFDCA does not gainsay the many *other* factors FIFRA review also encompasses. FIFRA's wider scope justifies that statute's periodic rereview timeline and the greater agency discretion that approach entails. By contrast, the FFDCA's singular focus on safety corresponds with the EPA's continuous duty to leave in effect a tolerance only if it finds that the tolerance is safe.

[113] 7 U.S.C. § 136(bb).

[114] *Id.* § 136d(b).

[115] *See* 21 U.S.C. § 346a(b)(2)(A)(i) ("The Administrator *shall* modify or revoke [an unsafe tolerance]." (emphasis added)).

was prepared to engage in the full multi-factor balancing assessment required for FIFRA registration.

Our dissenting colleague reaches a different conclusion regarding the EPA's obligations, or lack thereof, when confronted with a petition for revocation of tolerances. The Dissent focuses upon two sentences in the FFDCA:

> The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.[116]

We think that these two simple sentences are – with their emphasis on the word "only" – remarkably straightforward. As here explained, they mean that the EPA can lawfully deny the 2007 Petition and thereby "leave in effect" a tolerance "*only* if the Administrator determines that the tolerance is safe." The Dissent's more strained reading of these sentences is to the effect that there are three possible scenarios, one in which the EPA "determines that a tolerance is safe," one in which the EPA "determines it is not safe," and one in which the EPA is unwilling or unable to make a safety determination at this time. In this latter, middle world, the Dissent continues, the statute is silent as to the EPA's obligations, leaving the EPA with the discretion to leave in

[116] *Id.* The EPA and the Dissent also contend that our reading renders the second sentence superfluous, but it does not. The second sentence limits the EPA's discretion by explaining that when it finds that a tolerance is not safe, it may not, for example, convene a SAP or wait 15 years pending further research; its only options are to revoke or modify the tolerance.

effect a tolerance based on its *prior* safety finding (here, the 2006 safety finding).

One problem (among others) with the Dissent's imaginative reading is that other statutory provisions are not silent. The FFDCA imposes an overarching obligation that the EPA protect human safety, and particularly the safety of infants and children:

> In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall assess the risk of the pesticide chemical residue . . . and shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.[117]

Congress has excluded the middle, not this Court. The EPA can only lawfully take agency action to establish or leave in effect a tolerance (*e.g.*, denying the 2007 Petition) if the EPA finds that the tolerance is safe.

2. The Burdens of Production and Persuasion

The EPA claims that the issue of safety as it bears on an existing tolerance need not be addressed unless a petitioner meets a threshold burden to come forward with evidence that the existing tolerance is unsafe. In this regard, the EPA points to the fact that the FFDCA gives the EPA the authority to "establish the requirements for information and

[117] 21 U.S.C. § 346a(b)(2)(C) (punctuation and section lettering omitted).

data to support a petition to modify or revoke a tolerance."[118] In a regulation promulgated pursuant to that authority, the EPA requires such a petition to "furnish reasonable grounds for the action sought."[119] Reasonable grounds "include . . . an assertion of facts (supported by data if available) showing . . . that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance . . . may justify its modification or revocation."[120]

We do not doubt that the EPA has gatekeeping authority to reject a wholly frivolous petition – *i.e.*, a petition that fails even to "furnish reasonable grounds for the action sought" – without publishing a notice of its filing if the petition is deficient on its face, and in such circumstances we can assume the EPA need not address the concerns raised by the petition. But the record here unequivocally shows both that the 2007 Petition met all relevant requirements and that, in fact, it caused the EPA to re-evaluate the safety of the chlorpyrifos tolerances, thus triggering the EPA's duty to ensure a reasonable certainty of no harm.

The FFDCA requires the EPA to determine whether a petition satisfies the threshold requirements *prior* to publishing a notice of the filing of the petition.[121] Here, the EPA published a notice of the filing of the 2007 Petition in

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[118] 21 U.S.C. § 346a(d)(2)(B).

[119] 40 C.F.R. § 180.32(b).

[120] *Id.*

[121] *See* 21 U.S.C. § 346a(d)(3) ("A notice of the filing of a petition *that the Administrator determines has met the [data and information] requirements* . . . shall be published by the Administrator within 30 days after such determination." (emphasis added)).

October 2007,[122] thereby finding that it met the data and information requirements in the FFDCA and the EPA's regulations promulgated thereunder. The EPA cannot now be heard, more than a dozen years later, to claim that the petition did not, in fact, meet those threshold requirements.

Independently, even if the EPA had raised this issue thirteen years ago when the 2007 Petition was filed, the EPA offers no specific way in which the petition failed to comply with the EPA's technical requirements and no plausible argument for why the 2007 Petition does not contain "reasonable grounds" for revocation. The EPA points to the continued scientific uncertainty regarding how chlorpyrifos harms infants and children and the fact that the 2007 Petition did not attach complete underlying data for the studies that it cited. But the regulation does not say that the petition must *prove* that revocation is required; it requires only that the petition state "reasonable grounds" for revocation. And the grounds listed in the 2007 Petition meet any definition of "reasonable"; indeed, the EPA has implicitly acknowledged as much by reacting to the 2007 Petition with years of deliberation, hundreds of pages of analysis, several convenings of the SAP, and a Notice of Proposed Rulemaking and further Notice of Data Availability proposing to grant the requested relief, all substantially based on grounds cited in the 2007 Petition.

The Dissent contends that a petitioner who seeks revocation of a pesticide tolerance bears not only a burden of production, *i.e.*, to provide "reasonable grounds" for revocation, but also a burden of persuasion, *i.e.*, to offer valid, complete, and reliable data that affirmatively demonstrate that the tolerances are unsafe. However, as

[122] 72 Fed. Reg. 58,845 (Oct. 17, 2007).

previously explained, the Dissent's reading is inconsistent with the FQPA's health protective purpose and the FFDCA's overarching command that the EPA, whenever leaving in effect a tolerance, "assess the risk of the pesticide chemical residue . . . and . . . ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure . . . ."[123] The Dissent's reading is also inconsistent with the EPA's regulations, which only impose a burden of production on the petitioner.[124] Indeed, in its brief the EPA relies upon the burden-setting regulation that would apply if the EPA conducted an evidentiary hearing on the 2007 Petition. Although there was no evidentiary hearing here, the regulation is illustrative. Ordinarily, "[t]he party whose request for an evidentiary hearing was granted has the burden of going forward in the hearing with evidence as to the issues relevant to that request for a hearing."[125] However, when section 408 of the FFDCA is at issue, the section pertaining to "safety," then "[t]he party or parties who contend that a regulation satisfies the criteria of section 408 of the FFDCA has the burden of persuasion in the hearing on that issue, whether the proceeding concerns the establishment, modification, or revocation of a tolerance or exemption from the requirement for a tolerance."[126] Put simply, on the question of safety, while the burden of production is on the petitioners, the burden of persuasion always rests on the party claiming that a tolerance is safe. For these reasons, the Court concludes that when the EPA

[123] 21 U.S.C. § 346a(b)(2)(C).

[124] 40 C.F.R. § 180.32(b).

[125] 40 C.F.R. § 179.91(a).

[126] *Id.* § 179.91(b).

publishes a petition seeking revocation of a tolerance and later takes final action denying that petition, the EPA leaves that tolerance in effect. The EPA can only do so if it finds the tolerance to be safe for the general population and for infants and children.[127] Here, the EPA did not make such findings, so it acted directly contrary to the FFDCA.

B. Whether Denying the 2007 Petition Was Arbitrary and Capricious

Separately, in light of the present record and the EPA's assessment of that record, petitioners argue that, even if the FFDCA does not require a safety finding here (which we find it does), the EPA's denial of the 2007 Petition was arbitrary and capricious. The Court agrees.

An agency has a baseline obligation to "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[128] The EPA has not done so because none of the reasons proffered in the 2017 and 2019 Orders provides "a satisfactory explanation for" denying the 2007 Petition.

The EPA has not retracted the 2016 Revised Human Health Risk Assessment indicating that chlorpyrifos is not safe at current tolerances and has not issued a new Human

[127] This is not to say, of course, that the EPA must perform a new Human Health Risk Assessment in response to every petition. The EPA might consider the issues raised by the petition alongside all the other evidence considered in its most recent safety determination and conclude that it need not conduct further review before reaffirming its prior findings.

[128] *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

Health Risk Assessment or SAP report since 2016. Rather, the 2017 Order denied the 2007 Petition on purely discretionary grounds, relying upon the EPA's purported authority to demand more study through at least 2022. After 13 years of delay, a desire for yet more delay does not rationally support denial of a petition that the EPA's own prior studies indicate raises a genuine issue of ongoing harm to infants and children.

The EPA asserted in the 2017 Order that it "may lawfully re-prioritize the registration review schedule developed by earlier [presidential] administrations."[129] In other words, more delay. Furthermore, while the EPA recognized that the 2007 Petition was filed under the FFDCA and raised arguments concerning human safety, the EPA found in its 2017 Order that it had to be permitted to synchronize its review of the petition with FIFRA registration review. To find otherwise "would effectively give petitioners under the FFDCA the authority to re-order scheduling decisions regarding the FIFRA registration review process that Congress has vested in the Administrator."[130]

But the FIFRA registration review, as already noted, is a different animal, in that it permits a balancing of multiple factors, whereas a FFDCA review is limited to the sole issue of safety but allows no balancing as far as that factor is concerned. Chlorpyrifos's wide use and the significance of this issue to the Administration are not valid legal considerations, as the EPA recognized in its 2017 Order.[131]

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[129] 2017 Order, *supra* note 24, 82 Fed. Reg. at 16,590.

[130] *Id.*

[131] *Id.*

As already noted, the FQPA amended the FFDCA to explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns, in most instances. Thus, the EPA's citation to these admittedly extralegal factors in its denial of the 2007 Petition is telling. It strongly suggests that the EPA's about-face in 2017 was motivated by factors unrelated to human safety, contrary to the FFDCA's commands.

The reference in the denial to the FIFRA 15-year period of review is, instead, nothing but a red herring, as the 2007 Petition does not concern FIFRA registration review. It concerns a petition under the FFDCA that contends that chlorpyrifos is unsafe. The EPA's position would largely strip FFDCA petitions of meaning, converting them into comments for the EPA to consider whenever it gets around to the next FIFRA registration review. The EPA offers no statutory support for this – because there is none. When, as here, a petitioner files a detailed petition identifying new evidence providing reasonable grounds to believe that exposure at less than a pesticide's current tolerances may be unsafe, the EPA has a duty to "giv[e] due consideration to [the] petition . . . and any other information available"[132] and to act on that petition with reasonable dispatch to protect human health – not fifteen years later. For these reasons, consistent with what this Court has said for years, the EPA's desire for delay is not a satisfactory explanation for denying the 2007 Petition.

The 2019 Order (unlike the 2017 Order) relied upon a second ground for denial of the 2007 Petition. The EPA found that PANNA and the NRDC bore an initial burden of production that, according to the EPA, they did not meet.

[132] 21 U.S.C. § 346a(d)(4)(A).

The EPA pointed out that the FFDCA requires it to consider "the validity, completeness, and reliability of the available data"[133] and authorizes it to promulgate regulations stating what a petition must contain.[134] As noted above, under this authority, the EPA promulgated a regulation requiring a petition to include "reasonable grounds" for revocation, which include an "assertion of facts (supported by data if available)."[135] Given this initial burden of production, the "EPA conclude[d] that the information . . . presented by Petitioners is not sufficiently valid, complete, and reliable to support abandoning the use of AChE inhibition as the critical effect for regulatory purposes under the FFDCA section 408."[136] Thus, the EPA concluded that the FFDCA safety issue was not before it.

For reasons already stated, this finding is unreasonable and inconsistent with the petition itself. The 2007 Petition claimed in detail that chlorpyrifos posed a risk of neurotoxic harm, especially to infants and children, and it invoked the live animal studies and the Columbia Study as evidence. The EPA acknowledges that it "has, since [2006], consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of chlorpyrifos and for the susceptibility of the developing brain to chlorpyrifos."[137] Therefore, under any reasonable construction, the 2007 Petition met the low

[133] 21 U.S.C. § 346a(b)(2)(D)(i).

[134] *Id.* § 346a(d)(2)(B).

[135] 40 C.F.R. § 180.32.

[136] 2019 Order, *supra* note 96, 84 Fed. Reg. at 35,563.

[137] *Id.*

bar of stating "reasonable grounds" for revocation with an "assertion of facts" in support. Also, as noted above, the time for finding that the petition did not meet the burden of production was in 2007, *before* the EPA published the petition in the Federal Register.

Because the Court rejects both of the EPA's justifications for refusing to make a safety finding, the Court concludes that the EPA's denial of the 2007 Petition was arbitrary and capricious.[138]

Although not necessary for this determination, the Court, for completeness, also considers the EPA's four objections to the data.

First, the EPA objects, in general, that "the science on this question is not resolved and would benefit from additional inquiry."[139] It will always be possible to conduct additional studies or to reach a greater degree of certainty, but a generalized concern that the science is not resolved is not a rationale sufficient to support denying a revocation petition. The FFDCA requires that the EPA make a safety determination based on whatever "information" is

[138] The Dissent takes great umbrage at this conclusion, reminding us that "[w]hen an agency makes determinations 'within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential.'" Dissent, *infra*, at 109 (alteration in original) (quoting *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983)). If the 2019 Order had found that existing chlorpyrifos tolerances were safe, then such deference would be appropriate. But no such finding was made. It is the Order's utter *failure* to make a required safety determination that this Court finds was arbitrary and capricious. This has nothing to do with deference or non-deference to expertise and everything to do with simple compliance with the law.

[139] *Id*. at 35,560.

"available."[140] And, as this Court has said before, a statutory mandate to rely on "available" scientific data "does not mean 'the best scientific data possible.'"[141]

Second, the EPA argues that it does not know *how* chlorpyrifos's neurotoxic effects harm infants and children. But that is not the question before the EPA. The question is *whether* chlorpyrifos causes such harms. Even if the mechanism is unknown, if a tolerance is unsafe, then the EPA must revoke it.[142]

Third, the EPA argues that the studies of rats and mice applied a "dosing regimen . . . that differs from internationally accepted protocols."[143] The EPA says:

> [T]he in vivo laboratory animal studies generally use fewer days of dosing that are aimed at specific periods of rodent fetal or early post-natal development compared to internationally adopted guideline studies which are intended to cover both pre- and post-gestational periods. The degree to which these shorter dosing periods coincide

[140] 21 U.S.C. § 346a(d)(4)(A).

[141] *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Building Indus. Ass'n v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001)).

[142] *Cf. Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1055 (D.C. Cir. 1999) (finding the EPA was not required to prove "how particles actually interact with cells and organs to cause sickness and death"), *aff'd in part and rev'd in part on other grounds sub nom. Whitman v. Am. Trucking Assn's*, 531 U.S. 457 (2001).

[143] 2019 Order, *supra* note 96, 84 Fed. Reg. at 35,563.

> with comparable windows of susceptibility in human brain development is unclear.[144]

This argument, apparently raised for the first time in the 2019 Order, is stated in cursory fashion. The EPA does not identify these "internationally accepted protocols" or explain why the EPA did not find deviations from these protocols to be troubling in the 2015 Notice of Proposed Rulemaking, the 2016 Notice of Data Availability, the 2016 Revised Human Health Risk Assessment, or the many other publications by the EPA that relied upon the animal studies. In any event, however, even if the Court were convinced, for the sake of argument, that divergence from these internationally accepted dosing protocols might somewhat diminish the value of these studies, it would not change the result, for reasons described below.

Fourth and finally, the EPA objects that it has been unable to get the raw data, as well as information concerning how residential pesticides were applied, from the Columbia Study. (Columbia, for its part, has expressed reasonable concerns about the subjects' privacy, especially given that the study covered a small geographic radius. Nevertheless, Columbia suggested to the EPA that it could make at least

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[144] *Id*. The EPA also explains that "except for some studies conducted recently, most of the in vivo laboratory studies use doses that are higher than doses that cause 10% [red blood cell] AChE inhibition. These studies are therefore are [sic] not useful quantitatively to evaluate whether [the] EPA's current regulatory standard is or is not sufficient to preclude the potential for neurodevelopmental effects." *Id.* This objection is, of course, valid as far as it goes: studies that apply pesticide at doses above the current tolerance are less helpful in showing whether the tolerance is safe. But the EPA concedes that "some studies" use lower doses. The EPA offers no justification for refusing to consider these studies.

some of the datasets available for viewing in a secure data center.[145]) The EPA has changed its position over time regarding the value of this data. It initially requested the data, but after meeting with the Columbia researchers in 2014, the EPA abandoned its request for this data.[146] Later, when the EPA sought to develop a point of departure based upon the umbilical cord blood measurements in the Columbia Study, it sought the data again. However, the 2016 SAP took issue with an approach based upon those cord blood measurements, so, as explained above, the EPA moved to a time-weighted average approach based upon a registrant's PBPK model. As a result, the EPA once again determined that it did not need the Columbia data, explaining that its new approach "does not directly rely on quantitative measures of chlorpyrifos in cord blood obtained from [Columbia], and thus, the lack of access to the raw data from [Columbia] is less of an uncertainty."[147] The EPA has now reversed position yet again, reiterating its desire for the data.

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[145] *See* Chlorpyrifos Epidemiology Study Data De-identification Discussion (July 31, 2018).

[146] 2014 Revised Human Health Risk Assessment, *supra* note 54, at 391 ("As a result of this meeting and additional discussions with [Columbia] staff, [the] EPA concluded that access to the raw data would either not provide answers to [the] EPA's questions or that the information [the] EPA sought could be obtained without analyzing the raw data. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, [the] EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties. For these reasons, *[the] EPA decided that it would not further pursue its request for the analytic data file* from the [Columbia] researchers.") (emphasis added).

[147] 2016 Revised Human Health Risk Assessment, *supra* note 74, at 14.

The EPA's flip-flopping suggests the weakness of this objection. Nevertheless, even if the Court were to assume for the sake of argument that the underlying data, and information concerning the method of residential pesticide application, would be of some use and that the EPA's inability to access it might diminish the value of the Columbia Study, it would not change the result in this case.

This is because, while the EPA might reasonably conclude that divergences from international protocols and lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCA requires the EPA to consider the "information" that is "available"[148] and to make a safety determination based on that information. In this case, live animal studies showing sex-linked, neurotoxic harms from *in utero* chlorpyrifos exposure are available – even if such studies are supposedly not perfectly aligned with (unspecified) international standards. And peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available – even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: speculation. Such speculation "runs counter to the evidence before the agency,"[149] so it cannot form the basis for denying the 2007 Petition.

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[148] 21 U.S.C. § 346a(d)(4)(A).

[149] *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

II. Remedy

The Court concludes that the EPA lacked power to deny the 2007 Petition without making the safety findings required by the FFDCA and that the EPA's decision was arbitrary and capricious. Therefore, the Court must, at least, "set aside the order or regulation complained of"[150] and remand to the EPA. Petitioners argue that the Court should also order the EPA to revoke the current chlorpyrifos tolerances and registrations by a date certain. Under the APA, the Court has the power to "compel agency action unlawfully withheld or unreasonably delayed."[151] The Court returns once more to the two sentences of the FFDCA that are key to assessing whether the Court should order the relief petitioners request:

> The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.[152]

The second sentence is more than a mere gloss on the first because the command inherent in the second sentence

[150] 21 U.S.C. § 346a(h)(2).

[151] 5 U.S.C. § 706(1).

[152] 21 U.S.C. § 346a(b)(2)(A)(i).

is important.[153] To be sure, the "only if" clause in the first sentence, standing alone, limits what the EPA may do when it determines that a tolerance is unsafe: it may not leave it in effect. But what are the EPA's options? May it order additional study? Convene another SAP? Wait for fifteen years to see if further evidence appears? No. The second sentence makes clear that, once the EPA has determined that a tolerance is not safe, it has no discretion to temporize pending additional research; it must modify or revoke the tolerance. For these reasons, if the EPA has determined that the present chlorpyrifos tolerances are not safe – or if that is the only conclusion the EPA could reasonably draw on this record – then the EPA has unlawfully withheld the relief that petitioners request.

On the present record, the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA. The EPA can find a tolerance safe only if there is "a reasonable certainty" of "no harm,"[154] and for nearly a decade, the EPA and its SAPs have concluded that there is *not* a reasonable certainty of no harm:

- **2012 SAP:** "[E]vidence suggest[s] that chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition, and that the use of AChE inhibition data may not be the most appropriate for dose-response modeling and

[153] For this reason, the EPA and the Dissent are also incorrect to contend that petitioners' reading of the statute contains surplusage. *See* Dissent, *infra*, at 80.

[154] 21 U.S.C. § 346a(b)(2)(A)(ii).

derivation of a point of departure for assessment of the neurodevelopmental risks of chlorpyrifos."[155]

- **2014 Revised Human Health Risk Assessment:** "[C]hlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies."[156] Moreover, "it is unlikely mothers enrolled in the [Human Cohort Studies] experienced [red blood cell] AChE inhibition."[157]

- **2015 Notice of Proposed Rulemaking:** "[The] EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe."[158]

- **2016 SAP:** "[B]oth epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures

[155] 2012 SAP Minutes, *supra* note 48, at 53.

[156] SAP Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos 43 (Sept. 16–18, 2008).

[157] *Id.* at 46.

[158] 2015 Notice of Proposed Rulemaking, *supra*. note 58, 80 Fed. Reg. at 69,081.

below levels that result in 10% red blood cell [AChE] inhibition."[159]

- **2016 Revised Human Health Risk Assessment:** The Columbia Study, "with supporting results from the other [Human Cohort Studies] and the seven additional epidemiological studies reviewed in 2015, provides sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition."[160]

- **2016 Notice of Data Availability:** "[E]xpected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard under the [FFDCA] . . . . [The] EPA has not identified a set of currently registered uses that meets the FFDCA safety standard . . . ."[161]

Even in its brief here, the EPA, though it purports to withhold judgment on chlorpyrifos's safety, admits that it cannot conclude there is a reasonable certainty of no harm. Rather, the EPA represents that there are "*uncertainties* concerning the impact of chlorpyrifos on children" (emphasis added).

The EPA has not determined, and on this record reasonably could not determine to a "reasonable certainty"

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[159] 2016 SAP Minutes, *supra* note 65, at 18.

[160] 2016 Revised Human Health Risk Assessment, *supra* note 74, at 13.

[161] *Id.*

that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm. Therefore, by statutory definition, the present tolerances are not safe. Accordingly, the EPA's obligation is clear: it must modify or revoke chlorpyrifos tolerances and modify or cancel chlorpyrifos registrations.

The EPA cites cases counseling that upon reversal of agency action, an open-ended remand is the correct approach, "[g]enerally speaking"[162] and "except in rare circumstances."[163] But this is not a typical case. On the present record the EPA has limited legal discretion: its only options are to modify or revoke the tolerances. Nor would it be reasonable to remand for further factfinding after thirteen years of interminable delay. Indeed, further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself. This is precisely the sort of "rare circumstance" where yet another open-ended remand would only frustrate the purpose of the FFDCA.

Finally, the EPA argues that "any order by this Court unilaterally ordering [the] EPA to revoke the existing tolerances for chlorpyrifos or cancel the existing registrations would raise serious due process concerns" for registrants and "violate Congress's procedures." Here, however, the Court is not unilaterally ordering the EPA to revoke existing tolerances; as explained below, it may instead modify such tolerances if it can make the requisite safety findings.

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[162] *INS v. Orlando Ventura*, 537 U.S. 12, 16 (2002).

[163] *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

In any event, remanding with specific instructions does not raise due process concerns. In responding to a petition, the FFDCA explicitly authorizes the EPA to "issue a final regulation modifying or revoking a tolerance . . . (*which final regulation shall be issued without further notice and without further period for public comment*)."[164] On this record, immediate issuance of a final regulation is the only reasonable action, and the Court orders the EPA to do so.

Such a final regulation could take one of two forms: either it could revoke all chlorpyrifos tolerances or it could modify chlorpyrifos tolerances *and* conclude that under the new tolerances there is a "reasonable certainty that no harm will result" due to "aggregate exposure to the pesticide chemical residue" that would result from such modified tolerances, including "to infants and children."[165] To be clear, the EPA may only choose to modify chlorpyrifos tolerances, rather than to revoke them, if at the same time it publishes such a safety determination.[166] On this record, it

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[164] 21 U.S.C. § 346a(d)(4)(A)(i) (emphasis added) (comma omitted).

[165] *Id.* § 346a(b)(2)(A)(ii), (b)(2)(C)(ii)(I).

[166] The Dissent opines that the Court "may have effectively foreclosed other options Congress made available," Dissent, *infra*, at 112 n.11, such as the exceptional steps the EPA may take when "the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk" or when the tolerance "is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii). These provisions offer alternatives to the FFDCA's general safety requirement for certain "eligible pesticide chemical residues," but only for adults. While subparagraph (b)(2)(B) provides an exception to "subparagraph [(b)(2)(A)(i)]," the general safety rule, it expressly requires compliance with subsection (b)(2)(C), which

may well be that the EPA cannot make such a determination. In 2016, the EPA explained that it "ha[d] not identified a set of currently registered uses that meets the FFDCA safety standard,"[167] a finding consistent with more than a decade of EPA issue papers, revised human health risk assessments, and SAP proceedings.

Nevertheless, during the pendency of this proceeding, in December 2020, the EPA issued a Proposed Interim Registration Review Decision proposing to modify certain chlorpyrifos tolerances. The EPA also convened another SAP in 2020. If, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them.[168]

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mandates that the EPA assure a reasonable certainty of no harm to children specifically. *Id.* § 346a(b)(2)(B)(vi). Thus, these provisions are irrelevant because regardless of whether chlorpyrifos is an "eligible" pesticide for purposes of § 346a(b)(2)(B) – a question not briefed by the parties and raised sua sponte by the Dissent – the EPA may only leave in effect chlorpyrifos tolerances that are safe for children.

[167] 2016 Notice of Data Availability, *supra* note 3, 81 Fed. Reg. at 81,050.

[168] Whichever path the EPA chooses to take, the FFDCA also provides that within 60 days after the EPA publishes a final response to the 2007 Petition, either modifying chlorpyrifos tolerances and publishing a safety finding or revoking chlorpyrifos tolerances, anyone may object to the EPA's final order, 21 U.S.C. § 346a(g)(2)(A), and the EPA must then "issue an order stating the action taken" on those objections, *id.* § 346a(g)(2)(C). It is hard to imagine that registrants will have much to add, given the many opportunities they have already received to comment on the 2015 Notice of Proposed Rulemaking and the 2016 Notice of Data Availability, as well as to participate as *amici*

To be clear, however, this is not an open-ended remand or a remand for further factfinding. The EPA must act based upon the evidence and must immediately revoke or modify chlorpyrifos tolerances.

For these reasons, the Court remands this matter to the EPA with instructions to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate. That response must be a final regulation that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children.

While the Dissent effectively views this as a "tight deadline[],"[169] it agrees that the "EPA dithered far too long."[170] The EPA has had nearly 14 years to publish a legally sufficient response to the 2007 Petition. During that time, the EPA's egregious delay exposed a generation of American children to unsafe levels of chlorpyrifos. By remanding back to the EPA one last time, rather than compelling the immediate revocation of all chlorpyrifos tolerances, the Court is itself being more than tolerant. But the EPA's time is now up.

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curiae before this Court. But, in any event, registrants' 60-day period to object will follow the EPA's *final* revocation of chlorpyrifos tolerances (or modification with concomitant safety findings). If registrants ask the EPA to promulgate new chlorpyrifos tolerances or revert to higher tolerances, they must provide proof of safety, and the EPA can approve registrants' request only if the EPA concludes that there is a reasonable certainty of no harm, including for infants and children.

[169] Dissent, *infra*, at 115.

[170] Dissent, *infra*, at 67.

CONCLUSION

We **GRANT** the petitions for review. The 2017 Order and the 2019 Order are vacated, and the matter is remanded to the EPA, with instructions to (1) grant the 2007 Petition; (2) issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA "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,"[171] including for "infants and children";[172] and (3) modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

VACATED AND REMANDED, WITH INSTRUCTIONS.

BYBEE, Circuit Judge, dissenting:

This is a consequential proceeding. EPA has before it a petition to revoke the tolerances for chlorpyrifos, one of the most important pesticides in the United States. This is a very complicated statute and I agree with the majority that EPA dithered far too long before ruling on the petition. Beyond that, I disagree with the majority opinion and judgment. In

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[171] 21 U.S.C. § 346a(b)(2)(A)(ii).

[172] *Id.* § 346a(b)(2)(C)(ii)(I).

my view it has misread EPA's obligations to review pesticide chemical residue tolerances EPA has previously found to be "safe" under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(b)(2)(A)(i). Further, the majority has substituted its own judgment for EPA's decision and then concluded that, because there is a difference of opinion, EPA's decision must be arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A). Difference is not caprice. Finally, among the options Congress entrusted to EPA when an existing tolerance is determined to be unsafe, the majority effectively mandates the option that EPA will enforce.

As to the first point, I part with the majority over EPA's duty with respect to the petition. According to the majority, EPA must find that chlorpyrifos is safe for human use, and EPA did not do so here. Maj. Op. at 41–46. EPA did find chlorpyrifos safe. That was the result of the proceedings in 2006, made final shortly before the present petition was filed. The question EPA had to answer in this proceeding is whether new scientific evidence is sufficient to require EPA to "modify or revoke" its prior determination. Under the FFDCA, EPA must do so "if the Administrator determines it is *not safe*." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). Because EPA found that chlorpyrifos was safe when it concluded its prior rulemaking in 2006, EPA properly determined here that there was insufficient evidence to conclude that chlorpyrifos is "not safe" and thus it was not required to "modify or revoke" those tolerances. EPA does not start from scratch when it is reviewing a petition to revoke or modify, but may rely on its prior finding. The majority would require, contrary to the FFDCA, that EPA start all over again. I take this point up in Part I.

As to the second point, the majority cherry-picks EPA's careful and honest questions about the safety of chlorpyrifos in light of various studies produced in the petition. Admittedly, it feels like EPA had this question under review for far too long—through three administrations—but the majority then assumes EPA's tentative conclusions are proven and concludes that it was arbitrary and capricious for EPA to determine otherwise. However, EPA never concluded that the studies presented to it were scientifically established. At every step of its overly cautious proceedings, EPA referred these studies to its Scientific Advisory Panel (SAP), which ultimately advised EPA that it could not verify the studies' conclusions. When EPA requested the underlying data, the studies' authors declined to produce it. Left without means of authenticating the studies, EPA concluded there was insufficient verifiable evidence to conclude that chlorpyrifos was "not safe" and to require EPA to modify or revoke its prior approval. The petition failed for lack of scientifically verifiable evidence. EPA explained all of this in detail, explained why it needed additional time to conduct the appropriate inquiries, and advised how it would proceed through the reregistration required by the statute. There is nothing arbitrary and capricious about that. I address this problem in Part II.

Not only do we decide that EPA's decision was arbitrary and capricious, but we have effectively decided the appropriate remedy. By ordering EPA either to revoke all tolerances or modify the tolerances with the requisite safety findings within 60 days, our order virtually guarantees the EPA will revoke chlorpyrifos tolerances. This is a vast overreach, a clear abuse of our discretion, as I discuss in Part III.

We can be unhappy with EPA's dilatory proceedings, but the remedy for that is a writ of mandamus, which we issued in *League of United Latin American Citizens v. Wheeler* (*LULAC III*), 922 F.3d 443 (9th Cir. 2019) (en banc). Now that EPA has complied fully with our directions, we don't get to set aside EPA's decision "simply because [we are] unhappy with the result reached." *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 558 (1978). Nor do we get to "second-guess[] the [agency's] weighing of risks and benefits." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019). "[A] reviewing court must remember that" when an agency is acting "within its area of special expertise, at the frontiers of science," we "must generally be at [our] most deferential." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). I respectfully dissent.

I

For starters, I fundamentally disagree with the majority over its construction of the FFDCA. The majority reads § 346a(b)(2)(A)(i), which is the critical section of the FFDCA for setting standards for pesticide use, as creating a binary choice for EPA: either a tolerance is "safe" or it is "not safe." The majority concludes that because EPA did not conclude that the chlorpyrifos tolerances were "safe" when it denied the petition, EPA must have concluded that they were "not safe" and the petition should have been granted. *See* Maj. Op. at 41 (EPA "left in effect tolerances without determining that they are safe . . . ."). With respect, the majority has misread the statute and its logic. I will start with some background on the statutes, then turn to how the majority has misread the statute, and conclude by addressing two additional arguments the majority makes.

A

Let's start with some background. EPA regulates pesticides pursuant to two statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136a–136y. The provisions relevant here were adopted as amendments to those Acts in the Food Quality Protection Act of 1996 (FQPA), Pub. L. No. 104-170, 110 Stat. 1489 (Aug. 3, 1996). *See Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1046 (9th Cir. 2008). The FFDCA authorizes EPA to regulate pesticides used on food that pose safety risks to humans and to establish pesticide tolerance levels "necessary for the protection of public health." 21 U.S.C. § 346. FIFRA authorizes EPA to "limit the distribution, sale, or use" of pesticides "[t]o the extent necessary to prevent unreasonable adverse effects on the environment" and issue registrations for distribution or sale of pesticides. 7 U.S.C. § 136a(a).

The FFDCA begins with a presumption that all "pesticide chemical residue in or on a food . . . [is] unsafe." 21 U.S.C. § 346a(a)(1)(A). If the EPA Administrator determines that a pesticide is "safe," the Administrator may establish a regulatory "tolerance."[1] A pesticide may be deemed "safe" if EPA has found "that there is a reasonable

[1] EPA may also exempt a pesticide from the FFDCA, where either (1) use of the pesticide protects consumers from greater adverse health effects than the dietary risk of the pesticide or (2) the pesticide is necessary to avoid significant disruption in the food supply chain, so long as aggregate risk is not too high. 21 U.S.C. § 346a(b)(2)(B)(ii)–(iv).

Although some of the statutes I will cite here refer to exemptions, EPA did not consider exemption of chlorpyrifos in this proceeding.

certainty that no harm will result from aggregate exposure to the pesticide." *Id.* § 346a(b)(2)(A)(i), (ii). The FFDCA has a separate requirement protecting infants and children. EPA must separately assess the risk of the pesticide based on available information concerning consumption patterns, special susceptibility, and cumulative effects unique to infants and children. *Id.* § 346a(b)(2)(C)(i). Based on this assessment, EPA must "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 safety" of the pesticide for infants and children. *Id.* § 346a(b)(2)(C)(ii). In making these determinations, EPA "shall consider . . . the validity, completeness, and reliability of the available data" and "available information concerning the relationship of the results of such studies to human risk." *Id.* § 346a(b)(2)(D)(i), (iii).

In addition to establishing safe tolerance levels for pesticides under the FFDCA, EPA regulates pesticides under FIFRA by issuing registrations required for distribution or sale. 7 U.S.C. § 136a(a). EPA may register a pesticide where, in addition to other requirements, "it will perform its intended function without unreasonable adverse effects on the environment" and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C), (D). "Unreasonable adverse effects on the environment" are unreasonable risks to man or the environment, including "human dietary risk . . . inconsistent with the standard under section 346a of Title 21." *Id.* § 136(bb). Thus, FIFRA incorporates the FFDCA safety determination into its registration assessment.

At the time the FQPA was passed in 1996, there were a number of existing tolerances in effect. The use of

chlorpyrifos, for example, has been federally authorized since 1965. *See Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order*, 84 Fed. Reg. 35,555, 35,558 (July 24, 2019) (*Final Order*). The FFDCA, as amended by the FQPA, provided that "[r]egulations that establish tolerances" issued on or before August 3, 1996, "shall remain in effect unless modified or revoked." 21 U.S.C. § 346a(j)(3). The Act also instructed EPA to "review tolerances and exemptions for pesticide chemical residues in effect on [August 2, 1996]," and to determine whether to leave in effect, "modify or revoke" those tolerances in accordance with the new standards. *Id.* § 346a(q)(1).[2] The FFDCA provided that EPA "shall . . . modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements." *Id.* The FFDCA further provided that at any time EPA could, on its own initiative, issue regulations "establishing, modifying, . . . or revoking a tolerance for a pesticide . . . ." *Id.* § 346a(e)(1)(A). Once a pesticide has been approved and registered, FIFRA requires EPA to reevaluate the registration within 15 years, in this case no later than October 2022. 7 U.S.C. § 136a(g)(1)(A)(iii), (iv). During FIFRA reregistration, EPA must decide whether to leave a tolerance in effect or revoke or modify it. *Id.* § 136a(g)(1)(A).

The general standards for establishing, leaving in effect, modifying, or revoking tolerances are found in § 346a(b)(2)(A)(i):

[2] The FQPA required EPA to review tolerances in existence in 1996 according to a priority schedule. 21 U.S.C. § 346a(q)(1), (2). EPA placed chlorpyrifos in its first priority group and completed its review in 2006. *Final Order*, 84 Fed. Reg. at 35,558.

> The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

These sentences are awkwardly written. For readability we can transpose them as follows:

> Only if the Administrator determines that a tolerance for a pesticide chemical residue in or on a food is safe may the Administrator establish or leave in effect the tolerance.[3] If the Administrator determines a tolerance is not safe, the Administrator shall modify or revoke the tolerance.

These standards are consistent with the presumption against the use of pesticides in food. *If* EPA determines a pesticide is safe, *then* EPA *may* establish a new tolerance or leave in place a tolerance previously established. However, *if* EPA determines a tolerance is not safe, *then* EPA *shall* modify or revoke the tolerance. Establishing or leaving a tolerance in place is not mandatory, even if EPA determines that a pesticide is safe; but if EPA determines a tolerance is not safe, it must modify or revoke the tolerance.

[3] This sentence could also be written as "If the Administrator establishes or leaves in effect a tolerance, then he has determined that the tolerance is safe."

When acting on its own initiative or in response to a petition,[4] the FFDCA requires EPA to consider "the validity, completeness, and reliability of the available data from studies of the pesticide" as well as other available information concerning risks and effects. § 346a(b)(2)(D). The statute also authorizes EPA to adopt regulations governing "requirements for information and data to support a petition to modify or revoke a tolerance." § 346a(d)(1), (d)(2)(B). EPA has issued regulations establishing these requirements and mandating supporting data and studies. 40 C.F.R. § 180.32(b). A petition must be supported by "reasonable grounds for the action sought," including "an assertion of facts (supported by data if available)" that "may justify [the tolerance's] modification or revocation." *Id.* § 180.32(b). The regulations also specify the form and content required for a petition. *Id.* § 180.7(b). Under its regulations, EPA may deny a petition when it finds that a petition is not supported by "reasonable grounds" for revocation. *Id.* § 180.32(b).

B

Now to the majority's errors. The majority reads § 346a(b)(2)(A)(i) as creating a binary choice, an "either/or" scenario: either a tolerance is "safe" or it is "not safe." For the majority, there is no middle ground. *See* Maj. Op. at 13, ("If a tolerance is not safe—in other words, if the EPA cannot determine that there is a reasonable certainty of no harm across all sources of exposure for infants, children, and adults—then the EPA no longer has discretion."), 62–63

[4] The FFDCA provides a mechanism for interested persons to petition EPA to "propos[e] the issuance of a regulation establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." *Id.* § 346a(d)(1)(A).

("EPA has not determined . . . that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm. Therefore, by statutory definition, the present tolerances are not safe."). The majority's logic is irrefutable because the statement is, of course, a tautology. But as a tautology it is not helpful, because it doesn't tell us anything about the actual state of affairs. As Ludwig Wittgenstein once commented, "I know nothing about the weather when I know that it rains or does not rain."[5] The problem with the majority's reasoning is, in a phrase, the fallacy of the excluded middle. *See Wall v. Mich. Rental*, 852 F.3d 492, 496 (6th Cir. 2017) ("[A] statement of two contradictory facts [is] a statement of nothing at all under a venerable principle of logic—the law of the excluded middle."); *Miller v. Henman*, 804 F.2d 421, 426 (7th Cir. 1986) (rejecting the "Law of the Excluded Middle" in favor of "a third alternative"). It is true that § 346a(b)(2)(A)(i) uses the terms "safe" and "not safe." But the context for the terms is different. The terms are opposites, but they do not exhaust the possible outcomes.

We should be familiar with the problem of the excluded middle from other areas of law and life. For example, "guilty" and "not guilty," as logical opposites, describe the universe, so long as we don't care about factual innocence. But if we do, we have to consider a third alternative. Thus, we have examples where courts have gone beyond the binary thinking of guilty/not guilty to declare persons "factually innocent." *See Humphries v. Cnty. of L.A.*, 554 F.3d 1170, 1181–82 & nn. 6, 8 (9th Cir. 2009) (discussing the legality and effect of findings of "factually innocent" by a California criminal court and "not true" by a California juvenile court

[5] Ludwig Wittgenstein, *Tractatus Logico-Philosophicus*, *quoted in* Joseph G. Brennan, *A Handbook of Logic* 160 (2d ed. 1961).

in a child abuse case), *rev'd in part on other grounds*, *Cnty. of L.A. v. Humphries*, 562 U.S. 29 (2010). Other countries offer juries the option of a third verdict. *See* Samuel L. Bray, Comment, *Not Proven: Introducing a Third Verdict*, 72 U. Chi. L. Rev. 1299, 1299–1300 (2005) ("Not proven and not guilty are both acquittals, indistinguishable in legal consequence but different in connotation. Not guilty is for a defendant the jury thinks is innocent; not proven, for a case with insufficient evidence of guilt"; citing Scottish law as an example). In football, a ruling may be overturned only if there is indisputable evidence that it was wrong. But what if the ruling is not indisputably wrong? Do we care if it was correct, or just "not wrong"? Turns out that we do. The presumption will lie with the official who made the call. If the ruling cannot be overturned, "the ruling on the field stands." But if the ruling on the field is correct, then "the ruling on the field is confirmed." *See NCAA Football Rules Book* R. 12, § 6, art. 1.d (2019) (distinguishing three options: "the ruling on the field is confirmed," "the ruling on the field stands," and reversing a ruling). There is no practical difference in the immediate effect on the game between "the ruling on the field stands" and "the ruling on the field is confirmed," but there are collateral consequences for officials and for the lively debates among the fans that inevitably follow in close games.

The majority's premise that a pesticide is either "safe" or "not safe" ignores an important alternative—namely, that there is insufficient information to reach either of those conclusions. That is why Congress instructed EPA to consider "the validity, completeness, and reliability of the available data"—it understood that the evidence might be inconclusive. 21 U.S.C. § 346a(b)(2)(D)(i). That is also why § 346a(b)(2)(A)(i) allocates a burden of persuasion. I hesitate to use the term "burden of proof" because it suggests

that EPA and petitioners are adverse to each other; they are not. EPA is responsible for regulating pesticide use and, as a court, we assume that it has developed an expertise. We also assume that EPA will be an honest broker in assessing the safety of a pesticide; after all, agency employees have to eat the same food we do. So instead of "burden of proof," I am going to use the term "risk of nonpersuasion."

Here is how the risk of nonpersuasion figures into the FFDCA. When EPA receives a petition, it has a duty of inquiry, but it is a different duty depending on whether the decision on the table is whether to *establish or leave in effect* a tolerance (the first sentence of § 346a(b)(2)(A)(i)) or to *modify or revoke* a tolerance (the second sentence in that subsection). EPA (or a petitioner) has the initial burden to show that a proposed tolerance can be safely established. If the proposal does not satisfy that standard, EPA cannot adopt the proposed tolerance. EPA has the same burden when it considers an existing tolerance for reregistration. Recall that when the FQPA was adopted in 1996, that Act tightened the standards for pesticides. Because EPA had approved pesticides in use, the FQPA required EPA to review and reregister all existing tolerances to determine whether to "leave in effect" those tolerances. 21 U.S.C. §§ 346a(j)(3), (q)(1). Additionally, the FQPA, amending FIFRA, mandated that following that reregistration, EPA must review existing tolerances no less frequently than every 15 years. 7 U.S.C. § 136a(a), (g)(1)(A)(iv). In these reregistration proceedings, EPA must conclude that the existing tolerance is "safe" before it can "leave [it] in effect." 21 U.S.C. § 346a(b)(2)(A)(i). What happens if the evidence is inconclusive? Since there is a presumption that all pesticides are "unsafe," *id*. § 346a(a)(1), the risk of nonpersuasion means that EPA must either approve the tolerance or exempt it under other provisions of the FFDCA,

see id. § 346a(a)(1)(A), (B). As I transposed § 346a(b)(2)(A)(i) for readability, "only if the Administrator determines that the tolerance is safe may [the Administrator] establish or leave in effect a tolerance."

By contrast, when a petitioner requests modification or revocation of an existing tolerance, the risk of nonpersuasion cuts in the opposite direction. EPA has previously found the tolerance to be "safe." If EPA subsequently determines that the pesticide is "not safe," then it must modify or revoke the tolerance. What happens if the evidence is inconclusive? The risk of nonpersuasion means that EPA may, but does not have to, modify or revoke the tolerance. Section 346a(b)(2)(A)(i) is clear (as I have revised it for readability): "If the Administrator determines a tolerance is not safe, the Administrator shall modify or revoke the tolerance." Accordingly, when a petitioner files an appropriate petition claiming that a tolerance is not safe, EPA assumes a duty of inquiry, but not a duty of declaring anew that the tolerance is "safe." Here is the crucial distinction: *determining that a tolerance is "not safe"* is not the same as *not determining that a tolerance is "safe."* The majority's either/or approach has excluded the middle. As the First Circuit explained, albeit in a different context:

> Confronted by such conflict a reasonable person investigates matters further; he receives assurances or clarification before relying. A reasonable person does not gamble with the law of the excluded middle, he suspends judgment until further evidence is obtained. Explicit conflict engenders doubt, and to rely on a statement the veracity of which one should doubt is unreasonable. The law does not supply epistemological

> insurance. Nor does it countenance reliance on one of a pair of contradictories simply because it facilitates the achievement of one's goal.

Trifiro v. Nw. York Life Ins. Co., 845 F.2d 30, 33–34 (1st Cir. 1988).

The majority's either/or treatment of § 346a(b)(2)(A)(i) has two important consequences. First, it effectively reads the second sentence of that subsection out of the statute because, in the majority's understanding, EPA always has the burden to show that a tolerance is "safe," which means that it is, by definition, not "not safe." Or, to put it another way, in the majority's view, if at any time EPA does not affirmatively declare that a tolerance is "safe," the tolerance is, again by definition, "not safe." Under the majority's reading, the second sentence of § 346a(b)(2)(A)(i) doesn't do any work because in order to determine that a tolerance is "not safe" EPA must decide that it is not "safe." In other words, for the majority, in every case EPA has a duty of reregistration. The reason the majority has committed this error of logic is that it fails to appreciate the different context for the two sentences in § 346(b)(2)(A)(i). In the first sentence, the presumption runs against the tolerance because EPA is required to establish or reregister ("leave in effect") the tolerance. In the second sentence, *EPA has already determined that the tolerance is "safe,"* so the question is whether there is enough evidence to show that it is "not safe." When EPA denies a petition for insufficient evidence, it may rely on its prior determination that the tolerance is "safe." The two sentences operate in different contexts.

Second, the majority's reading means that petitioners can seize control of the statutory schedule for reviewing existing

tolerances. Under the FQPA, EPA had to review all existing tolerances, such as chlorpyrifos, under the new standard. And it had to do so "as expeditiously as practicable," but no later than 2006. 21 U.S.C. § 346a(q)(1). This EPA did in 2006, leaving in effect the chlorpyrifos tolerance. Under the FIFRA and the FFDCA, EPA would have to reevaluate chlorpyrifos for reregistration no later than October 2022. *See* 7 U.S.C. § 136a(g)(1)(A)(iv); *Final Order*, 84 Fed. Reg. at 35,558. In the interim, any interested person may petition EPA to modify or revoke the tolerance. Under the majority's reading of the FFDCA, to respond to the petition, EPA must either reregister chlorpyrifos as "safe" or modify or revoke the tolerance—but in either case the petition has altered the statutory review process for chlorpyrifos. Since petitioners can file petitions at will, EPA has lost control over its docket, and the statutory schedule has been derailed. As EPA put it, if

> EPA were required to truncate its ongoing registration review process to make a new FFDCA safety finding every time it received a petition to modify or revoke tolerances, petitioners would effectively have the authority to re-order the Administrator's scheduling of registration review decisions under FIFRA and dictate the extent of inquiry EPA may put to a matter before reaching a resolution.

Final Order, 84 Fed. Reg. at 35,565.

C

Despite the (relative) clarity of these provisions, the majority makes two arguments to get around this reading of § 346a(b)(2)(A)(i). First, the majority holds that any time

EPA considers a petition to modify or revoke an existing tolerance (which is governed by the second sentence of § 346a(b)(2)(A)(i)), it is "leav[ing] in effect" the tolerance (which is governed by the first sentence). Maj. Op. at 41–42. It concludes that EPA has "a continuous duty" under the FFDCA "to 'leave in effect' a tolerance 'only' if it finds it is safe." *Id.* at 42. Second, the majority claims that once EPA accepted the petition, because it was not "wholly frivolous," EPA had an independent duty to determine whether chlorpyrifos is "safe" and cannot now claim that the petition was "somehow inadequate." *Id.* at 42, 47. Neither point withstands scrutiny.

The majority's focus on EPA "leaving in effect" the chlorpyrifos tolerance misconceives the proceedings. Under the FFDCA, any petitioner had the right to petition EPA to "establish[], modify[] or revok[e]" a tolerance. 21 U.S.C. § 346a(d)(1)(A). "Leave in effect" is not mentioned as an option in the petition subsection, and for good reason: "leave in effect" has a particular context and meaning in the FFDCA. As I have explained, prior to the adoption of the FQPA in 1996, which established the current statutory standards in the FFDCA, there were tolerances in place for pesticides such as chlorpyrifos. The FQPA imposed a duty and a schedule on EPA to review all existing tolerances and to decide whether to "leave in effect" those tolerances. 21 U.S.C. § 346a(q)(1). *See also id.* § 346a(l)(3)(B) (explaining if EPA suspends a tolerance it "shall not be considered to be in effect," but if the suspension is terminated, "leaving the registration of the pesticide for such use in effect," EPA must rescind the suspension). Because the prior tolerances were not established under the same standards demanded by the FFDCA, as amended by the FQPA, EPA had to determine afresh that the preexisting tolerances were "safe." With respect to that review, EPA

could "leave in effect a tolerance . . . only if the Administrator determines that the tolerance is safe." *Id.* § 346a(b)(2)(A)(i). Under FIFRA, EPA must also re-certify its tolerances no less than every 15 years and decide whether to leave a tolerance in effect or modify or revoke it. 7 U.S.C. § 136a(g)(1)(A).[6] The majority has conflated EPA's responsibility with respect to the preexisting tolerances with its responsibility when it reviews a petition.

The majority reaches its conclusion because it reads § 346a(b)(2)(A)(i) in isolation from the rest of the statute. That leads the majority to consider a dictionary definition of the phrase. Maj. Op. at 42. Dictionaries can be useful for understanding terms. Here, recurring to a dictionary is neither necessary nor useful, because the term "leave in effect" is not ambiguous when it is read in context with the remainder of the statute. *See Carson Harbor Vill., Ltd. v. Unocal Corp.*, 270 F.3d 863, 878 (9th Cir. 2001) (en banc)

[6] Contrary to the majority's statements, FIFRA incorporates the FFDCA's standards. *See* 7 U.S.C. § 136(bb) (referring to "the standard under Section 346a of Title 21"). As part of its reregistration requirements for licensing, FIFRA requires EPA to review its FFDCA standards no less than every 15 years. *See Final Order*, 84 Fed. Reg. at 35,557 ("In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions for pesticide uses that result in residues in or on food."). Because FIFRA requires periodic recertification under FFDCA, the FFDCA standard governs chlorpyrifos's use, independent of anything required for licensing under FIFRA. The majority repeatedly misses this point. *See* Maj. Op. at 43–44 ("[EPA's claim that reregistration is required by FIFRA] is unpersuasive because of the differences between FIFRA and the FFDCA. The statutes impose different duties that require different assessments."), 51 ("FIFRA registration review . . . is a different animal, in that it permits a balancing of multiple factors, whereas a FFDCA review is limited to the sole issue of safety . . . .").

("Where the language is plain and admits of no more than one meaning the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion." (quoting *Caminetti v. United States*, 242 U.S. 470, 485 (1917)); *see also Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) ("[W]here the statutory language provides a clear answer, [the inquiry] ends there . . . ."); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) ("Our inquiry must cease if the statutory language is unambiguous and the statutory scheme is coherent and consistent." (internal quotation marks and citations omitted)); *United States v. Williams*, 659 F.3d 1223, 1225 (9th Cir. 2011) ("If the plain meaning of the statute is unambiguous, that meaning is controlling . . . ."). When the statute offers a definition of a term, the statutory definition—even if it is a functional usage—governs. *Carson Harbor Vill.*, 270 F.3d at 878 ("When a statute includes an explicit definition, however, we must follow that definition, even if it varies from that term's ordinary meaning." (quoting *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) (alteration omitted)); *see also United States v. Havelock*, 664 F.3d 1284, 1289 (9th Cir. 2012) (en banc) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose. That assumption, however, does not apply where Congress provides a statutory definition." (internal citations and quotation marks omitted)). The FFDCA, as amended by the FQPA, is quite clear that "leave in effect" refers to a particular kind of proceeding mandated by Congress.

That brings us to the majority's second point. The majority attempts to shift the risk of nonpersuasion through a contorted reading of EPA's regulations regarding the filing of a petition. According to the majority, EPA has a

"gatekeeping authority to reject a wholly frivolous petition." Maj. Op. at 47. But if EPA accepts a petition, it "trigger[s] the EPA's duty to ensure a reasonable certainty of no harm" by re-evaluating chlorpyrifos and, if it decides to "leave in effect" the tolerance, it must certify chlorpyrifos as "safe." *Id.* According to the majority, accepting a petition flips the risk of nonpersuasion. But EPA's regulations say nothing of the kind.

In an exercise of its "gatekeeping authority," EPA has adopted "Procedure for modifying and revoking tolerances or exemptions from tolerances." 40 C.F.R. § 180.32. That regulation provides in relevant part:

> Any person may file with the Administrator a petition proposing the issuance of a regulation modifying or revoking a tolerance or exemption from a tolerance for a pesticide chemical residue. The petition shall furnish reasonable grounds for the action sought. Reasonable grounds shall include . . . an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its modification or revocation.

Id. § 180.32(b). There is not a word in the regulation that would affect the risk of nonpersuasion. The regulation requires little to be a qualifying petition: "reasonable grounds," including "an assertion of facts" which shall be "supported by data *if available*." *Id.* (emphasis added). That

is the most modest of rules. EPA will generously accept such petitions and consider them. Accepting a petition—which in the majority's phrase means that they are not "wholly frivolous"[7]—is the lowest of bars. This is as it should be. We want interested persons—"any person"—to be able to go to EPA and suggest that it take a second look at a tolerance for a pesticide going on our food. But the majority takes EPA's decision to accept the petition as nullifying EPA's prior decision to approve the tolerance; effectively, EPA must start all over again. That's not how administrative law usually works. Under the FFDCA, EPA must modify or revoke the tolerance if it is "not safe." The majority would require EPA to prove that the tolerance is "safe."

Although EPA's *Final Order* was overdue, there was nothing improper in its form. EPA denied the petition and instead relied upon its 2006 safety determination for chlorpyrifos tolerances because it found that the data and studies supporting the petition were "not sufficiently valid, complete, and reliable" to support revocation. *Final Order*, 84 Fed. Reg. at 35,562–63. In other words, the data supporting the petition was not sufficient to support a determination that chlorpyrifos tolerances are "not safe." 21 U.S.C. § 346a(b)(2)(A)(i).

The FFDCA does not require EPA to make a new safety determination in response to a petition supported solely by studies that EPA has already considered and found insufficient for revocation while conducting its FIFRA review. Here, EPA considered the petition's cited studies at multiple instances during its own review and found that they

[7] So far as I can tell, the phrase "wholly frivolous" belongs to the majority.

were not reliable enough to support revocation without more information. *See Final Order*, 84 Fed. Reg. at 35,563. The agency's determination that the petition did not present sufficiently valid, complete, or reliable information to support revocation is thus supported by the record. *See* § 346a(b)(2)(D). Because the 2007 petition did not present reasonable grounds for modification or revocation, EPA was entitled to rely upon its 2006 safety finding while it engaged in its FIFRA review of chlorpyrifos tolerances. The tolerance had already been deemed "safe," and the petition did not raise sufficient grounds to overcome that presumption.

Under a correct reading of the statute, and proper allocation of the risk of nonpersuasion, we should be reviewing EPA's determination that the petition, and the evidence it mustered, was insufficient to determine that the chlorpyrifos tolerance is "not safe." That is not the inquiry the majority conducts, so in Part II I will review the proceedings before EPA, as punctuated by our orders, and its *Final Order*, which is the only decision we have authority to review. 5 U.S.C. § 704.

II

EPA's denial of the 2007 petition was not arbitrary or capricious. The denial of the petition did not conflict with any final agency findings or conclusions and, to the contrary, was supported by the extensive record of EPA's concerns with the petition's supporting studies over the course of nearly a decade. The only final agency action in effect for chlorpyrifos tolerances is the 2006 safety determination, and EPA's denial of the petition comports with this determination.

I will begin with a brief review of EPA's 2006–17 proceedings, with some emphasis on the questions and qualifications EPA raised at each step of those proceedings. I will then turn to the *Final Order* and our review under the APA.

A

In 2006, pursuant to the FFDCA, EPA completed a tolerance reassessment of chlorpyrifos and found that chlorpyrifos was eligible for reregistration and met the standard of 21 U.S.C. § 346a(b)(2). EPA, Office of Prevention, Pesticides and Toxic Substances, *Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides* (July 31, 2006) (*2006 Reregistration Decision*); *see also Final Order*, 84 Fed. Reg. at 35,558. In doing so, EPA found that chlorpyrifos tolerances were safe and left them in effect.

1. The Petition is filed; EPA conducts various studies for reregistration

In September 2007, the Pesticide Action Network North America (PANNA) and the National Resources Defense Council (NRDC) filed a petition with EPA to revoke all tolerances for chlorpyrifos based on new studies purporting to show that current chlorpyrifos tolerances were not safe. *See Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos; Notice of Availability*, 72 Fed. Reg. 58,845 (Oct, 17, 2007); *see also Final Order*, 84 Fed. Reg. at 35,556**.** Petitioners raised ten claims alleging numerous errors in the *2006 Reregistration*

Decision, including claims that EPA ignored or misinterpreted data.[8] EPA was able to resolve seven of the ten claims relatively quickly. In July 2012 and July 2014, EPA issued interim responses indicating its intent to deny all but the three claims at issue here (grounds 7–9 in the petition), and it informed Petitioners of its intent to finalize all interim conclusions (grounds 1–6, and 10) when it resolved the remaining three claims, a decision to which Petitioners did not object. *Final Order*, 84 Fed. Reg. at 35,556; *see also In re Pesticide Action Network North America* (*PANNA I*), 532 F. App'x 649 (9th Cir. 2013) (denying petition for mandamus). The three claims not addressed by EPA in those responses were interrelated and concerned the potential for chlorpyrifos exposure at current tolerance levels to cause neurodevelopmental effects in children. *Final Order*, 84 Fed. Reg. at 35,556. However, EPA did not give these claims short shrift. Instead, early in its review, in 2009, the agency found the issues raised important enough questions that they should be addressed as part of an accelerated reregistration review of chlorpyrifos. *Id.* at 35,556 (noting that these claims "raised novel, highly complex scientific issues" that should be addressed in EPA's

[8] Petitioners alleged that EPA: (1) "ignored genetic evidence of vulnerable populations"; (2) "needlessly delayed a decision regarding endocrine disrupting effects"; (3) "ignored data regarding cancer risks"; (4) "misrepresented risks and failed to apply FQPA 10X safety factor" in its 2006 cumulative risk assessment; (5) "over-relied on registrant data"; (6) "failed to properly address the exporting hazard in foreign countries from chlorpyrifos"; (7) "failed to quantitatively incorporate data demonstrating long-lasting effects from early life exposure to chlorpyrifos in children"; (8) "disregarded data demonstrating that there is no evidence of a safe level of exposure during pre-birth and early life stages"; (9) "failed to cite or quantitatively incorporate studies and clinical reports suggesting potential adverse effects below 10% cholinesterase inhibition"; and (10) "failed to incorporate inhalation routes of exposure." *Final Order*, 84 Fed. Reg. at 35,556.

expedited reregistration review). Despite its 2022 statutory deadline, EPA announced that it planned to prioritize review of chlorpyrifos and complete reevaluation by 2015, years ahead of schedule. *Id.* at 35,558. However, this review proved to be complex, particularly with regard to the potential human health risks and neurodevelopmental effects of chlorpyrifos tolerances. *Id.*

In the interim, EPA convened scientific panels to evaluate the evidence and published reports. In 2008, as part of its reregistration review, EPA published a Science Issue Paper addressing chlorpyrifos hazards. EPA, Office of Pesticide Programs, *Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization* (Aug. 21, 2008). The paper summarized "data relevant to infants, children, and pregnant women," interpreted this data, and suggested alternatives for updating the mechanism used to assess chlorpyrifos tolerance safety. *Id.* at 7. The paper "preliminarily concluded that chlorpyrifos likely played a role in" adverse health effects in children. *Id.* at 52**.** However, the paper specifically noted that there had not been "a full and complete risk assessment/characterization" of the human health risks of chlorpyrifos and that "the [EPA] has not developed any final conclusions regarding updates to the chlorpyrifos hazard assessment." *Id.* at 7.

Later that year, EPA convened a Science Advisory Panel (SAP or the Panel), a federal advisory committee "established under the provisions of FIFRA" that "serves as the [EPA's] primary scientific peer review mechanism" for pesticide matters, to peer review the paper. EPA, *SAP Minutes No. 2008-04: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos* 2 (Sept. 16–18, 2008). The SAP also

considered several new studies concerning the risk of chlorpyrifos to pregnant women and children. The SAP's evaluation noted that "Panel members were concerned that a high degree of uncertainty is evident in the available data . . . ." *Id.* at 10. First, the Panel expressed concerns about several laboratory studies involving live rodents and the meaning of phrases used and experimental methods employed, and concluded that this data was "insufficient." *Id.* at 11–12. The Panel also considered three epidemiology studies, referred to as the Mt. Sinai, CHAMACOS, and Columbia University studies. The Columbia Study, which assessed chlorpyrifos risk to pregnant women, infants, and children, commanded particular attention. *Id.* at 12. The Panel found defects in all three of the studies, including concerns that the Columbia Study—the most robust of the three—did not provide sufficient data to be the sole factor for risk assessment or modifying tolerances and produced uncertainty through its measurement method. *Id.* at 12–13, 32–35, 43–44. Although the SAP found that the studies "raise concerns," the SAP also agreed that the studies were inconclusive. *Id.* at 13–14. The SAP concluded that "chlorpyrifos could have contributed to the birth and neurodevelopmental outcomes" indicated in the studies, but "that due to their limitations, the epidemiological data currently available are useful primarily for hazard identification." *Id.* at 13.

In 2011, EPA published a Preliminary Human Health Risk Assessment (*PHHRA*) for chlorpyrifos as part of its forthcoming FIFRA review. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review* 1–2 (June 30, 2011). This assessment again considered the laboratory and epidemiology studies evaluated by the 2008 SAP and similarly noted their limitations. *Id.* at 29–34. The

PHHRA also considered developments since the 2008 SAP, including new data and follow-up analysis on the Columbia Study that had been recommended by the Panel. *Id.* at 34. EPA came to no definitive conclusion in the *PHHRA*, instead stating that analyses were ongoing and the final assessment would

> be based on a full scientific weight of evidence approach that considers the best available science and integrates all key lines of evidence, from empirical animal toxicology to observational human epidemiology studies, in an integrated framework analysis and will transparently address and clearly characterize the strength of the evidence and areas of remaining uncertainty and variability.

Id. at 42.

In April 2012, EPA again convened the SAP to consider the health effects of chlorpyrifos. EPA, *SAP Minutes 2012-04: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects* (April 10–12, 2012). The SAP recognized "a growing body of literature with laboratory animals (rats and mice) indicating that gestational and/or early postnatal exposure to chlorpyrifos may cause persistent effects into adulthood" and epidemiology studies "that have reported associations with birth outcomes, childhood neurobehavioral and neurodevelopment outcomes." *Id.* at 10. In addition to nine new laboratory studies, the 2012 SAP reviewed the same laboratory studies evaluated by the 2008 SAP, again noting the laboratory studies' limitations and "recommend[ing] these experimental outcomes be

regarded as exploratory, and hypothesis-generating, as opposed to being evidence of toxicity." *Id.* at 15. However, the Panel found that, despite concerns about the studies, "the collective weight of evidence from these studies demonstrate that it is probable that there are significant long-term adverse effects from chlorpyrifos exposure." *Id.* at 16. The 2012 SAP likewise considered the same epidemiology studies analyzed by the 2008 SAP, recognizing their strengths and limitations. *Id.* at 17–18, 48–50. The Panel noted that the epidemiological studies indicated "that chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies" but proposed further study because "the data generated from these studies alone are not adequate enough" to make a definitive risk assessment. *Id.* at 18–19. The SAP advised EPA to "explore additional ways of using these studies" and conduct additional research. *Id.* at 19–20.

In December 2014, EPA published a Revised Human Health Risk Assessment (*2014 RHHRA*) for chlorpyrifos. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* (Dec. 29, 2014). This revised assessment incorporated comments on the preliminary assessment and included assessment of new data. *Id.* at 5. The *2014 RHHRA* found that data, including the laboratory and epidemiology studies, "indicate that chlorpyrifos likely played a role in the neurodevelopmental outcomes reported by the epidemiologic study (Columbia University) investigators" but that "uncertainties . . . preclude definitive causal inference." *Id.* at 6. Yet again, EPA noted that the studies reflected both strengths and "notable limitations." *Id.* at 43. In this assessment, EPA also revised its approach to calculating chlorpyrifos "points of departure," or the

ceiling for safe exposure to a pesticide based on these studies. *Id.* at 40, 62–70, 131.

In January 2015, EPA announced the availability of the *2014 RHHRA* and sought public comments on "the Agency's risk assessment methodologies and assumptions . . . [and] suggestions for mitigating any risks identified in the [*2014 RHHRA*]." *Chlorpyrifos Registration Review; Revised Human Health Risk Assessment; Notice of Availability*, 80 Fed. Reg. 1,909, 1,910 (Jan. 14, 2015). Additionally, in March 2015, EPA advised counsel for the petitioners by letter that it intended to deny the three unresolved claims in the 2007 Petition—the claims at issue in this appeal. EPA, Office of Chemical Safety & Pollution Prevention, *Re: Chlorpyrifos Petition Dated September 12, 2007; March 2015 Provisional Response* (Mar. 26, 2015). EPA incorporated its prior partial petition responses from 2012 and 2014, which denied seven of the ten claims raised in the petition. *Id.* With respect to the three remaining claims, which were those related to infants and children and based on the Columbia, Mount Sinai, and CHAMACOS studies, EPA advised counsel that "EPA does not believe the claims raised in your petition establish a basis to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations." *Id.* at 3. The letter noted that EPA had "risk concerns" with exposure to chlorpyrifos in drinking water, but it was seeking comment on its *2014 RHHRA* and would "take appropriate action under the FFDCA and/or FIFRA to ensure that exposures to chlorpyrifos are consistent with the requirements of those statutes." *Id.* at 3–4.

2. We issue mandamus; EPA proposes to revoke the tolerances

Six months later, in August 2015, we issued a writ of mandamus ordering EPA "to issue either a proposed or final

revocation rule or a full and final response to the administrative petition." *In re Pesticide Action Network North America* (*PANNA II*), 798 F.3d 809, 815 (9th Cir. 2015). In response, EPA issued a proposed rule to revoke all chlorpyrifos tolerances because "EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe." *Chlorpyrifos; Tolerance Revocations*, 80 Fed. Reg. 69,080, 69,080–81 (Nov. 6, 2015) (*2015 Proposed Rule*). EPA advised that it was issuing the proposed rulemaking because of our mandamus order and that the proposal was "in advance of [EPA] completing its refined drinking water assessment." *Id.* at 69,083. EPA explained that it "believe[d] that acute dietary risk from food only does not present a significant risk" and that "EPA would therefore not be proposing the revocation of chlorpyrifos if dietary exposures were confined to food." *Id.* at 69,096–97. The basis for the proposed revocation was instead new data indicating that "for some portions of the country, food exposures, when aggregated with residential exposures and potentially more significant drinking water exposures, do present a significant risk concern and support revocation of all chlorpyrifos tolerances." *Id.* at 69,097. At the same time, EPA stated that it had "insufficient time to address comments received on the [2014] RHHRA," and it would "update this action . . . as EPA completes additional work." *Id.* at 69,083. EPA also cautioned that its analysis was incomplete and that it might yet modify the proposed rule based on the completed analysis and comments. *Id.* We then ordered EPA to take final action on the proposed rule and on PANNA and NRDC's petition no later than December 30, 2016. *In re Pesticide Action Network North America* (*PANNA III*), 808 F.3d 402, 403 (9th Cir. 2015).

In March 2016, EPA published a new Chlorpyrifos Issue Paper and solicited comment from the SAP regarding changing points of departure based solely on neurodevelopmental effects measured by the Columbia Study. EPA, Office of Pesticide Programs, *Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies* 9 (Mar. 11, 2016) (*2016 Issue Paper*). At the time EPA had proposed to revoke chlorpyrifos tolerances, "EPA had not completed a refined drinking water assessment or additional analysis of the hazard from chlorpyrifos that was suggested by several commenters." EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* 3 (Nov. 3, 2016) (*2016 RHHRA*). After engaging in additional research, EPA—in this Issue Paper—proposed using different "toxicological points of departure" based on data from the Columbia Study, and sought the advice of the 2016 SAP on this new approach. *2016 Issue Paper* at 9.

In April 2016, the SAP convened to review the Issue Paper. EPA, *SAP Minutes No. 2016-01: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Chlorpyrifos: Analysis of Biomonitoring Data* (April 19–21, 2016) (*2016 SAP Minutes*). The SAP expressed significant disagreement with the substance of the paper, including a lack of confidence that the Columbia Study "c[ould] accurately be used" in determining new points of departure. *Id.* at 18. The panel "thought the quality of the [Columbia Study] data is hard to assess when raw analytical data have not been made available, and the study has not been reproduced." *Id.* The SAP noted that review of the raw data from the Columbia Study could resolve some uncertainty regarding the study's conclusions. *Id.* at 20.

By mid-2016, claiming "extraordinary circumstances," EPA requested a six month extension on our order of final action. *In re Pesticide Action Network North America* (*PANNA IV*), 840 F.3d 1014, 1015 (9th Cir. 2016). EPA advised us that it had "issued its proposed rule before completing two studies that may bear on the Agency's final rule." *Id.* at 1015. We characterized EPA's request as "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action.'" *Id.* (quoting *PANNA II*, 798 F.3d at 811). We denied EPA's request and ordered final action by March 31, 2017. *Id.*

In November 2016, EPA released yet another Revised Human Health Risk Assessment, responding to the 2016 SAP's concerns. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* (Nov. 3, 2016) (*2016 RHHRA*). EPA recounted that in 2013 it had sought the raw data used in the Columbia Study, and although the researchers would not agree to provide EPA with the data, EPA "gained valuable insight into the conduct of the study." *Id.* at 9–10. EPA concluded that the SAP had rejected both the approach in the *2015 Proposed Rule* and the new method based on the Columbia Study. *Id.* at 3. EPA agreed with the SAP that, despite uncertainties in the studies, there was "sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels" below the tolerances. *Id*. at 13. As a result, EPA proposed following the 2016 SAP's recommendation to use a hybrid point of departure, rather than relying solely on the data from the Columbia Study. *Id.* at 13–14.

Within two weeks of issuing the *2016 RHHRA*, EPA reopened the comment period on the *2015 Proposed Rule*. *Chlorpyrifos; Tolerance Revocations; Notice of Data*

Availability and Request for Comment, 81 Fed. Reg. 81,049 (Nov. 17, 2016) (*2016 Request for Comments*). EPA noted that it was not proposing "a change to the EPA's proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP." *Id.* at 81,050; *see also id.* ("[T]he agency's analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard."). At the same time, EPA expressed frustration with the process, and advised that "the timing of EPA's issuance of the proposal was dictated" by our order in *PANNA II*. *Id*. EPA was clear that the basis for its proposed revocation depended on studies that were incomplete. It observed that EPA had completed a water assessment, but "[b]ecause of the court decision . . . EPA was not able to complete a more refined drinking water assessment for chlorpyrifos in advance of the proposed rule" and that with additional time it conducted the assessment to provide "a more tailored approach to risk mitigation." *Id.* at 81,051. EPA admitted that

> In the proposal, EPA proposed revoking all tolerances largely because the agency could not make a safety finding based on drinking water exposure in highly-vulnerable watersheds. EPA reasoned if it could better identify where such vulnerable areas might be, it could be possible for registrants to amend product labeling in ways that might make unnecessary some number of the proposed tolerance revocations.

Id. Importantly, EPA warned that its proposed course of conduct was not fixed:

> Since EPA is still in the process of deliberating the provisions of a final rule, EPA cannot definitively state whether this information will provide support for any provision of the final rule, or that the agency has determined that it is appropriate to rely on this information in developing the final rule.

Id.

3. EPA denies the petition; we issue mandamus

In April 2017, EPA reversed course, issuing a final response to the 2007 petition, which denied it in full. *Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances*, 82 Fed. Reg. 16,581 (April 5, 2017) (*2017 Denial*). The order stated:

> Following a review of comments on both the November 2015 proposal and the November 2016 notice of data availability, EPA has concluded that, despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without

> first attempting to come to a clearer scientific resolution on those issues.

Id. at 16,583. EPA thus denied the petition without resolving all scientific uncertainty concerning the tolerances "[b]ecause the 9th Circuit's August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted." *Id.* (referring to *PANNA IV*, 840 F.3d at 1015). EPA explained that the comments received in response to the *2015 Proposed Rule* "suggest that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA's risk assessment." *Id.* at 16,590. It then explained why it was denying the petition, rather than continuing its prior course:

> As the 9th Circuit has made clear . . . EPA must provide a final response to the Petition by March 31, 2017, regardless of whether the science remains unsettled and irrespective of whatever options may exist for a more complete resolution of these issues . . . .
>
> Although past EPA administrations had chosen to attempt to complete [FIFRA] review several years in advance of the statutory deadline (and respond to the Petition on the same time frame), it has turned out that it is not possible to fully address these issues early in the registration review period . . . . Accordingly, EPA is denying these Petition claims and intends to complete a full and appropriate review of the neurodevelopmental data before either

> finalizing the [2015] proposed rule . . . or taking an alternative regulatory path.

Id. EPA concluded that "given the importance of this matter and the fact that critical questions remain regarding the significance of the data addressing neurodevelopmental effects, EPA believes there is good reason to extend the registration review of chlorpyrifos and therefore to deny the Petition." *Id.*

Various organizations petitioned our court for review of EPA's order. On review of EPA's *2017 Denial*, the panel ordered EPA to revoke the chlorpyrifos tolerances. *League of United Latin American Citizens v. Wheeler* (*LULAC I*), 899 F.3d 814, 829 (9th Cir. 2018). Judge Fernandez dissented on the grounds that the *2017 Denial* was not a final action. *Id.* at 830–32 (Fernandez, J., dissenting). We granted en banc review, vacated the panel opinion, and ordered EPA to issue a final order. *League of United Latin American Citizens v. Wheeler* (*LULAC II*), 922 F.3d 443, 445 (9th Cir. 2019) (en banc). EPA issued its *Final Order* in July 2019, and we referred the petition back to the three-judge panel. *League of United Latin American Citizens v. Wheeler* (*LULAC III*), 940 F.3d 1126, 1127 (9th Cir. 2019).

B

EPA's *Final Order* responded to the two objections raised in *LULAC I*: (1) that the "EPA has unlawfully left chlorpyrifos tolerances in place without making the safety finding required by the FFDCA"; and (2) that EPA must revoke the tolerances because it "has previously found that chlorpyrifos tolerances are unsafe and has not disavowed those findings." *Final Order*, 84 Fed. Reg. at 35,561.

1. Failure to find that chlorpyrifos is "safe"

EPA first addressed Petitioners' argument that EPA was required to make a new safety finding to deny the petition. EPA found that it was not required to make a new safety determination in response to every revocation petition, the FFDCA did not require revocation in the absence of a new safety determination for each petition, and *even if* a new safety determination was required, both the FFDCA and EPA implementing regulations "require petitioners seeking withdrawal of a tolerance to support this request with valid, complete and reliable data that set forth why the tolerances are unsafe." *Id.* at 35,562.

The agency found that petitioners had not met their burden of presenting evidence that the tolerances must be revoked because "the information yet presented by Petitioners is not sufficiently valid, complete, and reliable." *Id.* at 35,562–63. EPA had already considered, during its 2006 review, the laboratory and epidemiological studies cited by Petitioners and had "consistently concluded" these studies did not warrant revocation based on "an evaluation across multiples lines of evidence." *Id*. at 35,563. EPA determined these studies were deficient because they lacked a "mechanistic understanding for effects on the developing brain," which precluded EPA from having a "valid or reliable way[] to bridge the scientific interpretation" of the studies with chlorpyrifos; the dosing regimen of the in vivo studies presented problems for "quantitative interpretation and extrapolation of the results" because they did not align with "internationally accepted protocols"; and EPA had been unable to obtain the raw data underlying the epidemiological studies, despite numerous efforts, to allow for verification of validity and reliability as well as replication. *Id.* EPA candidly acknowledged that its conclusion was "at odds"

with its *2016 RHHRA* but ultimately asserted that it had "undertaken considerable efforts to assess the available chlorpyrifos data." *Id.* at 35,564; *see also id.* ("EPA acknowledges this conclusion differs from the position supported in the 2016 revised human health risk assessment."). The agency concluded that "the shortcomings of the data identified raise issues of validity, completeness and reliability under the FFDCA that direct against using the data for risk assessment at this time." *Id.*

EPA explained that a majority of the 2016 SAP had concluded that use of the scientific studies under review for developing points of departure "could not be justified by any sound scientific evaluation." *Id.* at 33,564. The SAP "expressed significant reservations" about using the studies as the sole source of revised points of departure and "noted the incompleteness of the information," including the "reproducibility" of the data. *Id.* EPA concluded that "[b]ased on the uncertainties identified by the 2016 SAP," the data were "not complete." *Id*. EPA further laid out its requests to obtain the raw data underlying the studies and "visit[] [to] Columbia University in an attempt to better understand their study results and what raw data exist." *Id.* at 33,565. Although the university initially had pledged to share its data, it failed to produce it, citing "privacy concerns." *Id.* As a result, "EPA cannot validate or confirm the data analysis performed, the degree to which the statistical methods employed were appropriate, or the extent to which (reasonable or minor) changes in assumptions may have changed any final results or conclusions." *Id.* As a consequence, EPA concluded petitioners had "failed to meet their initial burden of providing sufficiently valid, complete, and reliable evidence that neurodevelopmental effects may be occurring at levels below EPA's current regulatory standard." *Id*.

EPA further concluded that denying the 2007 petition was appropriate because the claims in the petition would be subject to FIFRA registration review, which is a "more up-to-date, thorough and methodical" review. *Id.* EPA reiterated its commitment to complete FIFRA and FFDCA review of chlorpyrifos tolerances in advance of the October 2022 deadline, anticipating some updates "by summer of 2020." *Id.* at 35,566.

2. EPA's prior finding that chlorpyrifos is "not safe"

EPA also addressed petitioners' objection that the agency had already found chlorpyrifos to be unsafe in its 2015 proposed tolerance revocation. *Id.* at 35,566. EPA, however, was quite clear that "EPA has not made any findings that chlorpyrifos tolerances are not safe." *Id.* EPA pointed out that its last final action regarding the safety of chlorpyrifos tolerances—and the only regulatory finding in effect—was its 2006 reregistration and safety determination. *Id.* The *2015 Proposed Rule* was not a final agency action, and "EPA made clear it was issuing the proposal because of" the Ninth Circuit's order, "without having resolved many of the issues critical to EPA's FFDCA determination and without having fully considered comments previously submitted to the Agency." *Id.* It was up to EPA to "choose to finalize, modify or withdraw the proposal based on the comments received." *Id.* Accordingly, its prior proposed findings were "not binding pronouncements." *Id.*

C

EPA's decision to deny the petition in its entirety in response to our writ of mandamus is entirely reasonable. We ordered EPA to grant or deny the petitions; EPA did as we ordered. It has explained why it did so and explained how it will proceed with the chlorpyrifos reregistration, in which it

will have to decide whether it is "safe." There is nothing arbitrary or capricious in EPA's decision.

Although petitioners can argue that the denial of the petition conflicts with EPA's prior proposal, the *2015 Proposed Rule* is just that—a *proposed* rule. *2015 Proposed Rule*, 80 Fed. Reg. at 69,083 ("EPA may update this [proposed rule] with new or modified analyses as EPA completes additional work after this proposal."). "Agencies are entitled to change their minds." *Defenders of Wildlife v. Zinke*, 856 F.3d 1248, 1262 (9th Cir. 2017) (citation omitted); *see also Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658–59 (2007) ("[T]he only 'inconsistency' respondents can point to is the fact that the agencies changed their minds—something that, as long as the proper procedures were followed, they were fully entitled to do."). "The federal courts ordinarily are empowered to review only an agency's *final* action, *see* 5 U.S.C. § 704, and the fact that a preliminary determination . . . is later overruled . . . does not render the decisionmaking process arbitrary and capricious." *Nat'l Ass'n of Home Builders*, 551 U.S. at 659. Agencies that change their mind are not "subjected to more searching review." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009). What is important is that the agency "display awareness that it *is* changing position" and has explained itself. *Id.* at 515. EPA did not act arbitrarily and capriciously merely because it reversed course from its *2015 Proposed Rule*—a reversal that EPA explained.

Nor was the *2016 RHHRA* a final agency action. Human Health Risk Assessments are part of FIFRA reregistration review but are not in themselves safety determinations. *2016 RHHRA* at 3. It is the final Reregistration Eligibility Decision—which in this case was issued in 2006—that

serves as the final EPA action for determining safety pursuant to the FFDCA. *2006 Reregistration Decision* at 1–2. Although the *2016 RHHRA* stated that the studies cited by the petition provided "sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below" current tolerances, this conclusion is tentative until the agency adopts it as part of a final order or rule. *2016 RHHRA* at 13. The *2016 RHHRA* remains part of a broader review process that will culminate in another Registration Eligibility Decision no later than 2022. In the meantime, however, relying on its Scientific Advisory Panel, EPA has explained why that study is flawed. The methodology used in the *2015 Proposed Rule* was rejected by the SAP, and the *2016 RHHRA* attempted to address the SAP's concerns by using a different approach. *Id.* at 3–4.

As it is entitled to do, EPA has sufficiently explained its rationale for reversing course from the *2015 Proposed Rule* and *2016 RHHRA* and denying the petition. EPA was required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotations marks and citation omitted). EPA did articulate an explanation for its departure from the *2015 Proposed Rule* and the *2016 RHHRA* in its *2017 Denial* and *Final Order*. In its *2017 Denial* of the petition, EPA explained that responses from the 2016 SAP and comments received in response to the *2015 Proposed Rule* raised "considerable areas of uncertainty" regarding the studies. *2017 Denial*, 82 Fed. Reg. at 16,590. Based on this uncertainty, EPA concluded that it should instead "explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA's risk

assessment prior to finalizing any regulatory action in the course of registration review." *Id.*

EPA again explained the rationale for its departure from the *2016 RHHRA* in its *Final Order*. EPA explicitly recognized its denial of the petition was "at odds with" the *2016 RHHRA*, but it explained that it had "undertaken considerable efforts to assess the available chlorpyrifos data," summarizing its longstanding concerns about the studies relied on by petitioners. *Final Order*, 84 Fed. Reg. at 35,564. EPA discussed its decision to convene the SAP in 2016 to specifically consider the EPA's proposal to use information derived from the Columbia Study to develop a point of departure—a meeting EPA noted "was unique in focus compared to the previous meetings"—and the SAP's rejection of using that data alone as the basis for the new point of departure. *Id.* EPA explained that the 2016 SAP's feedback on the proposal based on the Columbia Study data was "consistent with concerns raised in public comments EPA received on the use of the epidemiology data throughout the course of registration review." *Id.* EPA further noted that, although the 2008 and 2012 SAPs recognized strengths in the Columbia Study, neither recommended changing points of departure based on the study, and the 2016 SAP expressed even more reservation about using the study in this way. *Id.* Thus, despite preliminary assessments that recognized potential in the Columbia Study data, EPA ultimately concluded that "the shortcomings of the data identified raise issues of validity, completeness and reliability under the FFDCA that direct against using the data for risk assessment at this time." *Id.* EPA also noted that this was not its final conclusion regarding the validity of the studies and that it "intends to continue its exploration of the uncertainty" with regards to the studies' conclusions. *Id.* Because these studies—which

met the threshold requirements for consideration on the merits—were not sufficiently valid, complete, and reliable to support revocation, EPA decided not to modify or revoke the chlorpyrifos tolerances.

Nothing in EPA's explanations is arbitrary or capricious. It is clear that the agency has struggled with the scientific studies before it. But nothing in either the procedure or the substance of EPA's actions—aside from playing Hamlet—suggests that the agency has been irresponsible. To the contrary, at every step of the way, EPA has conscientiously examined the evidence. In 2015, it told petitioners it would deny the petition outright. This was not surprising because EPA had long advised the petitioners and other interested persons of the flaws in the studies. It changed course later that year when it was forced to make a decision in response to our writ of mandamus. EPA then proposed revoking the chlorpyrifos tolerances based on a novel measure of the effect on infants and children—only to have the SAP disapprove of the measure in 2016 and recommend further study. EPA requested further comments on the science—and an extension of time to make a decision. When we told EPA that there would be no further extensions, EPA called for additional comments and repeated that the studies were inconclusive, but EPA continued to believe it had no choice but to revoke the tolerances. But even as it called for last comments, EPA advised that it was "still in the process of deliberating the provisions of a final rule." *2016 Request for Comments*, 81 Fed. Reg. at 81,051.

So how do we assess this convoluted history? It is certainly true that the agency had some stops and starts along the way, but that is evidence of deliberate decisionmaking, not dereliction of duty. We, of all institutions, should respect that there will be give-and-take in complicated matters of

consequence. The FFDCA does not demand unanimity within EPA, any more than it requires unanimity from this court before we may issue a judgment in this case.

In my view, the majority has intervened in ongoing debates within EPA over what the evidence proves and how it should be weighed. It is not our place to second-guess EPA's scientific assessment of laboratory and epidemiological studies supporting the petition. "Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters." *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989). When an agency makes determinations "within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). The majority improperly makes its own assessment of the reliability of the studies and whether EPA's concerns are sufficient to determine that chlorpyrifos tolerances are "not safe." Maj. Op. 54–58, 60–63. But EPA's assessment of the scientific strength of the studies supporting the petition is precisely the type of analysis that should be given deference. FFDCA safety determinations are within EPA's area of expertise. We should not second-guess EPA's scientific conclusions with regards to the value of these studies. EPA's denial of the 2007 petition was neither arbitrary nor capricious.

* * *

The FFDCA does not require EPA to engage in a full-blown FFDCA safety evaluation in response to every petition filed with the agency. Instead, where a petition presents reasonable grounds for revocation, EPA must consider whether the petition puts forth data that supports a determination that a pesticide tolerance is not safe. Where

the data supporting a petition are not sufficiently valid, reliable, or complete, EPA may deny the petition and rest on its operative safety determination. Here, EPA complied with its statutory obligation: the agency considered the petition on the merits and determined that the data supporting the petition was insufficient to support revocation. Based on this determination, EPA denied the petition and relied on its 2006 finding that chlorpyrifos tolerances are safe. EPA explained the deficiencies in the underlying petition's supporting studies and its rationale for departing from its prior preliminary determinations. EPA did all that the FFDCA required.

III

Even if I thought the majority had read the statute correctly and had a clear-eyed view of the validity and weight to be given to the scientific evidence, the remedy ordered by the majority is an abuse of our discretion. Assuming that petitioners have demonstrated that chlorpyrifos is "not safe," the FFDCA gives EPA the discretion to decide whether to modify or to revoke the tolerance. *See* 21 U.S.C. § 346a(b)(2)(A)(i); Maj. Op. at 60 ("[O]nce the EPA has determined that a tolerance is not safe, . . . it must modify or revoke the tolerance."). Concluding that on this record "the present tolerances are not safe," Maj. Op. at 63, the majority orders EPA to "modify or revoke chlorpyrifos tolerances and modify or cancel chlorpyrifos registrations,"[9] Maj. Op. at 63, and gives EPA 60 days to do

[9] In ordering the modification or cancellation of FIFRA registrations, Maj. Op. at 67, the majority has exceeded the scope of what a petition under the FFDCA allows: modification or cancellation of chlorpyrifos *tolerances* under the FFDCA. *See* 21 U.S.C. § 346a(d)(1)(A) (allowing petitions "proposing the issuance of a

so, Maj. Op. at 67. It is more than a little ironic that this court will have taken over a year since the filing of the last brief to decide this case, but we will expect EPA to make an informed decision in the next 60 days.

The 60 days the majority gives EPA is not a number drawn from the statutes, but one made up by the majority, and it may well foreordain the option EPA must choose. In my view, the stakes in this case are too high for the majority to take upon itself to decide what the United States will do with respect to chlorpyrifos. "By pounds of active ingredient, [chlorpyrifos] is the most widely used conventional insecticide in the country" and for some crops it is "currently the only cost-effective choice for control of certain insect pests." *Final Order*, 84 Fed. Reg. at 35,558.[10] That, of course, is not an argument for finding chlorpyrifos safe, as EPA recognized, but it should sharpen our focus on what we are doing. *See 2017 Denial*, 82 Fed. Reg. at 16,590 ("Although not a legal consideration, it is important to recognize that for many decades chlorpyrifos has been and remains one of the most widely used pesticides in the United States, making any decision to retain or remove this pesticide from the market an extremely significant policy choice."). That is why EPA should be considering the options Congress

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regulation establishing, modifying or revoking a *tolerance*" under that statute (emphasis added)). Although modification of revocation of a tolerance under the FFDCA will necessarily impact registrations under FIFRA, the FFDCA does not afford this court authority to order modification or cancellation under FIFRA.

[10] Chlorpyrifos tolerances are classified by crop (*e.g.*, alfalfa, almonds, apples, corn, cotton, grapes, oranges, pears, soybeans, walnuts, and wheat) and usage (*e.g.*, cockroach and fire ant control, mosquito abatement, utility pole treatments) and are region specific. The complexity of the tolerances is difficult to overstate.

made available, not us. And we have not given anything but the most fleeting consideration to the options.[11]

It is far from clear that EPA will be able to do anything in the next 60 days other than revoke the tolerances. Yet, between argument and the issuing of this decision, EPA advised us that it has issued an interim decision to reregister chlorpyrifos, with modifications. *Pesticide Registration Review; Proposed Interim Decision for Chlorpyrifos; Notice of Availability*, 85 Fed. Reg. 78,849 (Dec. 7, 2020) (*2020 Proposed Interim Decision*) (inviting comments on EPA, *Chlorpyrifos: Proposed Interim Registration Review Decision* (Dec. 3, 2020) (*2020 Proposed Interim Registration*)). In the *2020 Proposed Interim Registration*, EPA explained that it was proceeding with suggested modifications, but that it still faced "numerous novel scientific issues, notably the potential for neurodevelopment effects on the young." *2020 Proposed Interim Registration Decision* at 10. Candidly, EPA stated:

> Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. . . . Notwithstanding,

[11] The majority may have effectively foreclosed other options Congress made available to EPA. Under the FFDCA, if a petitioner can show that it not safe, EPA must modify or revoke the tolerance; or, in its periodic statutory review, if EPA cannot determine chlorpyrifos is safe, it cannot leave the tolerance in place. But if EPA arrives at that point, there is yet an additional option: EPA has the power to leave in effect or modify a tolerance if it concludes that certain consequences will follow—if "the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk" or if the tolerance "is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii). These contingencies would still require EPA to certify that the tolerances modified or left in effect satisfy the "no harm" to infants and children criteria in 21 U.S.C. § 346a(b)(2)(C).

> EPA recognizes that the science is evolving on this topic, and that there may be new information available prior to the completion of registration review that may impact the agency's conclusions about these effects.

Id. It further advised that it had convened a SAP in September 2020 "to assess new approval methodologies that might used to evaluate developmental neurotoxicity in EPA's assessment of risks to human health." *Id.*; *see also id.* at 40, 63. The SAP's report was issued a week later in December 2020. EPA, *FIFRA Scientific Advisory Panel Meeting Minutes and Final Report No. 2020-02*: *Peer Review of the Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment* (Sept. 15–18, 2020) (report released Dec. 15, 2020). For the reasons I have explained, in this latest proceeding, the risk of nonpersuasion runs against the existing tolerances. That means that EPA will have to decide the issues reserved in its interim proceedings—and, specifically, the question of safe tolerances for children and youth—and it must do so by 2022, the deadline set by Congress.

What effect the majority's order will have on EPA's latest proceeding is unclear, but the majority's order presents it with two unsatisfactory choices: either issue modified tolerances outside the procedure required by the FFDCA, FIFRA, and APA, or revoke the tolerances. Given the *2020 Proposed Interim Registration Decision*, maybe EPA will be comfortable issuing modified tolerances, but in order to do so it will have to accelerate its schedule, and that may mean skipping some steps. *See 2020 Proposed Interim Registration Decision* at 4, 8–9 (explaining that EPA is

awaiting revised biological opinions from the National Marine Fisheries Service and the U.S. Fish & Wildlife Service). Alternatively, EPA may be forced to revoke tolerances that it has tentatively concluded it will reregister or reregister with modifications. Perhaps EPA will again approve registration of chlorpyrifos at some future date once it completes full FIFRA and FFDCA review, but our precipitous order will have imposed tremendous costs on various sectors of the economy without waiting for the system to work.

Finally, I have to comment on the artificial schedule that our court has imposed on EPA, not only in this case, but time and again in these proceedings. EPA took the 2007 petition to revoke chlorpyrifos very seriously. Unlike reregistration under FIFRA, there is no statutory deadline for dealing with a petition, although in principle twelve years seems like more than enough time. The extraordinary delay, however, makes more sense in context: EPA initially believed that it could accelerate the FIFRA reregistration due in 2022 and address both the petition and the reregistration at the same time and well before that date. In the meantime, the petitioners asked us to intervene and order EPA to rule on its petition. EPA repeatedly advised us that it could not meet those demands if it was to complete the reregistration process properly. We insisted. Eventually, but reluctantly, EPA proposed to revoke the tolerances—even as it stated that it was doing so without complete information. *See, e.g.*, *2016 Request for Comments*, 81 Fed. Reg. at 81,050; *2015 Proposed Rule*, 80 Fed. Reg. at 69,080. After further proceedings, EPA concluded that it was better to deny the petitions outright because the petitioners had failed to show that the tolerances were not safe, and then complete the FIFRA reregistration process, where it would have a full record. EPA's decision is consistent with the FFDCA, as

amended by the FQPA. Although in hindsight the process took much longer than EPA anticipated, that was a reasonable decision on EPA's part at the time.

When we intervene in scientific inquiries with impatience and impose artificial deadlines, we bear some responsibility for the confusion that results. In *San Luis & Delta-Mendota Water Authority v. Jewell*, 747 F.3d 581 (9th Cir. 2014), the district court ordered the U.S. Fish & Wildlife Service to produce a complex, 400-page biological opinion in less than a year. The resulting biological opinion was

> a jumble of disjointed facts and analyses. It appears to be the result of exactly what we would imagine happens when an agency is ordered to produce an important opinion on an extremely complicated and technical subject matter covering multiple federal and state agencies and affecting millions of acres of land and tens of millions of people.

Id. at 605; *see also id.* at 605 n.15 (noting that "the FWS had less time to produce its opinion than either the district court or we will have had to review it"). We "wonder[ed] whether anyone was ultimately well-served by the imposition of tight deadlines in a matter of such consequence." *Id.* at 606. When we interject ourselves into technical proceedings, our "[d]eadlines become a substantive constraint on what an agency can reasonably do. . . . Such scientific tasks may not be as well suited to deadlines as producing written copy; the final product will necessarily reflect the time allotted to the agency." *Id.* We can only hope that "[f]uture analyses [will] be given the time and attention that these serious issues deserve." *Id.*

In any event, our order is an abuse of any discretion the APA confers on us. We have the power to "compel agency action . . . unreasonably delayed," 5 U.S.C. § 706(1), but we do not have the power to choose among the options available to EPA. Our deadline may effectively make the choice for EPA.

IV

There are manifest errors in the majority opinion. It has misread the FFDCA and misallocated the risk of nonpersuasion. It has overruled EPA's judgment on the validity and weight to be given technical evidence within EPA's expertise. And by its decision to give EPA 60 days to issue a final decision in this case, the majority has likely predetermined EPA's option. I respectfully, but firmly, dissent.