**No. 14-72794**

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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IN RE PESTICIDE ACTION NETWORK NORTH AMERICA, and NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

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# EPA'S RESPONSE TO RENEWED PETITION FOR A WRIT OF MANDAMUS

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|---|---|
| EPA | United States Environmental Protection Agency |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| MRI | Magnetic Resonance Imaging |
| NRDC | Natural Resources Defense Council, Inc. |
| OSHA | Occupational Safety and Health Administration |
| PANNA | Pesticide Action Network North America |
| PBPK/PD | Pharmacokinetic and Pharmacodynamic |

## INTRODUCTION

Petitioners Pesticide Action Network North America ("PANNA"), and Natural Resources Defense Council, Inc. ("NRDC") (collectively "Petitioners") argue in their Renewed Petition for a Writ of Mandamus that Respondent United States Environmental Protection Agency ("EPA") has unreasonably delayed action on their 2007 administrative petition (the "Administrative Petition") requesting that EPA revoke the tolerances for and ban the widely-used pesticide chlorpyrifos. EPA has not unreasonably delayed action, and Petitioners have not shown that they are entitled to the extraordinary remedy of a writ of mandamus.

EPA has already addressed seven of the ten complex scientific issues raised in the Administrative Petition and has been diligently working on the final three, while balancing competing statutory obligations and facing resource limitations. EPA expects to address the remaining issues within weeks in its revised Human Health Risk Assessment for Chlorpyrifos. EPA's thorough consideration of these issues will inform its ultimate decision whether to leave in place the tolerances for chlorpyrifos or cancel chlorpyrifos registrations, and a full record will facilitate any subsequent judicial review of those decisions. Moreover, despite Petitioners' claim to be without recourse, Petitioners have declined opportunities to expedite administrative and judicial review of the issues that EPA has already addressed. Thus, the Renewed Petition for Writ of Mandamus should be denied and the case

dismissed.

## BACKGROUND[1]

### I. Statutory and Regulatory Background

EPA regulates pesticides under both the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *see* 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y.

#### A. The Federal Food, Drug, and Cosmetic Act

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

[1] Consistent with this Court's July 10, 2013 ruling, EPA agrees that, because this Court would have jurisdiction to review any final EPA action on the Administrative Petition after exhaustion of all administrative remedies, 21 U.S.C. § 346a(h)(1), this Court has jurisdiction over this case alleging EPA's failure to act on the Administrative Petition. *In re PANNA*, 532 Fed. Appx. 649, 650-52 (9th Cir. July 10, 2013) (citing *In re Cal. Power Exch. Corp.*, 245 F.3d 1110, 1119-20 (9th Cir. 2001)).

[2] "Safe" means 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." 21 U.S.C. § 346a(b)(2)(A)(ii).

food is considered "adulterated" and may not be moved in interstate commerce legally. *Id.* §§ 331(a), 342(a)(2)(B), 346a(a). EPA must consider nine factors, and may consider other relevant factors, when it establishes, modifies, leaves in effect, or revokes a tolerance for a pesticide chemical residue. *Id.* § 346a(b)(2)(D).

In 1996, Congress amended the FFDCA with the Food Quality Protection Act, which instructed EPA, among other things, to assess the risks of pesticides based on available information concerning the special susceptibility of infants and children to pesticide chemical residues. *Id*. § 346a(b)(2)(C). To ensure that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to pesticide chemical residues, Congress mandated that EPA apply an additional ten-fold margin of safety in setting certain tolerances unless reliable data show that a different margin of safety will be safe for infants and children. *Id*. Congress also amended the FFDCA to require that EPA re-assess by August 3, 2006, the existing tolerances and exemptions for all pesticide chemical residues that were in effect on August 3, 1996. *Id.* § 346a(q)(1).

The FFDCA sets forth a multi-stage procedural framework for the establishment, modification, or revocation of tolerances. The first stage may be initiated by EPA acting on its own accord or in response to an administrative petition. *Id.* § 346a(d)(1), (e)(1). "Any person may file with [EPA] a petition proposing 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). If EPA determines that an administrative petition meets the statutory and regulatory requirements governing petition contents, EPA publishes a notice of the administrative petition's filing. *Id.* § 346a(d)(3). EPA must then give "due consideration" to the petition and take one of three actions: (i) issue a final regulation establishing, modifying, or revoking a tolerance; (ii) issue a proposed regulation under the separate provisions of 21 U.S.C. § 346a(e), and thereafter issue a final regulation after additional public notice and comment; or (iii) issue an order denying the petition. *Id*. § 346a(d)(4)(A).

Congress has directed that EPA give priority to petitions to establish tolerances regarding pesticide chemical residues that appear to pose a significantly lower risk to human health from dietary exposure than pesticides with existing tolerances for the same or similar uses. *Id.* § 346a(d)(4)(B). Congress has also directed that EPA provide expedited review of complete petitions proposing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which an existing tolerance has been left in place or modified under 21 U.S.C. § 346a(b)(2)(B). *Id.* § 346a(d)(4)(C). EPA is to take final action on those petitions within one year of its determination that a petition is complete. *Id.* Congress has not otherwise set forth any specific deadline for EPA's action on an administrative petition. *See id.*

When EPA issues a regulation or order establishing, modifying, or revoking a tolerance, any person may file written objections with EPA and may also request an evidentiary hearing on those objections. *Id.* § 346a(g)(2)(A). After considering any objections and any hearing, if held, EPA must issue a final order with respect to the objection. *Id.* § 346a(g)(2)(C). Such an order is subject to judicial review in the United States Courts of Appeals. *Id.* § 346a(h).

### B. The Federal Insecticide, Fungicide, and Rodenticide Act

EPA also regulates pesticides under FIFRA. FIFRA requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id.* § 136a(c)(5). As part of the application process, FIFRA requires EPA to review and approve pesticide labeling, and provides that use of a registered pesticide inconsistent with its labeling is illegal. *Id.* § 136j(a)(2)(G).

FIFRA also requires periodic reevaluation of pesticides. Section 4 of FIFRA, 7 U.S.C. § 136(a)-1, requires EPA to make reregistration determinations for all pesticides first registered prior to November 1, 1984. Following the reregistration process for these older pesticides (which is now largely complete), FIFRA directs EPA to re-evaluate through a process known as "registration

review" all currently registered pesticides by the later of October 1, 2022, or 15 years after the date on which the first pesticide containing a new active ingredient is registered, and at 15-year intervals thereafter. *Id.* § 136a(g)(1)(A)(iii)–(iv).

## II. Factual and Procedural Background

### A. Chlorpyrifos

Chlorpyrifos is an organophosphate insecticide that was first registered under FIFRA in 1965. *See* Renewed Pet. for Writ of Mandamus (hereinafter "Mandamus Pet.") Exh. 1 ¶ 4 (hereinafter "Housenger Decl."). Prior to 2000, chlorpyrifos was widely used as both a household and an agricultural pesticide. Housenger Decl. ¶¶ 5, 9. In 2000, virtually all residential uses were eliminated. *Id.* ¶ 9. Chlorpyrifos remains one of the most widely used agricultural insecticides in the United States. *Id.* ¶ *5*.

In connection with the reregistration of chlorpyrifos under FIFRA and tolerance reassessment under the FFDCA, EPA completed an Interim Reregistration Eligibility Decision in September 2001. *See id.* Attach. A.[3] That decision evaluated both aggregate human health and ecological effects and led to significant risk mitigation measures, such as amendments to product labels that

[3] Attachment A to the Housenger Declaration is EPA's Reregistration Eligibility Decision for Chlorpyrifos, which contains both the 2001 chlorpyrifos Interim Reregistration Eligibility Decision and the 2006 final decision document as to all organophosphates.

would impose no-spray buffer zones around water bodies. *Id.* In August 2006, EPA completed a cumulative risk assessment for organophosphates with the common endpoint mechanism acetylcholinesterase inhibition,[4] including chlorpyrifos, thereby completing reregistration and tolerance reassessment for those pesticides. *Id*. The risk assessment evaluated the combined human dietary and non-occupational exposures of all the organophosphate pesticides and determined that the cumulative exposures were safe. *Id.* In short, with the existing limitations on the use of chlorpyrifos in place, EPA determined that both the aggregate human exposure assessment regarding chlorpyrifos and the cumulative risk assessment for all the organophosphate pesticides met the strict FIFRA and FFDCA human health safety standards, including the safety standards for infants and children established under the Food Quality Protection Act. *Id.*

### B. EPA's Action on the Administrative Petition

In September 2007, PANNA and NRDC submitted to EPA a joint petition to

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[4] Chlorpyrifos, like all organophosphates, achieves its pesticidal effect by inhibiting the nervous system enzyme acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system in both target pests and humans. Housenger Decl. ¶ 6. Because acetylcholinesterase inhibition can be measured at very low levels in the blood, acetylcholinesterase inhibition is used as a biomarker in developing safe levels of exposure. *Id.* 10% acetylcholinesterase inhibition is currently used as the point of departure for regulatory purposes. *Id.* ¶ 7. "Point of departure" refers to the exposure level or dose of chlorpyrifos where statistically significant acetylcholinesterase inhibition occurs based upon controlled dosing in a laboratory setting. *Id.* ¶ 7.

revoke all FFDCA tolerances and cancel all FIFRA registrations for chlorpyrifos ("Administrative Petition"). Mandamus Pet. Sass Decl. Attach. 1, Exh. B (hereinafter "Admin. Pet."). The Administrative Petition makes ten claims regarding EPA's registration decision for chlorpyrifos, namely, that: (1) EPA ignored genetic evidence of vulnerable populations; (2) EPA needlessly delayed a decision regarding endocrine disrupting effects; (3) EPA ignored data regarding cancer risks; (4) EPA's cumulative risk assessment misrepresented risks and failed to apply an appropriate safety factor for children; (5) EPA over-relied on registrant-generated data; (6) EPA failed to properly address the exporting hazard from chlorpyrifos; (7) EPA failed to incorporate inhalation routes of exposure; (8) EPA disregarded data demonstrating that there is no evidence of a safe level of exposure during pre-birth and early life stages; (9) EPA failed to cite or quantitatively incorporate studies and clinical reports suggesting potential adverse effects below 10% cholinesterase inhibition; and (10) EPA failed to quantitatively incorporate data demonstrating long-lasting effects from early life exposure to chlorpyrifos. *Id.*

Even though EPA had just finished its reregistration and reassessment for organophosphates in 2006 and was not required by law to complete another review until 2022, EPA moved chlorpyrifos and the other organophosphates forward in the re-evaluation schedule and began its review in 2008. Housenger Decl. ¶¶ 13-

14. On October 17, 2007, EPA sought public comments on the Administrative Petition. *See* 72 Fed. Reg. 58,845 (Oct. 17, 2007).

On July 16, 2012, EPA issued a partial response to the Administrative Petition stating EPA's intent to deny the petition as to the first six issues. *See* Housenger Decl. Attach. J. The partial response stated that it was a final agency action as to one of the issues—whether EPA failed to address the exporting hazard from chlorpyrifos—which arose solely under FIFRA. *Id*. at 6. EPA offered to take final action as to the other five issues by issuing an order denying those parts of the Administrative Petition so that Petitioners could start immediately the objection process under the FFDCA as to those issues, which would ultimately allow them to seek judicial review. *Id*. at 4.[5] Petitioners did not act on this offer. Vogel Decl. ¶ 6.[6] Nor did Petitioners pursue judicial review of the exporting hazard issue. *Id*.

EPA also partially addressed a complicated seventh issue—Petitioners' assertion that EPA failed to address inhalation risks to bystanders in areas where chlorpyrifos is applied—in July 2012 by issuing an Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures. Housenger Decl. Attach. B. This evaluation updated the preliminary human health

[5] EPA reiterated this offer again in a January 25, 2013 letter to Petitioners discussing additional developments. *See* Mandamus Pet. Exh. 8 at 5.

[6] Dana Vogel is the acting director of the Health Effects Division in EPA's Office of Pesticide Programs. Her declaration is attached to this Response.

risk assessment as to bystander inhalation risk (and dermal risk) from "primary" spray drift, *i.e.*, drift that occurs at the time of application. *Id*. As a result, chlorpyrifos registrants agreed to amend product labeling to reduce application rates and impose no-spray buffers that mitigate risk from primary spray drift. Housenger Decl. Attach. K. This effectively granted some of the relief requested in the Administrative Petition by limiting the use of existing chlorpyrifos products.

In February 2013, EPA released for public comment its preliminary evaluation of risks from chlorpyrifos volatilization following application of the pesticide, another part of the inhalation issue raised in the Administrative Petition. Vogel Decl. ¶ 6 & Attach. A. In response, Dow AgroSciences LLC ("Dow") conducted two new studies on vapor phase inhalation, whose results contradicted EPA's preliminary evaluation, demonstrating that volatilized chlorpyrifos, which is in vapor form, does not present a risk concern because the air cannot hold sufficient amounts of chlorpyrifos vapor to cause acetylcholinesterase inhibition. *Id*. ¶ 6. Consideration of public comments, especially the new studies, took longer than EPA expected, and EPA issued a revised volatility assessment on June 25, 2014. *Id*. ¶ 6 & Attach. B. EPA then completed its response on the bystander inhalation issue on July 15, 2014, when it issued its final evaluation of risks from chlorpyrifos volatization. *Id*. ¶ 6; Mandamus Pet. Exh. 9. EPA offered to take final action on the bystander inhalation issue so that Petitioners could start the

objection process, but, once again, Petitioners chose not to take advantage of this opportunity. Vogel Decl. ¶ 6.

### C. Remaining Work on the Administrative Petition

EPA has been diligently analyzing the remaining three issues raised in the Administrative Petition, which concern chlorpyrifos toxicity to humans, and is near completion of its assessment of those issues. As explained further in Paragraphs 11-20 of the Housenger Declaration, these are extremely complex issues of evolving science. In order to fully address them, EPA has been evaluating and implementing recommendations made by the 2012 Scientific Advisory Panel that would inform whether or not EPA's current regulation of chlorpyrifos is sufficiently protective of human health. *See* Vogel Decl. ¶¶ 7-11.[7] For example, the Scientific Advisory Panel recommended that EPA perform a cohort exposure evaluation by reconstructing and analyzing the likely doses of chlorpyrifos to which participants in a key epidemiological study by Columbia University were exposed. *Id.* EPA has conducted a number of complex assessments and also solicited input from experts in the areas of magnetic resonance imaging ("MRI")

[7] EPA received the Scientific Advisory Panel's report shortly before filing its response to the 2012 mandamus petition and had not then had time to assess how long it would take for EPA to implement the report's recommendations. *See* Housenger Decl. ¶ 19. The Scientific Advisory Panel is an independent body of scientists directed by Congress to provide EPA with scientific peer review on health and safety issues related to pesticides. *See* 7 U.S.C. § 136w(d).

and neurobehavioral testing in children. *Id*. ¶¶ 7, 10-11; Mandamus Pet. Exh. 9 at 4. These experts assisted EPA in interpreting a follow-up MRI study involving some of the same participants in the Columbia epidemiological study. Vogel Decl. ¶ 11. In addition, EPA has been evaluating and using an updated pharmacokinetic and pharmacodynamic ("PBPK/PD") model submitted by Dow in 2014. *Id*. ¶¶ 12-13. The PBPK/PD model represents a significant step in assessing the toxicity of chlorpyrifos, because it allows EPA to directly predict human responses to exposures rather than extrapolating from animal studies. *Id*.

Despite EPA's intention to complete its response to the Administrative Petition by early 2014, unexpected developments contributed to extending the time frame. First, EPA's implementation of the Scientific Advisory Panel's recommendation to reconstruct and analyze the likely doses of chlorpyrifos that participants in a key epidemiological study were exposed to was delayed when the authors of the study refused to provide the raw data to EPA. *Id*. ¶¶ 8-10. Second, EPA's time estimate did not take into account that the PBPK/PD model submitted by Dow would be sufficiently robust in its consideration of such a wide range of potential human exposures that EPA had to significantly refine its human health risk assessment. *Id*. ¶¶ 12-14. Third, EPA employees were furloughed for 18 days as a result of the fiscal year 2013 budget sequestration and October 2013 government shutdown, further limiting resources. *Id*. ¶ 15. Where possible, EPA

kept Petitioners apprised of the above developments and its evolving time frame. *See id.* ¶ 4; Mandamus Pet. Exhs. 8-9.[8]

EPA is on track to address the three toxicity issues in its Revised Human Health Risk Assessment within weeks and to formally act on the Administrative Petition by mid-2015. Vogel Decl. ¶ 5. EPA cautions that it remains difficult to anticipate all of the scientific variables that could affect this time frame.

### D. Procedural History

On April 12, 2012, PANNA and NRDC filed a petition for writ of mandamus in this Court seeking to require EPA to respond to the Administrative Petition within 60 days. *See PANNA v. EPA (In re PANNA)*, No. 12-71125 (9th Cir.). Applying the six-factor *TRAC* test for determining whether to compel agency action on the basis of unreasonable delay, this Court denied the petition without prejudice on July 10, 2013. *In re PANNA*, 532 Fed. Appx. at 650-52 (citing *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 74-79 (D.C. Cir. 1984) ("*TRAC*")). This Court held, *inter alia*, that: (1) the time EPA was taking to consider the Administrative Petition was "not unreasonable in light of the complexity of the issue"; (2) the FFDCA and FIFRA did not require EPA to

[8] EPA's time frame even shifted during the course of the first mandamus action as events unfolded, but EPA continued to keep Petitioners and the Court apprised. *E.g.*, Mandamus Pet. Exhs. 7-8; *In re PANNA*, No. 12-71125, Dkt. No. 15-1 (Dec. 18, 2012) & Dkt. No. 18-1 (Jan. 29, 2013).

respond to the Administrative Petition "on a particular timeline" and in fact required EPA to prioritize other petitions; (3) the scope of potential harm did not justify mandamus where EPA found chlorpyrifos exposures safe in 2006; and (4) EPA's time frame was reasonable in light of other statutory obligations and that accelerating action on the petition could "come at the expense of delay of EPA action elsewhere." 532 Fed. Appx. at 650-52 (citations omitted).

On September 10, 2014, Petitioners filed their Renewed Petition for Writ of Mandamus. Petitioners claim that EPA broke its "promise" to respond to the Administrative Petition by February 2014[9] and ask the Court to compel EPA to issue an updated health risk assessment and proposed order on the Administrative Petition by December 2014 and a final decision by summer 2015.

## STANDARD OF REVIEW FOR A WRIT OF MANDAMUS

"Mandamus is an extraordinary remedy and one that will be employed only in extreme situations." *Clorox Co. v. U.S. Dist. Court for N. Dist. of Cal.*, 779 F.2d 517, 519 (9th Cir. 1985) (citations omitted). The issuance of writs directed to agency action is rare and the scope of relief granted, if any, should be narrow.

[9] EPA's July 24, 2012 response to the first petition for writ of mandamus in fact stated "EPA cannot now advise the Court as to precisely how long it may take to act on the petition" but gave an estimate of February 2013 to February 2014. *In re PANNA*, No. 12-71125, Dkt. No. 9-1, at 29 (July 24, 2012). In December 2012 and January 2013, EPA informed Petitioners and the Court that its estimate had shifted to early 2014. *See supra* note 8.

*Pub. Util. Comm'r of Or. v. Bonneville Power Admin.*, 767 F.2d 622, 630 (9th Cir. 1985). The circumstances that will justify interference with non-final agency action must be truly extraordinary, because this Court's supervisory province as to agencies is not as direct as its supervisory authority over trial courts. *Id.* The party seeking a writ of mandamus bears the burden of proving that its right to issuance of the writ is "clear and indisputable." *In re Cal. Power Exch. Corp.*, 245 F.3d at 1120 (citation omitted).

Regarding unreasonable delay claims such as this one, an agency is entitled to substantial deference in establishing a timetable to complete administrative proceedings. *Sierra Club v. Thomas*, 828 F.2d 783, 797 (D.C. Cir. 1987). Courts have recognized that they are generally "ill-suited to review the order in which an agency conducts its business" and are "hesitant to upset an agency's priorities by ordering it to expedite one specific action, and thus to give it precedence over others." *Id.* Thus, mandamus relief may be warranted only where agency action has been delayed to such an extent that it frustrates the court's role of providing a forum for review. *In re Cal. Power Exch. Corp.*, 245 F.3d at 1124.

## ARGUMENT

Petitioners request that the Court order EPA to issue a risk assessment and proposed rulemaking by December 2014 and to take final action on their Administrative Petition by July 2015. However, Petitioners have failed to meet

their burden of proving a clear and indisputable right to the extraordinary remedy of mandamus. As explained above, EPA has already acted on seven of the ten issues raised in the Administrative Petition and has been diligently addressing the last three issues despite competing statutory priorities and unexpected events such as employee furloughs. EPA plans to issue its updated human health risk assessment addressing the last three issues within weeks. These scientific issues are complex and evolving; EPA cannot simply revoke tolerances or cancel registrations without conducting a thorough analysis taking into account newly available data. Thus, EPA has not unreasonably delayed action, and the Court should not take the drastic step of granting mandamus relief establishing deadlines for EPA. Rather, EPA should be allowed to complete its review in a time frame dictated by sound science and in recognition of other competing priorities. The petition for a writ of mandamus should thus be denied.

## I. Mandamus Relief Is Not Warranted Under the *TRAC* Factors.

In cases seeking mandamus based upon claims of unreasonable agency delay, this Court has adopted the factors set forth by the D.C. Circuit in *TRAC*. *In re Cal. Power Exch. Corp.*, 245 F.3d at 1124-25. *TRAC* articulated six factors as guidance for review of unreasonable delay claims:

> (1) the time agencies take to make decisions must be governed by a 'rule of reason,' . . . ; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply

> content for this rule of reason . . . ; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake . . . ; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority . . . ; (5) the court should also take into account the nature and extent of the interests prejudiced by delay . . . ; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

750 F.2d at 79-80 (citations omitted). Of course, "[w]hen [it] assess[es] these factors, [a court] must remember that, '[a]bsent a precise statutory timetable or other factors counseling expeditious action, an agency's control over the timetable of a rulemaking proceeding is entitled to considerable deference.'" *Sierra Club*, 828 F.2d at 797 (citation omitted). With this guiding principle in mind, consideration of the factors here should not result in a writ of mandamus.

### A. A Rule of Reason Supports Additional Time in This Case.

The first and "most important factor" is that "'the time agencies take to make decisions must be governed by a rule of reason.'" *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (quoting *TRAC*, 750 F.2d at 80). As this Court previously held, the time EPA has taken to respond to the Administrative Petition is not unreasonable because of the complex science involved and because EPA has already addressed the majority of issues. *See In re PANNA*, 532 Fed. Appx. at 651. Moreover, EPA expects to address the final three issues through an updated risk assessment within weeks, and anticipates acting on the Administrative

Petition by, depending on the outcome, either issuing a proposed rule to revoke tolerances in early 2015 or a final denial order in mid-2015. *See* Vogel Decl. ¶ 5.

EPA's ultimate decision regarding the issues raised in the Administrative Petition may be challenged in a federal court of appeals. EPA needs time to analyze the complex scientific issues in order to reach a considered decision that is appropriately protective of public health and supported by substantial evidence. *See Sierra Club*, 828 F.2d at 798-99. The time EPA has spent evaluating the evolving science will allow EPA to make a fully considered decision and should both decrease the chance of future challenges to that decision and increase the information available to a court if judicial review is sought. *Id.*; *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 554-55 (D.C. Cir. 1999) ("*United Mine Workers*") (finding agency's schedule not facially unreasonable in light of, *inter alia*, the agency's need to collect and analyze data in order to develop a rulemaking record because "the agency's plan may well shorten the overall period of delay by resolving issues that would otherwise become the subject of litigation").

Petitioners argue that, in the year and a half since the prior mandamus proceedings, "it is no longer credible for EPA to claim novelty as an excuse for delay." Mandamus Pet. 24. However, this Court expressly recognized in its July 2013 order dismissing Petitioners' first petition for writ of mandamus the "complexity" of the issues raised in the Administrative Petition. *In re PANNA*, 532

Fed. Appx. at 651. The final three issues concerning chlorpyrifos toxicity are particularly complex and continue to evolve, requiring EPA's thorough consideration. *See* Housenger Decl. ¶¶ 18-19; Vogel Decl. ¶¶ 7-14. This Court also noted that EPA had taken numerous "concrete steps" since the Administrative Petition was filed in 2007, such as "convening four Scientific Advisory Panels, and issuing a preliminary Human Health Risk Assessment, an updated evaluation of pesticide spray drift risk, and a partial response to the 2007 Petition." 532 Fed. Appx. at 651. Since this Court's ruling last year, EPA issued its response on the complicated bystander inhalation issue and has been diligently working on the final three issues raised in the Administrative Petition by implementing the Scientific Advisory Panel's recommendations, conducting peer review, and evaluating Dow's robust PBPK/PD model, among other work. Vogel Decl. ¶¶ 7-14.

EPA anticipates that it will be able to issue the updated human health risk assessment that would address the last three issues within weeks. At that point, EPA will need additional time to decide how to act on the Administrative Petition, issue a proposed order or rule, seek and consider public comments, and issue a final order or rule.

Finally, Petitioners' assertion that EPA violated the rule of reason by missing its own "deadline" is misplaced. Mandamus Pet. 24-25. In its July 24, 2012 response to the first petition for writ of mandamus and February 4, 2013 oral

argument in *In re PANNA*, EPA estimated that its complete response would be provided not later than February 2014. EPA was clear, however, that it could *not* give a date certain. Later events such as EPA's inability to obtain raw data for an epidemiologic study, Dow's completion of the complex PBPK/PD model, and the government shutdown, *see* Vogel Decl. ¶¶ 7-15, explain why EPA was unable to meet its previous prediction and highlight why a deadline would be impractical.

Therefore, under the first *TRAC* factor, this Court should defer to EPA's determination that it reasonably requires additional time to act on the remaining issues raised in the Administrative Petition, and it should deny mandamus relief.

**B. The Statutory Scheme Supports Additional Time in This Case.**

The second *TRAC* factor asks whether the statutory scheme provides a timetable or other indication of the speed with which Congress expects the agency to proceed. Here, the FFDCA fully supports affording EPA the time necessary to consider the complex and evolving science raised in the Administrative Petition.

The FFDCA requires EPA to prioritize or take expedited action on certain categories of administrative petitions concerning tolerances or exemptions for pesticide chemical residues that present a lower risk to human health than existing tolerances. *See* 21 U.S.C. § 346a(d)(4)(B)–(C). The Administrative Petition does not fall into these categories. Thus, the statutory scheme does not require that EPA give priority to, or expedite its action on the Administrative Petition. *See id.*

Rather, EPA must give "due consideration" and take one of three actions on the petition. *Id*. § 346a(d)(4)(A). The level of consideration that is "due" will necessarily depend upon the complexity of the issues raised in any particular petition. As noted above, the issues raised in the Administrative Petition are complex and on the frontiers of science and require consideration of new data.

Petitioners concede that "the FFDCA and FIFRA establish no deadline for acting on a petition to revoke tolerances or cancel a pesticide registration" and instead point to the statutory "context," Mandamus Pet. 27-28, namely the Food Quality Protection Act's mandate that EPA assess the risks of pesticides based on information concerning the special susceptibility of infants and children to pesticide chemical residues, 21 U.S.C. § 346a(b)(2)(C). Contrary to Petitioners' assertions, however, EPA took these risks into account in the 2001 Interim Reregistration Eligibility Decision and the 2006 tolerance reassessment and final reregistration decisions for chlorpyrifos, specifically concluding that dietary and non-occupational exposures to chlorpyrifos, including exposures to infants and children, were safe. *See* Housenger Decl. ¶ 9. Thus, EPA has satisfied the mandate of the Food Quality Protection Act regarding the special susceptibility of infants and children to chlorpyrifos, and Congress has not required that EPA expedite administrative petitions implicating that mandate.

In light of the statutory framework requiring "due consideration," this Court

should be wary of substituting its judgment for that of EPA as to what time is reasonably necessary to appropriately address the Administrative Petition.

### C. Health and Welfare Concerns Are Not Dispositive Here and Do Not Support a Finding of Unreasonable Delay.

For similar reasons, the third *TRAC* factor, which concerns the length of delay when health and welfare are at stake, does not counsel in favor of finding any unreasonable delay in this case. This factor is certainly not dispositive here because EPA's entire docket involves issues concerning human health and welfare. *Sierra Club*, 828 F.2d at 798. Rather, as this Court previously noted, "whether the public health and welfare will benefit or suffer from accelerating this particular rulemaking depends crucially upon the competing priorities that consume EPA's time, since any acceleration here may come at the expense of delay of EPA action elsewhere." *In re PANNA*, 532 Fed. Appx. at 651 (quoting 828 F.2d at 798).

In addition, in 2006, EPA determined that the existing tolerances for chlorpyrifos *are* safe. EPA agrees that the Administrative Petition raises questions that EPA must address. But given EPA's 2006 determination, neither EPA nor this Court can presume that Petitioners' claims regarding the safety of chlorpyrifos are necessarily correct, especially where the science continues to evolve.

Moreover, the fact that health and welfare concerns are implicated does not mean that EPA should not be afforded the time necessary to get it right. The third *TRAC* factor merely recognizes that human health concerns are, on balance, more

important than economic concerns in the sense that delay is more tolerable when only economic concerns are at stake. It does not stand for the proposition that EPA should not be afforded the time necessary to evaluate evolving science just because EPA regulates in the realm of human health.

Petitioners quote several cases but they are distinguishable. For example, *Public Citizen Health Research Group v. Auchter* concerned the Occupational Safety and Health Administration's ("OSHA") regulation of worker exposure to ethylene oxide, a carcinogenic synthetic chemical. 702 F.2d 1150, 1151-52 (D.C. Cir. 1983) (*per curiam*) ("*Auchter*"). The existing 13-year old exposure standard preceded the scientific community's recognition that ethylene oxide was carcinogenic, and there was a significant risk that workers and their offspring were in "grave danger" from exposure to the chemical. *Id.* at 1152-54 & n.4. OSHA had denied a petition for an emergency temporary standard but announced that it would proceed with rulemaking in light of the new research. *Id*. at 1152. When OSHA had still not issued a proposed rule almost two years later, the court found its delay unreasonable in light of the serious risks. *Id.* at 1157-58. The nature of the health risk was substantially greater in *Auchter* than it is here. The science does not establish that chlorpyrifos use results in potentially *lethal* exposures in food or to people who live near where pesticides are applied. Rather, Petitioners challenge whether the current margins of safety are adequate to provide a

reasonable certainty that *no harm* exists. While EPA continues to evaluate Petitioners' claims in the context of evolving science, it is important to note that in 2001 and again in 2006 EPA determined that chlorpyrifos exposures were safe. *See* Housenger Decl. ¶ 9.

In *Cutler v. Hayes*, a case concerning the Food and Drug Administration's ("FDA") action on its over-the-counter drug review program, the D.C. Circuit remanded the unreasonable delay issue because the district court had not applied the *TRAC* factors. 818 F.2d 879, 899 n.169, 901 (D.C. Cir. 1987). Even though a quarter century had passed since Congress imposed the statutory mandate in question upon the FDA, the court held that the district court still had discretion to determine whether the FDA had unreasonably delayed action and, if so, what the remedy should be. *Id.* at 899 n.169, 901. Thus, under *Cutler*, even a lengthy delay may be reasonable in cases where human health and welfare are implicated.[10]

Finally, *Public Citizen Health Research Group v. FDA* concerned whether the FDA had unreasonably delayed acting on a petition to require a new warning on aspirin labels in light of new research showing a link between the medication, when taken by children with certain illnesses, and a rare but fatal disease. 740 F.2d 21 (D.C. Cir. 1984). The D.C. Circuit was troubled by what appeared to be a

[10] The court also made clear that there is no *per se* rule limiting agency action to any particular time frame. *Cutler*, 818 F.2d at 897 n.156.

reversal of agency course due to industry pressure despite ample scientific support that the warning was justified, and it therefore remanded the claim to the district court, which had not considered it. *Id*. at 35-36.[11] Here, in contrast, there is no allegation that EPA switched positions at all, let alone any allegation that EPA may have relied on suspect reasons to make a switch. Rather, EPA found in 2001 and again in 2006 that chlorpyrifos exposures were safe, and the Agency continues to evaluate Petitioners' claims in the context of evolving science.

Thus, the third TRAC factor does not warrant mandamus in this case.

### D. EPA's Competing Priorities Impact the Time Frame for Action on the Administrative Petition.

The fourth *TRAC* factor takes into account the effect that expediting agency action may have on agency activities of a higher or competing priority. Here, Congress has assigned EPA a very broad mandate not only under the FFDCA and FIFRA but also under other, equally complex environmental statutes. *Sierra Club*, 828 F.2d at 798. Congress has also provided EPA with finite resources to meet these competing responsibilities. *Id.* But Congress has not required that EPA prioritize administrative petitions like Petitioners' over any of EPA's numerous other obligations. *See id.;* 21 U.S.C. §§ 346a(b)(2)(B), 346a(d)(4)(C).

[11] The FDA issued a regulation requiring the warning label before the district court ruled on the merits of the unreasonable delay claim. *See Pub. Citizen Health Research Grp. v. Young*, 700 F. Supp. 581, 583 (D.D.C. 1988), *aff'd in part, rev'd in part*, 909 F.2d 546 (D.C. Cir. 1990).

EPA has many competing obligations, some of which are subject to statutory deadlines. For example, EPA is charged with re-evaluating over 1000 other pesticide active ingredients contained in registered pesticide products under FIFRA's periodic registration review requirements. *See* 7 U.S.C. § 136a(g); Housenger Decl. ¶ 24. In addition, EPA must devote considerable scientific resources to evaluating applications for new and amended pesticide products and other pesticide regulatory actions on short time frames (three months to two years, depending upon the nature and complexity of the action requested). 7 U.S.C. § 136w-8(f); Housenger Decl. ¶ 24. In fiscal year 2013, EPA completed over 2000 such actions—500 more than the previous three years' average. Vogel Decl. ¶ 15. But EPA had less time to work on them due to employee furloughs. *Id*. As a result, EPA had no choice but to devote fewer resources to actions not subject to statutory deadlines. *Id*.

EPA must also balance work on other matters without statutory deadlines. Here, EPA already moved chlorpyrifos and the other organophosphates forward in the re-evaluation schedule. Housenger Decl. ¶ 13. Requiring EPA to devote all of its resources to responding to the Administrative Petition would necessarily detract from EPA's ability to respond to other matters, including other petitions. As the D.C. Circuit explained, "[a]ssuming constant resources . . . , a judicial order putting [one petition] at the head of the queue simply moves all others back one

space and produces no net gain." *In re Barr Labs., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991). As 2013 showed, however, EPA is not even guaranteed to have "constant resources." Thus, the fourth *TRAC* factor shows that EPA has not unreasonably delayed action here.

Petitioners quote *United Mine Workers*, 190 F.3d at 554, to the effect that there is a limit to how much claims of competing priorities may justify delay in the face of a congressional command to act. Mandamus Pet. 33. But Petitioners fail to mention that the relevant congressional command to act in that case was "within 90 days." *United Mine Workers*, 190 F.3d at 554. In fact, the court distinguished its previous decision in *Sierra Club*, 828 F.2d at 797, where there was no statutory deadline and no generalized congressional mandate for EPA to expedite action. Like *Sierra Club*, there is no statutory deadline for EPA to act—and no congressional mandate for EPA to expedite its action—on the Administrative Petition. Rather, Congress has provided only that EPA must act on petitions like Petitioners' after giving them "due consideration." *See* 21 U.S.C. § 346a(d)(4).

Moreover, despite the fact that the Mine Safety and Health Administration was eight years beyond the 90-day statutory deadline in *United Mine Workers*, the court determined not to issue a writ of mandamus and instead retained jurisdiction until such time as the agency completed its statutory obligation to act, which the agency estimated would take three additional years. 190 F.3d at 554-56. Given

that a delay of 11 years beyond a *statutory deadline* to issue a final health and welfare regulation did not warrant mandamus relief in *United Mine Workers*, such relief is likewise not warranted in consideration of all the relevant circumstances here, where there is *no* statutory deadline.

### E. Competing Interests Do Not Warrant a Finding of Unreasonable Delay.

Petitioners assert that EPA's delay in responding to the Administrative Petition has prejudiced them in two ways. First, Petitioners assert that their members are harmed by exposure to chlorpyrifos through a number of routes and that scientific studies show that chlorpyrifos can have serious health impacts. Mandamus Pet. 29-32. However, in 2006, EPA determined that the existing tolerances for chlorpyrifos, along with additional mitigation measures, are safe. That there may be tension between Petitioners' claims that the existing tolerances for chlorpyrifos are not, in fact, safe and EPA's need for additional time to address those claims, does not mean that *TRAC* factor five favors mandamus relief. Chlorpyrifos is widely used across the country, and the issues raised in the Administrative Petition as to whether that use should be curtailed are complex and in some cases entirely novel. Congress has directed that EPA should have the time necessary to give "due consideration" to administrative petitions based upon the nature of the particular issues raised. In fact, the very people who claim to be injured by the delay will ultimately benefit from EPA's thorough consideration of

new research and updated models. Especially in light of the nature of the scientific issues raised in the Administrative Petition, EPA has not unreasonably delayed acting on the petition under the statutory scheme.

Second, Petitioners assert that EPA's delay in responding to their Administrative Petition has prevented them from pursuing further administrative and judicial remedies. Mandamus Pet. 34-35. In fact, Petitioners have had opportunities to seek administrative and judicial review and chose not to pursue them. EPA's July 16, 2012 partial response constituted final agency action as to one of the issues raised by the Administrative Petition, namely whether EPA properly addressed the exporting hazard from chlorpyrifos. Housenger Decl. Attach. J at 6. Petitioners could have sought judicial review of EPA's denial as to that issue under FIFRA. 7 U.S.C. § 136n. They did not. Vogel Decl. ¶ 6. EPA also offered on multiple occasions to publish formal denial orders on the other six issues addressed in its July 16, 2012 and July 15, 2014 partial responses so that Petitioners could file an objection—an administrative prerequisite to judicial review under the FFDCA, 21 U.S.C. § 346a(h)—on some or all of those issues rather than waiting for EPA to respond to the rest of the Administrative Petition. Housenger Decl. Attach. J at 4; Mandamus Pet. Exh. 8 at 5; Mandamus Pet. Exh. 9 at 3-4. Petitioners, however, declined EPA's offers, Vogel Decl. ¶ 6, even as to the bystander inhalation issue, which Petitioners appeared to give more weight to than

any other issue in the Administrative Petition, *see* Admin. Pet. at 17-21.

Accordingly, the nature and extent of the interests Petitioners claim have been prejudiced do not warrant a finding of unreasonable delay here.

**F. There Is No Allegation of Impropriety Here.**

The sixth *TRAC* factor provides that the Court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" *TRAC*, 750 F.2d at 80 (citations omitted). PANNA has not suggested that EPA is acting in bad faith. Nor has there been any "lassitude" on EPA's part. Rather, as explained above and in the Vogel Declaration, EPA is and has been diligently addressing the complex scientific issues raised in the Administrative Petition, and it reasonably requires additional time to finish its review. Therefore, to the extent the sixth *TRAC* factor has any bearing on this case at all, it counsels *against* a finding of unreasonable delay.

In sum, consideration of the *TRAC* factors here shows that EPA has not unreasonably delayed action on the Administrative Petition and that the extreme remedy of mandamus is not warranted.

## CONCLUSION

For all of these reasons, this Court should deny the Renewed Petition for a Writ of Mandamus and dismiss the case.

Dated: December 23, 2014

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on December 23, 2014. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/ *Erica M. Zilioli*