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1 UNITED STATES DISTRICT COURT  
2 FOR THE WESTERN DISTRICT OF WASHINGTON

3 UNITED FARM WORKERS OF AMERICA, ) Civ. No. CV04-0099C  
4 AFL-CIO; SEA MAR COMMUNITY )  
5 HEALTH CENTER; PINEROS Y )  
6 CAMPESINOS UNIDOS DEL NOROESTE ) PLAINTIFFS' MEMORANDUM IN  
7 ("PCUN"); BEYOND PESTICIDES, FRENTE ) OPPOSITION TO DEFENDANT'S  
8 INDIGENA OAXAQUENO BINACIONAL ) MOTION TO DISMISS  
9 ("FRENTE INDIGENA"), and ARNULFO )  
10 LOPEZ, )  
11 Plaintiffs, )  
12 v. )  
13 ADMINISTRATOR, U.S. )  
14 ENVIRONMENTAL PROTECTION )  
15 AGENCY, )  
16 Defendant. )

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1 INTRODUCTION

2 This case challenges reregistration decisions made by defendant Environmental  
3 Protection Agency (“EPA”) under the Federal Insecticide Fungicide and Rodenticide Act, 7  
4 U.S.C. §§ 136-136y (“FIFRA”), for two pesticides, azinphos-methyl (“AZM”) and phosmet,  
5 which retain registered uses that pose extensive risks to workers, their families, and the  
6 environment. Plaintiffs United Farm Workers et al. (“UFW”) challenge EPA’s continuation of  
7 harmful uses of these pesticides on three grounds: (1) EPA based its decision on a flawed risk-  
8 benefit analysis that quantified the economic benefits to farmers from using these pesticides, but  
9 not the harm and economic costs of exposures to workers, their families, communities, and the  
10 environment; (2) EPA relied on assumptions and data contradicted by peer-reviewed scientific  
11 studies and other data provided by plaintiffs in public comments without integrating or  
12 explaining its reasons for disregarding the submitted scientific data; and (3) EPA used data  
13 provided by an industry task force on worker exposure to pesticides without making the data  
14 publicly available, despite FIFRA’s mandate that EPA release such information, and despite  
15 requests for the data on behalf of the plaintiffs.

16 EPA’s motion to dismiss focuses on one particular regulatory action – EPA cancellation  
17 of pesticide registrations – while this case focuses on a different regulatory action – the  
18 continued registration of pesticides that cause harm to workers, their children, and the  
19 environment. It is only by characterizing the “action” as EPA cancellations that EPA can  
20 contend that the AZM and phosmet reregistration decisions are non-final, interim steps that could  
21 possibly lead to such pesticide cancellations at some future date. EPA’s characterization  
22 sidesteps the very real impacts precipitated by its authorization of continued uses of these  
23 pesticides with mitigation entailing protective clothing and gear that lessen but still expose  
24 workers to harmful pesticide levels.

1 The challenged EPA decisions constitute final agency actions because they mark the  
2 culmination of the agency’s FIFRA decision-making process, and they have pervasive ongoing  
3 and sometimes life-threatening impacts to workers. While EPA still must assess the cumulative  
4 food risks posed by these two pesticides and other organophosphate pesticides, the challenged  
5 decisions embody EPA’s first FIFRA reregistration decisions for these two pesticides in over  
6 three decades and the only reregistration decisions that will concern risks to workers and the  
7 environment. These decisions, which currently regulate agricultural uses of these chemicals,  
8 may or may not be changed by a subsequent determination on food tolerances based on EPA’s  
9 cumulative risk assessment decision made under a different statute concerned with levels of  
10 pesticide residue on food, not risks to farm workers. The 2001 decisions currently have  
11 detrimental on-the-ground impacts on workers and their families from the reregistered uses that  
12 EPA continues to allow. Accordingly, the decisions are final, the case is ripe, and FIFRA’s  
13 exhaustion prerequisites are inapplicable.

## 14 BACKGROUND

### 15 I. THE STATUTORY AND REGULATORY SCHEME GOVERNING PESTICIDE USE.

16 EPA regulates pesticides under two statutes, FIFRA and the Federal Food, Drug, and  
17 Cosmetic Act (“FFDCA”), 21 U.S.C. §§ 301-394, as amended by the Food Quality Protection  
18 Act of 1996. Pub. L. No. 104-170, 110 Stat. 1486 (1996). (“FQPA”) FIFRA governs pesticide  
19 use. EPA must register a pesticide before it may be sold or used in the United States. 7 U.S.C. §  
20 136(a). Since its original enactment in 1947, FIFRA has been amended first in 1972 and on  
21 several occasions since to impose more stringent environmental standards. A 1988 FIFRA  
22 amendment requires EPA to complete a review and reregistration of previously registered  
23 pesticides to ensure their compliance with these upgraded standards. 7 U.S.C. § 136a-1. EPA  
24 may register or reregister a pesticide under FIFRA only if “it will perform its intended function



1 without unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5). This standard  
2 calls for risk-benefit balancing; EPA determines whether a pesticide poses “any unreasonable  
3 adverse effect to man or the environment, taking into account the economic, social, and  
4 environmental costs and benefits of the use of any pesticide.” *Id.* §§ 136(bb), 136a(c)(5), &  
5 136d(b). As such, FIFRA regulates occupational and environmental exposures to pesticides.

6 The FFDCA authorizes EPA to set tolerances (*i.e.*, maximum allowable levels) for  
7 pesticide residues in or on food, subject to certain exemptions not applicable here. 21 U.S.C. §§  
8 346a(b) & (c). EPA may establish a food tolerance only upon determining that the tolerance is  
9 safe. 21 U.S.C. § 346a(b)(2)(A)(i). The Food Quality Protection Act of 1996 (“FQPA”)  
10 amended the FFDCA safety standards and established a schedule for EPA to reassess existing  
11 tolerances and ensure their compliance with the new standards. 21 U.S.C. §§ 346(b)(2)(A)(ii);  
12 346a(q). Among the FQPA’s more stringent standards, EPA must ensure there is a reasonable  
13 certainty of no harm from food and certain other non-occupational exposures, must provide  
14 additional safeguards for infants and other vulnerable subpopulations, and must guard against  
15 unsafe exposures from the cumulative effects of pesticides sharing a common mechanism of  
16 toxicity. 21 U.S.C. §§ 346a(b)(2)(A)(i)-(ii); 346a(b)(2)(C); 346a(b)(2)(D)(v).

17 While FIFRA and FFDCA employ independent legal standards for registering a pesticide,  
18 EPA cannot register or reregister a pesticide use for a food use in the absence of a food tolerance  
19 for residues related to that use. 40 C.F.R. § 152.112(g); see also 7 U.S.C. § 136(bb) (FIFRA  
20 definition of “unreasonable adverse effect” includes a human dietary risk from any food  
21 inconsistent with FFDCA standards). Accordingly, EPA conducts its FFDCA dietary, drinking  
22 water, and residential use risk assessments at the same time as it conducts its FIFRA  
23 occupational and ecological risk assessments that form the underpinnings of its reregistration  
24

1 decision. EPA is in the midst of the process of reviewing pesticides to bring them into  
2 compliance with both the FIFRA and FFDCFA standards.

3 The 1988 FIFRA amendments set out a five-phase process for reregistering older  
4 pesticides under current environmental standards. The fifth and final stage of this process  
5 consists of a reregistration decision, which “shall determine whether pesticides containing such  
6 active ingredients are eligible for reregistration.” 7 U.S.C. § 136a-1(g)(2)(A); see also id. §  
7 136a-1(g)(2)(C) (EPA “shall determine whether to reregister a pesticide by determining whether  
8 such pesticide meets the requirements of section 3(c)(5)”). FIFRA requires that: “If the  
9 Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall  
10 reregister such pesticide” within six months of the submission of certain product-specific data.  
11 Id. Only if the Administrator determines that uses of a pesticide should not be reregistered must  
12 it “take appropriate regulatory action,” including cancellations and/or suspensions of the  
13 registration. Id. § 136a-1(g)(2)(D).

14 A reregistration eligibility decision (“RED”) is the agency action required under the 1988  
15 FIFRA amendments. It embodies EPA’s determination as to which pesticide uses meet FIFRA’s  
16 risk-benefit standard and which ones do not. It prescribes mitigation measures and label changes  
17 that are prerequisites for reregistration, informing registrants of label changes they need to make  
18 in order to comply with FIFRA or face initiation of cancellation proceedings. Often a RED will  
19 spur the registrants to voluntarily cancel uses that EPA has found ineligible for reregistration.

20 Although not prescribed – or anticipated – under the FIFRA 1988 amendments, EPA has  
21 adopted a practice of issuing interim reregistration eligibility determinations (“IREDs”) for  
22 pesticides that share a common mechanism of toxicity that must be assessed under FQPA. Like  
23 a RED, an IRED determines which pesticide uses are eligible and ineligible for reregistration  
24

1 under EPA’s FIFRA risk-benefit standard and based on its tolerance reassessments for the  
2 pesticide completed to date. Also like a RED, an IRED prescribes mitigation that must be  
3 implemented in order for the pesticide use to pass muster under FIFRA. The sole difference  
4 between a RED and an IRED is that

5 EPA issues IREDs for pesticides that are undergoing reregistration, require a  
6 reregistration eligibility decision, and also must be included in a cumulative  
7 assessment under FQPA because they are part of a group of pesticides that share a  
8 common mechanism of toxicity [e.g., OPs] ... An IRED may include measures to  
9 reduce ... risks, to gain the benefit of these changes before the final RED can be  
10 issued following the Agency’s consideration of cumulative risks.

11 68 Fed. Reg. 44,767, 44,770-71 (July 30, 2003) (EPA’s annual reporting on completion of  
12 reregistration and tolerance decisions).

## 13 II. EPA’S REREGISTRATION ELIGIBILITY DECISIONS FOR AZM AND PHOSMET

14 Phosmet and AZM are highly toxic organophosphate insecticides derived from nerve gas  
15 used during World War II. They kill insects by attacking the nervous system. In humans, they  
16 inhibit the body’s ability to produce cholinesterase, an essential enzyme in the nervous system,  
17 which can result in acute poisonings, permanent nerve damage, and even death. AZM is one of  
18 the registered pesticides responsible for a large number of reported farmworker poisonings.

19 Interim Reregistration Eligibility Decision for Azinphos-Methyl at 42-44 (Oct. 30, 2001) (“AZM  
20 IRED”) (Exhibit 1).<sup>1</sup>

21 Both AZM and phosmet are used on apples, pears, and other labor-intensive crops. AZM  
22 IRED at 54-5; Interim Reregistration Eligibility Decision for Phosmet at 52 (Oct. 30, 2001)  
23 (“Phosmet IRED”) (Exhibit 2). About two million pounds of AZM and over one million pounds  
24 of phosmet are used annually in the United States. AZM IRED at vii; Phosmet IRED at 5.

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25 <sup>1</sup> This factual presentation is drawn from the amended complaint, which must be taken as true on  
26 the motion to dismiss. Fed. R. Civ. P. 12(b). Plaintiffs are also attaching the IREDs and certain  
associated documents as exhibits to this opposition to substantiate the finality of those decisions.

1 EPA originally registered AZM and phosmet long before Congress had amended FIFRA  
2 and FFDCA to embody the more protective health and environmental standards in place today.

3 AZM was originally registered in 1959 and phosmet in 1966. AZM IRED at 3.

4 EPA has long had a legal obligation to determine whether these pesticides are eligible for  
5 reregistration under FIFRA. To meet this obligation, EPA required the registrants to submit data  
6 on worker risks from these pesticides and after lengthy delays completed its review of the data  
7 and made the reregistration eligibility determinations required under the 1988 FIFRA  
8 amendments. AZM IRED at 3-4. EPA's review culminated in its issuance of IREDs for AZM  
9 and phosmet in October 2001.

10 The IREDs embody EPA's reregistration eligibility determination with respect to the  
11 pesticides' worker and ecological risks. As the phosmet IRED states: "Based on its current  
12 evaluation of phosmet alone, the Agency has determined that phosmet products, unless labeled  
13 and used as specified in this document, would present risks inconsistent with FIFRA." Phosmet  
14 IRED at 41. Similarly, EPA found that workers are exposed to unsafe levels of AZM from a  
15 variety of activities, such as mixing and loading AZM and pruning or harvesting treated crops,  
16 and "that all uses of azinphos-methyl are ineligible for reregistration based on their currently  
17 approved labeling." AZM IRED at 32, 36, 42, 54.

18 Despite these findings, EPA did not decide that all AZM and phosmet uses are ineligible  
19 for reregistration. Instead, based on their economic benefits for crop production, EPA decided  
20 that some uses should be continued under FIFRA's risk-benefit standard, despite the risks to  
21 workers. EPA decided that 28 AZM uses must be cancelled immediately, that seven uses must  
22 be phased out over four years, and that eight uses would be given a four-year time-limited  
23 registration that could be renewed if the registrants meet certain requirements by the end of that  
24

1 period. AZM IRED, Cover Letter at 3; IRED at 68-70, 75-105. For both AZM and phosmet,  
2 EPA expressly conditioned all continued uses on label changes that impose significantly  
3 increased mitigation measures, such as imposing longer worker re-entry periods, limiting mixing  
4 and loading activities to closed systems, and requiring the maximum protective clothing. Indeed,  
5 EPA's press release on the issuance of the IREDs trumpeted them as: "New Restrictions on two  
6 Pesticides to Protect Agricultural Workers." EPA Press Release (Oct. 31, 2001) (Exhibit 5).

7 The IREDs are final except with respect to one discrete issue not challenged here. As the  
8 AZM IRED explains, the IRED "presents the Agency's reregistration decision except for the  
9 decision on tolerance reassessment." AZM IRED Cover Letter at 2; Phosmet IRED at 41. EPA  
10 further explained that it issued the IREDs to put needed protections into place immediately:

11 Although the Agency has not yet considered cumulative risks for the  
12 organophosphates, the Agency is issuing this interim assessment now in order to  
13 identify risk reduction measures that are necessary regardless of the outcome of  
14 the cumulative risk assessment. Based on its current evaluation of azinphos-  
15 methyl alone, the Agency has determined that azinphos-methyl products, unless  
16 labeled and used as specified in this document, would present risks inconsistent  
17 with FIFRA.

18 . . .

19 By publishing this interim decision on reregistration eligibility and defining  
20 mitigation measures now for the individual chemical azinphos-methyl, the  
21 Agency is not deferring or postponing FQPA requirements; rather, EPA is taking  
22 steps to assure that uses which exceed FIFRA's unreasonable risk standard do not  
23 remain on the label indefinitely, pending completion of assessment required under  
24 the FQPA.

25 AZM IRED at 56-57. EPA may take further actions, if warranted, once it has completed a  
26 cumulative risk assessment for all organophosphates, but any such changes would be driven by  
the food tolerances established to address cumulative food, drinking water, and residential  
exposures, rather than worker risks. Phosmet IRED at 41; AZM IRED Cover Letter at 2.

The two IREDs precipitated changes in the registrations to conform to EPA's decision.

1 In May 2002, EPA and the registrants of products containing AZM entered into a Memorandum  
2 of Agreement that is identical in significant respects to the IRED's reregistration determinations.  
3 EPA, Agreement Between EPA and the Registrants of Pesticide Products Containing AZM (May  
4 23, 2002) ("AZM MOA") (Exhibit 3). Specifically, the AZM MOA provides for the immediate,  
5 voluntary cancellation of numerous AZM uses and for label changes requiring the mitigation  
6 prescribed by EPA in the IRED for remaining uses. In September 2002, the registrants sent EPA  
7 requests to delete uses of AZM pursuant to the AZM MOA. 67 Fed. Reg. 61,337 (Sept. 30,  
8 2002).

9 The makers of products containing phosmet likewise entered into a Memorandum of  
10 Agreement in which the registrant agreed to make label changes incorporating the mitigation  
11 required in the IRED. EPA, Agreement Between EPA and Gowan Company Regarding the  
12 Registrations of Pesticide Products Containing Phosmet (Jan. 17, 2002) ("Phosmet MOA")  
13 (Exhibit 4). The agreement "constitutes a request by the Registrant, and approval of the request  
14 by EPA, to amend all of Registrant's phosmet product registrations bearing label direction for  
15 any use identified in the risk mitigation table in the October 2001 Phosmet Interim Reregistration  
16 Eligibility Decision Document." *Id.* at 1. Both agreements continue many uses of the pesticides  
17 that pose extensive risks to workers as allowed under the IREDs.

18 Under the FQPA and FIFRA, EPA has established a schedule for issuing tolerance  
19 reassessments and for making reregistration eligibility determinations. In NRDC v. Whitman,  
20 No. C-99-3701, 2001 WL 1221774 (N.D. Cal. 2001), the district court approved a consent decree  
21 requiring EPA to issue reregistration eligibility determinations and tolerances for certain  
22 pesticides, including AZM and phosmet. Both to comply with that order and to demonstrate its  
23 progress toward complying with the FIFRA and FQPA deadlines, EPA regularly identifies its  
24

1 completed pesticide decisions. In July 2003, EPA included the AZM and phosmet IREDs among  
2 the FIFRA decisions that it characterizes as completed in fiscal year 2002. 68 Fed. Reg. at  
3 44,769. As of August 2, 2002, EPA states that it had reassessed 52 tolerances for AZM and 27  
4 tolerances for phosmet. EPA, OP Tolerance Reassessment Status, at  
5 [http://www.epa.gov/pesticides/tolerance/pdf\\_files/OPXTab-8-02-2002.PDF](http://www.epa.gov/pesticides/tolerance/pdf_files/OPXTab-8-02-2002.PDF) (Aug. 2, 2002).

## 6 ARGUMENT

7 EPA's motion to dismiss depends on its mischaracterization of this case as one  
8 challenging, or seeking cancellations of, pesticide registrations. To the contrary, UFW is  
9 challenging EPA's final determination that harmful uses of AZM and phosmet satisfy FIFRA's  
10 risk-benefit standard and warrant reregistration, even though they pose extensive worker risks.  
11 Based on this determination, EPA reregistered these pesticide uses, subject to mitigation that is  
12 insufficient to protect workers. An EPA reregistration decision that continues registrations and  
13 that constitutes the agency's final word on the worker risks and compliance with the FIFRA risk-  
14 benefit standard is a final agency action that is ripe for judicial review. Moreover, such a  
15 challenge falls outside the enumerated FIFRA causes of action that must be heard in the court of  
16 appeals. Accordingly, this Court has jurisdiction under 7 U.S.C. § 136n(a) to decide this case  
17 challenging "final actions" of EPA.

18 While the bulk of EPA's motion seeks dismissal on jurisdictional grounds, EPA also  
19 seeks dismissal of UFW's third claim challenging EPA's use of industry worker exposure data in  
20 its IRED without making the data available for public comment. This aspect of EPA's motion is  
21 based on a faulty factual premise – that none of the plaintiffs ever sought access to the exposure  
22 data. Accordingly, it must be denied.

1 I. EPA'S REREGISTRATION ELIGIBILITY DECISIONS FOR AZM AND PHOSMET  
2 ARE FINAL AGENCY ACTIONS.

3 The Supreme Court has prescribed a two-part test for determining whether an agency  
4 action is final. To be final, the challenged action must: (1) "mark the consummation of the  
5 agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature";  
6 and (2) "be one by which rights or obligations have been determined or from which legal  
7 consequences will flow." Bennett v. Spear, 520 U.S. 152, 177-78 (1997) (internal quotations and  
8 citations omitted).

9 The IREDs for AZM and phosmet satisfy both of these criteria. First, they mark the  
10 consummation of EPA's FIFRA reregistration decisionmaking for these two pesticides. As  
11 required under the FIFRA 1988 amendments, EPA has conducted its data review and has  
12 determined the pesticide uses eligible for reregistration. See 7 U.S.C. § 136a-1(g)(2). EPA has  
13 made its final determinations under FIFRA's risk-benefit standard for worker and ecological  
14 risks. The AZM and phosmet IREDs, which were issued in 2001, have already embodied EPA's  
15 final determinations with on-the-ground consequences for workers for nearly three years. While  
16 EPA will decide whether changes to the food tolerances are necessitated by the cumulative risk  
17 assessment, EPA will not revisit its FIFRA risk-benefit determination on occupational and  
18 ecological exposures.

19 Second, not only do the IREDs mark the consummation of the FIFRA decisionmaking  
20 process, but they also determine obligations and have legal consequences. In the IREDs, EPA  
21 has decided which pesticide uses satisfy FIFRA's risk-benefit standard and under what  
22 conditions. Indeed, EPA's press release announced the number of uses being phased out and the  
23 number being continued. Exhibit 5. The IREDs also prescribe mandatory mitigation that must  
24 be required on the product labels as a condition of reregistration and authorize continued



1 registration as long as the mandated label changes are made.

2         If the IREDs had no legal consequences, EPA would not issue them. Rather, EPA would  
3 simply await the completion of its cumulative risk assessment and make final decisions at that  
4 time for the groups of pesticides sharing a common mechanism of toxicity. Such an approach,  
5 however, would leave in place – for years – uses that EPA has already determined do not pass  
6 muster under FIFRA’s cost-benefit standard. To avoid such an untoward result, EPA issued the  
7 IREDs to secure prompt implementation of its risk mitigation decisions for individual pesticides.

8 As EPA’s press release explains:

9             To enhance protection of agricultural workers during the phase-out and time-  
10 limited registration periods, a variety of stringent new precautions are being  
11 implemented to reduce exposure, including longer periods before a worker can  
12 enter a treated area, significantly limiting the number of applications, and  
13 prohibiting aerial application for almost all uses.

12 Id.

13         Nevertheless, EPA contends that the IREDs are interlocutory in nature prior to the  
14 issuance of the ultimate RED for AZM and phosmet. EPA asserts: “An IRED, as the name  
15 implies, is not a final action.” Motion to Dismiss at 12. In analyzing finality, however, the  
16 Ninth Circuit has unequivocally placed the focus on the action’s effect, not its label.

17 Abramowitz v. EPA, 832 F.2d 1071, 1075 (9<sup>th</sup> Cir. 1987). The question is whether “EPA  
18 asserted its final position on the factual circumstances upon which a decision is made.” Alaska  
19 v. EPA, 244 F.3d 748, 750 (9<sup>th</sup> Cir. 2001).

20         The IREDs themselves confirm that they culminate the FIFRA reregistration process and  
21 determine which pesticide uses registrants may continue. In the AZM IRED, EPA explained its  
22 decision to continue pesticide uses that subject workers to unsafe levels of exposure:

23             For the eight remaining uses, there are significant economic benefits associated  
24 with the use of azinphos-methyl, and EPA believes that other pesticides or

1 agricultural practices cannot substitute for azinphos-methyl in providing adequate  
2 control of key target pests at the present time. [EPA] also believes that the  
3 benefits associated with these uses outweigh the risks associated with these uses,  
4 provided that the mitigation measures and other provisions specified in this IRED  
5 are adopted.

6 AZM IRED at 70. In the phosmet IRED, EPA states that the agency “concluded its assessment  
7 of the [ ] worker risks.” Phosmet IRED at 2. For certain uses:

8 Although EPA has determined that the benefits of these uses currently exceed the  
9 mitigated risks, these mitigated risks are still high enough that they would  
10 outweigh the benefits if the benefits changed appreciably. EPA is, therefore,  
11 requiring that after October 30, 2006, the reentry intervals for phosmet products  
12 registered for these 9 uses shall be extended as specific in the risk mitigation  
13 tables.

14 Id. at 43. EPA has appropriately characterized the AZM and phosmet IREDs as “completed”  
15 reregistration decisions in its annual reporting on its compliance with the FIFRA and FQPA  
16 reregistration and tolerance reassessment deadlines. 68 Fed. Reg. at 44,769.

17 EPA also argues that the IREDs are not final agency actions because EPA or the  
18 registrant must take another regulatory action to cancel a pesticide registration. Motion to  
19 Dismiss at 13. This argument extends to all REDs, not simply those denominated interim. In  
20 making this assertion, EPA is focusing on cancellations rather than decisions to continue  
21 pesticide registrations. While an IRED or RED may form the basis for both outcomes, a  
22 cancellation requires a separate FIFRA proceeding, while retaining a registration does not.  
23 Indeed, FIFRA describes EPA’s reregistration decisions as the final step toward reregistering a  
24 pesticide. See 7 U.S.C. § 136a-1(g)(2)(C) (EPA “shall determine whether to reregister a  
25 pesticide by determining whether such pesticide meets the requirements of section 3(c)(5)”). It  
26 is only where EPA “determines that a pesticide should not be reregistered” that FIFRA further  
states that EPA “shall take appropriate regulatory action.” Id. § 136a-1(g)(2)(D).

UFW is not challenging the aspects of the IREDs that determined that AZM and phosmet

1 uses are ineligible for reregistration. In fact, it is hard to imagine how those aspects of EPA's  
2 decision would injure UFW. EPA, however, is trying to contort this case into one mounting a  
3 challenge to the parts of the IREDs that impose the greatest restrictions on AZM and phosmet,  
4 while insulating the continued authorization of harmful uses from legal challenge.

5 Because EPA has made a final decision as to the continued authorizations of these  
6 pesticide uses and has acted upon that decision, Center for Biological Diversity v. Veneman, 335  
7 F.3d 849, 853 (9<sup>th</sup> Cir. 2003), is inapposite. In that case, the Forest Service had published a  
8 report identifying rivers and streams that could potentially be added to the wild and scenic river  
9 system in Arizona, but that inventory constituted only the first step in a two-step decisionmaking  
10 process. The Forest Service still had to make a policy decision deeming the river segments  
11 suitable for wild and scenic river designation based on its consideration of conflicts with future  
12 uses of the waterbodies and state and local interests. In contrast to Center for Biological  
13 Diversity, EPA has made reregistration eligibility determinations for AZM and phosmet,  
14 completing the five-step decisionmaking process specified in the FIFRA 1988 amendments.<sup>2</sup>

15 Furthermore, if there were any doubt, EPA's entry into Memoranda of Agreements with  
16 the registrants of AZM and phosmet removes it. See Exhibits 3 and 4. Spurred by the IREDs,  
17 the registrants agreed to cancel uses that EPA found ineligible for reregistration. Even under  
18

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19 <sup>2</sup> Nor is the IRED analogous to the study that was a precursor to the cumulative risk assessment  
20 discussed in NRDC v. Whitman, 2001 WL 122177 at \*17. The district court stressed that the  
21 objecting plaintiffs (registrant and pesticide user trade associations) would have a subsequent  
22 opportunity to present their views in their comments on the cumulative risk assessment. Here  
23 UFW has commented on the reregistration eligibility decisions, and the occupational and  
24 ecological risk-benefit decision made in the IRED will not be the subject of a future comment  
25 period when EPA acts on the cumulative risk assessment. Any suggestion that REDs are not  
26 final agency actions was dicta that arose in the context of establishing deadlines for tolerance  
reassessments, rather than a challenge to FIFRA decisions made and actions compelled by a  
RED.

1 EPA's view, the MOAs embody final and legally binding action based on EPA's risk-benefit  
2 reregistration decisions on worker and ecological risks.

3 II. THIS CASE IS RIPE FOR JUDICIAL REVIEW.

4 Courts determine if an agency's decision is ripe for judicial review by examining "the  
5 fitness of the issue for judicial decision and the hardship to the parties of withholding court  
6 consideration." Abbott Laboratories v. Gardner, 387 U.S. 136, 149 (1967).

7 A. EPA's Decisions in the IREDs to Reregister Pesticide Uses Are Fit for Judicial  
8 Review.

9 An issue is generally fit for judicial review if "no further factual amplification is  
10 necessary." City of Auburn v. Qwest Corp., 260 F.3d 1160, 1172 (9<sup>th</sup> Cir. 2001), cert. denied,  
11 534 U.S. 1079 (2002) (internal quotation omitted); see also Ohio Forestry Association v. Sierra  
12 Club, 523 U.S. 726, 732 (1998). As demonstrated above, the IREDs constitute EPA's definitive  
13 and final decision on worker and ecological risks from AZM and phosmet and on whether  
14 reregistration of particular uses of these pesticides comports with FIFRA's risk-benefit standard.  
15 The IREDs also establish mandatory mitigation measures as conditions for continuing particular  
16 uses of AZM and phosmet.

17 This case challenges EPA's risk-benefit determination because it was based on a one-  
18 sided view that calculated the economic benefits of continued use to farmers but not the costs to  
19 workers, their families, and communities. This case also challenges the assumptions made in the  
20 economic benefits assessment because they run counter to peer-reviewed scientific articles and  
21 other evidence in the record. The benefits assessment is final. It will not be implicated in the  
22 tolerance assessments made under the FQPA's safety standard, under which such benefits are  
23 irrelevant. Based on the benefits assessment and EPA's consequent risk-benefit calculus, EPA  
24 decided which pesticide uses need to be cancelled, phased out, or allowed subject to required

1 mitigation and label changes. These determinations have governed and will continue to govern  
2 use of AZM and phosmet during the four-year phase-out and time-limited registration period.

3 EPA points to two remaining analysis, but neither renders the issues presented in this  
4 case unfit for review. First, EPA will revisit the AZM and phosmet food tolerances based on the  
5 cumulative risk assessment for organophosphates. The cumulative risk assessment pertains to  
6 FQPA decisions and food safety, not health risks to farm workers. AZM IRED at 61; Phosmet  
7 IRED at 44. EPA's future decision regarding food tolerances for organophosphates will not  
8 revisit the basis for its FIFRA reregistration actions.

9 Second, EPA contends that it will respond to the public comments submitted by plaintiffs  
10 and others on the scientific basis for the assumptions made in the economic benefits assessment.  
11 Motion to Dismiss at 19. By then, of course, it is too late. EPA has already acted on its risk-  
12 benefit determination by issuing the IRED and codifying that determination in its MOAs with the  
13 registrants. Any later consideration of the public comments cannot undo the harm caused to  
14 workers poisoned by AZM or phosmet over the last several years. Moreover, this contention is  
15 not limited to reregistration decisions embodied in IREDs, as opposed to REDs. In fact, EPA  
16 has solicited comments on final REDs where no further decisionmaking steps remain even under  
17 EPA's theory. See, e.g., 67 Fed. Reg. 67,617 (Nov. 6, 2002) (endosulfan); 64 Fed. Reg. 67,902  
18 (Dec. 3, 1999) (captan). Nothing in the FIFRA 1988 amendments envisions a second  
19 reregistration eligibility determination that responds to comments made on the first one. Nor has  
20 EPA identified the time and context in which it would address the comments on the AZM and  
21 phosmet IREDs. The old adage "too little, too late" rings true.

22 Given the real and immediate consequences of EPA's IREDs for AZM and phosmet,  
23 EPA's attempt to draw an analogy to Ohio Forestry falls flat. That case challenged a national  
24

1 forest plan on the ground that it allowed an excessively high amount of clearcut logging.  
2 Because the plan itself did not require or authorize any particular on-the-ground logging activity  
3 to occur, and because the agency would make another challengeable decision before any timber  
4 sale could go forward, the Court held the plan challenge was unripe. Ohio Forestry, 523 U.S. at  
5 733-35.

6 Here the IREDs have produced continued authorizations of harmful uses of AZM and  
7 phosmet. As long as the product label prescribes the mitigation required by the IREDs, the  
8 pesticides may remain on the market, in the fields, and in the bodies of farm workers exposed to  
9 the pesticide in the course of their daily tasks. EPA's reregistration decisions made in the IREDs  
10 will remain in place until superseded by a subsequent reregistration decision, should there be  
11 one, and will continue to have direct and harmful impacts to workers, their children, and their  
12 communities.

13 B. Postponing Judicial Review Would Cause Extreme Hardship.

14 Postponing judicial review would cause hardship to workers exposed to levels of these  
15 pesticides that can cause extremely damaging health effects. EPA's IREDs leave registrations in  
16 place that exposes workers and their children to high levels of risk with only minimal safeguards.  
17 EPA estimated that under the required mitigation measures, workers would be exposed to unsafe  
18 levels of AZM for some uses for up to 22 weeks each spray season. It is hard to imagine a more  
19 serious consequence of an agency action. EPA's IREDs have already exposed workers to these  
20 excessive risks for two full growing seasons and a third season is now upon us.

21 In an attempt to claim hardship from judicial review, EPA argues that judicial review  
22 may make it difficult for EPA to meet its August 31, 2006 statutory deadline for reregistering  
23 food use pesticides. Motion to Dismiss at 15-16. This case challenges how EPA has made its  
24 reregistration decisions for two highly toxic pesticides. Certainly, EPA cannot shield its

1 arbitrary, one-sided determination on worker and ecological risks from judicial review on the  
2 highly speculative ground that the agency would miss a statutory deadline more than two years  
3 in the future.

4         Given the severe risks that AZM and phosmet pose to workers, postponing review would  
5 cause hardship of the most serious kind. Because the issues presented are fit for review and  
6 UFW would suffer hardship from delay, this case is ripe for review.

7 III. UFW HAS EXHAUSTED ALL APPLICABLE ADMINISTRATIVE PROCEDURES.

8         EPA’s claim that UFW has not exhausted administrative remedies is predicated on the  
9 erroneous assertion that UFW is seeking pesticide cancellations. Motion to Dismiss at 17. EPA  
10 goes so far as to assert that: “Plaintiffs are not challenging the continued registrations of AZM  
11 and phosmet.” Motion to Dismiss at 18. Yet that is precisely what UFW is challenging.

12 Amended Complaint for Declaratory and Injunctive Relief ¶¶ 1 & 5. This case challenges EPA’s  
13 erroneous FIFRA risk-benefit determinations, which formed the basis for its decisions to  
14 reregister numerous harmful uses of AZM and phosmet.

15         EPA further mischaracterizes this case when it asserts that deciding this case would place  
16 this Court “in the position of making decisions on complex scientific and/or regulatory matters  
17 without the benefit of EPA’s reasoning on those issues.” *Id.* EPA has made its decision and  
18 supplied its reasoning in the IREDs. This case seeks review of those decisions to reregister  
19 AZM and phosmet uses for violating FIFRA’s statutory mandates and for running counter to  
20 evidence in the record. This type of challenge does not ask the Court to engage in de novo  
21 consideration of scientific issues; instead, it seeks judicial review of administrative actions under  
22 well-established administrative law principles. Motor Vehicle Mfrs. Ass’n. v. State Farm Mutual  
23 Automobile Ins., 463 U.S. 26, 40-41 (1983).

24         Ultimately, UFW asks the Court to direct EPA to conduct a new risk-benefits analysis

1 that takes into account the risks to workers and their families, as well as economic benefits to  
2 farmers, and the scientific studies and data provided to EPA in public comments. While new  
3 reregistration eligibility determinations might lead EPA to conclude that some or all remaining  
4 AZM and phosmet uses are ineligible for reregistration or require greater mitigation, this is a  
5 decision for EPA to make in the first instance, based on an even-handed consideration of the  
6 factual record. 7 U.S.C. §§ 136a(c)(2); 136a(c)(5). In this case, UFW is not petitioning for the  
7 cancellation of any particular use. Instead, it seeks reregistration eligibility decisions that  
8 comply with FIFRA and are in accord with the administrative record.

9 A. FIFRA Provides for District Court Jurisdiction Over This Challenge.

10 FIFRA establishes a system of judicial review in which some actions are reviewed in the  
11 courts of appeals and others in the district court. The courts of appeals hear cases that result in  
12 EPA orders issued after a quasi-judicial administrative hearing before the agency. Subsection  
13 136n(b) grants the courts of appeals exclusive jurisdiction to review “the validity of any order  
14 issued by the Administrator following a public hearing.” 7 U.S.C. § 136n(b).

15 Under section 136n(b), the defining features of appellate review are: (1) EPA’s issuance  
16 of an order (2) following a public hearing in an administrative quasi-judicial proceeding. Courts  
17 have looked to the Administrative Procedure Act, 5 U.S.C. §§ 550 et seq. (“APA”) to define the  
18 term “order” under FIFRA. Environmental Defense Fund v. Costle, 631 F.2d 922, 926 (D.C.  
19 Cir. 1980), cert. denied, 449 U.S. 1112 (1981). Congress contrasted “orders” and “rules” in the  
20 APA. National Mining Ass’n v. Department of Labor, 292 F.3d 849, 856 (D.C. Cir. 2002)  
21 (citation omitted). The APA defines “rule” to mean “the whole or a part of an agency statement  
22 of general or particular applicability and future effect designed to implement, interpret, or  
23 prescribe law or policy,” 5 U.S.C. § 551(4), while “order” is defined as “the whole or a part of a  
24 final disposition . . . of an agency in a matter other than a rule making but including licensing.” 5



1 U.S.C. § 551(6). “Orders” generally result from trial-type proceedings and can have retroactive  
2 effect, while rules are the outcome of notice and comment rulemaking procedures and establish  
3 policies of general, prospective applicability. Georgetown University Hosp. v. Bowen, 821 F.2d  
4 750, 757 (D.C. Cir. 1987), aff’d, 488 U.S. 204 (1988) (citations omitted).

5 While orders resulting from a quasi-judicial proceeding must be reviewed in the courts of  
6 appeals, the district courts have jurisdiction to hear challenges to certain specified and other final  
7 actions undertaken by EPA under FIFRA without a quasi-judicial proceeding before the agency.  
8 Thus, 7 U.S.C. § 136n(a) provides: “Except as otherwise provided in” section 136n, district  
9 courts have the authority under subsection 136n(a) to review “the refusal of [EPA] to cancel or  
10 suspend a registration or to change the classification not following a hearing and other final  
11 actions of the Administrator.”

12 FIFRA’s legislative history confirms Congress’s intent to bifurcate judicial review in this  
13 manner. The Senate Agriculture and Forestry Committee’s description of FIFRA’s judicial  
14 review procedures leaves no room for a contrary interpretation: “In short, the Committee . . .  
15 believes that matters which have not been heard before should go to courts of original  
16 jurisdiction and appeals from cases which have already been administratively heard and decided  
17 should go to appellate courts. The question is really that simple.” S. Rep. No. 92-838, reprinted  
18 in 1972 U.S. Code Cong. & Ad. News 3993, 4070. The Senate Committee further explained:

19 After a hearing judicial review on petition by any person adversely affected is  
20 properly lodged in courts of appeals, since an adequate record exists for such  
21 review. Where, however, the Administrator has determined no substantial  
22 question of safety exists which warrants formal review, and thus has refused to  
23 hold a hearing, review should be by district court since there is no record for the  
24 court of appeals.

1 Id. at 4004.<sup>3</sup>

2 EPA does not contend that the IREDs are orders subject to exclusive judicial review in  
3 the court of appeals. Nor could it make such a claim. The challenged IREDs do not qualify as  
4 “orders” because they have a prospective effect only and they do not result from an  
5 administrative adjudicatory process before the agency. Instead, EPA solicited public comment at  
6 various stages of its reregistration review, borrowing from notice and comment rulemaking  
7 procedures, and reregistration decisions are prospective in nature.

8 B. FIFRA Prescribes No Administrative Procedures That Must Be Exhausted Before  
9 Bringing This Challenge.

10 While UFW’s claims properly arise under 7 U.S.C. § 136n(a), EPA contends that UFW  
11 should be compelled to file a petition for cancellation of AZM and phosmet uses. Motion to  
12 Dismiss at 17-18. The fatal defect in EPA’s exhaustion argument is that nothing in FIFRA  
13 compels UFW to petition for cancellation when it is challenging EPA’s decision to reregister  
14 AZM and phosmet uses. To the contrary, 7 U.S.C. § 136n(a) authorizes district court review of  
15 “other final actions,” like reregistrations of pesticide uses, without any administrative exhaustion  
16 prerequisites. As the Supreme Court has held, a jurisdictional exhaustion obligation must be  
17 “clearly required” in the statute. McCarthy v. Madigan, 503 U.S. 140, 144, 149-50 (1992).

18 The petition that EPA urges UFW to file would amount to little more than a make-work  
19 exercise, delaying litigation of the flaws in EPA’s reregistration decisions. In the IREDs, EPA  
20 decided which uses will be reregistered and which must be cancelled. The former decision leads  
21 to no further administrative review procedures, while the latter could lead to a cancellation

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22 <sup>3</sup> While it is true that Congress rejected a provision that would have authorized citizen suits to  
23 enforce FIFRA, the provision would have allowed citizens to sue registrants and others who  
24 violated FIFRA, not EPA for failing to comply with its statutory duties in implementing FIFRA.  
Id. at 4023, 4060-61. Such lawsuits against EPA fall under the FIFRA’s judicial review  
provisions that found their way into the law and remain there.

1 proceeding if the registrant did not acquiesce in EPA's announced determination.

2 FIFRA expressly authorizes district court review of "other final actions" that do not  
3 involve issuance of an order following a public hearing. UFW should not be required to ask  
4 EPA to make the same decision again in order to challenge illegalities inherent in EPA's  
5 underlying data and analysis. If the IREDs had determined that certain uses must be cancelled,  
6 the registrant had failed to cancel those uses voluntarily, and EPA had not initiated cancellation  
7 proceedings, UFW could have petitioned EPA to cancel those uses. However, that is a very  
8 different case. Such a case would seek to implement EPA's decision to cancel particular uses,  
9 rather than challenge its decision to retain registrations for other uses.

10 In sum, because EPA made final reregistration decisions in the IREDs, and these  
11 decisions have led to the continuation of AZM and phosmet uses that harm workers for more  
12 than two years and they will continue to authorize those uses for at least another 1-2 years, the  
13 challenged action is final, this case is ripe, and UFW can proceed to Court without initiating new  
14 petitions seeking a different action than what they are challenging here.

15 IV. UFW'S THIRD CAUSE OF ACTION CHALLENGING EPA'S FAILURE TO MAKE  
16 INDUSTRY-GENERATED EXPOSURE DATA AVAILABLE FOR COMMENT  
17 STATES A CLAIM AND IS APPROPRIATE FOR REVIEW WITHOUT FURTHER  
18 REQUESTS FOR ACCESS TO THE DATA.

18 UFW's third cause of action challenges EPA's failure to make available to the public  
19 industry-generated exposure data used in the IREDs. More specifically, the amended complaint  
20 alleges at ¶ 88:

21 EPA's assessment of occupational re-entry worker risks and re-registration  
22 decisions for azinphos-methyl and phosmet used data produced by the  
23 Agricultural Re-entry Task Force without making that data available to the  
24 general public. When members of the public had opportunities to comment on  
EPA's risk assessments and the interim re-registration eligibility decision, they  
lacked sufficient information to submit fully informed comments on the worker  
exposure data and underlying methods.

1 Moreover, the amended complaint alleges at ¶¶ 80-93 that this failure to make the exposure data  
2 available to the public violates EPA's duty under FIFRA, 7 U.S.C. § 136a(c)(2)(A), to make data  
3 supporting a registration available to the public within 30 days after the registration, and under  
4 FIFRA, 7 U.S.C. § 136h, to make data concerning the effects of a pesticide on human health  
5 available for public disclosure.

6 In its motion to dismiss, EPA contends that this claim must fail on the (erroneous) ground  
7 that UFW never requested access to the data under 40 C.F.R. § 152.119. UFW is submitting the  
8 Declaration of Shelley Davis ¶¶ 1, 3 (May 20, 2004), who made requests for such data on behalf  
9 of UFW. In response, EPA provided some documents related to a peer review of the industry-  
10 generated data. *Id.* ¶ 2. However, over two years after publishing the IREDs and more than one  
11 year after Ms. Davis' first request, EPA has still not provided the industry-generated data.

12 The Davis Declaration substantiates EPA's failure to provide the industry-generated  
13 exposure data – despite requests for such data – in violation of FIFRA's requirements. To the  
14 extent that EPA's regulations can be read to establish an exhaustion requirement, UFW has more  
15 than satisfied any such prerequisites. The regulation cited by EPA refers to 40 C.F.R. part 2 for  
16 the procedures to access “data on which the Agency based its decision to register” a pesticide  
17 product. *See* 40 C.F.R. § 152.119(c). As required under 40 C.F.R. § 2.102(a), Ms. Davis  
18 submitted a written request to EPA for the exposure data used by EPA in the AZM and phosmet  
19 IREDs. Exhibit 1 to Davis Decl. While EPA supplied some initial information, the agency  
20 failed to supply the remainder of the requested information, despite Ms. Davis's subsequent  
21 request for such information. Davis Decl. ¶ 3.

22 Stripped of its erroneous exhaustion claim, EPA's motion essentially asserts that UFW  
23 cannot state a claim upon which relief may be granted. Having made requests for the data and  
24

1 having failed to receive the data, particularly in time to submit meaningful comments informed  
2 by the underlying data, UFW more than states a viable claim for violations of FIFRA's data  
3 disclosure mandates.<sup>4</sup>

4 CONCLUSION

5 For these reasons, EPA's motion to dismiss should be denied and EPA should be ordered  
6 to file and serve the administrative record within ten days of such dismissal, as provided in Fed.  
7 R. Civ. P. 12(a)(4)(A).

8 Respectfully submitted this 24<sup>th</sup> day of May, 2004.

9  
10 /s/ Grant Cope

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23 \_\_\_\_\_  
24 <sup>4</sup> To further substantiate its standing, UFW is submitting the Declarations of Jay Feldman,  
Arnulfo Lopez, Erik Nicholson, Ramon Ramirez, and Rogelio Riojas.

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CERTIFICATE OF SERVICE

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

On May 24, 2004, I served a true and correct copy of:

- 1. Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss;
- 2. Declaration of Jay Feldman;
- 3. Declaration of Arnulfo Lopez;
- 4. Declaration of Erik Nicholson;
- 5. Declaration of Ramon Ramirez;
- 6. Declaration of Rogelio Riojas;
- 7. Declaration of Shelley Davis.

on the following parties:

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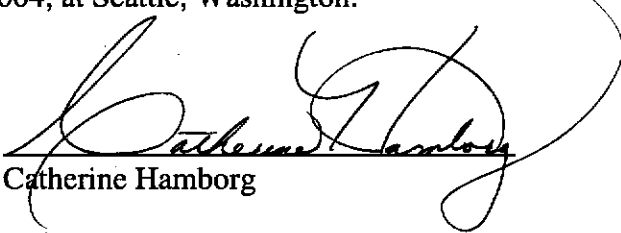
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I, Catherine Hamborg, declare under penalty of perjury that the foregoing is true and correct. Executed on this 24<sup>th</sup> day of May, 2004, at Seattle, Washington.

  
Catherine Hamborg

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