1	JOSHUA OSBORNE-KLEIN (WSB #36736)		
2	KRISTEN L. BOYLES (CSB #158450) Earthjustice		
3	705 Second Avenue, Suite 203 Seattle, WA 98104		
4	(206) 343-7340 (206) 343-1526 [FAX]		
5	josborne-klein@earthjustice.org kboyles@earthjustice.org		
6	SHELLEY DAVIS (CSB #84539) VIRGINIA RUIZ (CSB #194986)		
7	Farmworker Justice 1126 – 16 th Street, N.W., Suite 270		
8	Washington, D.C. 20036 (202) 293-5420		
9	(202) 293-5427 [FAX] sdavis@nclr.org		
10	vruiz@nclr.org		
11	Attorneys for Plaintiffs PESTICIDE ACTION NETWORK NORTH AMERICA, UNITED FARM WORKERS, PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE, FARM LABOR		
12	ORGANIZING COMMITTEE, AFL-CIO, BEYOND PESTICIDES, NATURAL RESOURCES DEFENSE COUNCIL, SEA MAR		
13	COMMUNITY HEALTH CENTER, and TEAMSTERS LOCAL 890		
14	GEORGE TORGUN (CSB #222085) Earthjustice		
15	426 Seventeenth Street, 5 th Floor Oakland, CA 94612-2807 (510) 550-6725 (510) 550-6749 [FAX]		
16			
17	gtorgun@earthjustice.org Local Counsel for Plaintiffs		
18	MICHAEL MEUTER (CSB #161554)		
19	JONATHAN GETTLEMAN (CSB #243560) California Rural Legal Assistance, Inc.		
20	3 Williams Road Salinas, CA 93905		
21	(831) 757-5221 (831) 757-6212		
22	mmeuter@crla.org jgettleman@crla.org		
23	Attorneys for Plaintiff MOISES LOPEZ		
24			
25			
26	COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF		

1 2	UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA AT SAN FRANCISCO			
3 4 5	PESTICIDE ACTION NETWORK NORTH AMERICA, UNITED FARM WORKERS, PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE, FARM LABOR ORGANIZING COMMITTEE, AFL-CIO, BEYOND	COMPLAINT FOR DECLARATORY AND		
6 7	PESTICIDES, NATURAL RESOURCES)DEFENSE COUNCIL, SEA MAR)COMMUNITY HEALTH CENTER,)TEAMSTERS LOCAL 890, and MOISES)LOPEZ,)Plaintiffs,)	 INJUNCTIVE RELIEF Administrative Record Review Case 		
8 9		 Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y; Endangered Species Act, 16 U.S.C. §§ 1531- 1544 		
10	v. U.S. ENVIRONMENTAL PROTECTION)		
11 12	AGENCY, an agency of the United States; STEPHEN L. JOHNSON, Administrator, U.S. Environmental Protection Agency, in his			
13	official capacity, Defendants.			
14 15	Derendunts.			
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24 25	COMPLAINT FOR DECLARATORY AND	Earthjustice 705 Second Ave., Suite 203		
26	INJUNCTIVE RELIEF	705 Second Ave., Suite 205 Seattle, WA 98104 (206) 343-7340		

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INTRODUCTION

1. This is an action for declaratory judgment and injunctive relief. It arises under and asserts violations of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, and the Endangered Species Act ("ESA") 16 U.S.C. §§ 1531-1544.

2. Pesticides are inherently dangerous substances that may not be used in the United States unless the U.S. Environmental Protection Agency ("EPA") has registered the pesticide for a particular use. In registering a pesticide use, EPA must ensure that the pesticide will not have unreasonable adverse effects on farmworkers, children and other bystanders, or the environment. EPA must also ensure that such use will not jeopardize the survival and recovery of threatened and endangered species and will not adversely modify designated critical habitat.

3. EPA failed to satisfy these obligations when it re-registered the organophosphate 12 pesticides methidathion, oxydemeton-methyl ("ODM"), methamidophos, and ethoprop. For example, EPA recognized that these four pesticides pose severe risks to farmworkers and have 14 the potential to harm children and other bystanders when they drift into nearby homes and schools following application. However, EPA never adequately assessed such risks and failed to adopt measures necessary to guard farmworkers, children, and other bystanders against the adverse effects from such exposures.

Similarly, EPA recognized that methidathion, ODM, methamidophos, and 4 ethoprop have the potential to harm endangered and threatened species but never consulted with the National Marine Fisheries Service ("NMFS") and/or the U.S. Fish and Wildlife Service ("FWS") (collectively "the Services") to ensure that the re-registrations would not jeopardize the survival and recovery of the listed species or destroy or adversely modify their critical habitat.

5 Plaintiffs Pesticide Action Network North America, United Farm Workers, 24 Pineros y Campesinos Unidos del Noroeste, Farm Labor Organizing Committee, Beyond

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Pesticides, Natural Resources Defense Council, Sea Mar Community Health Center, Teamsters Local 890, and Moises Lopez (collectively "the Workers") seek a judgment declaring that EPA acted arbitrarily, capriciously, and in violation of FIFRA in re-registering uses of methidathion, ODM, methamidophos, and ethoprop. The Workers seek an injunction that (1) requires EPA to make new re-registration eligibility decisions for the four pesticides based on unreasonable adverse effects findings and risk-benefit analyses that incorporate all health, environmental, economic, and social risks and benefits of each use as well the data submitted to fill gaps in the 2002 Interim Re-registration Eligibility Decisions ("IREDs"); (2) prohibits EPA from reregistering uses of these four pesticides if the pesticide registrants have not provided sufficient data to make the unreasonable adverse effects determinations that are prerequisites for reregistration; and (3) grants interim protective measures to prevent harm to farmworkers, children, and other bystanders in agricultural communities near areas where these four pesticides are used while EPA complies with the law.

6. Plaintiffs Beyond Pesticides and Natural Resources Defense Council also seek a judgment declaring that EPA has violated the ESA by re-registering and allowing continued use of methidathion, ODM, methamidophos, and ethoprop without completing consultations with the Services and without ensuring that the pesticide re-registrations will not jeopardize listed species and will not destroy and/or adversely modify their designated critical habitat. Beyond Pesticides and Natural Resources Defense Council seek an order (1) compelling EPA to initiate consultations with the Services regarding the effects of methidathion, ODM, methamidophos, and ethoprop on threatened and endangered species that may be affected by these pesticides; and (2) granting interim protective measures to prevent harm to listed species and their designated critical habitat until the consultation process is complete, and EPA brings the registrations into

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1 compliance with the ESA.

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JURISDICTION, VENUE, AND INTRADISTRICT ASSIGNMENT

7. This action is brought pursuant to section 16(a) of FIFRA, 7 U.S.C.§ 136n(a), and section 11(g)(1) of the ESA, 16 U.S.C. § 1540(g)(1). This Court has jurisdiction pursuant to 7 U.S.C.§ 136n(a), 16 U.S.C. § 1540(g)(1), and 28 U.S.C. § 1331. As required by the ESA citizen suit provision, plaintiffs Beyond Pesticides and NRDC provided 60 days' notice of intent to sue on January 31, 2008, to the Services and defendant EPA. A copy of the notice is appended as Exhibit A.

9 8. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) and 16 U.S.C.
10 § 1540(g)(3) as a number of the plaintiffs reside in this district and many of the events,
11 omissions, and consequences of the defendant's violations of the law giving rise to the claims
12 occurred or will occur in this district.

9. This case is properly assigned to the San Francisco/Oakland Division under Civil
 L.R. 3-2(c) as at least two of the plaintiffs are located in San Francisco county.

PARTIES

10. The plaintiffs in this action are:

Pesticide Action Network North America ("PANNA"), a San Francisco-based 17 A. non-profit organization that serves as an independent regional center for Pesticide Action 18 19 Network International, a coalition of over 600 public interest organizations in more than 90 20 countries. For more than 20 years, PANNA has worked to replace hazardous and unnecessary pesticide uses with ecologically sound pest management across North America. PANNA 21 provides scientific expertise, public education, and access to pesticide data and analysis, policy 22 23 development, and other support to its approximately 225 member organizations. PANNA has approximately 2,700 individual members nationwide and approximately 90 organizational 24

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members in California alone. PANNA's U.S. membership includes a number of groups who directly represent or advocate on behalf of farmworkers and whose membership includes farmworkers and persons living on or near farms.

B. United Farm Workers ("UFW"), the nation's oldest and largest farmworker
membership organization. UFW is based in California and has more than 27,000 members in
Washington, Oregon, California, and other states across the nation. It works to protect the health
and safety of farmworkers from occupational injuries, including injuries caused by exposure to
methidathion, ODM, methamidophos, and ethoprop.

C. Pineros y Campesinos Unidos del Noroeste (Northwest Treeplanters and Farmworkers United or "PCUN"), based in Woodburn, Oregon, the state's only union of farmworkers, nursery, and reforestation workers. Its mission is to establish better working and living conditions for its members, who work on crops treated with methidathion, ODM, methamidophos, and ethoprop, and live in communities where these pesticides drift and are tracked in following application.

D. Farm Labor Organizing Committee, AFL-CIO ("FLOC"), a national union that represents migrant and seasonal farmworkers. It was founded in 1968 and is based in Toledo, Ohio. FLOC's mission is to organize farmworkers so that they can secure more power to improve their working conditions, including reducing their exposure to pesticides. FLOC currently has approximately 12,000 members in Ohio, Michigan, North Carolina, and Virginia. FLOC members work in more than two dozen different crops, including cucumbers, tomatoes, potatoes, peppers, string beans, onions, strawberries, blueberries, apples, tobacco, and Christmas trees. FLOC members also work in greenhouses and nurseries.

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Beyond Pesticides, a nonprofit organization based in Washington, D.C., that

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serves a nationwide network of more than 1,000 individual and organizational members.
 Beyond Pesticides' primary mission is to assist and advocate for the safe use of pesticides and to
 reduce or end the use of dangerous pesticides.

F. Natural Resources Defense Council ("NRDC"), a national environmental advocacy group organized as a New York not-for-profit membership corporation. NRDC is registered to do business in California and maintains an office in San Francisco. NRDC has over 420,000 members nationwide, over 79,000 of whom reside in California. NRDC's mission is to establish sustainability and good stewardship of the Earth as the central ethical imperatives of human society. As part of this mission, NRDC and its members work to ensure that the health of humans, wildlife, and ecosystems is not diminished by the use of toxic pesticides.

11 G. Sea Mar Community Health Center ("Sea Mar"), headquartered in Seattle, 12 Washington. Sea Mar is dedicated to caring for the medically underserved Latino population in 13 the Washington State cities of Seattle, Bellingham, Bonney Lake, Des Moines, Everett, Everson, 14 Marysville, Mt. Vernon, Olympia, Tacoma, and Vancouver. Sea Mar provides comprehensive 15 medical services, including general medical treatment, laboratory services, adult medicine, health 16 education, social work, mental health counseling, and ambulatory care. Sea Mar serves 17 approximately 75,000 individuals each year. Many of Sea Mar's patients are migrant and 18 seasonal farmworkers who work in crops that are treated with methidathion, ODM, 19 methamidophos, and ethoprop. Sea Mar clinicians have treated and will continue to treat 20 patients that manifest signs and symptoms of organophosphate poisoning, including headaches, 21 vomiting, disorientation, abdominal cramps, spasms, and neurobehavioral impairments.

H. Teamsters Local 890, a union founded in 1943 that represents approximately
12,000 workers in southern and central California and southwestern Arizona. Its members
include workers who have harvested and will continue to harvest fresh fruits and vegetables

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1 || treated with methidathion, ODM, methamidophos, and ethoprop.

I. Plaintiff Moises Lopez is a farmworker who has supported himself and his family for many years by working in agricultural fields in California. He has been exposed to ODM and other pesticides while working in and around fields in Monterey County treated with ODM. Mr. Lopez plans to continue working in agriculture and is at risk of future exposure to ODM and other pesticides.

J. The Workers have been and will continue to be injured when they and/or their members mix, load, and apply methidathion, ODM, methamidophos, and ethoprop to crops; prune, thin, or harvest crops that contain residues of these pesticides; and work or live in areas where these pesticides drift and settle. Every year, the Workers and/or their members experience adverse health effects from exposure to these pesticides. The continued exposure of the Workers and/or their members to the harmful effects of methidathion, ODM, methamidophos, and ethoprop are a direct result of EPA's decisions to re-register those pesticide uses.

11. Plaintiffs Beyond Pesticides, NRDC, and their members use areas near where methidathion, ODM, methamidophos, and ethoprop are applied for recreational, scientific, and aesthetic purposes. Beyond Pesticides, NRDC, and their members have professional, economic, aesthetic, and recreational interests that have been and will continue to be injured by the re-registrations of methidathion, ODM, methamidophos, and ethoprop and the impacts that these pesticides have and will continue to have on beneficial insects and threatened and endangered species.

12. The past, present, and future enjoyment of these interests by the Workers and/or their members have been, are being, and will continue to be irreparably harmed by defendants'

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disregard of their statutory duties and by the unlawful injuries imposed on farmworkers, children
 and other bystanders, and the environment.

13. The aesthetic, conservation, recreational, commercial, and scientific interests of the Workers and/or their members in minimizing harm to people and the environment from the use of methidathion, ODM, methamidophos, and ethoprop, as well as in the compliance with environmental law by federal agencies, have been, are being, and, unless the relief prayed for is granted, will continue to be directly and adversely affected by the failure of defendants to comply with the law.

14.

The defendants in this action are:

A. United States Environmental Protection Agency, an agency of the United States
charged with registering and re-registering pesticides under FIFRA and with ensuring that the
authorized pesticide uses will not cause unreasonable adverse effects on the environment. EPA
is also charged with ensuring, through consultation with the Services, that its pesticide
registrations will not jeopardize the survival and recovery of listed species or destroy or
adversely modify their designated critical habitat.

B. Stephen L. Johnson, Administrator of EPA, in his official capacity. BACKGROUND
I. STATUTORY FRAMEWORK FOR REGISTERING AND RE-REGISTERING PESTICIDES
A. <u>FIFRA</u>
15. FIFRA establishes a registration scheme 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 that:

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1 2	 (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other material required to be submitted comply with the requirements of this Act; 			
3	(C) it will perform its intended function without unreasonable adverse effects			
5		n the environment; and hen used in accordance with widespread and commonly	recognized	
4	pr	actice it will not generally cause unreasonable adverse over a vironment.		
5	Id. at § 136a(c)(5).			
6	16. FI	FRA defines "unreasonable adverse effects on the envir	conment" to mean "any	
7				
8	unreasonable risk to man or the environment, taking into account the economic, social, and			
9	environmental costs and benefits of the use of any pesticide" <u>Id.</u> at § 136(bb). In order for			
10	EPA to register or re-register a pesticide use, it must find that the use will not pose any			
11	unreasonable adverse effects under this standard.			
12	17. T	ne culmination of the registration process is EPA's appr	oval of both a	
12	registration and a label for the particular pesticide use. FIFRA makes it unlawful to use a			
14	pesticide in a manner inconsistent with the label, $\underline{id.}$ at § 136j(2)(G), or to make any claims that			
15	differ substantially from the label, <u>id.</u> at $ 136j(1)(B) $.			
16	18. E	PA has the authority to cancel a pesticide registration where the second	henever the "pesticide or	
17	its labeling or oth	her material required to be submitted does not comply w	with the provisions of this	
18	Act or, when used in accordance with widespread and commonly recognized practice, generally			
19	causes unreasonable adverse effects on the environment." Id. at § 136d(b).			
20	19. W	henever possible, EPA conducts quantitative risk assess	sments to assess whether	
21	pesticide uses pose risks of concern. It typically conducts separate risk assessments for human			
22	health risks and for ecological risks.			
23	20. E	PA's human health risk assessments evaluate human risk	ks from pesticides	
23	through such exp	osure routes as food, drinking water, and occupational a	activities. EPA typically	
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23 26	COMPLAINT F INJUNCTIVE R	OR DECLARATORY AND ELIEF -8-	Earthjustice 705 Second Ave., Suite 203 Seattle, WA 98104 (206) 343-7340	

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conducts separate dietary and occupational risk assessments. Where the human health effects
have a threshold level at which observable effects occur, EPA reviews laboratory studies to
determine the dose in scientific studies that caused no observed adverse effects, known as the No
Observed Adverse Effect Level ("NOAEL").

21. EPA typically establishes its "risk of concern" level, which it also has called an "unacceptable risk," by adding two ten-fold safety factors to this NOAEL—EPA generally uses a tenfold interspecies safety factor to account for the uncertainties inherent in extrapolating from animal studies to humans and a tenfold intraspecies safety factor to account for the varying sensitivities to pesticide exposures among individual human beings.

22. EPA then assesses how close occupational exposures will come to the NOAEL, which it typically calls the Margin of Exposure ("MOE"). For most pesticides, EPA incorporates the two ten-fold safety factors and takes the position that a MOE greater than 100 does not pose a risk of concern but a MOE less than 100 poses a risk of concern to workers. The lower the MOE, the greater the risk to workers.

23. If EPA determines that different routes of exposure require different safety factors for a particular pesticide, EPA typically combines the MOEs for the different exposure routes into an aggregate risk index ("ARI"). EPA considers an ARI of less than one to be a risk of concern. The lower the ARI, the greater the risk to workers.

24. When EPA deems a pesticide use to present a risk of concern, it generally requires the adoption of "feasible" mitigation. Such mitigation typically begins with increased personal protective equipment ("PPE") such as chemical resistant clothing and respirators, and escalates to "engineering controls" such as closed pesticide mixing, loading, and application systems designed to reduce contact that farmworkers who mix and load pesticides have with the

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poisons. If feasible mitigation fails to eliminate a risk of concern resulting from a particular pesticide use, the use is ineligible for re-registration unless the pesticide registrant proves that the benefits of the use outweigh the risks.

25. When a human health effect has no threshold level at which effects occur, such as for cancer-causing effects, EPA estimates the risk facing exposed populations. For dietary exposures to pesticides, Congress has deemed a lifetime cancer risk of less than 1×10^{-6} (one in one million) to be a negligible risk. Any non-negligible cancer risk would not satisfy the statutory standard for food risks from pesticide residues. See 21 U.S.C. § 346a(b)(2). For occupational exposures, EPA typically considers cancer risk greater than 1×10^{-6} to be a risk of concern and allows risks between 1×10^{-6} and 1×10^{-4} (one in ten thousand) to persist only if the risk can be mitigated or registrants have proved that the benefits of the use outweighs the risk. An occupational cancer risk greater than 1×10^{-4} is normally considered an unreasonable risk to farmworkers.

26. EPA also prepares ecological risk assessments to determine whether pesticide uses will unreasonably affect the environment. To assess ecological risk, EPA establishes its "levels of concern" for wildlife based on laboratory studies that typically assess lethal toxicity to test species. EPA then calculates "risk quotients" for pesticide uses, which are ratios of estimated environmental concentrations and toxicity endpoint values. When a risk quotient for a pesticide use exceeds a level of concern established for wildlife, EPA considers the pesticide use to present a "risk of concern" and typically imposes mitigation to eliminate such risks.

27. Under FIFRA's risk-benefit standard, EPA cannot allow pesticide uses that result in human or ecological risks of concern to persist unless the pesticide registrant proves that the benefits of the pesticide use outweigh the risks (considering all risks and benefits). 7 U.S.C.

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§§ 136a(c)(5)(C)-(D).

28. EPA has no regulation or policy establishing a uniform process for assessing the benefits of pesticide uses that pose risks of concern to humans and/or wildlife. Expert bodies, such as the National Academy of Sciences, have recommended that EPA develop such a policy to avoid arbitrary and unprincipled risk-benefit decisionmaking under FIFRA. In the absence of such a regulation or policy, EPA staff compiles information on the risks and benefits of pesticides on an *ad hoc* basis.

B.

FFDCA and FQPA

29. While FIFRA regulates pesticide use, the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301-394, regulates consumer exposure to pesticide residues through food, drinking water, and all other aggregate sources of exposure. Under the FFDCA, EPA establishes tolerances that authorize and place limits on the amount of pesticide residues lawfully permitted on foods. Id. at § 346a.

30. In 1996, Congress unanimously passed the Food Quality Protection Act ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489 (1996), which substantially amended the food safety standards governing issuance of tolerances under the FFDCA and directed EPA to bring its food tolerances into compliance with the new standard over a ten-year period. At the same time, Congress amended FIFRA to require EPA to re-register pesticides according to a statutory schedule that required re-registration decisions for food-use pesticides by August 2006 and for all other pesticides by August 2007. 7 U.S.C. § 136a-1.

С. ESA

31. Section 7(a)(2) of the ESA requires that "each federal agency shall, in consultation with and with the assistance of [the Services], insure that any action authorized, 24 funded, or carried out by such agency is not likely to jeopardize the continued existence of any

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endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary. . . to be critical." 16 U.S.C. § 1536(a)(2).

32. The section 7(a)(2) consultation duty arises whenever a federal action "may affect" a listed species and/or designated critical habitat. See 50 C.F.R. § 402.14(a). The threshold for a "may affect" determination and the required ESA section 7(a)(2) consultation is low. See 51 Fed. Reg. 19926, 19949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement.").

33. Federal agencies and the Services must use the best available science and commercial data in their section 7(a)(2) consultations. 16 U.S.C. § 1536(a)(2).

34. Section 7(d) of the ESA, 16 U.S.C. § 1536(d), prohibits federal agencies, after the initiation of consultation under section 7(a)(2), from making any irreversible or irretrievable commitment of resources if doing so would foreclose the implementation of reasonable and prudent alternatives. The section 7(d) prohibition is additive to the requirements of section 7(a)(2) and ensures that the substantive mandate of section 7(a)(2) is satisfied.

II. EPA'S RE-REGISTRATION OF THE ORGANOPHOSPHATE PESTICIDES AT ISSUE

35. The four pesticides at issue in this case are organophosphate pesticides. Such pesticides are derived from nerve gas that the Nazis developed during World War II. Exposure to just a few drops of organophosphates can cause harmful effects to humans and wildlife.

36. Organophosphates are acutely toxic and cause systemic illnesses to workers and wildlife by inhibiting their ability to produce cholinesterase, an enzyme necessary for the proper transmission of nerve impulses. Symptoms of cholinesterase inhibition include muscle spasms, confusion, dizziness, loss of consciousness, seizures, abdominal cramps, vomiting, diarrhea,

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cessation of breathing, paralysis, and death. Acute poisonings can also cause chronic (long-term)
effects, such as permanent nerve damage, loss of intellectual functions, and neurobehavioral
effects. Exposure to organophosphate pesticides can also cause developmental and reproductive
effects, endocrine disruption, and carcinogenic effects.

37. Workers are exposed to organophosphate pesticides primarily through inhalation and dermal contact when they mix, handle, or apply the pesticide or come into contact with treated crops. People are also exposed to these pesticides from eating food with residues of the pesticides. Children and other bystanders are exposed to the pesticides through drift, eating contaminated food, and having contact with residues on treated surfaces, clothing, or soils.

38. 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." 65 Fed. Reg. 42,021 (Aug. 4, 1997).
EPA completed numerous interim re-registration eligibility decisions ("IREDs") for
organophosphates between 2000 and 2002, including the IREDs for the four organophosphates at
issue in this case. It called these re-registration eligibility decisions "interim" because EPA had
yet to complete a cumulative risk assessment for all organophosphates and make appropriate
adjustments in food tolerances in order to comply with the FQPA.

39. EPA signed its final re-registration eligibility decisions ("REDs") for methidathion, ODM, methamidophos, and ethoprop on July 31, 2006.

A.

1. History and Usage

Methidathion

40. Methidathion was first registered in 1972 for use on a variety of crops, including alfalfa, citrus, and cotton. Between 1987 and 1997, approximately 241,000 pounds of methidathion active ingredient were used annually in the United States. In 2004, EPA estimated

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that 90% to 95% of methidathion use occurred in California, with the remainder of the use in Florida, Arizona, Washington State, New York, and Virginia. In terms of total pounds, the largest uses in 2004 were almonds (18%), oranges (17%), plums and prunes (15%), and walnuts (13%). Although amounting to less poundage, at the time of re-registration, over 50% of artichoke acreage was treated with methidathion.

41. In 2001, the Canadian Pest Management Regulatory Agency cancelled all methidathion registrations, noting the high worker and environmental risks and the availability of alternatives. As of 2003, all use of methidathion in Canada had ceased.

42. EPA signed the IRED for methidathion on Sept. 28, 2001, but the IRED was not completed until April 2002. EPA signed the methidathion RED on July 31, 2006.

2. Toxicity

43. Methidathion has been linked to numerous human poisonings. While incident reporting databases vastly under-report actual incidents, methidathion is regularly among the top pesticides associated with poisonings. Indeed, there have been numerous reports of incidents involving methidathion poisoning of both agricultural workers and bystanders as a direct result of handling the pesticide and from drift following application.

44. Exposure to methidathion causes cholinesterase inhibition in humans and wildlife.
In addition to cholinesterase inhibition, there is evidence that exposure to methidathion causes
cancer. EPA has acknowledged the evidence that methidathion is carcinogenic but dismissed
this evidence because it was not conducive to quantification and incorporation into EPA's
quantitative human health risk assessment.

45. In May 2007, the California DPR proposed to list methidathion as a toxic air
contaminant, which necessitates measures to reduce public exposures and protect public health.
DPR based this proposal on the findings of its Scientific Review Panel that data on

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carcinogenicity and cholinesterase inhibition supported such a finding. DPR anticipated that the lack of complete data on methidathion's metabolites and degradates, synergistic effects, and the carcinogenic mechanism likely results in an underestimation of risks of methidathion.

46 Methidathion is one of the pesticides that EPA has designated for screening as a potential endocrine disrupting chemical.

> 3. Worker Risks

47. EPA re-registered uses of methidathion that pose risks of concerns to farmworkers without requiring the pesticide registrants to prove that the benefits of those uses outweighed the risks. For some of those uses, EPA recognized that it had insufficient data to determine whether the mitigation prescribed in the IRED would eliminate the risks of concern. E.g., Methidathion IRED at 41-42. In other cases, EPA conceded that the risks of concern would 12 persist even after implementation of the prescribed mitigation. Id. at 18, 41-42. EPA recognized that requiring enclosed cabs would eliminate at least two risks of concern, but EPA failed to 14 mandate such mitigation and, on information and belief, never assessed whether such mitigation was feasible. Id. at 18, 41.

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4. Children and Bystander Risks

48. Methidathion has been reported to travel far away from the application sites. For example, it has been detected in the air of Sequoia National Park, which is many miles away from the nearest application sites. It has also been detected in the air in locations closer to field applications.

49. EPA has recognized that the children and families of workers and other 21 bystanders may be subjected to harmful exposures to methidathion as a result of drift of the 22 23 insecticide from application sites:

There are no registered uses of methidathion at the present time that could result

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1	in residential exposures. The Agency recognizes that there are many issues				
2	related to the use of agricultural chemicals in the general population, i.e., spray drift exposures and exposures to farm worker children and farm residents. The				
3	Agency is in the process of developing guidance and procedures for characterizing these kinds of risks. An assessment of the potential exposure and				
4	risk from these kinds of exposures associated with the agricultural use of methidathion are not addressed in this document.				
5	Methidathion IRED at 19-20. EPA also acknowledged it had received comments on				
6	methidathion's risks to bystanders and children.				
7	50. Despite recognizing the potential for children and bystanders to be exposed to				
8	methidathion in the air, EPA confined its assessment of children's risks from methidathion to				
9	residential exposures considered as part of its aggregate food exposure assessment under FQPA				
10	and considered only dietary sources in its aggregate exposure risk assessment for methidathion.				
11	5. Ecological Risks				
12	51. EPA found that methidathion poses significant risks to the natural environment.				
13	As EPA summarized:				
14 15	Methidathion represents a serious risk to the ecosystem in areas of use. It exceeds the levels of concern for both acute and chronic effects to mammals, birds, fish, and aquatic invertebrates. For both terrestrial and aquatic organisms, chronic risk				
16	quotients are larger than acute risk quotients. Based on the magnitude of aquatic risk quotients, freshwater and estuarine invertebrates are at greater acute and				
17	chronic risk than fish. In certain areas of use, shrimp fisheries or other commercial aquatic invertebrate operations may be adversely impacted by				
18	methidathion. Effects on invertebrate numbers and/or diversity could also affect commercial and recreational fisheries, since aquatic invertebrates are the basis of				
19	the food supply for many fish species.				
20	Methidathion IRED at 48-49; see also id. at 47 ("All uses of methidathion exceed the endangered				
21	species LOC for all forms of endangered animal species."); id. at 28 ("[T]he methidathion				
22	concentration has been detected as high as 15.1 μ g/L" in California's surface waters.). EPA also				
23	noted concerns about the risks to beneficial insects and the likelihood of significant mortality to				
24	bees. <u>Id.</u> at 44.				
25	Earthjustice				
26	COMPLAINT FOR DECLARATORY ANDLaminusticeINJUNCTIVE RELIEF-16-705 Second Ave., Suite 203Seattle, WA 98104(206) 343-7340				

52. EPA adopted mitigation to address some of the risks of concern that methidathion poses to wildlife. E.g., Methidathion IRED at 27, 30, 43. However, EPA recognized that in some cases the ecological mitigation would not eliminate such risks of concern. Nonetheless, EPA re-registered the uses of methidathion posing risks of concern without requiring registrants to prove that the benefits of such uses outweigh the risks.

6 53. Methidathion is used in areas near where threatened and endangered species 7 occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, 8 threatened Western snowy plover, and threatened California red-legged frog all live within one mile of methidathion uses. EPA acknowledged its duty under the Endangered Species Act to 10 ensure that its pesticide registrations are not likely to jeopardize listed species or adversely modify designated critical habitat. Methidathion IRED at 44. It also acknowledged its duty to 12 consult with the Services where registered pesticide uses may impact listed species or their 13 critical habitat. Id. EPA completed no consultations before issuing its 2002 Methidathion IRED. 14 Nor has it since completed such consultations.

54. Pursuant to a court order, EPA has begun to initiate consultations with NMFS on the effects of methidathion on 19 listed salmonid populations. See Methidathion: Analysis of Risks to Endangered and Threatened Salmon and Steelhead at 54-56 (Apr. 1, 2004). Although this consultation is not complete, EPA has continued to allow methidathion uses that may affect the listed salmonids and other threatened and endangered species.

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6. **Benefits** Assessments

55 Under FIFRA, when EPA finds risks of concern to workers or the environment, it cannot re-register the pesticide use unless the registrant proves that the benefits outweigh the risks. For other pesticides, when EPA has found risks of concern to workers, EPA conducted benefits assessments to provide a basis for conducting the risk-benefit balancing mandated by

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56. On information and belief, EPA conducted no comparable benefits assessments for methidathion uses that pose risks of concern to workers or the environment. In the absence of adequate benefits assessments or other evidence of the health, social, economic, and environmental risks and benefits of each such use, EPA had no basis for finding that the benefits outweighed the risks of the re-registered uses.

7 57. The Methidathion IRED contains conclusory statements, spanning less than one
8 page, asserting that the benefits outweighed the risks of a few of the re-registered uses.
9 Methidathion IRED at 39-40. EPA merely describes three pests that methidathion is used to
10 control and lists some available chemical alternatives.

58. EPA never aggregated the total risks posed by the methidathion uses to workers, the environment, bystanders, or children. EPA found risks of concern to both workers and the environment from the same methidathion uses, yet it never considered whether the benefits outweighed the combined impacts of these types of risks.

B. <u>ODM</u>

1. History and Usage

59. EPA registered the organophosphate insecticide oxydemeton-methyl ("ODM") for food crops and ornamentals in the 1960s. ODM IRED at 3. From 1987 through 1997, growers in the United States used 145,000 to 186,000 pounds of ODM active ingredient annually on 213,000 to 283,000 acres. The most pervasive uses of ODM were on Brussels sprouts (75% of crop treated), broccoli (62% of crop treated), and cauliflower (46% of crop treated). ODM IRED at 6. Other significant uses of ODM were on mint, cotton, and alfalfa. <u>Id.</u> at 6-7. Use on lettuce was increasing at the time of the re-registration decision. <u>Id.</u> at 6. The majority of ODM use is on fruits and vegetables in California. <u>Id.</u> at 48.

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60. In a 1994 settlement agreement, the ODM registrant, Gowan Company, agreed to not to market ODM for use on citrus, field corn, popcorn, onions, pears, safflower, snap beans, sorghum, and turnips. ODM IRED at 3. However, when EPA re-registered ODM in August 2002, EPA reinstated the previously discontinued uses of ODM on citrus, onions, safflower and sorghum.

61. EPA signed the IRED for ODM on August 5, 2002; an amendment to the IRED was signed on Sept. 23, 2005. EPA signed the ODM RED on July 31, 2006.

2. Toxicity

62. Like other organophosphates, ODM causes inhibition of cholinesterase in humans and wildlife. Between 1998 and 2000, there were 32 reported poisoning cases involving ODM in humans, making it one of the top 20 pesticides implicated in poisoning cases for those years.
ODM was among the 10 pesticides with the highest rankings of the hazard measures in EPA's assessment of incident reports.

63. In addition to cholinesterase inhibition, studies indicate that ODM has reproductive effects such as reduced fertility, viability, ovarian and testicular weights, and increased estrous cycles. ODM IRED at 10, 46.

3.

Worker Risks

64. In assessing risks to farmworkers who mix, load, and apply ODM, EPA combined the MOEs for dermal and inhalation exposure into an aggregate risk index ("ARI"). ODM IRED at 18-19. EPA considers an ARI of less that 1 to be a risk of concern. <u>Id.</u> at 18. The lower the ARI, the greater the risk posed to farmworkers from a pesticide use.

65. Using cholinesterase inhibition as the endpoint, EPA found that several ODM
scenarios presented risks of concern after application of maximum feasible mitigation. <u>E.g.</u>,
ODM IRED at 23-25. EPA also acknowledged that it lacked adequate data to assess the risks to

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Earthjustice 705 Second Ave., Suite 203 Seattle, WA 98104 (206) 343-7340 workers from some ODM scenarios. See, e.g., id. at 23-24. Yet EPA re-registered these uses of ODM without requiring registrants to prove that the benefits of such uses outweigh the risks.

66. EPA determined that reentry intervals of up to 59 days would be necessary to protect post-application workers from ODM. ODM IRED at 30-33. However, with little justification, EPA re-registered ODM uses with far shorter reentry intervals that will expose post-application workers to risks of concern.

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4. Children and Bystander Risks

8 67. EPA's analysis of incident reporting confirmed that children and other bystanders 9 have been exposed to and harmed by ODM as a result of drift of the insecticide from application 10 sites. Specifically, as of 1997, of more than 600 entries in the poison control database, 11 approximately 5% were occupational exposure, 74% adult bystanders, and 20% children under 12 six.

68. However, on information and belief, EPA did not consider or adequately assess the risks posed to children and other bystanders from exposure to ODM drift. Instead, EPA's aggregate risk assessment considered only dietary risks from consumption of food and drinking water. Nor did it require mitigation for such risks.

5.

Ecological Risks

69. EPA also found that ODM posed ecological risks of concern to birds, mammals, and endangered species, and that ODM was highly toxic to bees and other non-target insects. ODM IRED at 34-47.

70. To reduce the risks to wildlife, EPA imposed measures to reduce drift of ODM into wildlife habitat. ODM IRED at 78. EPA also imposed a vaguely worded buffer 23 requirement of 25 feet for groundboom and chemigation, 50 feet for airblast, and 100 feet for aerial applications "between the application site and any area managed for wildlife or wildlife 24

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habitat." <u>Id.</u> at 61; <u>see also id.</u> at 62, 78. However, EPA recognized that risks of concern to wildlife would persist after implementation of the mitigation prescribed in the re-registration decisions.

71. EPA acknowledged that it lacked adequate data to fully assess the ecological risks of ODM uses. ODM IRED at 38; see also id. at 46, 47, 50. EPA issued data call-ins for studies relating to some of these ecological risks. Id. at 81-82. It also indicated that additional studies may be required based on the outcome of these studies, and that endocrine disruption testing would be required once protocols had been developed. Id. at 46-47, 82. Yet, in 2006, EPA signed the RED for ODM, reaffirming the re-registration determinations made in the 2002 IRED, without addressing the data gaps it had previously identified.

72. In a 1989 biological opinion, the Services found that ODM would jeopardize the survival and recovery of several listed species. ODM IRED at 47. EPA did not implement the measures identified in that biological opinion to avoid jeopardy or minimize take of listed species.

73. In the ODM IRED, EPA noted that its endangered species levels of concern were exceeded for acute and chronic risks to birds and mammals for most uses, and that it lacked sufficient data to assess risks to fish. ODM IRED at 47. ODM is used in areas near where threatened and endangered species occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, threatened Western snowy plover all live within one mile of ODM uses. Despite noting risks to listed species, EPA did not consult with the Services before issuing its re-registration for ODM. Nor has EPA completed ESA consultations on ODM since the 2002 re-registration.

74. Pursuant to a court order, EPA has begun to initiate consultation with the Services

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on the effects of ODM on the California red-legged frog. Although this consultation is not complete, EPA has continued to allow ODM uses that may affect the California red-legged frog and other threatened and endangered species.

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Benefits Assessments

75. EPA justified its ODM re-registration decisions on the grounds that "none of the available alternatives" to ODM "provided adequate control" and that ODM "fits well with existing integrated pest management programs." ODM IRED at 73. To support these findings, EPA cited to an "Oxydemeton-methyl Addendum," id. at 74, which is not publicly available.

76. The ODM IRED, however, indicates that many of the uses posing risks of 10 concern are rarely relied upon by growers. For example, less than 0.5% of the acreage of strawberry, citrus, pepper, corn, cotton, and beet crops are treated with ODM. ODM IRED at 6-12 7. For these crops, growers have found efficacious alternatives to ODM. Growers similarly used 13 alternatives to ODM for the previously discontinued ODM uses that were reinstated in the 2002 14 IRED.

C. Methamidophos

1. History and Usage

77. EPA registered methamidophos for use on cotton, potatoes, and numerous other crops in 1972. Methamidophos IRED at 1. In 1997, the registrant agreed to cancel all methamidophos uses except for cotton, potatoes, tomatoes, and a special local needs registration alfalfa grown for seed in California. Id. at 8. Subsequently, the registrant agreed that closed mixing and loading systems should be implemented for all remaining methamidophos uses to address worker exposures. Id. at 8.

78. Growers used approximately 676,000 pounds of methamidophos active ingredient in 2000. Methamidophos IRED at 10. Most of this use was on potatoes (77%), followed by 24

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cotton (12%), fresh and processed tomatoes (5%), and California alfalfa grown for seed (5%).Id.Id.California alfalfa grown for seed was the most significant use (50% of acreage treated),followed by potatoes (29% of acreage treated), tomatoes (15% of fresh tomato acreage and 3%of processed tomato acreage treated), and cotton (2% of acreage treated).Id.Id.at 31-33.

79. EPA signed the IRED for methamidophos on April 5, 2002. EPA signed the methamidophos RED on July 31, 2006.

2. Toxicity

80. Methamidophos is an organophosphate insecticide that is classified in "Toxicity Category I" for all routes of exposure – the most toxic category of pesticides. Methamidophos IRED at 22. In re-registering methamidophos, EPA found that the pesticide is "acutely toxic, causing death to laboratory animals shortly after exposure to relatively low oral, dermal, or inhalation doses." <u>Id.</u>

81. EPA's 1999 assessment of incident reports indicates that methamidophos "poses one of the highest risks to workers of any organophosphate insecticide currently registered."
Based on Poison Control Center data for 1985-1992, methamidophos ranked second out of 28 cholinesterase-inhibiting insecticides on combined measures of hazard.

82. Methamidophos is one of the pesticide active ingredients that EPA has designated
for screening as a potential endocrine disrupting chemical. In addition, methamidophos is
believed to cause developmental neurotoxicity. Methamidophos IRED at 13. EPA required
additional data to determine the likelihood that exposure to methamidophos would have
developmental effects on humans and wildlife. Id.

Worker Risks

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83. For pesticide handlers, EPA found that methamidophos presented risks of concern for most scenarios even when maximum PPE is used and, for many scenarios, even when

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engineering controls such as enclosed cabs and closed mixing systems are implemented.

Methamidophos IRED at 24. To reduce handler risks, EPA mandated mitigation, such as closed mixing and loading systems, enclosed cabs and cockpits, and restrictions on the number of applications per season for tomatoes. <u>Id.</u> at 46-47. However, EPA determined that most methamidophos occupational use scenarios presented risks of concern even after implementation of such mitigation.

84. Regarding risks to post-application workers, EPA determined in a preliminary assessment, that the reentry intervals for methamidophos would have to be increased to between
8 and 31 days to achieve MOEs equal to or greater than 100. However, in the Methamidophos IRED, EPA changed course and concluded that shorter reentry intervals would sufficiently mitigate post-application risk. Methamidophos IRED at 26. The rationale for the shorter reentry intervals is not publicly available.

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4. Children and Bystander Risks

85. Children and other bystanders can be exposed to methamidophos through volatilization and drift during and after application. EPA recognized these potential exposures and risks prior to re-registering methamidophos in 2002. However, EPA did not assess the risks to children and bystanders from drift and take-home exposures in its 2002 IRED.

86. After re-registering methamidophos, EPA supported a 2004 study on methamidophos that confirmed the pesticide's potential to cause drift exposures. EPA did not mention the 2004 study or consider any additional evidence relating to child and bystander exposures when it reaffirmed its methamidophos re-registration decisions in 2006. Nor did EPA ever consider requiring buffer zones to reduce risks to children and other bystanders.

87. In addition to drift exposures, children and bystanders are at risk from exposure to
methamidophos in drinking water. Methamidophos IRED at 1-2, 18-19. EPA expressed

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1 particular concern about the acute risks to infants and the chronic risks to 1 to 6 year olds from 2 such exposures. Id. at 2-3.

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Ecological Risks

4 88. All methamidophos use patterns pose acute and chronic risks of concern to birds 5 and mammals. Methamidophos IRED at 2, 30. There are recorded incidents of bird and 6 mammal kills from methamidophos. Methamidophos affects bird reproduction by causing 7 reduced thickness of the eggshells. Id. at 28. For aquatic species, methamidophos poses acute 8 risks of concern for freshwater invertebrates and possibly for estuarine invertebrates. Id. at 2, 31. 9 EPA did not assess chronic aquatic risks because it lacked chronic data for aquatic species. Id. at 10 4, 31. Methamidophos is also highly toxic to bees and has been associated with harm to bee 11 colonies from use on potatoes. Id. at 29, 31.

89. Methamidophos is used in areas near where threatened and endangered species occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and the threatened Western snowy ployer all live within one mile of methamidophos uses. In the Methamidophos IRED, EPA noted that its endangered species levels of concern "are exceeded for acute and chronic risks to birds and mammals and acute risks to freshwater invertebrates for all currently registered uses of methamidophos." Methamidophos IRED at 31.

18 90 The mitigation EPA prescribed to address such ecological risks did not eliminate the risks of concern that methamidophos uses pose to wildlife. For example, to reduce risks to 20 birds and mammals, EPA required a reduction in the number of applications to tomatoes to four per season, but EPA prescribed no similarly reduced application rates for potatoes or alfalfa. See Methamidophos IRED at 57.

23 EPA acknowledged its duty to ensure that its pesticide registrations are not likely 91 24 to jeopardize listed species or adversely modify designated critical habitat. Methamidophos

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IRED at 58. It recognized that it must consult with the Services when registered pesticide uses may affect listed species or their critical habitat. Id. Despite noting risks to listed species and its obligation to consult with the Services, EPA did not initiate consultations on numerous listed species before issuing its re-registration for methamidophos. Nor has EPA completed ESA consultations on methamidophos since the 2002 re-registration.

92. Pursuant to court orders, EPA has begun to initiate consultation with the Services on the effects of methamidophos on the endangered California red-legged frog and three listed salmonid populations. Although these consultations are not complete, EPA has continued to allow methamidophos uses that may adversely affect the listed salmonids, the California redlegged frog, and other threatened and endangered species.

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6. Benefits Assessments

93. EPA found that the potential chemical alternatives to methamidophos for potatoes, tomatoes, and alfalfa were inadequate but found viable alternatives for cotton. Methamidophos IRED at 31-34. Based on the assessment of chemical alternatives alone, the agency determined that the benefits of methamidophos to alfalfa, potato, and tomato growers were substantial but the benefits to cotton growers were less significant. Id. at 31-34. Accordingly, EPA decided that use of methamidophos on cotton would be phased out over five years. Id. at 47.

19 94. For potatoes, tomatoes, and alfalfa, EPA decided that the benefits of 20 methamidophos outweighed the risks and it could be re-registered provided the prescribed mitigation was implemented. Methamidophos IRED at 46-47, 52. EPA imposed some mitigation measures; however, risks of concern persist despite these mitigations. EPA justified allowing these risks based in part on uncertainties in its worker risk assessments. Id. at 55-56.

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D. Ethoprop

1. History and Usage

95. Ethoprop is an organophosphate pesticide that was originally registered in 1967. Ethoprop IRED at 1. EPA announced its re-registration of granular ethoprop formulations in December 2002 and re-registered the emulsifiable concentrate (liquid) formulation in 2006. As of re-registration, one million pounds of ethoprop active ingredient were used annually in the 7 United States. Ethoprop IRED at 10. Up to 60% of total ethoprop applied was on potatoes; the 8 other major uses of ethoprop are sugarcane, tobacco, and bananas. Id. at 10.

96. EPA signed the IRED for ethoprop on Sept. 28, 2001; an amendment to the IRED was signed on Feb. 25, 2006. EPA signed the ethoprop RED on July 31, 2006.

2. *Toxicity*

97. Ethoprop is among the most toxic of registered pesticides—it is "classified in Toxicity Category I for all acute endpoints, except acute inhalation which is classified in Toxicity Category II." Ethoprop IRED at 22. Ethoprop is "likely to result in '... above average evidence of effects . . . [and is] nearly twice as likely to require hospitalization as did cases due to other cholinesterase inhibitors." Id. at 35 (citation omitted) (ellipses in original).

98. In addition to toxicity from cholinesterase inhibition, ethoprop is classified as "a 'likely' human carcinogen' Ethoprop IRED at 14. Ethoprop is "moderately to very highly toxic" to birds and has the potential to affect avian reproduction. Id. at 39. Ethoprop is "highly toxic" to mammals and is "moderately toxic" to honey bees. Id.

99. EPA identified five ethoprop metabolites/degradates of toxicological concern. 21 Two of those metabolites/degradates pose both cancer and non-cancer toxicological risks of 22 concern. Ethoprop IRED at 14-15. The remaining three posed only cancer risks of concern. Id. 23 EPA required the registrants to submit studies regarding the ethoprop metabolites/degradates and 24

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1 promised that "the risk assessment and tolerance expression may be revisited" once the Agency 2 received the additional data. Id. at 47; see also id. at 48.

Worker Risks

3.

4 100. Ethoprop is registered in both granular and an emulsifiable concentrate 5 formulations. Regarding the granular formulation, EPA determined that "[a]t the maximum label 6 application rates, all of the handler exposure scenarios exhibited risks of concern to the Agency, 7 even when utilizing engineering controls." Ethoprop IRED at 2; see also id. at 28-33.

101. EPA determined that, even with maximum feasible mitigation, some ethoprop use scenarios presented cancer risks for mixers, loaders, or applicators. Many scenarios presented cancer risks exceeding 1×10^{-6} , and some scenarios resulted in cancer risks exceeding 1×10^{-4} . Ethoprop IRED at 63-64. EPA acknowledged that it lacked data to assess cancer risks for some pesticide handler scenarios. E.g., id. at 30.

102. Despite acknowledging that risks of concern would persist, and that it lacked information on certain risks, EPA decided that most uses of ethoprop were eligible for reregistration. Ethoprop IRED at 3. EPA proclaimed that it could mitigate these risks of concern by requiring the manufacturer to reformulate the granular products, which purportedly would reduce inhalation exposures. Id. at 60-62. While EPA believed the product modifications would result in risks "below their respective targets and not of concern," EPA acknowledged that it required "confirmatory data to support this conclusion." Id. at 2-3.

20 103. EPA postponed its re-registration decision for emulsifiable concentrate formulations after the registrant insisted that "actual exposures to workers that mix/load and apply the ethoprop [emulsifiable concentrate] product are possibly lower than indicated by the risk assessment presented in this document " Ethoprop IRED at 63. To support this position, the registrant provided a biomonitoring study revealing that some farmworkers were

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indeed exposed to ethoprop emulsifiable concentrate formulation at levels posing risks of
concern to those workers. EPA used the "level of care" by which the test subjects handled the
pesticide to discount the risks posed to farmworkers who apply ethoprop in real-world
conditions:
The daily dose MOEs ranged widely among individual handlers. The Agency

[T]he daily dose MOEs ranged widely among individual handlers. The Agency believes that these results are to be expected when considering the actual work practices of multiple individuals.... The level of care with which an individual handles a pesticide greatly influences the overall exposure to the pesticide. Given this study monitored the actual work practices of 23 handlers, degrees of caution will differ. Therefore, the Agency also considered the arithmetic mean MOEs of the daily dose samples with engineering controls – these ranged from 14 to 160, with most averages ≥ 100 .

Ethoprop Addendum at 6. EPA provided a similar assessment relating to an inhalation study.

<u>Id.</u> at 7.

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4. Children and Bystander Risks

104. EPA has acknowledged incident reports in which ethoprop drifted following application and caused poisoning to children and other bystanders. In the Ethoprop IRED, EPA discusses a California incident in which seven people were exposed to ethoprop drift "from an air-blast application onto soil." Ethoprop IRED at 35. EPA also noted a Washington incident in which one adult and two children were exposed to ethoprop "drift towards a home adjacent to a nursery." <u>Id.</u>

105. In a 1998 study, the California Air Resources Board found concentrations of ethoprop in the air at application sites and in the ambient air in Siskiyou County, California. In the study, the highest ethoprop concentration in the ambient air was observed approximately onequarter mile from the nearest agricultural fields at the Doris Elementary School.

106. Despite the potential for ethoprop to drift and poison children and bystanders, in re-registering ethoprop, the only non-occupational and non-dietary exposure scenario EPA

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considered was the risk to golfers following application of ethoprop on golf courses. <u>Id.</u> at 34.
EPA's aggregate risk assessments considered only risk from dietary exposures from
consumption of food and water. On information and belief, EPA never considered or assessed
the risks to children and other bystanders who may be exposed to ethoprop that drifts, volatizes,
or is tracked-in near homes, schools, and other areas where children and bystanders may be
present.

5.

Ecological Risks

107. Ethoprop is persistent in the environment, linked to fish and waterfowl kills, and a detected contaminant in surface and groundwater. See Ethoprop IRED at 19-20. Ethoprop poses ecological risks of concern for birds, mammals, aquatic species, and non-target insects.

Ethoprop IRED at 39-43.

108. In addition to the parent compound, four ethoprop degradates are of toxicological concern to wildlife. However, EPA's environmental fate model "did not include any of the environmental degradates of ethoprop due to a lack of fate information." Ethoprop IRED at 22.

109. Ethoprop also poses risks of concern to threatened and endangered species.
Ethoprop IRED at 42. Many threatened and endangered species live in those counties and may be affected by ethoprop. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and threatened Western snowy plover occur within one mile of ethoprop uses. In 2003, EPA initiated a consultation with NMFS after determining that registered ethoprop uses "may affect" 18 threatened or endangered salmon and steelhead populations in Washington, Oregon, and California. Ethoprop: Analysis of Risks to Endangered and Threatened Pacific Salmon and Steelhead at 71-72 (Dec. 1, 2003). This consultation has never been completed.

110. In biological opinions issued in the 1980s, FWS made jeopardy determinations for ethoprop and prescribed mitigation measures to reduce the incidental take of fish, invertebrates,

Earthjustice 705 Second Ave., Suite 203 Seattle, WA 98104 (206) 343-7340 and birds. EPA has not implemented the mitigations that FWS prescribed; rather, EPA held off on addressing endangered species issues pending completion of revisions to the ESA consultation regulations and implementation of EPA's Endangered Species Protection Program.

111. To address the ecological risks, EPA adopted some mitigation measures.
Ethoprop IRED at 67-70. For example, for the emulsifiable concentrate formulation only, EPA maintained buffer zones it had adopted for application of the emulsifiable concentrate formulation around water bodies (800 feet from brackish water habitats along the Atlantic seaboard 140 feet from inland freshwater habitats, and 140 feet from "people or these surface waters"). Id. at 70, 89. EPA never assessed whether the mitigation prescribed in the reregistration decisions would eliminate risks of concern to wildlife.

6. Benefits Assessment

112. EPA ultimately determined that ethoprop emulsifiable concentrate uses on potatoes, sweet potatoes, cabbage in California, and ornamental field nursery stock in California, Oregon, and Washington were eligible for re-registration. Regarding potatoes, EPA noted that the use of emulsifiable concentrate ethoprop had recently increased by 239% and, while other alternatives were available, they would be more costly than emulsifiable concentrate ethoprop.
EPA also asserted that emulsifiable concentrate ethoprop was "important" for use on cabbage in California and ornamental field nursery stock in California, Oregon, and Washington.

113. EPA failed to conduct adequate benefits assessments when it re-registered the granular and emulsifiable formulations of ethoprop. In the Ethoprop IRED, EPA made only the most conclusory findings regarding the benefits of ethoprop that were unsupported by any objective data. On information and belief, EPA never conducted an objective analysis of the efficacy of potential ethoprop alternatives or the economic benefits to growers of continued ethoprop availability.

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114. In 2006, EPA found that potential alternatives to the emulsifiable concentrate ethoprop use on potatoes were so costly that the benefits of this ethoprop use outweighed the risks. On information and belief, EPA's conclusion regarding the benefits of emulsifiable concentrate ethoprop on potatoes was not supported by any objective data or analysis such as actual data regarding the costs of the proposed chemical alternatives, the comparative efficacy of the chemical alternatives, or the relative costs of adopting non-chemical pest control methods.

E. <u>The 2006 Organophosphate Cumulative Risk Assessment.</u>

115. In 2006, EPA completed its organophosphate Cumulative Risk Assessment and re-affirmed its IREDs for methidathion, ODM, methamidophos and ethoprop without change. It concluded that the Cumulative Risk Assessment compelled no changes in these IREDs and that the pesticide uses covered by the IREDs continue to be eligible for re-registration. In making this determination, EPA did not address or incorporate the data submitted in response to the previous data call-ins described in the IRED. Nor did EPA revisit the troubling risks posed to children and other bystanders from use of these pesticides.

CAUSES OF ACTION

ALLEGATIONS COMMON TO FIRST THROUGH FOURTH CAUSES OF ACTION

116. In order to register or re-register a pesticide use, EPA must determine that the use "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. §§ 136a(c)(5), 136a-1(a)(2). 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" <u>Id.</u> at § 136(bb). In order to satisfy this standard, EPA must consider all relevant health, environmental, economic, and social risks and benefits of the pesticide use and determine that the benefits outweigh the risks.

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- 117. The registrant bears the burden of proving that the benefits of a pesticide use outweigh the risks. The registrant bears this burden at all times. EPA cannot re-register a pesticide use unless the registrant has met its burden with respect to that use.
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FIRST CAUSE OF ACTION—EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND IN VIOLATION OF FIFRA IN RE-REGISTERING METHIDATHION.

118. In determining whether methidathion was eligible for re-registration, EPA inadequately investigated and failed to fully consider the risks posed to farmworkers, children and other bystanders, and the environment from methidathion uses. EPA also failed to conduct a full and objective assessment of the benefits to growers and society from continued availability of methidathion.

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119. Under FIFRA, EPA cannot register or re-register a pesticide use that poses risks of concern to workers or the environment unless the registrant has proved that the benefits of the use outweigh all of the health, environmental, economic, and social risks posed by that use. Here, EPA failed to put the burden of proof on the registrant to prove that methidathion was eligible for re-registration under FIFRA. EPA also conducted an inadequate investigation into the risks and benefits of methidathion and failed to consider important factors relating to the reregistration eligibility of methidathion. In addition, EPA never aggregated the total risks posed by the methidathion uses to workers, the environment, or children and other bystanders. In the absence of a complete assessment of the risks and benefits of methidathion, EPA lacked a sufficient basis to determine that the benefits of each methidathion use outweighed the risks and would therefore not have unreasonable adverse effects on human health and the environment. By re-registering methidathion uses that pose risks of concern to workers and the environment without requiring the registrant to prove that the uses are eligible for re-registration, and without an adequate basis to make the FIFRA-mandated risk-benefit findings, EPA acted arbitrarily,

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capriciously, and contrary to FIFRA.

II.

SECOND CAUSE OF ACTION—EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND IN VIOLATION OF FIFRA IN RE-REGISTERING ODM.

120. In determining whether ODM was eligible for re-registration, EPA inadequately investigated and failed to fully consider the risks posed to farmworkers, children and other bystanders, and the environment from ODM uses. EPA also failed to conduct a full and objective assessment of the benefits to growers and society from continued availability of ODM.

121. Under FIFRA, EPA cannot register or re-register a pesticide use that poses risks of concern to workers or the environment unless the registrant has proved that the benefits of the use outweigh all of the health, environmental, economic, and social risks posed by that use. Here, EPA failed to put the burden of proof on the registrant to prove that ODM was eligible for re-registration under FIFRA. EPA also conducted an inadequate investigation into the risks and benefits of ODM and failed to consider important factors relating to the re-registration eligibility of ODM. In addition, EPA never aggregated the total risks posed by the ODM uses to workers, the environment, or children. In the absence of a full assessment of the risks and benefits of ODM, EPA lacked a sufficient basis to determine that the benefits of each ODM use outweighed the risks and would therefore not have unreasonable adverse effects on human health and the environment. By re-registering ODM uses that pose risks of concern to workers and the environment without requiring the registrant to prove that the uses are eligible for re-registration, and without an adequate basis to make the FIFRA-mandated risk-benefit findings, EPA acted arbitrarily, capriciously, and contrary to FIFRA.

III. THIRD CAUSE OF ACTION—EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND IN VIOLATION OF FIFRA IN RE-REGISTERING METHAMIDOPHOS.

122. In determining whether methamidophos was eligible for re-registration, EPA inadequately investigated and failed to fully consider the risks posed to farmworkers, children

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and other bystanders, and the environment from methamidophos uses. EPA also failed to conduct a full and objective assessment of the benefits to growers and society from continued availability of methamidophos.

4 123 Under FIFRA, EPA cannot register or re-register a pesticide use that poses risks 5 of concern to workers or the environment unless the registrant has proved that the benefits of the 6 use outweigh all of the health, environmental, economic, and social risks posed by that use. 7 Here, EPA failed to put the burden of proof on the registrant to prove that methamidophos was 8 eligible for re-registration under FIFRA. EPA also conducted an inadequate investigation into 9 the risks and benefits of methamidophos and failed to consider important factors relating to the 10 re-registration eligibility of methamidophos. In addition, EPA never aggregated the total risks 11 posed by the methamidophos uses to workers, the environment, and children and other 12 bystanders. In the absence of a full assessment of the risks and benefits of methamidophos, EPA 13 lacked a sufficient basis to determine that the benefits of each methamidophos use outweighed 14 the risks and would therefore not have unreasonable adverse effects on human health and the 15 environment. By re-registering methamidophos uses that pose risks of concern to workers and 16 the environment without requiring the registrant to prove that the uses are eligible for re-17 registration, and without an adequate basis to make the FIFRA-mandated risk-benefit findings, 18 EPA acted arbitrarily, capriciously, and contrary to FIFRA.

IV. FOUL AND

FOURTH CAUSE OF ACTION—EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND IN VIOLATION OF FIFRA IN RE-REGISTERING ETHOPROP.

124. In determining whether ethoprop was eligible for re-registration, EPA inadequately investigated and failed to fully consider the risks posed to farmworkers, children and other bystanders, and the environment from ethoprop uses. EPA also failed to conduct a full and objective assessment of the benefits to growers and society from continued availability of

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3 of concern to workers or the environment unless the registrant has proved that the benefits of the 4 use outweigh all of the health, environmental, economic, and social risks posed by that use. 5 Here, EPA failed to put the burden of proof on the registrant to prove that ethoprop was eligible 6 for re-registration under FIFRA. EPA also conducted an inadequate investigation into the risks 7 and benefits of ethoprop and failed to consider important factors relating to the re-registration 8 eligibility of ethoprop. In addition, EPA never aggregated the total risks posed by the ethoprop 9 uses to workers, the environment, or children and other bystanders. In the absence of a full 10 assessment of the risks and benefits of ethoprop, EPA lacked a sufficient basis to determine that 11 the benefits of each ethoprop use outweighed the risks and would therefore not have 12 unreasonable adverse effects on human health and the environment. By re-registering ethoprop 13 uses that pose risks of concern to workers and the environment without requiring the registrant to 14 prove that ethoprop was eligible for re-registration, and without an adequate basis to make the 15 FIFRA-mandated risk-benefit findings, EPA acted arbitrarily, capriciously, and contrary to 16 FIFRA. 17 V. FIFTH CAUSE OF ACTION—EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO FIFRA WHEN IT AFFIRMED ITS REGISTRATIONS FOR 18 METHIDATHION, ODM, METHAMIDOPHOS, AND ETHOPROP IN 2006 WITHOUT FILLING IN THE DATA GAPS IDENTIFIED IN THE EARLIER RE-19 **REGISTRATION DECISIONS** 20 In re-registering uses of methidathion, ODM, methamidophos, and ethoprop, EPA 126. 21 recognized that there were "data gaps" relating to the risks and benefits of certain pesticide uses. 22 Nonetheless, EPA determined that such uses were eligible for registration provided that the 23 agency addressed the data gaps in the FQPA-mandated cumulative risk assessment for the 24 organophosphates. 25 Earthjustice COMPLAINT FOR DECLARATORY AND 705 Second Ave., Suite 203 **INJUNCTIVE RELIEF** -36-Seattle, WA 98104 26 (206) 343-7340

Under FIFRA, EPA cannot register or re-register a pesticide use that poses risks

1 EPA released its Organophosphate Cumulative Risk Assessment in 2006. In this 127. 2 assessment, EPA reaffirmed all of its methidathion, ODM, methamidophos, and ethoprop re-3 registration determinations without change and without addressing may of the data gaps 4 identified in the IREDs. EPA acted arbitrarily, capriciously, and in violation of FIFRA by 5 reaffirming the methidathion, ODM, methamidophos, and ethoprop eligibility determinations 6 without filling the data gaps identified in the IREDs and without addressing the data and 7 comments submitted in response to the IREDs. 8 ALLEGATIONS COMMON TO SIXTH THROUGH NINTH CAUSES OF ACTION 9 Section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), requires federal agencies to 128. 10 ensure that their actions will not jeopardize the survival and recovery of listed species and will 11 not adversely modify designated critical habitat. To comply with this duty, federal agencies, like

EPA, must consult with the FWS and/or NMFS whenever the agency takes an action that "may affect" a listed species or the species' critical habitat. Id.; see also 50 C.F.R. § 402.14(a). The federal agency must determine whether its actions "may affect" listed species at the earliest possible time.

129. On its face and under ESA implementing regulations, section 7(a)(2) of the ESA applies to licenses such as EPA's registration and re-registration of pesticides. 50 C.F.R. § 402.02. EPA's findings of risks of concern for threatened and endangered species equates with a "may affect" finding that triggers ESA's consultation mandates.

20 130. Separately, section 7(d) of the ESA, 16 U.S.C. § 1536(d), prohibits federal agencies, after the initiation of consultation under section 7(a)(2), from making any irreversible or irretrievable commitment of resources if doing so would foreclose the implementation of 23 reasonable and prudent alternatives.

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VI.

SIXTH CAUSE OF ACTION—EPA'S REREGISTRATION OF METHIDATHION VIOLATES SECTIONS 7(A)(2) AND 7(D) OF THE ENDANGERED SPECIES ACT.

131. In its ecological risk assessments for methidathion, EPA found that uses of the pesticide pose risks of concern to threatened and endangered species. Over 50 threatened and endangered species live in counties where such uses are authorized to occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and threatened Western snowy plover live within one mile of methidathion application sites and may be affected by methidathion uses.

132. EPA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by reregistering methidathion without completing the ESA-mandated consultations and without ensuring that the re-registered pesticide uses will not jeopardize the survival and recovery of threatened and endangered species and will not destroy and/or adversely modify their critical habitat.

133. Pursuant to court orders, EPA has begun to initiate, but has not completed, consultations on the effects of methidathion on 19 listed salmonid populations. As EPA continues to allow uses of methidathion prior to completion of the consultations, it makes irreversible and irretrievable commitments of resources that will foreclose the implementation of reasonable and prudent alternatives that may result from the salmonid consultations and, therefore, is in violation of section 7(d) of the ESA.

VII. SEVENTH CAUSE OF ACTION—EPA'S REREGISTRATION OF ODM VIOLATES SECTIONS 7(A)(2) AND 7(D) OF THE ENDANGERED SPECIES ACT.

134. In its ecological risk assessments for ODM, EPA found that uses of the pesticide pose risks of concern to threatened and endangered species. Over 50 threatened and endangered species live in counties where such uses are authorized to occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and threatened Western snowy plover live

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within one mile of ODM application sites and may be affected by ODM uses.

135. EPA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by reregistering ODM without completing ESA consultations and without ensuring that the reregistered pesticide uses will not jeopardize the survival and recovery of threatened and endangered species and will not destroy and/or adversely modify their critical habitat.

136. Pursuant to court orders, EPA has begun to initiate, but has not completed, consultations on the effects of ODM on the California red-legged frog. As EPA continues to allow uses use of ODM prior to completion of the consultation, it makes irreversible and irretrievable commitments of resources that will foreclose the implementation of reasonable and prudent alternatives that may result from the red-legged frog consultation and, therefore, is in violation of section 7(d) of the ESA.

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VIII. EIGHTH CAUSE OF ACTION—EPA'S REREGISTRATION OF METHAMIDOPHOS VIOLATES SECTIONS 7(A)(2) AND 7(D) OF THE ENDANGERED SPECIES ACT.

137. In its ecological risk assessments for methamidophos, EPA found that uses of the pesticide pose risks of concern to threatened and endangered species. Over 50 threatened and endangered species live in counties where such uses are authorized to occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and threatened Western snowy plover live within one mile of methamidophos application sites and may be affected by methamidophos uses.

138. EPA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by reregistering methamidophos without completing ESA consultations and without ensuring that the re-registered pesticide uses will not jeopardize the survival and recovery of threatened and endangered species and will not destroy and/or adversely modify their critical habitat.

139. Pursuant to court orders, EPA has begun to initiate, but has not completed,

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consultations on the effects of methamidophos on the California red-legged frog and three listed salmonid populations. As EPA continues to allow use of methamidophos prior to completion of the consultations, it makes irreversible and irretrievable commitments of resources that will 4 foreclose the implementation of reasonable and prudent alternatives that may result from the 5 salmonid and red-legged frog consultations and, therefore, is in violation of section 7(d) of the 6 ESA.

7 IX.

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NINTH CAUSE OF ACTION—EPA'S REREGISTRATION OF ETHOPROP VIOLATES SECTIONS 7(A)(2) AND 7(D) OF THE ENDANGERED SPECIES ACT.

In its ecological risk assessments for ethoprop, EPA found that uses of the 140. pesticide pose risks of concern to threatened and endangered species. Over 50 threatened and endangered species live in counties where such uses are authorized to occur. For example, the endangered San Joaquin kit fox, endangered Least Bell's vireo, and threatened Western snowy plover live within one mile of ethoprop application sites and may be affected by ethoprop uses.

141. EPA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by reregistering ethoprop without completing ESA consultations and without ensuring that the reregistered pesticide uses will not jeopardize the survival and recovery of threatened and endangered species and will not destroy and/or adversely modify their critical habitat.

142. Pursuant to court orders, EPA has begun to initiate, but has not completed, consultations on the effects of ethoprop on 18 listed salmonid populations. As EPA continues to allow uses of ethoprop prior to completion of the consultations, it makes irreversible and irretrievable commitments of resources that will foreclose the implementation of reasonable and prudent alternatives that may result from the salmonid consultations and, therefore, is in violation of section 7(d) of the ESA.

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PRAYER FOR RELIEF

WHEREFORE, the Workers pray that this Court:

Adjudge and declare that EPA acted arbitrarily, capriciously, and contrary to A. FIFRA in re-registering uses of methidathion, ODM, methamidophos, and ethoprop;

B. Adjudge and declare that EPA violated sections 7(a)(2) and 7(d) of the ESA by failing to complete ESA consultations before re-registering methidathion, ODM,

methamidophos, and ethoprop uses and for failing to ensure that the re-registered uses will avoid jeopardizing the survival and recovery of threatened and endangered species and destroying and/or adversely modifying their designated critical habitat;

C. Order EPA to make new re-registration eligibility decisions for methidathion, ODM, methamidophos, and ethoprop uses on an expeditious basis in which EPA: (1) makes unreasonable adverse effects determinations based on consideration, and balancing of all health, environmental, economic, and social risks and benefits from the use, including those to children and other bystanders; (2) re-registers a use of the pesticides only when the pesticide registrants have proved that the health, environmental, economic, and social benefits outweigh the risks; and (3) ensures, based on completed section 7(a)(2) consultations, that the re-registered pesticide uses will avoid jeopardizing the survival and recovery of threatened and endangered species and destroying and/or adversely modifying their critical habitat;

D. Order EPA to consult with the Services pursuant to section 7(a)(2) of the ESA on the re-registered uses of methidathion, ODM, methamidophos, and ethoprop that "may affect" threatened and endangered species and/or their designated critical habitat, and direct EPA to ensure that it conducts the consultations in a manner that addresses the most significant threats posed to listed species by pesticide use in an expeditious fashion;

E. Order interim protective measures to prevent harm to farmworkers, children, and

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other bystanders in agricultural communities near areas where methidathion, ODM,
 methamidophos, and ethoprop are used while EPA makes new re-registration decisions for
 methidathion, ODM, methamidophos, and ethoprop;

F. Order interim protective measures to prevent harm to threatened and endangered
species and their designated critical habitat until the ESA section 7(a)(2) consultation process has
been completed and EPA has brought its methidathion, ODM, methamidophos, and ethoprop
registrations into compliance with the law;

G. Award plaintiffs PANNA, UFW, PCUN, FLOC, Beyond Pesticides, NRDC, Sea
Mar, Teamsters Local 890, and Moises Lopez their reasonable expenses, costs, and
disbursements, associated with this litigation under the Equal Access to Justice Act 28 U.S.C. §
2412;

H. Award plaintiffs PANNA, UFW, PCUN, FLOC, Beyond Pesticides, NRDC, Sea Mar, and Teamsters Local 890, and their counsel Earthjustice and Farmworker Justice, only their reasonable fees, including attorneys' fees associated with this litigation, under the Equal Access to Justice Act 28 U.S.C. § 2412;

I. Award Beyond Pesticides and NRDC their reasonable fees, expenses, costs, and disbursements, including attorneys' fees associated with this litigation under the citizen suit provision of the ESA, 16 U.S.C. § 1540(g)(4);

J. Grant the Workers such further and additional relief as the Court may deem just and proper.

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1	Respectfully submitted this day	of April, 2008.
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4		GEORGE TORGUN (CSB #222085) Earthjustice
5	4	126 Seventeenth Street, 5 th Floor Dakland, CA 94612-2807
		510) 550-6725
6		510) 550-6749 [FAX] gtorgun@earthjustice.org
7		Local Counsel for Plaintiffs
8	J	OSHUA OSBORNE-KLEIN (WSB #36736)
9		KRISTEN L. BOYLES (CSB #158450) Earthjustice
10		705 Second Avenue, Suite 203 Seattle, WA 98104
11		206) 343-7340
12	j	206) 343-1526 [FAX] osborne-klein@earthjustice.org
13	ŀ	xboyles@earthjustice.org
14		SHELLEY DAVIS (CSB #84539) VIRGINIA RUIZ (CSB #194986)
15	I	Farmworker Justice
		Washington, D.C. 20036
16		202) 293-5420 202) 293-5427 [FAX]
17		davis@nclr.org /ruiz@nclr.org
18		Attorneys for Plaintiffs Pesticide Action Network
19	I	North America, United Farm Workers, Pineros y
20		Campesinos Unidos del Noroeste, Farm Labor Organizing Committee, AFL-CIO, Beyond
21	1	Pesticides, Natural Resources Defense Council, Sea Mar Community Health Center, and Teamsters
22		Local 890
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25	COMPLAINT FOR DECLARATORY AND	Earthjustice 705 Second Ave., Suite 203 Seattle, WA 98104
26	INJUNCTIVE RELIEF -43-	(206) 343-7340

