No. _____

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Petitioners.

PETITION FOR A WRIT OF MANDAMUS AND FOR RELIEF FROM UNREASONABLY DELAYED AGENCY ACTION BY THE ENVIRONMENTAL PROTECTION AGENCY

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CORPORATE DISCLOSURE STATEMENT
REQUIRED BY FRAP 26.1

Petitioners Pesticide Action Network North America and Natural Resources Defense Council, Inc. have no parent, subsidiary, or affiliate that has issued shares or debt securities to the public.

Respectfully submitted this 12th day of April, 2012.

s/ Kevin E. Regan
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INTRODUCTION

Pesticide Action Network North America and Natural Resources Defense Council (collectively "PANNA") petition this Court for a Writ of Mandamus requiring the U.S. Environmental Protection Agency ("EPA") to respond to a long-pending petition regarding a dangerous pesticide that poses a human health risk. Chlorpyrifos is a widely used pesticide that threatens human health, and, in particular, threatens the long-term neurological development of exposed children and infants. PANNA petitioned EPA to act quickly and ban chlorpyrifos in 2007. Over four and a half years have passed, and EPA has still not issued a written response as required by law, let alone banned this chemical. This Court should find that EPA has unreasonably delayed fulfilling its legal obligations and compel it to respond to the petition within 60 days.

This Court has authority to issue a writ pursuant to Federal Rule of Appellate Procedure 21, Circuit Rule 21, the All Writs Act, 28 U.S.C. § 1651, the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. PANNA seeks an order finding EPA has unreasonably delayed responding to its September 12, 2007 Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos (the "2007 Petition"). The 2007 Petition asked EPA to revoke all tolerances (levels of pesticide residue that may

remain on food) and cancel all registrations (licenses for a product containing a pesticide) for chlorpyrifos, and it highlighted the urgent need for EPA to act.

Mandamus relief is warranted because EPA has delayed for over four and a half years in fulfilling its statutory duty to respond to the 2007 Petition, and EPA's recent actions show that a decision addressing chlorpyrifos' human health risks, which were presented to EPA in the 2007 Petition, is not forthcoming.

STATEMENT OF JURISDICTION AND APPLICABLE LAW

This Court has the authority to issue a writ of mandamus requiring EPA to respond to PANNA's petition under the All Writs Act. 28 U.S.C. § 1651(a) ("The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law."). This Court has jurisdiction to hear PANNA's Petition for a Writ of Mandamus under the Administrative Procedure Act ("APA"). The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The reviewing court shall "compel agency action unlawfully withheld or unreasonably delayed." Id. § 706(1).

Because this Court would have exclusive jurisdiction to review any final action taken by EPA in response to the 2007 Petition, this Court also has

jurisdiction to review this challenge to the agency's failure to act.[1] See In re California Power Exch. Corp., 245 F.3d 1110, 1124 (9th Cir. 2001) (finding jurisdiction over a petition for writ of mandamus on the basis of unreasonable delay) (citing Telecomm. Research & Action Ctr. v. FCC, 750 F.2d 70, 75 (D.C. Cir. 1984) (hereinafter "TRAC")). See also In re Tennant, 359 F.3d 523, 530 (D.C. Cir. 2004) ("When…an agency delays taking action that, if and when taken, would be within our appellate jurisdiction, the All Writs Act confers authority to issue writs of mandamus 'in aid of' that prospective jurisdiction.").

Here, any final decision by EPA relating to the 2007 Petition would be reviewable only by a United States Court of Appeals. In terms of the FDCA, which is the primary statute relied upon by PANNA in the 2007 Petition, EPA must respond to a petition relating to pesticide tolerances in one of three ways, by issuing: (1) a final regulation; (2) a proposed regulation, and thereafter issuing a final regulation; or (3) an order denying the petition. 21 U.S.C. § 346a(d)(4)(A)(i)-(iii). The FDCA establishes further administrative procedures through which one may file an objection to any resulting regulation or order. Id. § 346a(g)(2)(A)-(C). EPA regulations, promulgated pursuant to the FDCA, require the exhaustion of

[1] PANNA originally filed an unreasonable delay suit in the Southern District of New York, and that case is currently stayed. See NRDC v. EPA, No. 10- 05590-CM (S.D.N.Y.). PANNA had hoped to be able to reach a settlement regarding the timing of EPA's response to the 2007 Petition, but those efforts were unsuccessful, and PANNA will seek to maintain the stay in that case as a protective matter.

administrative remedies through that objection process as a prerequisite to seeking judicial review. 40 C.F.R. § 180.30(b) (stating that "judicial review is not available unless an adversely affected party exhausts these objection procedures, and any petition procedures preliminary thereto"). EPA must issue a final order at the conclusion of that objection process. 21 U.S.C. § 346a(g)(2)(C). Any challenge to such a final order must be filed in a United States Court of Appeals within 60 days. Id. § 346a(h)(1).

Further, the FDCA's broadly worded judicial review provision provides for exclusive jurisdiction in a Court of Appeals: "[a]ny issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law." See id. §§ 346a(h)(1), (5). Although the 2007 Petition also relates to FIFRA through the request that EPA cancel the registration for chlorpyrifos, a provision in the FDCA provides for exclusive jurisdiction in a Court of Appeals for issues relating to pesticide tolerances. See id.; Natural Res. Defense Council v. Johnson, 461 F.3d 164, 172-76 (2d Cir. 2006) (affirming district court's grant of motion to dismiss for lack of subject matter jurisdiction and holding that 21 U.S.C. § 346a(h)(5) precludes a challenge under FIFRA's judicial review provision). Because this Court would have exclusive jurisdiction to review any final decision that EPA reaches relating to the 2007 Petition, this Court also has jurisdiction to determine if EPA's four and a half year intransigence constitutes

unreasonable delay. See In re California Power Exch. Corp., 245 F.3d at 1125.

STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

Whether, after receiving a petition to ban a pesticide that threatens human health, and children in particular, EPA's failure to respond for nearly five years is such an unreasonable delay that this Court should order the agency to respond?

STATUORY FRAMEWORK

EPA regulates pesticides under two statutes, the FDCA, 21 U.S.C. § 346a, and FIFRA, 7 U.S.C. § 136 et seq. The FDCA authorizes EPA to set tolerances (maximum allowable levels) for pesticide residues in food or to grant exemptions from the requirement to have a tolerance. 21 U.S.C. §§ 346a(b) & (c). 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." Id. § 346a(b)(2)(A)(i). The FDCA requires that EPA must assess the risk that a pesticide poses to infants and children when establishing a tolerance. Id. § 346a(b)(2)(C).

The FDCA specifically provides for a process through which any person may file a petition to revoke a tolerance for a pesticide chemical residue in or on a food. Id. § 346a(d). That section of the FDCA describes the contents required in such a petition and requires EPA to publish a notice of a petition that has met those content requirements. Id. § 346a(d)(2) & (3). The FDCA sets forth a clear

statutory requirement that the EPA Administrator "shall, after giving due consideration to a petition … and any other information available to the agency": (1) issue a final regulation establishing, modifying, or revoking a tolerance, (2) issue a proposed regulation and thereafter issue a final regulation, or (3) deny the petition. Id. §§ 346a(d)(4)(i)-(iii).

FIFRA establishes a registration system for pesticides. Under FIFRA, a pesticide may generally not be sold or used in the United States unless it has an EPA registration for a specified use. 7 U.S.C. § 136a(a). To register or re-register a pesticide, EPA must determine, among other things, that its use "will not generally cause unreasonable adverse effects on the environment." Id. § 136a(c)(5)(D). FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide . . . ." Id. § 136(bb). EPA has the authority to cancel a pesticide registration whenever the "pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Id. § 136d(b).

FACTUAL BACKGROUND

Chlorpyrifos is an organophosphate insecticide, and it is one of the most

widely used pesticides in the United States. Declaration of Dr. Jennifer Sass ¶¶ 3-4; 2007 Petition at 1. Organophosphate insecticides were originally derived from technology associated with nerve gas developed in World War II. 2007 Petition at 1. Chlorpyrifos is acutely toxic and causes systemic illnesses by inhibiting the body's ability to produce cholinesterase, an enzyme necessary for the proper transmission of nerve impulses. See id. EPA included organophosphates in the first group of pesticides slated for tolerance reassessment and FIFRA re-registration because organophosphates are among the pesticides that "pose the greatest risk to public health." 62 Fed. Reg. 42,020, 42,021 (Aug. 4, 1997).

Exposure to chlorpyrifos causes serious harmful effects to humans. 2007 Petition at 1. Symptoms of cholinesterase inhibition caused by chlorpyrifos poisoning include muscle spasms, confusion, dizziness, loss of consciousness, seizures, abdominal cramps, vomiting, diarrhea, cessation of breathing, paralysis, and death. Sass Decl. ¶¶ 4-5; 2007 Petition at 1. In addition to cholinesterase inhibition, scientific studies associate exposure to chlorpyrifos with other harmful human health effects and neurodevelopmental disorders, in utero developmental brain impairments, low birth weights, and endocrine disruption. Petition at 6-10.

Chlorpyrifos is used on various food and feed crops, on golf courses, as a non-structural wood treatment, and as an adult mosquitocide. 2007 Petition at 1. Approximately 10 million pounds are applied annually in agricultural settings. Id.

According to EPA's chlorpyrifos fact sheet, use on corn comprises the largest market. Id. EPA cancelled most residential uses of chlorpyrifos ten years ago. Id. at 5; Sass Decl. ¶ 5. Workers are exposed to chlorpyrifos through inhalation and dermal contact when they mix, handle, or apply the pesticide or come into contact with treated crops. 2007 Petition at 4; Sass Decl. ¶ 4. People are also exposed to chlorpyrifos from eating food with chlorpyrifos residues. See 40 C.F.R. § 180.342 (setting forth tolerances for chlorpyrifos residues that may remain on food). Children are exposed to chlorpyrifos from being exposed to drift, eating contaminated food, and having contact with residues on treated surfaces, clothing, or soils. See 2007 Petition at 6-9; Sass Decl. ¶ 8.

There is scientific evidence that children and infants exposed to chlorpyrifos can exhibit long-term neurological and neurodevelopmental difficulties. 2007 Petition at 6-9. Notably, there is increasing evidence of long-lasting effects from early life exposure to chlorpyrifos in children. See id.; see also Sass Decl. ¶¶ 19-21. A number of studies published since 2001, which were cited in the 2007 Petition, report that fetal exposure to chlorpyrifos is more damaging than adult exposure. 2007 Petition at 6-9. The data associated with those studies provide strong evidence that prenatal and early-life stage exposure to chlorpyrifos is associated with not only poor birth outcomes (lower birth weight and length), but also long-lasting, and possibly permanent, impaired cognitive development. Id.

Further, an assessment of chlorpyrifos by EPA scientific experts shows substantial scientific evidence that early life exposures to chlorpyrifos are extensively more harmful than adult exposures, and that the magnitude of the differential response is uncertain. Id.

PROCEDURAL HISTORY

On September 12, 2007, PANNA and NRDC jointly submitted the 2007 Petition to EPA, which cited the statutory petition process set forth in the FDCA. Sass Decl. ¶¶ 11-12; 2007 Petition at 1 (citing 21 U.S.C. § 346a(d)).

The 2007 Petition presented evidence that EPA's Cumulative Risk Assessment for chlorpyrifos was deficient in several respects. It noted that (1) the Cumulative Risk Assessment failed to account for the full spectrum of toxicity, (2) a proper risk assessment must include consideration of genetic evidence of vulnerable populations, (3) there is evidence of long-standing effects from early life exposure in children, (4) evidence from rodent studies shows that there is no safe level for chlorpyrifos, (5) there is evidence of endocrine disrupting effects and cancer risks, and (6) there is evidence that there are potential adverse effects at levels below 10% cholinesterase inhibition. 2007 Petition at 5-22.

The 2007 Petition also argued that EPA's cumulative risk assessment misrepresented risks and failed to apply the required safety factor for early life exposure. 2007 Petition at 4-21. It further argued that EPA over-relied on data

submitted to EPA by the pesticide registrant, failed to incorporate inhalation routes of exposure, and failed to consider hazards associated with chlorpyrifos use in other countries—creating a health and environmental hazard in those countries, and a risk of contaminated food re-entering the United States. Id.

In response to PANNA's 2007 Petition, EPA filed a notice in the Federal Register requesting public comments on the petition on October 17, 2007. 72 Fed. Reg. 58,845 (Oct. 17, 2007). That notice established a deadline of December 17, 2007 for any comments. Id. EPA did not further respond to the 2007 Petition. Sass Decl. ¶ 14; Declaration of Margaret Reeves ¶ 15.

After nearly three years of unexplained inaction on the part of EPA, PANNA filed a lawsuit in the Southern District of New York on July 22, 2010 alleging that EPA unreasonably delayed responding to the 2007 Petition in violation of the APA. NRDC v. EPA, No. 10-05590-CM, Compl., Dkt. 1.[2] On December 22, 2010, the parties to that lawsuit executed a stipulation agreeing that the case would be transferred to the Southern District of New York's "suspense docket" pending further actions by EPA. Id. Dkt. 17. (suspense docket order). Specifically, EPA stipulated that it would complete a preliminary human health risk assessment for chlorpyrifos by June 1, 2011, and that it would respond to the 2007 Petition on or before November 23, 2011. Id. at 2-3.

[2] PANNA believes that jurisdiction is proper in this Court, but in an abundance of caution, it will seek to keep the district court case stayed as a protective matter.

Following that stipulation, EPA convened a Scientific Advisory Panel meeting related to chlorpyrifos that took place from February 15-18, 2011. 75 Fed. Reg. 76457 (Dec. 8, 2010) (notice of meeting). Later, EPA issued a preliminary human health risk assessment on June 30, 2011, 76 Fed. Reg. 39399 (Jul. 6, 2011) (announcing availability of assessment and requesting comments), and received comments on that document until October 6, 2011. 76 Fed. Reg. 52945 (Aug. 24, 2011) (extending initial comment period by 30 days).

Notwithstanding these initial efforts, EPA ultimately failed to meet the date upon which it had agreed to reach a decision and issue a written response to the 2007 Petition. See No. 10-05590-CM, Dkt. 19 at 2. Subsequently, counsel for PANNA engaged in settlement discussions regarding the time for EPA to issue a written decision. PANNA and federal Defendants agreed by stipulation to extend the deadline the case would remain pending on the suspense docket to allow further settlement discussions. Id.

On February 15, 2012, rather than reaching a decision on the 2007 Petition, EPA announced that it was convening another Scientific Advisory Panel to discuss the human health effects associated with chlorpyrifos. 77 Fed. Reg. 8856 (Feb. 15, 2012). The meeting of the Scientific Advisory Panel is currently scheduled to take place from April 10-13, 2012. Id. In the Federal Register Notice, EPA stated that the Scientific Advisory Panel will prepare meeting minutes summarizing its

recommendations to the Agency approximately 90 days after the meeting. Id. at 8859. Further, EPA is not scheduled to complete its periodic registration review of chlorpyrifos until 2015. See Chlorpyrifos Final Work Plan Registration Review (Sept. 25, 2009)[3] at 5.

To date, EPA has not issued a final decision on the 2007 Petition, nor has it imposed any interim measures, such as buffer requirements around areas where chlorpyrifos is sprayed or use restrictions, that will protect human health. See Sass Decl. ¶ 14; Reeves Decl. ¶ 15.

SUMMARY OF ARGUMENT

EPA has a clear statutory duty under the FDCA to respond to NRDC's petition to revoke tolerances in one of three ways: (1) by issuing a final rule, (2) by issuing a proposed rule followed by a final rule, or (3) by issuing an order denying the petition. Under the APA, EPA must act "within a reasonable time." Over four and a half years have passed since the 2007 Petition was submitted to EPA, PANNA has a right to a timely response from EPA, and a writ of mandamus is the only remedy that will adequately cure the injury PANNA has suffered as a result of EPA's delay. Members of PANNA, as well as their children, who live and work near areas where chlorpyrifos is used, and who eat foods that contain its residue, are suffering ongoing harm. This harm provides ample equitable justification for

[3] Available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0020;oldLink=false (last accessed Apr. 12, 2012).

granting mandamus under the six factors identified by the Court in TRAC v. FCC.

STANDING

PANNA's standing to seek a writ of mandamus in this case is based on the procedural injury each organization has suffered while trying to protect the underlying health interests of its members.

To satisfy Article III's standing requirements, a petitioner must show (1) it has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the respondent; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Friends of the Earth v. Laidlaw Envtl. Servs., 528 U.S. 167, 180-81 (2000); Citizens for Better Forestry v. U.S. Dep't of Agric., 341 F.3d 961, 969 (9th Cir. 2003).

To establish the "injury in fact" prong of standing in a case alleging procedural harm, a petitioner must show: (1) the respondent agency violated certain procedural rules; (2) these rules protect petitioner's concrete interests; and (3) it is reasonably probable that the challenged action will threaten their concrete interests. See Ctr. for Food Safety v. Vilsack, 636 F.3d 1166, 1171-72 (9th Cir. 2011) (citing Citizens for Better Forestry, 341 F.3d at 969-70). A party that "has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy."

Summers v. Earth Island Inst., 555 U.S. 488, 496 (2009); see also Lujan v. Defenders of Wildlife, 504 U.S. 555, 573 n.8 (1992) ("We do not hold that an individual cannot enforce procedural rights; he assuredly can, so long as the procedures in question are designed to protect some threatened concrete interest of his that is the ultimate basis of his standing.").

EPA's failure to respond to the 2007 Petition has caused an ongoing injury that only a writ from this Court can remedy. PANNA is a human health organization with over 70,000 members nationwide. Reeves Decl. ¶ 4. It is dedicated to preventing harm to the public from pesticides and challenging the proliferation of pesticides. Reeves Decl. ¶ 5. PANNA's members include individuals who live near agricultural areas where chlorpyrifos is used, some of whom have been directly exposed to the pesticide. Reeves Decl. ¶¶ 5, 7, 12-15; Medellin Decl. ¶¶ 2-10. Exposure to chlorpyrifos during prenatal and early childhood periods is particularly troubling because infants and children are more susceptible than adults to the toxic effects of pesticides, and because there is scientific evidence of long-term neurodevelopmental disorders associated with early life exposure to chlorpyrifos. Sass Decl. ¶¶ 19-21. Parents and family members who are aware of such risks are nevertheless unable to completely protect their children from exposure to chlorpyrifos, because there is often no way to know whether a food contains chlorpyrifos residue, and residents who live near

agricultural areas are often subject to pesticide drift. See Reeves Decl. ¶¶ 9, 13; Medellin Decl. ¶¶ 3-9. A writ of mandamus compelling the EPA to take final action would redress the harm suffered by PANNA members who are exposed to chlorpyrifos and are unable to fully protect themselves and their families from that exposure. See Reeves Decl. ¶¶ 5, 7, 16; Medellin Decl. ¶ 10.

Similarly, NRDC is an environmental action and human health organization with approximately 357,000 members nationwide. Declaration of Linda Lopez ¶¶ 3-4. One of NRDC's organizational priorities is reducing and eliminating human exposure to dangerous chemicals, including pesticides in food. Lopez Decl. ¶¶ 5-6. Its members include parents and relatives of young children who are particularly concerned about the effects of chlorpyrifos on the mental and physical development of their children. Declaration of Sattie Clark ¶¶ 4-13; Declaration of Sharon Bolton ¶¶ 3-14. Parents who are aware of such risks are nevertheless unable to completely protect their children from exposure to chlorpyrifos, because there is often no way to know whether a food contains chlorpyrifos residue, and residents who live near agricultural areas are often subject to pesticide drift. Reeves Decl. ¶ 9; Sass Decl. ¶ 8; Bolton Decl. ¶¶ 5-12; Medellin Decl. ¶¶ 3-4.

PANNA and NRDC also satisfy the requirements for organizational standing. Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977); Veterans for Common Sense v. Shinseki, 644 F.3d 845, 862 n.16 (9th Cir. 2011).

Members of PANNA and NRDC would have standing to sue in their own right, because of the injuries described above. See Medellin Decl. ¶¶ 2-10; Reeves Decl. ¶¶ 4, 5-16; Clark Decl. ¶¶ 4-15. The interests PANNA and NRDC seek to protect are germane to each organization's purposes, Reeves Decl. ¶¶ 4-5; Lopez Decl. ¶¶ 2-6, and the litigation will not require the participation of individual PANNA or NRDC members. Hunt, 432 U.S. at 343.

In sum, PANNA and NRDC members are at risk of being harmed by the human health effects of chlorpyrifos, and PANNA and NRDC have a right to have the concerns of their members regarding chlorpyrifos addressed through EPA's petition process by receiving a response as required by law. EPA's unreasonable delay in answering the 2007 Petition is a procedural injury linked to a concrete harm that gives the organization standing to petition this Court for relief.

ARGUMENT

I. A WRIT OF MANDAMUS IS THE ONLY REMEDY THAT WILL ADEQUATELY ENFORCE EPA'S DUTY TO RESPOND TO THE CHLORPYRIFOS PETITION.

This Court generally employs a three-part test to determine whether to grant mandamus relief: (1) the petitioner's claim is clear and certain; (2) the duty is so plainly prescribed as to be free from doubt; and (3) no other adequate remedy is available. In re California Power Exch. Corp., 245 F.3d at 1120 (citing Or. Natural Res. Council v. Harrell, 52 F.3d 1499, 1508 (9th Cir. 1995); Fallini v. Hodel, 783

F.2d 1343, 1345 (9th Cir. 1986)). However, this Court has also noted that in the case of a petitioner seeking a writ of mandamus for unreasonable delay, "the standards for mandamus … are, at least in form, somewhat different than the traditional three-part mandamus test." Id. at 1125 (discussing and applying the six-factor test laid out in the D.C. Circuit's TRAC decision). PANNA prevails under either test.

Here, EPA has a clear statutory duty to act in response to the 2007 Petition. The FDCA lays out a process by which one can file "a petition proposing the issuance of a regulation … establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." 21 U.S.C. § 346a(d)(1)(A). There are three possible outcomes of this process. After giving due consideration to a petition, EPA shall: (1) "issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance of the pesticide chemical residue … (which final regulation shall be issued without further notice and without further period for public comment)," id. § 346a(d)(4)(A)(i); (2) "issue a proposed regulation under subsection e of this section ["Action on Administrator's own initiative"], and thereafter issue a final regulation under such subsection," id. § 346a(d)(4)(A)(ii); or (3) issue an order denying the petition, id. § 346a(d)(4)(A)(iii). Under the plain language of these statutory provisions, PANNA's claim to relief is clear and certain. Although EPA has three options for

how it may respond to the 2007 Petition, the duty to respond is plainly prescribed and free from doubt. See id. § 346a(d)(4)(A).

Moreover, PANNA has no other adequate remedy available. The FDCA gives a petitioner the right to object to any regulation or order made in response to the petition. Id. § 346a(g)(2). But with no regulation or order to which PANNA can object, see id., the only option is to seek judicial review under the APA. See 5 U.S.C. § 706.

II. A WRIT OF MANDAMUS IS JUSTIFIED UNDER THE EQUITABLE FACTORS ESTABLISHED BY TRAC V. FCC.

Like many, if not all other Circuit Courts of Appeals, the Ninth Circuit has adopted a flexible, six-factor test for judging whether to compel agency action on the basis of unreasonable delay based on the D.C. Circuit's TRAC decision. In re California Power Exch. Corp., 245 F.3d at 1124-25 (noting that the Ninth Circuit has "adopted the TRAC guidelines"); Independence Mining Co. v. Babbitt, 105 F.3d 502, 507 (9th Cir. 1997) (applying the TRAC factors to assess whether APA relief for unreasonable delay was appropriate). The six TRAC factors are:

> (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 the delay[;] and
>
> (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

Independence Mining Co., 105 F.3d at 507 n.7 (quoting TRAC, 750 F.2d at 80) (internal citations omitted). When these factors are applied here, it is clear that the Court should order EPA to respond to the 2007 Petition.

A. EPA's Four-and-a-Half-Year Delay in Responding to the 2007 Petition is Excessive.

The first, "and most important" TRAC factor, is the guiding principle "the time agencies take to make decisions must be governed by a 'rule of reason.'" In re Core Communications, Inc., 531 F.3d 849, 855 (D.C. Cir. 2008) (citing TRAC, 750 F.2d at 80). Although "[t]here is no per se rule as to how long is too long to wait for agency action," id. at 855, a number of Circuit Courts have stated generally that "a reasonable time for an agency decision should encompass 'months, occasionally a year or two, but not several years or a decade.'" In re American Rivers, 372 F.3d 413, 419 (D.C. Cir. 2004) ("FERC's six-year-plus delay is nothing less than egregious") (citing MCI Telecomms. Corp. v. FCC, 627 F.2d 322, 340 (D.C. Cir. 1980)); Pub. Citizen Health Research Grp. v. Chao, 314

F.3d 143, 153 (3d Cir. 2002) (same)). This Court has noted "[t]he cases in which courts have afforded relief have involved delays of years, not months." In re California Power Exch. Corp., 245 F.3d at 1125 (finding that FERC's four-month delay "does not run afoul of any 'rule of reason.'"). Further, at least one Circuit Court of Appeals has found that an agency delay of three years was unacceptable where human health was at risk. See Pub. Citizen Health Research Grp. v. Auchter, 702 F.2d 1150, 1154, 1157 (D.C. Cir. 1983) (requiring federal agency to issue a workplace standard governing exposure to a potential mutagen/carcinogen on an expedited schedule).

In this case, EPA's four-and-a-half-year delay in responding to the 2007 Petition—with no clear end to the delay in sight—violates the rule of reason. See Biodiversity Legal Found. v. Norton, 285 F. Supp. 2d 1, 16-17 (D.D.C. 2003). ("[An] ambiguous, indefinite time frame for review of [a] petition [can] constitute[] unreasonable delay within the meaning of APA § 706(1)") (quoting Muwekma Tribe v. Babbitt, 133 F. Supp. 2d 30, 37 (D.D.C. 2000)). There can be no dispute that EPA has not yet responded to the 2007 Petition. Sass Decl. ¶ 14; Reeves Decl. ¶ 15. Further, EPA's recent notice in the Federal Register indicates that the Scientific Advisory Panel will not report its findings to EPA before mid-July, 2012. See 77 Fed. Reg. at 8859 (stating that the "FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately

90 days after the meeting"). There is no indication in that Notice as to when EPA will reach a decision on the 2007 Petition. See generally id.

EPA's prior track record on petitions to revoke tolerances further illustrates that EPA's four-and-a-half-year delay in this case is unreasonable. EPA has previously responded to petitions to modify or revoke tolerances for pesticides within a year and a half, and often under four years. See, e.g., 73 Fed. Reg. 64229 (Oct. 29, 2008) (order denying NRDC's January 10, 2005 petition requesting that EPA revoke all tolerances for the pesticide carbaryl); 76 Fed. Reg 49318 (Aug. 10, 2011) (order denying the American Bird Conservancy's July 23, 2009 petition requesting that EPA revoke the "import" tolerances for several pesticides); 72 Fed. Reg. 68662 (Dec. 5, 2007) (order denying NRDC's June 2, 2006 petition requesting that EPA revoke all tolerances for the pesticide dichlorvos (DDVP)); 71 Fed. Reg. 43906 (Aug. 2, 2006) (order denying in part a petition dated December 17, 2004, which was filed by the States of New York, California, and Connecticut, and the Commonwealth of Massachusetts, requesting the modification or revocation of tolerances for the pesticides alachlor, chlorothalonil, methomyl, metribuzin, and thiodicarb).

B. EPA's Delay Is Unreasonable in Light of the FDCA Requirement That EPA Protect Children and Infants From Pesticides.

TRAC provides that "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." Independence Mining Co., 105 F.3d at 507 n.7 (quoting TRAC, 750 F.2d at 80). Here, although the FDCA and FIFRA do not provide a fixed deadline for EPA to respond to a petition to revoke tolerances, the broad protective goal of those statutes, as amended by the Food Quality Protection Act, includes a focus on protection for children and other sensitive human populations. This statutory focus supplies context for fully gauging the unreasonableness of EPA's delay in this case. See Auchter, 702 F.2d at 1158 n.30 (D.C. Cir. 1983) ("The reasonableness of the delay must be judged 'in the context of the statute' which authorizes the agency's action.") (citing Nat'l Congress of Hispanic Am. Citizens v. Marshall, 626 F.2d 882, 888 (D.C. Cir. 1979)).

In 1996, Congress amended the FDCA and FIFRA by enacting the Food Quality Protection Act ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489. See NW Coalition for Alternatives to Pesticides v. U.S. E.P.A., 544 F.3d 1043, 1046 (9th Cir. 2008) (describing FQPA amendments to the FDCA). Under the FQPA amendments to the FDCA, EPA can establish a tolerance only if the agency has determined that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii). To ensure that then-existing pesticides would comply with the new safety standard, Congress instructed EPA to reassess the tolerances and

review the registrations for all pesticides by 2006. Id. § 346a(q)(1); 7 U.S.C. § 136a(g)(1). EPA reviewed the chlorpyrifos registrations and tolerances in 2006, and it determined that chlorpyrifos was eligible for registration. Registration Eligibility Decision for Chlorpyrifos, EPA (July 31, 2006).[4]

One of the key provisions of the FQPA amendments to the FDCA requires the EPA to give special consideration to risks posed to infants and children when establishing pesticide tolerances. 21 U.S.C. § 346a(b)(2)(C). Specifically, the FQPA directs the EPA to use "an additional tenfold margin of safety . . . to take into account potential pre-and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. § 346a(b)(2)(C). This tenfold (or "10x") child safety factor is presumptively applied to all tolerances. See id. In making tolerance decisions, the EPA must assume that the risk to children from the use of a particular pesticide on food is ten times greater than for adults. See id.; see also NW Coalition for Alternatives to Pesticides, 544 F.3d at 1046. EPA may "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." Id.

EPA's four-and-a-half-year delay is unreasonable in light of the broad, protective purposes of the FDCA and its particular focus on the health of children

[4] Available at http://www.epa.gov/oppsrrd1/REDs/chlorpyrifos_red.pdf (last accessed Apr. 12, 2012).

and infants. The 2007 Petition clearly states that there is a significant body of evidence demonstrating a link between chlorpyrifos exposure and long-term neurological and neurodevelopmental impairment. 2007 Petition at 6-9. Indeed, some studies suggest that fetal exposure is more damaging than adult exposure. Id. The data associated with these studies, which were cited in the 2007 Petition, provide strong evidence that prenatal and early-life exposure to chlorpyrifos is associated with not only poor birth outcomes (lower birth weight and length), but also long-lasting and possibly permanent, impaired cognitive development. Id.; see also Sass Decl. ¶¶ 19-20 (explaining scientific evidence since 2007 Petition submitted further supports the need for prompt action).

When gauged in the statutory context of the FDCA's broad, child-health protected focus, inexplicable delay appears even more egregious. See Cutler v. Hayes, 818 F.2d 879, 897-98 (D.C. Cir. 1987) ("the court must also estimate the extent to which delay may be undermining the statutory scheme"); Auchter, 702 F.2d at 1154 (finding three-year delay unreasonable); In re Am. Rivers & Idaho Rivers United, 372 F.3d at 414 (finding six-year delay unreasonable). A writ of mandamus will significantly relieve the harm PANNA members and the public have suffered and continue to suffer by forcing EPA to address the danger posed by a pesticide used in agricultural areas across the country.

C. The 2007 Petition Bears on Human Health and Welfare.

EPA's delay is even less tolerable because the 2007 Petition directly relates to human health and welfare, as opposed to economic injury. See Independence Mining Co., 105 F.3d at 507 (citing TRAC, 750 F.2d at 80). This is particularly true because the objective of the FDCA is to protect people from unsafe aggregate levels of pesticide exposure, and FIFRA is designed to eliminate unreasonable risks to man or the environment when taking into account the costs and benefits of the use of any pesticide. See Auchter, 702 F.2d at 1157–58 (noting that delay is particularly unreasonable where purpose of governing statute is to protect public health). The serious consequences of exposure to chlorpyrifos include muscle spasms, confusion, dizziness, loss of consciousness, seizures, abdominal cramps, vomiting, diarrhea, cessation of breathing, paralysis, and even death. See 2007 Petition at 1. In addition to cholinesterase inhibition, scientific studies associate exposure to chlorpyrifos with other harmful human health effects and neurodevelopmental disorders, and there is scientific evidence that children and infants exposed to chlorpyrifos can exhibit long-term neurological and neurodevelopmental difficulties. 2007 Petition at 6-9; Sass Decl. ¶¶ 19-21. "When lives are at stake," as they are here, the agency "must press forward with energy and perseverance in adopting regulatory protections." Pub. Citizen Health Research Grp. v. Brock, 823 F.2d 626, 629 (D.C. Cir. 1987).

It is impossible to avoid exposure to this pervasive pesticide. Chlorpyrifos is found in food and drinking water, in the air near agricultural communities, and in breast milk. See 2007 Petition at 4; Sass Decl. ¶ 8. The risk of exposure is not limited to those persons who choose to buy or use products containing the pesticide; it can travel on the wind from where it was first sprayed, and it can be tracked inside the home on the shoes and clothes of persons who never handled the chemical themselves. Sass Decl. ¶ 8; Reeves Decl. ¶¶ 5, 9, 14. "Lack of alternative means of eliminating or reducing the hazard necessarily adds to unreasonableness of a delay." Cutler, 818 F.2d at 898.

An agency delay of more than four and a half years where human health is at risk is unacceptable. See Auchter, 702 F.2d at 1154, 1157. The public health threat posed by chlorpyrifos justifies expedition in responding to the petition, rendering EPA's prolonged delay all the more unreasonable.

D. No Competing Priorities Justify EPA's Delay.

Federal agencies invariably face the challenge of limited resources with which to address competing priorities. Courts must bear this in mind while weighing the reasonableness of agency delay in responding to requests for action. See TRAC, 750 F.2d at 80. Here, however, EPA has never stated that competing priorities or limited resources would interfere with reaching a decision on the 2007 Petition. Further, chlorpyrifos is one of the organophosphate pesticides, which

EPA has long recognized "pose the greatest risk to public health." 62 Fed. Reg. 42,020, 42,021 (Aug. 4, 1997) (placing organophosphate pesticides in the first category for tolerance reassessments "which based on the best available information to date appear to pose the greatest risk to the public health").

Courts have previously recognized that claims of competing agency priorities cannot be used to delay action indefinitely when they are under a statutory duty to protect human health and safety. The D.C. Circuit held in In re United Mine Workers that "[h]owever many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to how long it may use these justifications to excuse inaction in the face of the congressional command to act . . . ." 190 F.3d 545, 554 (D.C. Cir. 1999). It is appropriate here for this Court to "let [the] agency know, in no uncertain terms, that enough is enough." Brock, 823 F.2d at 627 (imposing a one-year deadline on OSHA, following a five-year delay). In In re Int'l Chemical Workers Union, the D.C. Circuit retained jurisdiction to enforce deadlines for agency action where the agency had delayed regulating exposure to cadmium for six years. 958 F.2d 1144, 1150 (D.C. Cir. 1992).

In light of the amount of time that has passed since the 2007 Petition was filed, an argument that EPA might raise now of competing agency priorities loses any force. See In re Int'l Chem. Workers Union, 958 F.2d 1144, 1150 (D.C. Cir.

1992) (stating that the agency's "asserted justifications for the delay become less persuasive the longer the delay continues"). Moreover, justifications for delay "must always be balanced against the potential for harm." Cutler, 818 F.2d at 898. In this case, the consequences of inaction on public health are serious. EPA should be moving expeditiously to respond to the 2007 Petition and cancel all registrations and revoke all tolerances for chlorpyrifos.

E. The Harm Caused by EPA's Delay Is Serious and Wide-Ranging.

The fifth TRAC factor, the nature and extent of the harm caused by delay, weighs strongly in favor of issuing a writ of mandamus in this case. EPA's failure to respond to the 2007 Petition perpetuates the underlying harm suffered by PANNA's members and the general public, namely, exposure to chlorpyrifos through a number of routes, including food, drinking water, and inhalation. See 2007 Petition at 4. PANNA's members are justifiably concerned about the health effects of chlorpyrifos exposure to themselves and their children, particularly with respect to the acute effects and potential long-term neurological developmental consequence for children with early-life exposure. See Medellin Decl. ¶¶ 2-10; Sass Decl. ¶¶ 19-21; Reeves Decl. ¶¶ 5, 9-12. Numerous scientific studies establish that chlorpyrifos poses a risk of serious human health effects, including nausea, dizziness, confusion, convulsions, involuntary urination and defecation, and, in extreme cases, death by suffocation resulting from loss of respiratory

muscle control. 2007 Petition at 1. The extent of this harm is wide-ranging; Americans are being placed at risk of illness and death through exposure to this pervasive pesticide. Infants and young children are particularly susceptible to chlorpyrifos exposures, and are being exposed to higher levels of the pesticide than adults. 2007 Petition at 6-9; Sass Decl. ¶¶ 6-7.

Each day that EPA delays action on the 2007 Petition, PANNA's members are unwittingly and involuntarily coming into contact with chlorpyrifos, and they are procedurally harmed because EPA has refused to address the grievances they submitted in the 2007 Petition.

F. The Court Need Not Find Any Impropriety Behind EPA's Delay to Grant Mandamus.

EPA need not be acting in bad faith for the Court to grant PANNA's petition for writ of mandamus. In re California Power Exch. Corp., 245 F.3d at 1124 (citing TRAC, 750 F.2d at 80). It is unclear what is causing EPA's delay, especially in light of the 2007 Petition's clear request that EPA give expedited consideration, but that does not matter for the purposes of this Court's judgment.

Regardless of whether EPA's inaction is in good faith, the delay here is unreasonable in light of the urgent human health threats of chlorpyrifos, especially its serious and long-term risks to children and infants, and the harm from that delay can only be remedied by mandamus.

CONCLUSION

Over 10 million pounds of chlorpyrifos were used in the United States in 2007. The human health risks posed by this pesticide, particularly to infants and children, are too troubling to ignore. PANNA has a right to receive a response from EPA to its 2007 Petition requesting that EPA revoke all tolerances and cancel all registrations for chlorpyrifos. After four and a half years, and recent EPA indications in a Federal Register Notice that no decision is forthcoming, PANNA respectfully requests that this Court establish an enforceable deadline by which the EPA must respond to the 2007 Petition with either a denial or a responsive rulemaking.

Respectfully submitted this 12th day of April, 2012.

s/ Kevin E. Regan
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STATEMENT OF RELATED CASES

The undersigned, counsel of record for Petitioners Pesticide Action Network North America and Natural Resources Defense Council, Inc., are aware of no cases related to this petition pending before this Court.

Respectfully submitted this 12th day of April, 2012.

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CERTIFICATE OF SERVICE

I am a citizen of the United States and a resident of the State of Washington. I am over 18 years of age and not a party to this action. My business address is 705 Second Avenue, Suite 203, Seattle, Washington 98104.

On April 12, 2012, I served a true and correct copy of:

1. Petition for a Writ of Mandamus and for Relief From Unreasonably Delayed Agency Action by the Environmental Protection Agency;
2. Declaration of Sharon Bolton in Support of Petition for a Writ of Mandamus;
3. Declaration of Sattie Clark in Support of Petition for a Writ of Mandamus;
4. Declaration of Linda Lopez in Support of Petition for a Writ of Mandamus;
5. Declaration of Luis Medellin in Support of Petition for a Writ of Mandamus;
6. Declaration of Margaret Reeves in Support of Petition for a Writ of Mandamus; and
7. Declaration of Jennifer Sass in Support of Petition for a Writ of Mandamus.

on the following parties:

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- ☐ via facsimile
- ☒ via overnight courier
- ☐ via first-class U.S. mail
- ☐ via hand delivery
- ☐ via e-mail
- ☐ via electronic service by Clerk

Eric Holder United States Attorney General U.S. Department of Justice 950 Pennsylvania Avenue, N.W. Washington, D.C. 20530-0001 (202) 514-2001 *United States Attorney General*	☐ via facsimile ☒ via overnight courier ☐ via first-class U.S. mail ☐ via hand delivery ☐ via e-mail ☐ via electronic service by Clerk
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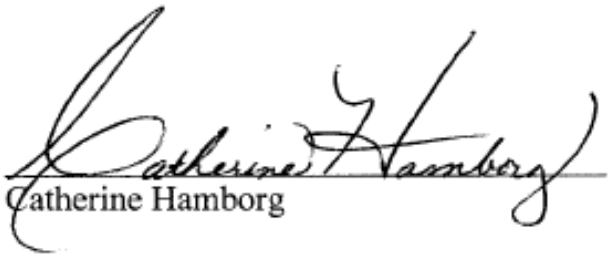
I, Catherine Hamborg, declare under penalty of perjury that the foregoing is true and correct. Executed on this 12th day of April, 2012, at Seattle, Washington.



Catherine Hamborg