

No. _____

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

IN RE NATURAL RESOURCES DEFENSE COUNCIL, INC.,
PETITIONER

On Petition for a Writ of Mandamus and for Relief from Unreasonably Delayed
Agency Action by the Environmental Protection Agency

BRIEF FOR PETITIONER

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Dated: February 6, 2014

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to District of Columbia Circuit Rule 28(a)(1), petitioner Natural Resources Defense Council certifies as follows:

A. Parties

Natural Resources Defense Council is the petitioner in this case.

Gina McCarthy, in her official capacity as Administrator of the U.S.

Environmental Protection Agency, and the U.S. Environmental Protection Agency are the respondents in this case.

B. Rulings Under Review

This petition challenges the Administrator of the U.S. Environmental Protection Agency's refusal to answer Natural Resources Defense Council's petitions for regulation of harmful pesticides. Because the agency has refused to take the final action required by law, there is no agency ruling under review in this case.

C. Related Cases

There are no cases related to this petition.

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Petitioner Natural Resources Defense Council, Inc. submits this Corporate Disclosure Statement pursuant to Federal Rule of Appellate Procedure 26.1 and District of Columbia Circuit Rule 26.1. Natural Resources Defense Council has no parent, subsidiary, or affiliate that has issued shares or debt securities to the public. Natural Resources Defense Council is a not-for-profit, tax-exempt membership organization engaging in research, lobbying, educational, and litigation activities.

TABLE OF CONTENTS

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES i

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIESv

GLOSSARY viii

INTRODUCTION1

STATEMENT REGARDING ADDENDA1

STATEMENT OF JURISDICTION AND APPLICABLE LAW1

STATEMENT OF THE ISSUE PRESENTED FOR REVIEW4

STATUTORY FRAMEWORK.....4

FACTUAL BACKGROUND.....6

PROCEDURAL HISTORY.....9

I. Propoxur.....9

II. Tetrachlorvinphos15

SUMMARY OF ARGUMENT17

STANDING18

ARGUMENT20

I. A Writ of Mandamus Is the Only Remedy that Will Adequately Enforce EPA’s Duty to Answer the Petition20

II. A Writ of Mandamus Is Justified under the
Equitable Factors Established in *TRAC*.....21

A. EPA’s Delay Is Unreasonable22

B. EPA’s Delay Is Unreasonable Even in the
Absence of a Statutory Deadline24

C. EPA’s Delay Affects Human Health and
Welfare25

D. No Competing Priorities Justify EPA’s
Delay.....27

E. The Harm Caused by EPA’s Delay Is
Serious and Wide-Ranging.....28

F. The Court Need Not Find EPA Acted in Bad
Faith.....29

CONCLUSION30

CERTIFICATE OF SERVICE31

TABLE OF AUTHORITIES

Authorities upon which we chiefly rely are marked with asterisks.

Cases

<i>Am. Broad. Co. v. FCC</i> , 191 F.2d 492 (D.C. Cir. 1951).....	29
<i>Cutler v. Hayes</i> , 818 F.2d 879 (D.C. Cir. 1987).....	23, 27, 28
<i>Env'tl. Def. Fund, Inc. v. Costle</i> , 631 F.2d 922 (D.C. Cir. 1980).....	3
<i>Ferebee v. Chevron Chem. Co.</i> , 736 F.2d 1529 (D.C. Cir. 1984).....	23
<i>Hunt v. Wash. State Apple Adver. Comm'n</i> , 432 U.S. 333 (1977).....	20
<i>In re Am. Rivers & Idaho Rivers United</i> , 372 F.3d 413 (D.C. Cir. 2004).....	22, 24, 25
<i>In re Core Commc'ns, Inc.</i> , 531 F.3d 849 (D.C. Cir. 2008).....	22, 25
<i>In re Int'l Chem. Workers Union</i> , 958 F.2d 1144 (D.C. Cir. 1992).....	25
<i>Lemon v. Geren</i> , 514 F.3d 1312 (D.C. Cir. 2008).....	18
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	18
<i>Muwekma Tribe v. Babbitt</i> , 133 F. Supp. 2d 30 (D.D.C. 2000).....	27
<i>N. States Power Co. v. Dep't of Energy</i> , 128 F.3d 754 (D.C. Cir. 1997).....	21

Natural Res. Def. Council v. U.S. EPA,
658 F.3d 200 (2nd Cir. 2011)5

Pub. Citizen Health Research Grp. v. Auchter,
702 F.2d 1150 (D.C. Cir. 1983)..... 23, 25

**Telecomm. Research & Action Ctr. (TRAC) v. FCC*,
750 F.2d 70 (D.C. Cir. 1984)..... 2, 18, 21, 22, 29

United Farm Workers of Am. v. EPA,
592 F.3d 1080 (9th Cir. 2010)2, 3

Statutes and Regulations

5 U.S.C. § 555(b) 2, 21, 24

5 U.S.C. § 702.....2

*5 U.S.C. § 706(1)2

5 U.S.C. §§ 500 *et seq.*.....1

7 U.S.C. § 136(bb) 4, 25

7 U.S.C. § 136a(a).....4

7 U.S.C. § 136a(c)(5)(C)..... 4, 23

7 U.S.C. § 136a(g) 5, 12

7 U.S.C. § 136a-1(a)5

7 U.S.C. § 136a-1(b)-(g)5

7 U.S.C. § 136a-1(g)5

7 U.S.C. § 136d(b)23

7 U.S.C. § 136d(b)(1).....4

7 U.S.C. § 136n(b)2, 3

7 U.S.C. §§ 136 *et seq.*.....1
21 U.S.C. § 346a(b)(2)(C)10
21 U.S.C. § 346a(b)(2)(D)5
21 U.S.C. § 346a(q)5
28 U.S.C. § 1651(a)3

Other Authorities

60 Fed. Reg. 3,210 (Jan. 13, 1995)10
74 Fed. Reg. 15,980 (Apr. 8, 2009) 3, 11
74 Fed. Reg. 27,035 (Jun. 5, 2009)..... 3, 11, 17
74 Fed. Reg. 66,645 (Dec. 16, 2009)12

GLOSSARY

APA	Administrative Procedure Act
EPA or Agency	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act of 1996
NRDC	Natural Resources Defense Council
RED	Reregistration Eligibility Decision

INTRODUCTION

This petition for a writ of mandamus seeks an order requiring the U.S. Environmental Protection Agency (EPA) to respond to petitioner Natural Resources Defense Council's (NRDC's) petitions to cancel the use of the pesticides propoxur and tetrachlorvinphos in flea collars and other pet products. In its petitions and supporting documentation, NRDC presented evidence to EPA that toddlers may be exposed to residues from flea collars containing these pesticides in amounts that exceed the levels EPA has found to be safe. EPA has failed to answer NRDC's petitions regarding the use of tetrachlorvinphos and propoxur for over four and six years respectively, leaving potentially millions of children, adults, and pets at risk of exposure to unsafe levels of these dangerous pesticides. The Court should order EPA to respond.

STATEMENT REGARDING ADDENDA

Relevant statutes and regulations, and supporting declarations and exhibits, are submitted with this brief as separate addenda.

STATEMENT OF JURISDICTION AND APPLICABLE LAW

NRDC submitted petitions to EPA in 2007 and 2009 pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.*, and the Administrative Procedure Act (APA), 5 U.S.C. §§ 500 *et seq.*, seeking cancellation of all pet collar uses for the pesticide propoxur and all pet uses for the

pesticide tetrachlorvinphos.¹ This is a challenge to EPA's failure to respond to NRDC's petitions.

This Court has jurisdiction to hear NRDC's request for a writ of mandamus under the 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. A federal agency is obligated to "conclude a matter" presented to it "within a reasonable time," *id.* § 555(b), and a reviewing court may "compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

Where review of final agency action is committed by statute to a U.S. court of appeals, jurisdiction to review agency inaction also lies exclusively with the same courts. *Telecomm. Research & Action Ctr. (TRAC) v. FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984). Here, the courts of appeals have jurisdiction to review any final action by EPA under FIFRA. The statute provides the courts of appeals with "exclusive jurisdiction" to review "the validity of any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). The Ninth Circuit has held that the opportunity for submission of written comments constitutes such a "public hearing." See *United Farm Workers of Am. v. Adm'r, EPA*, 592 F.3d

¹ The petitions are included in Petitioner's Supplemental Materials addendum, attached to the Declaration of Miriam Rotkin-Ellman as Exhibits L and M.

1080, 1082 (9th Cir. 2010); *cf. Env'tl. Def. Fund, Inc. v. Costle*, 631 F.2d 922, 926, 932 (D.C. Cir. 1980) (a “public hearing” pursuant to Section 136n(b) does not require oral presentation of arguments to an agency decision-maker).

NRDC submitted administrative petitions to EPA with written arguments for canceling pet uses of propoxur and tetrachlorvinphos. The Agency published notices of NRDC’s petitions in the *Federal Register* and solicited public comments. *See* Petition Requesting Cancellation of Propoxur Pet Collar Uses; Notice of Availability, 74 Fed. Reg. 15,980 (Apr. 8, 2009); Petition Requesting Cancellation of all Tetrachlorvinphos Pet Uses and Extension of Comment Period for Petition Requesting Cancellation of Propoxur Pet Collar Uses; Notice of Availability, 74 Fed. Reg. 27,035 (June 5, 2009). This process satisfies FIFRA’s public hearing requirement and creates a suitable record for appellate review. *See United Farm Workers of Am.*, 592 F.3d at 1082-83. Thus, because the Court would have jurisdiction to review any final action taken by EPA in response to NRDC’s petitions, the Court also has jurisdiction to review this challenge to EPA’s failure to respond to these petitions.

The Court has the authority to issue a writ of mandamus requiring EPA to respond to NRDC’s petitions under the All Writs Act, 28 U.S.C. § 1651(a). The All Writs Act provides that “[t]he 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.” *Id.*

STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

Whether, after receiving petitions to cancel pet uses for the pesticides tetrachlorvinphos and propoxur that pose unreasonable adverse risks to human health, EPA’s failure to respond for more than four years and six years, respectively, is an unreasonable delay such that this Court should order the Agency to respond?

STATUTORY FRAMEWORK

EPA oversees pesticide regulation under FIFRA. FIFRA requires pesticides to be registered prior to sale or distribution in the U.S. 7 U.S.C. § 136a(a). EPA may register a pesticide only if it will “perform its intended function” without causing “unreasonable adverse effects on the environment.” *Id.* § 136a(c)(5)(C). A pesticide causes unreasonable adverse effects on the environment if it poses “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). The Administrator may cancel the registration of any pesticide that causes unreasonable adverse effects on the environment. *Id.* § 136d(b)(1).

FIFRA was amended in 1988 to require the reregistration of pesticides containing an active ingredient that was first registered prior to November 1, 1984.

Pub. L. No. 100-532, 102 Stat. 2554 (1988) (codified at 7 U.S.C. § 136a-1(a)). As part of the reregistration process, EPA reviewed the scientific data underlying a pesticide's registration, including an assessment of human health and ecological risks. *See* 7 U.S.C. § 136a-1(b)-(g). The results of EPA's reviews were published in Reregistration Eligibility Decisions for each pesticide. *See, e.g.*, EPA, Reregistration Eligibility Decision for Propoxur (1997) [hereinafter 1997 Propoxur RED].² FIFRA required EPA to complete its reregistration of all pesticides by October 3, 2008. 7 U.S.C. § 136a-1(g). Following reregistration, EPA must conduct a periodic review of each pesticide's registration—referred to as “registration review”—every 15 years. 7 U.S.C. § 136a(g).

The Food Quality Protection Act of 1996 (FQPA) also directed EPA to reassess all pesticide tolerances, or the maximum permissible levels of pesticide residue on food products, by 2006. 21 U.S.C. § 346a(q). In conducting its assessment, EPA was required to consider the cumulative effects of pesticides that share a common mechanism of toxicity. *Id.* § 346a(b)(2)(D). After FQPA was enacted, EPA frequently conducted FIFRA's reregistration and FQPA's tolerance reassessment processes together. *See Natural Res. Def. Council v. U.S. EPA*, 658 F.3d 200, 204 (2d Cir. 2011).

² Petitioner's Supplemental Materials, Chaudhary Decl., Ex. A.

FACTUAL BACKGROUND

Propoxur and tetrachlorvinphos are two pesticides currently used in pet collars to control fleas and ticks. 1997 Propoxur RED at 2; EPA, Reregistration Eligibility Decision for Tetrachlorvinphos 15 (2006) [hereinafter 2006 Tetrachlorvinphos RED].³ Tetrachlorvinphos is also used in pet products such as flea dips, powders, aerosol and pump sprays. *Id.*

Propoxur belongs to a class of pesticides called N-methyl carbamates and is toxic to the nervous system. Rotkin-Ellman Decl. ¶ 6. EPA designated propoxur as a probable human carcinogen in 1996. EPA Memorandum from Jess Rowland to Division Directors, Chemicals Evaluated for Carcinogenic Potential by the Office of Pesticide Programs 17 (Sept. 24, 2008) [hereinafter Sept. 24, 2008 Rowland Memo].⁴ Tetrachlorvinphos belongs to a class of pesticides called organophosphates. Rotkin-Ellman Decl. ¶ 6. These pesticides are chemically similar to wartime nerve agents, such as sarin gas, and interact similarly with the human nervous system. *Id.* EPA designated tetrachlorvinphos as “likely to be carcinogenic to humans” in 2002. Sept. 24, 2008 Rowland Memo at 19.

³ Petitioner’s Supplemental Materials, Chaudhary Decl., Ex. B. This document incorporates and finalizes a 2002 Interim Tolerance Reassessment Eligibility Decision for tetrachlorvinphos issued by EPA. For ease of reference, this petition refers to the full document as “2006 Tetrachlorvinphos RED.”

⁴ Petitioner’s Supplemental Materials, Chaudhary Decl., Ex. D.

Both propoxur and tetrachlorvinphos interfere with an essential enzyme, acetylcholinesterase, that normally controls messaging between nerve cells. Rotkin-Ellman Decl. ¶ 7. The result of exposure to these pesticides is spasmodic overstimulation of the nervous system; this is the mechanism by which fleas and ticks are killed. *Id.* In large doses, these pesticides can harm or kill cats, dogs, and in extreme poisoning cases even humans. *Id.* ¶ 8. At lower levels, they can cause a variety of poisoning symptoms, including eye pupil contraction and tearing, increased salivation, sweating, dizziness, and confusion. *Id.* More severe poisoning can cause involuntary urination and defecation, vomiting, and seizures. *Id.*

Flea collars are designed to create a coating of the pesticide on the fur of a pet. *Id.* ¶ 10; EPA Memorandum from Shalu Shelat to Monica Wait, Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars 8 (Apr. 7, 2010) [hereinafter April 7, 2010 EPA Propoxur Memo].⁵ Accordingly, exposure to propoxur and tetrachlorvinphos primarily occurs when children or adults come into contact with treated flea collars directly, or come into contact with residues on pets from the flea collars.⁶ Rotkin-Ellman Decl. ¶ 10. These residues also can be transferred to the skin and clothing of an adult or child during normal contact and play with a pet wearing a flea collar. *Id.*

⁵ Petitioner's Supplemental Materials, Chaudhary Decl., Ex. E.

⁶ Exposure to tetrachlorvinphos can also occur when individuals mix, load, or apply other tetrachlorvinphos-containing flea-control products to their pets, or when they enter or contact treated sites. 2006 Tetrachlorvinphos RED at 26.

Additional exposure can result from contact with household items that the treated pet comes into contact with, such as carpets and bedding. Davis et al., *Assessing Intermittent Pesticide Exposure from Flea Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*, 2008 J. of Exposure Sci. & Env't'l Epidemiology 1, 6-7 (2008) [hereinafter Miss. State Univ. Study].⁷ Once transferred off of the pet, people can absorb pesticide residues through their skin and ingest them by touching their hands to their mouth. Rotkin-Ellman Decl. ¶ 10.

Children are particularly at risk from exposure to propoxur and tetrachlorvinphos because their neurological and metabolic systems are still developing. *Id.* ¶ 11. Recent research indicates that low-level prenatal and early life exposure to these pesticides can impair children's neurological development, which can result in pervasive disorders that may include delays in motor development and attention deficit/hyperactivity disorder. *Id.* ¶ 9. Children—especially toddlers—are also more likely than adults to put their hands and other objects in their mouths, and so are more likely to ingest residues of pesticides with which they come into contact. *Id.* ¶ 11.

Exposure to propoxur and tetrachlorvinphos pesticides is widespread. EPA estimates that ten percent of households with dogs or cats treat their animals with products containing tetrachlorvinphos; an unknown number treat their animals with

⁷ Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. K.

propoxur. Tetrachlorvinphos RED at 15.⁸ A 2008 study of the residue levels from tetrachlorvinphos-treated flea collars estimated that there are potentially “millions of children who could be in direct contact” with pesticides in flea collars, merely from contact with their dogs. Miss. State Univ. Study at 1.

Although widely used, flea collars containing tetrachlorvinphos and propoxur are regarded by veterinarians as ineffective. Stone Decl. ¶ 9; *see also* Rotkin-Ellman Decl. ¶ 12. Many alternatives, such as oral tablets or less toxic treatments, exist on the market to control fleas and ticks. Rotkin-Ellman Decl. ¶ 13.

PROCEDURAL HISTORY

I. Propoxur

Propoxur was first registered for use as an insecticide in the U.S. in 1963, and was originally used to control ants, roaches, hornets, and other pests in and around buildings, as well as on pets as a flea dip and flea spray, and in flea and tick collars. 1997 Propoxur RED at v, 4, 5. Most outdoor uses, as well as uses in pet dips and shampoos, were voluntarily canceled by the early 1990s after EPA notified registrants that it was considering a “special review” based on concerns about the risk of bladder and uterine cancer. Propoxur (Baygon, Sendran);

⁸ An undated EPA review of incident data related to propoxur noted that a single company estimated it sold eight million propoxur-formulated collars between 1990 and 1995, but more recent and comprehensive data on propoxur use does not appear to be available. *See* EPA Memorandum from Virginia A. Dobozy to David Jacquith, Propoxur – Review of Pesticide Poisoning Incident Data, attached to Petitioner’s Supplemental Materials, Chaudhary Decl., Ex. H.

Proposed Decision Not to Initiate a Special Review, 60 Fed. Reg. 3,210, 3,219 (Jan. 13, 1995). Indoor residential uses of propoxur sprays for cracks and crevices were canceled in 2007. EPA, Revised N-Methyl Carbamate Cumulative Risk Assessment 251-52 (2007) [hereinafter 2007 Carbamate Risk Assessment].⁹ Today, EPA permits propoxur's use in a small number of insect-control products. *Id.* EPA also permits its use in pet flea collars. *Id.* at 87.

As part of FIFRA's pesticide reregistration process, EPA issued a Reregistration Eligibility Decision for propoxur in 1997. 1997 Propoxur RED. In this assessment, EPA established a "reference dose" for propoxur—EPA's estimate of a daily exposure of propoxur that is likely to be without appreciable risk of deleterious effects during a lifetime. *Id.* at 22. EPA also determined that flea collar uses of propoxur could be reregistered, although it did not use its reference dose to evaluate the risk of neurological harm from oral or dermal exposure to propoxur residues. *Id.* at 55, 31.

EPA subsequently published a cumulative risk assessment evaluating the exposure risks of all N-methyl carbamate pesticides, pursuant to its obligations under FQPA. *See* 21 U.S.C. § 346a(b)(2)(C); 2007 Carbamate Risk Assessment at 2. This assessment evaluated likely routes of exposure to propoxur, including hand-to-mouth exposure by a toddler playing with a pet wearing a flea collar. 2007

⁹ Petitioner's Supplemental Materials, Chaudhary Decl., Ex. C.

Carbamate Risk Assessment at 90-94, 110-12. It concluded that the risk of harmful health effects to adults and children from exposure to propoxur-formulated flea collars was below EPA's level of concern. *Id.* at 9.

On November 26, 2007, NRDC submitted a petition to EPA, together with its comments on EPA's Carbamate Risk Assessment, requesting that the Agency cancel all pet collar uses of propoxur. NRDC, *Petition to Cancel Carbaryl and Propoxur for Pet Collar Uses* (Nov. 26, 2007).¹⁰ NRDC noted that EPA's assessment modified the Agency's standard method for assessing toddler hand-to-mouth exposure. *Id.* at 6. This modification resulted "in a repeated and additive bias towards reducing the exposure estimate," making it appear that use of propoxur in flea collars did not exceed EPA's level of concern. *Id.* NRDC also questioned the need for propoxur-formulated collars to remain on the market given that less toxic alternatives were effective and readily available. *Id.* at 5-6. EPA published notice of NRDC's petition in the *Federal Register* on April 8, 2009, providing for a sixty-day comment period. *Petition Requesting Cancellation of Propoxur Pet Collar Uses*; 74 Fed. Reg. at 15,980.¹¹

¹⁰ Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. L.

¹¹ This comment period was later extended to August 4, 2009. *Petition Requesting Cancellation of all Tetrachlorvinphos Pet Uses and Extension of Comment Period for Petition Requesting Cancellation of Propoxur Pet Collar Uses*; 74 Fed. Reg. at 27,035.

In 2007 and 2008, NRDC conducted a study of a toddler's exposure to propoxur due to residues from flea collars containing the pesticide. NRDC, *Poison on Pets II: Toxic Chemicals in Flea and Tick Collars* (April 2009) [hereinafter *Poison on Pets II*].¹² NRDC tested the residues of propoxur on pets' fur after the pets had worn a collar for three days and fourteen days. *Id.* at 7. Using EPA's exposure assessment methods and other parameters from the published literature, NRDC then calculated the potential dose to toddlers: how much of these residues could be ingested and absorbed through the skin, for an average toddler playing with their pet. *Id.* at 7-8. NRDC found that an average toddler playing with a pet after it had worn a propoxur flea collar for three days would be dosed with propoxur at levels exceeding EPA's reference dose, and thus exceeding the level EPA had found to be safe. *Id.* at 9-10. NRDC submitted this finding to EPA on April 23, 2009, as further support for its 2007 petition to cancel pet collar uses for propoxur. NRDC, *Supplement to Natural Resources Defense Council Petition to Cancel Pet Collar Uses for the Pesticide Propoxur* (Apr. 2009).¹³

On December 16, 2009, EPA announced the commencement of its registration review of propoxur, pursuant to FIFRA Section 136a(g). Registration Review; Pesticide Dockets Opened for Review and Comment, 74 Fed. Reg. 66,645 (Dec. 16, 2009). EPA's work plan for registration review acknowledged that "the

¹² Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. A.

¹³ Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. M.

registration review process is not a substitute for EPA's consideration of NRDC's petition to cancel propoxur pet collar uses" and that it "anticipates responding to the petition prior to the completion of registration review." EPA, Propoxur Final Work Plan for Registration Review 8 (June 2010) [hereinafter Propoxur Final Work Plan].¹⁴ EPA represented that it would complete its registration review of propoxur by 2015. *Id.* at 7.

In 2010, EPA conducted an initial occupational and residential exposure and risk assessment for propoxur-formulated flea collars. April 7, 2010 EPA Propoxur Memo at 1. This assessment found that the risk of exposure to children from ingesting residues from propoxur-formulated pet collars exceeds the level EPA found to be safe, and therefore was "of concern to the Agency." *Id.* at 10. EPA then received new data from one flea collar company to "refine the risk calculations." EPA Memorandum from Shalu Shelat to Monica Wait, Issues for Consideration Related to Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars 1 (July 12, 2010).¹⁵ EPA revised its assessment with this updated industry data, but still found the risks to children exceeded the Agency's own safety threshold. *Id.* at 2. EPA noted that it would incorporate this revised data into "a future revised risk assessment." *Id.* To date, EPA has not released this revised assessment.

¹⁴ Petitioner's Supplemental Materials, Chaudhary Decl., Ex. F.

¹⁵ Petitioner's Supplemental Materials, Chaudhary Decl., Ex. G.

On January 18, 2011, NRDC submitted a second supplement to its petition to cancel pet collar uses for propoxur, commenting on EPA's residential exposure and risk assessment. NRDC, *Supplement to Natural Resources Defense Council Petition to Cancel Pet Collar Uses for the Pesticide Propoxur* (Jan. 2011).¹⁶

NRDC noted that the Agency itself had found unacceptable risks to children from exposure to propoxur-formulated flea collars. *Id.* at 2-3. NRDC also observed that the risk associated with propoxur exposure was likely even greater than EPA estimated because EPA failed to consider risks from dermal exposure to adults and children, underestimated a toddler's exposure to a treated pet, and ignored the cancer risk associated with propoxur. *Id.* at 4. NRDC again called on EPA to immediately cancel flea collar uses of the pesticide. *Id.* at 11.

It has been more than six years since NRDC petitioned EPA to cancel all pet collar uses of propoxur. EPA has acknowledged that levels of propoxur in flea collars exceed its own safety threshold for children's exposure and that it must respond to NRDC's petition before completing its registration review. Yet EPA refuses to issue a decision on NRDC's petition or provide a specific date for its response. Rotkin-Ellman Decl. ¶ 22. In the meantime, potentially millions of adults and children continue to be exposed to unacceptable risks from propoxur-formulated flea collars.

¹⁶ Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. O.

II. Tetrachlorvinphos

Tetrachlorvinphos was first registered for use as a pesticide in 1966, and originally used on vegetables, feed crops, livestock, pets, and around buildings. 2006 Tetrachlorvinphos RED at 19. Crop uses were voluntarily cancelled in 1987. *Id.* Today tetrachlorvinphos is primarily used to control flies, larvae, and mites in livestock. *Id.* at 15. It is also still allowed in pet products such as flea dips, powders, aerosol and pump sprays, and collars. *Id.*

EPA issued its most recent reregistration eligibility decision for tetrachlorvinphos in July of 2006. *Id.* at cover page. As part of this decision, EPA evaluated exposure to children and adults after an initial pesticide application from various residential uses of tetrachlorvinphos on pets, including sprays, dips, and powders, and compared those exposures with levels EPA has found to be safe. *Id.* at 36. EPA did not evaluate post-application exposure to residues from pet collar uses because EPA considered it “to be insignificant when compared with exposure to other products.” *Id.* In declining to evaluate post-application exposure to pet collars, EPA ignored evidence that such exposure could be significant. *Id.* at 37 (finding that the “worst case” scenario for adult aggregate risk was exposure to pet collars). Based on its assessment, EPA determined that tetrachlorvinphos could be reregistered, including for use in pet collars.

In 2008, researchers from the Center for Environmental Health Sciences at Mississippi State University published a study assessing children and adults' exposure to tetrachlorvinphos from the use of a tetrachlorvinphos-formulated collar on a pet dog. *See* Miss. State Univ. Study at 1-2. The study concluded that significant amounts of tetrachlorvinphos residue are transferred from pets to skin and clothing, indicating potential sources of exposure. *Id.* at 6-7.

In 2009, NRDC conducted a similar study of human exposure caused by residues from flea collars containing tetrachlorvinphos. *See Poison on Pets II* at 7-8. As with NRDC's study of propoxur, NRDC tested the residues of tetrachlorvinphos on a pet's fur after the pet had worn a collar for three days and fourteen days, respectively, and calculated the exposure to toddlers from playing with a treated pet. *Id.* Using EPA's exposure assessment methods and other parameters from the published literature, NRDC found some residue levels translated to exposures at more than twice the level EPA has found to be safe. *Id.* at 9-10.

On April 23, 2009, NRDC filed a petition with EPA to cancel all pet uses for tetrachlorvinphos. NRDC, *Petition to Cancel All Pet Uses for the Pesticide Tetrachlorvinphos* (April 23, 2009) [hereinafter NRDC Tetrachlorvinphos Petition].¹⁷ NRDC highlighted the results of its own exposure study, and further

¹⁷ Petitioner's Supplemental Materials, Rotkin-Ellman Decl., Ex. N.

noted that EPA's 2006 risk assessment employed flawed assumptions to underestimate toddlers' exposure to flea collar residue. *Id.* at 3-6. Using EPA's exposure assessment methods, NRDC also calculated that the residue levels found by the Mississippi State University Study translated to exposures for an average toddler up to 150 times higher than the level EPA had found was safe. *Id.* at 6. EPA published a notice of NRDC's petition in the *Federal Register* on June 7, 2009, providing for a sixty-day comment period. Petition Requesting Cancellation of all Tetrachlorvinphos Pet Uses and Extension of Comment Period for Petition Requesting Cancellation of Propoxur Pet Collar Uses, 74 Fed. Reg. at 27,035.

It has now been over four years since NRDC filed its petition, and EPA has still not provided a response.

SUMMARY OF ARGUMENT

EPA has a statutory duty under the APA to respond to NRDC's petitions for cancellation of pet uses for tetrachlorvinphos and propoxur without unreasonable delay. Over four years have now passed since NRDC filed its tetrachlorvinphos petition, and more than six years have passed since NRDC filed its propoxur petition. Regardless of whether EPA grants or denies these petitions, NRDC has a right to a determination of the issues it presented to the Agency. In the case of a denial of the petitions, NRDC is entitled to seek further relief from the Agency and the Court, but it cannot exercise those rights until EPA acts. A writ of mandamus is

the only remedy that will adequately cure the injury NRDC members have suffered and continue to suffer as a result of EPA's ongoing delay. The harm caused by exposure of NRDC members to tetrachlorvinphos and propoxur provides ample justification for granting a writ of mandamus under the six factors identified by this Court in *TRAC v. FCC*.

STANDING

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

A party suffers a cognizable procedural injury when an agency fails to follow a statutorily mandated procedure if that procedure has the potential to change the agency's mind in a particular matter. *See Lemon v. Geren*, 514 F.3d 1312, 1315 (D.C. Cir. 2008) (“[P]laintiffs suffer harm from the agency's failure to follow [the National Environmental Policy Act's] procedures, compliance with which might have changed the agency's mind[.]”). Additionally, organizations suing for redress of a procedural injury must show that such redress will relieve a concrete underlying harm. *See 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.”).

NRDC satisfied both parts of this standard.

First, NRDC’s petitions have the potential to change EPA’s position regarding the use of propoxur and tetrachlorvinphos in flea collars and other pet products.

Second, EPA’s failure to respond to NRDC’s petitions has caused NRDC’s members an ongoing injury that only a writ of mandamus from this Court can remedy. NRDC is an environmental and public health organization with approximately 330,000 members nationwide. Lopez Decl. ¶ 4-6. NRDC’s organizational priorities include reducing and eliminating members’ exposures to dangerous chemicals. *Id.* ¶ 6.

NRDC’s members include parents of young children who come into contact with pets and are concerned about the effects of propoxur and tetrachlorvinphos on their children’s health. Louchheim Decl. ¶¶ 8-10; Stone Decl. ¶¶ 10-13. NRDC’s members also include veterinarians who come into contact with pets wearing flea collars through their professional work, and who are concerned about transferring residues from these collars to their hands and clothing, and ultimately to their children. Stone Decl. ¶¶ 4, 7-8, 12. Exposure of children to propoxur and tetrachlorvinphos is particularly troubling because their neurological and metabolic systems are still developing. Rotkin-Ellman Decl. ¶ 11. Parents who are aware of

such risks are nevertheless unable to protect themselves and their children because they cannot know if a particular pet they or their child comes into contact with is wearing (or has recently worn) a propoxur or tetrachlorvinphos-treated flea collar. Louchheim Decl. ¶¶ 9-10. They also cannot always control whether their child pets or interacts with treated pets, or objects with which those pets come into contact. *Id.* ¶¶ 5-7; Stone Decl. ¶ 12. A writ of mandamus compelling the EPA to take final action would redress the harm suffered by NRDC members who seek a decision on NRDC's petitions, and EPA's withdrawal of its approval for pet uses of these pesticides.

NRDC also satisfies the requirements for organizational standing. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). Under *Hunt's* three-part test, NRDC has standing to sue because: (1) NRDC's "members would otherwise have standing to sue in their own right" because of the injuries described above; (2) the interests NRDC seeks to protect "are germane to the organization's purpose"; and (3) "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.*

ARGUMENT

I. A Writ of Mandamus Is the Only Remedy that Will Adequately Enforce EPA's Duty to Answer the Petition

The facts of this case satisfy the three-part threshold test for granting a writ of mandamus. A court may grant mandamus relief "if (1) the plaintiff has a clear

right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to plaintiff.” *N. States Power Co. v. U.S. Dep’t of Energy*, 128 F.3d 754,758 (D.C. Cir. 1997) (internal quotation marks omitted). “The party seeking mandamus has the burden of showing that its right to issuance of the writ is clear and indisputable.” *Id.* (internal quotation marks omitted).

Here, EPA has a clear duty to respond to NRDC’s petitions, and NRDC has a clear right to relief. The APA requires that a petition submitted to an agency be decided by the agency within a reasonable time. *See* 5 U.S.C. § 555(b). EPA has acknowledged that it has a duty to respond promptly to NRDC’s petitions, regardless of any other registration review it may be undertaking with regard to these chemicals. *See* Propoxur Final Work Plan at 8. Nevertheless, EPA refuses to respond to NRDC’s petitions.

NRDC, moreover, has no other remedy available. Without agency action on NRDC’s petitions, NRDC cannot exercise its right to judicial review. In view of EPA’s extraordinary delay, a writ of mandamus requiring EPA’s compliance with the APA is appropriate.

II. A Writ of Mandamus Is Justified under the Equitable Factors Established in *TRAC*

In judging whether a writ of mandamus is necessary to compel agency action in the face of unreasonable delay, this Court has established a flexible, six-factor test: (1) the time agencies take to act is subject to a rule of reason; (2) a

statutory scheme may supply the 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 mandamus on competing agency priorities; (5) the court should consider the nature and extent of the interests harmed by agency delay; and (6) the agency need not be acting in bad faith for its delay to be unreasonable. *TRAC*, 750 F.2d at 80. The balance of factors here supports the conclusion that EPA’s delay warrants mandamus.

A. EPA’s Delay Is Unreasonable

The “first and most important factor” in assessing the reasonableness of an agency’s delay is that the time the agency takes to make a decision “must be governed by a rule of reason. *In re Core Commc’ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (internal quotation marks omitted). In this case, it has been more than four years since NRDC filed its petition requesting that EPA cancel all pet uses for tetrachlorvinphos, and more than six years since NRDC filed its petition requesting that EPA cancel all pet collar uses for propoxur. EPA has still not issued decisions on the petitions. This delay is unreasonable.

A reasonable time for an agency to respond to a petition “is typically counted in weeks or months, not years.” *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004). “[E]xcessive delay saps the public confidence

in an agency's ability to discharge its responsibilities [, and] may undermine the statutory scheme and could inflict harm on individuals in need of final action." *Cutler v. Hayes*, 818 F.2d 879, 896-97 (D.C. Cir. 1987). This Court has previously found that an agency delay of three years in granting or denying a petition was unacceptable where human health was at risk. *See Pub. Citizen Health Research Grp. v. Aucter*, 702 F.2d 1150, 1154, 1157 (D.C. Cir. 1983) (noting that "a more than three-year span from [the] petition to projected final regulation is not tolerable" and constitutes "agency action unreasonably delayed").

The reasonableness of the agency's delay must also "be judged in the context of the statute which authorizes the agency's action." *Id.* at 1158 n.30 (internal quotation marks omitted). One of the principal purposes of FIFRA is to keep off the market pesticides whose adverse effects on human health and the environment outweigh any benefits. *See* 7 U.S.C. §§ 136a(c)(5)(C), 136d(b); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1540 (D.C. Cir. 1984). Propoxur and tetrachlorvinphos-treated flea collars are regarded by veterinarians as ineffective. Stone Decl. ¶ 9; Rotkin-Ellman Decl. ¶ 12. At the same time, exposure to these collars poses a significant public health threat to humans and pets that come into contact with their chemical residues. *Poison on Pets II* at 4. Delay thus contravenes the intent of FIFRA to keep unsafe and ineffective pesticides like these off the market.

EPA has provided no response at all to NRDC's tetrachlorvinphos petition, nor has the Agency provided a specific date when it expects to respond. Rotkin-Ellman Decl. ¶ 23. EPA has similarly failed to decide whether to grant or deny NRDC's propoxur petition. *Id.* ¶ 22. Although EPA has conducted a risk assessment as part of its registration review for propoxur (and purportedly as part of its response to NRDC's petition), that assessment does not relieve EPA of its obligation to make a decision on NRDC's petition. EPA's assessment, moreover, simply confirmed that propoxur-formulated collars are unsafe, lending additional urgency to NRDC's petition for cancellation. April 7, 2010 EPA Propoxur Memo at 10. EPA's ongoing delay in deciding NRDC's petitions is unreasonable.

B. EPA's Delay Is Unreasonable Even in the Absence of a Statutory Deadline

Although FIFRA contains no specific deadline for responding to a petition to revoke uses of a pesticide, EPA cannot play "administrative keep-away" interminably by refusing to grant or deny NRDC's petitions. *In re Am. Rivers & Idaho Rivers United*, 372 F.3d at 420. In the absence of a statutory deadline, EPA's obligation under the APA to "conclude a matter" presented to it "within a reasonable time" still applies. 5 U.S.C. § 555(b); *see also In re Am. Rivers & Idaho Rivers United*, 372 F.3d at 418.

This Court has repeatedly found agency delay to be unreasonable under the APA notwithstanding the lack of a statutory deadline for agency action. *See In re*

Am. Rivers & Idaho Rivers United, 372 F.3d at 419 (finding six-year delay “egregious”); *In re Int’l Chem. Workers Union*, 958 F.2d 1144, 1150 (D.C. Cir. 1992) (finding six-year delay an “extraordinarily long time”); *Auchter*, 702 F.2d at 1154 (finding three-year delay unreasonable). EPA has failed to give NRDC any decision for more than four years on NRDC’s tetrachlorvinphos petition, and for more than six years on NRDC’s propoxur petition, even while admitting that it must respond promptly to NRDC’s propoxur petition. *See Propoxur Final Work Plan* at 8. By any standard, EPA’s delay is unreasonable.

C. EPA’s Delay Affects Human Health and Welfare

EPA’s delay is particularly intolerable because it impacts human health and welfare. *See Auchter*, 702 F.2d at 1157-58; *Core Commc’ns*, 531 F.3d at 855. “Delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake. This is particularly true when the very purpose of the governing Act is to protect those lives.” *Auchter*, 702 F.2d at 1157-58 (citations omitted).

Here, a principal purpose of FIFRA is to protect the public from “unreasonable risk” from pesticide exposure. *See* 7 U.S.C. § 136(bb). NRDC has presented EPA with two studies showing that propoxur and tetrachlorvinphos residue can easily be transferred to the skin or clothing of children and adults while petting or playing with a flea-collar-wearing pet. NRDC Tetrachlorvinphos

Petition at 4; NRDC, *Supplement to Natural Resources Defenses Council Petition to Cancel Pet Collar Uses for the Pesticide Propoxur* 3-4 (Apr. 2009). Once transferred off a pet, these residues can then be absorbed through the skin or ingested, resulting in dangerous exposure levels. Rotkin-Ellman Decl. ¶ 10. High levels of exposure to propoxur and tetrachlorvinphos can cause symptoms of poisoning. *Id.* ¶ 8. But more perniciously, low levels of exposure can quietly impair children's neurological development, and may result in disorders including delays in motor development and attention deficit/hyperactivity disorder. *Id.* ¶ 9. And not only are young children more susceptible to the dangerous effects of these pesticides, young children also face the highest levels of exposure because they are most likely to ingest residues with which they come into contact. *Id.* ¶ 11.

EPA has already found, almost four years ago, that the risks to children from propoxur-formulated pet collars were "of concern to the Agency." April 7, 2010 EPA Propoxur Memo at 10. And NRDC has presented unrefuted evidence that tetrachlorvinphos-formulated collars also pose risks that exceed EPA's safety threshold. *See Poison on Pets II* at 9-11; Miss. State Univ. Study at 5-6.

These risks of exposure are not limited to those who chose to buy flea collars. For example, NRDC members include veterinarians who frequently interact with pets, but who cannot control whether those pets have recently worn propoxur or tetrachlorvinphos-treated flea collars. Stone Decl. ¶ 7-8. NRDC

members also include parents of young children who cannot always control whether their child comes into contact with a pet that has recently worn a flea collar. Louchheim Decl. ¶¶ 6-7, 9. Given these risks, NRDC members are justifiably concerned about their own exposure and their children's exposure to these pesticides. Louchheim Decl. ¶ 10; Stone Decl. ¶ 12. The inability of these individuals to eliminate or reduce the hazards presented by treated flea collars compounds the unreasonableness of EPA's delay. *Cutler*, 818 F.2d at 898.

Instead of issuing decisions on NRDC's petitions, EPA has left health risks unabated in the face of compelling evidence that pet uses of these dangerous pesticides should be canceled. The Court should not permit further delay.

D. No Competing Priorities Justify EPA's Delay

Federal agencies invariably face the challenge of limited resources with which to address competing priorities. *See id.* at 896. Here, however, EPA has not cited competing priorities that would limit its ability to respond to NRDC's petitions. In light of the amount of time that has passed since NRDC submitted its petitions, any justifications EPA now raises concerning competing agency priorities have lost force. *Id.*, 818 F.2d at 898 (explaining that an agency's "justifications [for delay] become less persuasive as delay progresses"); *see also Muwekma Tribe v. Babbitt*, 133 F. Supp. 2d 30, 40 (D.D.C. 2000) (noting that the

D.C. Circuit has found extensive delays are unacceptable notwithstanding competing interests).

The scope of NRDC's petitions is modest: NRDC has requested cancellation of one type of use for two pesticides. NRDC has submitted compelling evidence that pet uses of these pesticides exceed EPA's own safety thresholds. EPA has had ample time to consider any scientific or technical issues raised by NRDC's petitions. EPA's justification for its delay, moreover, must be "balanced against the potential for harm." *Cutler*, 818 F.2d at 898. In this case, EPA's delay has resulted in ongoing exposure to unsafe levels of toxic pesticides. This harm clearly outweighs any justification for delay.

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

The nature and extent of the interests harmed by agency delay also weigh heavily in favor of a writ of mandamus. EPA's failure to respond to NRDC's petitions only perpetuates the underlying harm suffered by NRDC members through exposure to tetrachlorvinphos and propoxur. Until EPA decides NRDC's petitions and withdraws approval of the use of propoxur and tetrachlorvinphos in pet products, NRDC's members and their children will continue to be exposed to these pesticides. *See* Louchheim Decl. ¶¶ 8-10; Stone Decl. ¶¶ 6-8, 12-13.

The prevalence of propoxur and tetrachlorvinphos-treated flea collars means that exposure is wide-ranging. 2006 Tetrachlorvinphos RED at 15. Potentially

millions of children and adults may be exposed to dangerous levels of these pesticides simply by hugging, petting, and playing with their pet. Miss. State Univ. Study at 1. And as discussed above, numerous scientific studies have established that exposure to these pesticides poses serious risks, especially to young children. *See supra* II.C. The Court should order EPA to act in light of the serious and wide-ranging harm posed by these pesticides.

NRDC's interest in challenging the registration of these pesticides is also prejudiced by delay. Without a final decision on its petitions, it cannot challenge the merits of EPA's decision to allow these dangerous pesticides to remain on the market. The Court should not permit EPA to skirt challenges to this decision by endlessly delaying final action. *Cf. Am. Broad. Co. v. FCC*, 191 F.2d 492, 501 (D.C. Cir. 1951) ("Agency inaction can be as harmful as wrong action. The [agency] cannot, by its delay, substantially nullify rights which the [statute] confers, though it preserves them in form.").

F. The Court Need Not Find EPA Acted in Bad Faith

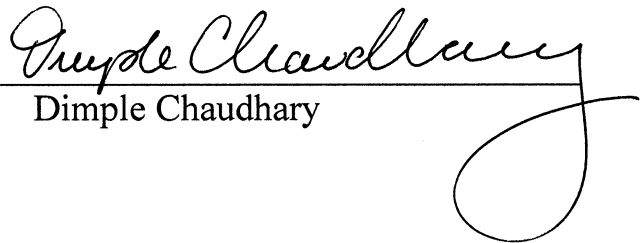
The Court "need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." *TRAC*, 750 F.2d at 80 (internal quotation marks omitted). NRDC has no evidence that EPA is acting in bad faith. But EPA has failed for over four and six years to provide any response to

NRDC's petitions. Whether based on bad faith or extreme inattention, the Court should find that EPA acted and has continued to act with unreasonable delay.

CONCLUSION

EPA's failure to respond for more than four years to NRDC's tetrachlorvinphos petition, and more than six years to NRDC's propoxur petition, is unreasonable in light of the serious, wide-ranging harm caused by exposure to these pesticides. NRDC respectfully requests that this Court order EPA to respond to NRDC's petitions within sixty days by either denying the petitions or issuing responsive rulemakings.

Dated: February 6, 2014

By: 
Dimple Chaudhary

CERTIFICATE OF SERVICE

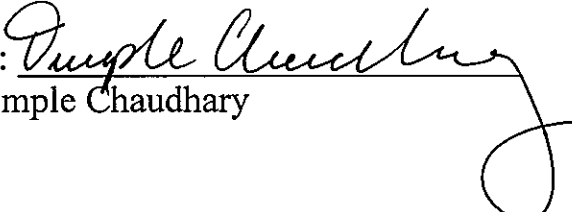
I hereby certify that I have this date served a copy of the foregoing Petition for Writ of Mandamus and Petition upon all parties by overnight mail or hand delivery at the following addresses:

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