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

3 UNITED FARM WORKERS OF AMERICA, ) Civ. No. CV04-0099-RSM  
4 AFL-CIO; SEA MAR COMMUNITY )  
5 HEALTH CENTER; PINEROS Y )  
6 CAMPEÑINOS UNIDOS DEL NOROESTE ) THIRD AMENDED COMPLAINT FOR  
7 (“PCUN”); BEYOND PESTICIDES, FRENTE ) DECLARATORY AND INJUNCTIVE  
8 INDIGENA OAXAQUENO BINACIONAL ) RELIEF  
9 (“FRENTE INDIGENA”), and ARNULFO )  
10 LOPEZ, )  
11 )  
12 Plaintiffs, )  
13 )  
14 v. )  
15 )  
16 ADMINISTRATOR, U.S. )  
17 ENVIRONMENTAL PROTECTION )  
18 AGENCY, )  
19 )  
20 Defendant, )  
21 )  
22 and )  
23 )  
24 GOWAN COMPANY, MAKHTESHIM )  
25 AGAN of NORTH AMERICA, INC, and )  
26 BAYER CROPSCIENCE LP, )  
27 )  
28 Defendant-Intervenors. )  
29 )  
30 )

31 INTRODUCTION

32 1. This case challenges re-registration determinations made by defendant  
33 Administrator of the Environmental Protection Agency (“EPA”) under the Federal Insecticide,  
34 Fungicide and Rodenticide Act (“FIFRA”) for azinphos-methyl, phosmet, and chlorpyrifos, three  
35 insecticides that pose extensive risks to workers, bystanders, and the environment. EPA  
36 determined that many uses of these pesticides pose risks of concern to workers and the  
37 environment, but it authorized continuation of these harmful uses based on a flawed risk-benefit  
38 analysis, without considering all relevant factors, and contrary to evidence in the record.

1           2.       Plaintiffs ask the Court to declare that EPA acted arbitrarily, capriciously, and  
2 contrary to FIFRA in re-registering uses of azinphos-methyl (“AZM”), phosmet, and  
3 chlorpyrifos that pose risks of concern to workers and the environment based on a flawed risk-  
4 benefit analysis, without considering all relevant factors, and contrary to evidence in the record.  
5 Plaintiffs ask the Court to enjoin EPA to make new re-registration determinations on an  
6 expeditious basis for AZM, phosmet, and chlorpyrifos based on a full assessment of all relevant  
7 factors and evidence, including the human and societal costs of exposing workers and the  
8 environment to risks that exceed EPA’s established level of worker and environmental  
9 protection.

#### 10   PARTIES

11           3.       Plaintiff United Farm Workers of America (“UFW”), the nation’s leading farm  
12 worker membership organization, is based in California and has more than 27,000 members in  
13 Washington, Oregon, California and other states located across the nation. UFW works to  
14 protect the health and safety of farm workers from occupational injuries, including injuries caused  
15 by exposure to pesticides. UFW members have been and will continue to be injured when they  
16 mix, load, and apply pesticides, including AZM, phosmet, and chlorpyrifos, to crops; prune, thin  
17 or harvest crops that contain residues from such pesticides; or work or live in areas where these  
18 pesticides drift and settle.

19           4.       Plaintiff Sea Mar Community Health Center (“Sea Mar”), headquartered in  
20 Seattle, Washington, is dedicated to caring for the medically underserved Latino population in  
21 the Washington State towns and cities of Seattle, Bellingham, Bonney Lake, Des Moines,  
22 Everett, Everson, Marysville, Mt. Vernon, Olympia, Tacoma, and Vancouver. Sea Mar provides  
23 comprehensive medical services, including general medical treatment, laboratory services, adult  
24 medicine, health education, social work, mental health counseling, and ambulatory care. Sea

1 Mar serves approximately 75,000 individuals each year. Many of Sea Mar's patients are migrant  
2 and seasonal farm workers who work in crops that are treated with AZM, phosmet, and  
3 chlorpyrifos, including apples, pears, and cherries. Sea Mar clinicians have treated patients that  
4 manifest signs and symptoms of organophosphate pesticide poisonings, including headaches,  
5 vomiting, disorientation, abdominal cramps, spasms, and neurobehavioral impairments.

6 5. Plaintiff Pineros y Campesinos Unidos del Noroeste (Northwest Treeplanters and  
7 Farmworkers United, or "PCUN"), is based in Woodburn, Oregon, and is the state's only union  
8 of farm workers, nursery, and reforestation workers. PCUN's mission is to establish better  
9 working and living conditions for its members. PCUN's members are exposed to AZM,  
10 phosmet, and chlorpyrifos when they prune, thin, or harvest crops such as apples and pears on  
11 which these pesticides are applied, and/or when they are in or around their homes located  
12 throughout Oregon in areas where these pesticides drift following application. PCUN's  
13 members have been and will continue to be injured by such exposures.

14 6. Beyond Pesticides is a nonprofit organization, based in Washington, D.C., that  
15 serves a nationwide network of more than 1,000 individual and organizational members by  
16 working to reduce threats to human health and environmental quality from the use of dangerous  
17 pesticides. Beyond Pesticides' primary goal is to assist and advocate for the safe use of  
18 pesticides and to reduce or end the use of dangerous pesticides. Pesticides, including AZM,  
19 phosmet, and chlorpyrifos, drift and settle in areas where members of Beyond Pesticides live and  
20 work. Beyond Pesticides members are also injured by the loss of beneficial insects, such as bees,  
21 following application of AZM, phosmet, and chlorpyrifos.

22 7. Plaintiff Frente Indigena Oaxaqueno Binacional ("FIOB") is a coalition of  
23 individuals, communities, and organizations of indigenous origin (from the Mixtec, Zapotec, and  
24

1 Triqui regions of the Mexican state of Oaxaca). Headquartered in Fresno, California, it has  
2 approximately 10,000 members working and residing in Oregon, Washington, and the Mexican  
3 states of Oaxaca and Baja California Norte. The FIOB works to promote and defend the human,  
4 labor, and civil rights of the indigenous peoples of Oaxaca, and to promote the economic, social,  
5 and cultural development of indigenous communities in both the United States and Mexico.  
6 Nearly all of FIOB's members are migrant and seasonal farm workers, and many are exposed to  
7 AZM, phosmet, and chlorpyrifos through their work on crops that are treated with these  
8 pesticides.

9 8. Plaintiff Arnulfo Lopez ("Mr. Lopez") is a migrant farm worker who has  
10 supported himself and his family since 1982 by working in fields and orchards in California,  
11 Oregon, and Idaho. Mr. Lopez has worked primarily on several major crops, including  
12 strawberries, blueberries, blackberries, almonds, raisin grapes, and potatoes. Mr. Lopez has  
13 worked in and around fields treated with AZM. Additionally, Mr. Lopez has applied other  
14 pesticides to control rodents while working in almond orchards in Fresno County, California.

15 9. Defendant Administrator of the U.S. Environmental Protection Agency ("EPA")  
16 is the Administrator of EPA, which is a federal agency. The Administrator and EPA are charged  
17 with registering pesticides under FIFRA and with ensuring that the pesticide uses EPA  
18 authorizes will not have unreasonable adverse effects on the environment, including on human  
19 health and on threatened and endangered species and their habitat. FIFRA, 7 U.S.C. §§ 136-  
20 136y.

## 21 JURISDICTION

22 10. This Court has jurisdiction pursuant to 7 U.S.C. § 136n(a) and 28 U.S.C. § 1331.

## 23 VENUE

24 11. Venue lies in this judicial district under 28 U.S.C. § 1391(e) because plaintiff Sea

1 Mar resides in this district.

2 I. STATUTORY FRAMEWORK FOR REGISTERING PESTICIDES

3 A. FIFRA's Registration Standards Governing Pesticide Use

4 12. FIFRA establishes a registration scheme for pesticides. Under FIFRA, a pesticide  
5 may generally not be sold or used in the United States unless it has an EPA registration for  
6 specified uses. 7 U.S.C. § 136a(a).

7 13. Under FIFRA, the Administrator “shall register a pesticide if the Administrator  
8 determines that, . . .

- 9 (A) its composition is such as to warrant the proposed claims for it;  
10 (B) its labeling and other material required to be submitted comply with the  
11 requirements of this Act;  
12 (C) it will perform its intended function without unreasonable adverse effects  
13 on the environment; and  
14 (D) when used in accordance with widespread and commonly recognized  
15 practice it will not generally cause unreasonable adverse effects on the  
16 environment.”

17 7 U.S.C. § 136a(c)(5).

18 14. FIFRA defines “unreasonable adverse effects on the environment” to mean “any  
19 unreasonable risk to man or the environment, taking into account the economic, social, and  
20 environmental costs and benefits of the use of any pesticide . . . .” 7 U.S.C. § 136(bb).

21 15. The culmination of the registration process is EPA’s approval of both a  
22 registration and a label for the particular pesticide use. FIFRA makes it unlawful to use a  
23 pesticide in a manner inconsistent with the label, id. § 136j(2)(G), or to make any claims that  
24 differ substantially from the label, id. § 136j(1)(B).

25 16. FIFRA also makes it unlawful to sell or distribute a misbranded pesticide. Id.  
26 § 136j(1)(E)-(F). A pesticide is misbranded if its label fails to contain warnings, cautionary  
statements, or directions necessary to protect public health and the environment. 7 U.S.C.

1 § 136(q)(F)-(G).

2 17. In making a re-registration determination, the Administrator must make the  
3 FIFRA-prescribed findings for a registration, namely, that when used in accordance with  
4 widespread and commonly recognized practice, the pesticide will not generally cause  
5 unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5).

6 18. The EPA Administrator has the authority to cancel pesticide registrations  
7 whenever “a pesticide or its labeling or other material required to be submitted does not comply  
8 with the provisions of this Act or, when used in accordance with widespread and commonly  
9 recognized practice, generally causes unreasonable adverse effects on the environment.”  
10 7 U.S.C. § 136d(b). The Administrator may immediately suspend a pesticide registration to  
11 prevent an imminent hazard. Id. § 136d(c). An announcement by the Administrator of an intent  
12 to cancel a pesticide use often results in the registrant’s voluntary cancellation of, or agreement  
13 to further constraints upon, that use.

14 B. The Inter-Related Standards Governing Pesticide Residues in Food

15 19. While FIFRA regulates pesticide use, the Federal Food Drug and Cosmetic Act  
16 (“FFDCA”) regulates consumer exposure to pesticide residues through food, drinking water, and  
17 all other non-occupational, aggregate sources of exposure. Under the FFDCA, EPA establishes  
18 tolerances that authorize and place limits on the amount of pesticide residues lawfully permitted  
19 on foods. 21 U.S.C. § 346a. The EPA Administrator must ensure that tolerances are set at levels  
20 that are “safe.” Id. EPA may not issue a pesticide registration for a food use unless it has  
21 established a tolerance for that use. 21 U.S.C. § 346a(a)(1); 40 C.F.R. § 152.112(g); see also 7  
22 U.S.C. § 136(bb) (defining “unreasonable adverse effects on the environment” to include “a  
23 human dietary risk from residues that result from a use of a pesticide in or on any food  
24 inconsistent with the standard under section 408 of the [FQPA].”). Any pesticide chemical

1 residue in or on food is deemed unsafe unless a tolerance or exemption is in effect and the  
2 residue is in compliance with that tolerance or exemption. If a pesticide is used on more than  
3 one food crop, a separate tolerance must be established for each crop.

4 20. The Food Quality Protection Act (“FQPA”) of 1996, Pub. L. No. 104-170, 110  
5 Stat. 1489 (1996), substantially amended FIFRA and the FFDCA in 1996 by mandating that  
6 health-based and child-protective standards drive decisions about acceptable levels of pesticide  
7 residues in the food supply and the environment. EPA was required to re-register pesticides and  
8 re-assess tolerances according to a statutory schedule that gave priority to certain pesticide uses,  
9 including food uses and crops where worker exposure is most likely to occur. 7 U.S.C. § 136a-1;  
10 21 U.S.C. § 346a(q). EPA included organophosphate pesticides in the first group of pesticides  
11 slated for re-assessment because organophosphates are among the pesticides that “pose the  
12 greatest risk to public health.” 65 Fed. Reg. 42,021 (Aug. 4, 1997). After EPA missed deadlines  
13 for re-assessing tolerances for organophosphates and other priority pesticides, the Natural  
14 Resources Defense Council sued the agency. In 2001, NRDC and EPA settled the case in a  
15 partial consent decree and settlement agreement that established a schedule for further pesticide  
16 safety reviews. NRDC v. Whitman, No. 99-3701 WHA, 2001 WL 1221774 (N.D. Cal. Sept. 24,  
17 2001) (order approving consent decree).

18 21. The FFDCA established an August 3, 2006, deadline for tolerance re-assessments,  
19 21 U.S.C. § 346a(q)(1)(C), and FIFRA required re-registration eligibility determinations  
20 (“REDS”) for food use pesticides by that same date, 7 U.S.C. § 136-1a-1(g)(2)(A). Accordingly,  
21 EPA was required to make a determination as to eligibility for re-registration for all food use  
22 pesticides by August 3, 2006. Id.

23 C. EPA’s Process and Standards Governing Risks to Workers and the Environment.

24 22. To comply with the deadlines for re-registering pesticides, EPA issued interim re-



1 registration eligibility decisions (“IREDs”) for various organophosphates, including IREDS  
2 issued for AZM, phosmet, and chlorpyrifos in late 2001. The IREDS concluded EPA’s  
3 assessment of the worker and ecological risks associated with use of the pesticides. The IREDS  
4 were called “interim” because EPA still had to complete a cumulative risk assessment for all  
5 organophosphates and make appropriate adjustments in order to comply with the FQPA. In July  
6 2006, EPA issued a cumulative risk assessment for organophosphates for public comment, and  
7 EPA did not propose to make changes to the IREDS for AZM, phosmet, and chlorpyrifos IREDS  
8 based on that assessment.

9         23. As part of the re-registration process, EPA conducts human health risk  
10 assessments by evaluating human risks from pesticides through such exposure routes as diet,  
11 drinking water, and occupational activities. In its human health risk assessments, EPA first  
12 determines the dose in scientific studies that caused no observed adverse effects, known as the  
13 No Observed Adverse Effect Level (“NOAEL”). It then assesses how close occupational  
14 exposures will come to the NOAEL, which it calls the Margin of Exposure (“MOE”). EPA takes  
15 the position that MOEs greater than 100 generally do not exceed the EPA’s risks of concern, but  
16 MOEs less than 100 pose risks of concern to workers. The tenfold interspecies safety factor  
17 accounts for the uncertainties inherent in extrapolating from animal studies to humans. The  
18 tenfold intraspecies safety factor accounts for the varying sensitivities to pesticide exposures  
19 among individual human beings. The lower the MOE, the greater the risk to workers.

20         24. EPA also prepares an ecological risk assessment that establishes levels of concern  
21 for test species based on registrant-studies assessing lethal toxicity. EPA estimates the  
22 environmental concentrations of the pesticides likely to reach the test species’ habitat under the  
23 authorized uses. Estimated environmental concentrations that exceed doses that cause lethal  
24

1 effects are deemed “levels of concern.” EPA uses a safety factor to capture potential sublethal  
2 effects to test species. In its ecological risk assessments, EPA identifies risks of concern to such  
3 species as fish, birds, and mammals. EPA may require mitigation for such risks in an IRED. If  
4 ecological risks of concern persist, EPA cannot register the pesticide use unless it finds that the  
5 pesticides’ benefits outweigh these risks. EPA must also ensure that its pesticide registrations  
6 protect threatened and endangered species in keeping with the Endangered Species Act,  
7 16 U.S.C. §§ 1531-1544.

8 25. When occupational exposures reach EPA’s risk level of concern of an MOE of  
9 less than 100, the agency requires the adoption of mitigation measures, beginning with increased  
10 personal protective clothing and escalating to engineering controls, such as “closed” pesticide  
11 mixing and loading and application systems in which farm workers who mix and load pesticides  
12 have little or no contact with the chemicals. If these protective measures fail to produce an  
13 acceptable MOE, EPA finds that the pesticide use poses risks that it has called “unacceptable” or  
14 “risks of concern.” Under FIFRA, EPA cannot register pesticides for uses that pose such risks  
15 unless the pesticides’ benefits outweigh the worker and other risks posed by the use. 7 U.S.C. §  
16 136a(c)(5)(C)-(D).

## 17 II. EPA’S RE-REGISTRATION DECISIONS FOR AZM, PHOSMET, AND 18 CHLORPYRIFOS

19 26. The three pesticides at issue – AZM, phosmet, and chlorpyrifos – are  
20 organophosphate insecticides. Organophosphate insecticides were derived from nerve gas used  
21 in World War I. They are acutely toxic and cause systemic illnesses to workers by lowering the  
22 level of cholinesterase, an enzyme in the blood. They poison the nervous system by inhibiting  
23 the breakdown of the neurotransmitter acetylcholine. Most poisonings and deaths of  
24 farmworkers have been attributed to cholinesterase-inhibiting chemicals.

1           27.     Just a few drops of organophosphates can cause harmful effects. Symptoms  
2 include muscle spasms, confusion, dizziness, loss of consciousness, seizures, abdominal cramps,  
3 vomiting, diarrhea, cessation of breathing, paralysis, and death. Acute poisonings can cause  
4 chronic (long-term) effects, such as permanent nerve damage, loss of intellectual functions, and  
5 neurobehavioral effects.

6           28.     EPA found that each of these pesticides poses risks of concern to workers and the  
7 environment from various uses. It identified mitigation that could reduce and in some cases  
8 eliminate the risks of concern. It nonetheless re-registered the uses without imposing the  
9 mitigation based on the registrants' and/or growers' costs or resistance to such measures.

10           A.     AZM

11           29.     EPA first registered AZM for use in the United States in 1959. Prior to the 2001  
12 IRED, approximately two million pounds of AZM were applied each year to fruit, nut, and  
13 vegetable crops to control a variety of pests. AZM continues to be used on apples, pears, and  
14 other labor-intensive crops. For example, AZM is used extensively in Washington State on  
15 apples to control codling moths. Given the widespread use of AZM on labor-intensive crops,  
16 workers are frequently exposed to this chemical.

17           30.     AZM is acutely toxic at relatively low oral and dermal doses. Like other  
18 organophosphates, it inhibits production of cholinesterase, an enzyme that is essential for normal  
19 neurological functions.

20           31.     AZM is among the registered pesticides responsible for the largest number of  
21 farm worker poisonings. Poisoning incident data from California, which has the most  
22 comprehensive human incident data, confirm that workers have been subjected to a significant  
23 incidence of poisonings from this chemical. In the early 1990s, EPA reviewed poisoning  
24 incident data and determined that farm worker risks from AZM are excessive and in need of

1 mitigation. In 1998, the California Department of Pesticide Regulation adopted emergency  
2 regulations to protect farm workers exposed to AZM on tree crops and grapes. The required  
3 mitigation included extended periods during which treated fields could not be entered, reduced  
4 application rates, additional protective equipment, some closed mixing and loading systems, and  
5 some deleted uses. EPA worked with the registrant to extend the mitigation nationwide and to  
6 other uses. Despite EPA's past efforts to reduce some human exposure to AZM, this pesticide  
7 still poses excessive health risks to farm workers.

8 32. The National Institute for Occupational Safety and Health ("NIOSH") has  
9 published a guideline for industrial worker exposure to AZM, which recommends that workers  
10 be tested to establish baseline cholinesterase levels and that they be removed from exposure  
11 when their red blood cell cholinesterase levels drop by 40%. AZM IRED at 26. The California  
12 Environmental Protection Agency requires testing of pesticide handlers (i.e., workers who mix,  
13 load or apply pesticides) exposed to cholinesterase-inhibiting pesticides and removal of workers  
14 from exposure when their blood levels drop to certain levels. AZM IRED at 26-27.

15 33. In 2004, Washington state began implementing a similar medical monitoring  
16 program for pesticide handlers who mix, load or apply organophosphate or carbamate pesticides  
17 50 or more hours per month. In 2005, the medical monitoring extended to workers who handled  
18 the pesticides for 30 hours or more per month. AZM and chlorpyrifos were two of the four  
19 pesticides most frequently handled in cases where cholinesterase depression occurred in both  
20 years. Phosmet was among the top four pesticides used where depressions occurred in 2004.  
21 Because the monitoring requirements apply only when a worker has handled pesticides for a  
22 significant amount of time over a month, most workers are exposed to multiple pesticides and  
23 cannot pinpoint a single pesticide as the cause of the cholinesterase depression. The Washington  
24

1 medical monitoring does not capture cholinesterase depression triggered by a single exposure.

2 1. *EPA's 2001 IRED for AZM*

3 34. Workers are exposed to AZM through mixing, loading, and applying the pesticide  
4 as well as through re-entering treated sites. AZM IRED at 22.

5 35. EPA assessed both short-term (seven day) and intermediate-term (one week to  
6 several months) risks for mixing, loading, and applying AZM. Id. at 28-36. All but three  
7 exposure scenarios posed risks of concern because they would result in MOEs less than 100. Id.  
8 at 36. These estimates do not account for cumulative exposures when the same individual is  
9 engaged in multiple tasks, such as mixing and application of the pesticide. EPA concluded that:

10 Even after factoring in exposure reductions provided by closed mixing and  
11 loading systems, closed cab application equipment, and all feasible personal  
12 protective equipment, safety margins (margins of exposure or MOEs) still fall  
well below the target of 100 for the majority of pesticide handler exposure  
scenarios considered.

13 Id. at vii (risks to workers who mix, load, and apply AZM).

14 36. EPA also assessed post-application risks to workers who re-enter treated sites to  
15 perform tasks such as irrigating, hand-thinning, and harvesting. EPA determined the MOEs for  
16 various re-entry activities based on current label restricted entry intervals (“REIs”) and pre-  
17 harvest intervals (“PHIs”). An REI is the amount of time a worker must wait after the  
18 application of a pesticide before entering the treated field to conduct non-harvest activities, such  
19 as pruning or thinning. For harvesting activities, a PHI is the length of time a worker must wait  
20 to harvest a crop after a pesticide application. EPA also calculated the REIs and PHIs required  
21 for the MOEs to reach 100. EPA found that “the risks to re-entry workers are above the level of  
22 concern for all assessed activities in all the crops where azinphos-methyl is used.” AZM IRED  
23 at 42 (meaning that MOEs are less than 100 and exceed EPA’s level of concern). For example,  
24 the MOE for hand harvesting apples was 2 and would not reach an MOE of 100 until 102 days

1 after application.

2 Risk to field workers who reenter azinphos-methyl treated sites to harvest, thin,  
3 prune and perform other post-application activities is of particular concern.  
4 MOEs for many of these workers are less than 10 for critical activities. Even  
5 taking into account the additional margins of safety afforded by using a very  
6 protective endpoint, MOEs for many reentry workers are less than 30, where the  
7 target MOE is 100.

8 Id. at vii-viii, xx.

9 37. When EPA found unacceptable risks to human health from uses of AZM, it  
10 prepared benefits assessments for those uses. The benefits assessments are intended to form the  
11 basis for EPA's determination whether the benefits from continued use of the pesticide outweigh  
12 the risks the pesticide poses to workers, consumers, and the environment.

13 38. EPA has no policy defining and governing the preparation of benefits  
14 assessments. In preparing the AZM and phosmet benefits assessments, EPA solicited  
15 information on an ad hoc basis from growers and extension agents. EPA did not review  
16 pertinent scientific literature and data. Nor did it consider viable organic methods of controlling  
17 pests. EPA solicited public comment on its benefits assessments in the fall of 2001. Plaintiff  
18 Beyond Pesticides and others submitted comments and scientific studies, which substantiated the  
19 viability of alternative pest control methods, presented evidence of economic costs from these  
20 pesticide uses omitted from EPA's benefits assessments, and called into question many of EPA's  
21 assumptions. Prior to the January 2006 settlement in this case, EPA had never responded to  
22 these public comments nor had it modified its benefits assessments to incorporate the scientific  
23 or other evidence provided in the comments.

24 39. EPA prepared a combined benefits assessment covering use of both AZM and  
25 phosmet on apples, the dominant use of these pesticides. This benefits assessment focused  
26 exclusively on the possible crop production repercussions of various strategies for mitigating

1 post-application worker risks. It did not address mitigation directed at pesticide handlers or  
2 environmental risks.

3 40. Even as to the worker risks that it addressed, the apple benefits assessment looked  
4 solely at the effects of the mitigation scenarios on crop production, omitting entirely any  
5 assessment of the individual and societal costs of allowing workers to be exposed to what EPA  
6 has deemed to be unacceptable risks. The benefits assessment is one-sided, quantifying the  
7 economic consequences to growers who would be unable to use the pesticides at current levels  
8 but failing to account for the costs of the harm to workers, their children, water quality, or  
9 endangered species. EPA prepared similar one-sided benefits assessments for other AZM and  
10 phosmet uses that posed post-application risks of concern to workers.

11 41. In its IRED for AZM, EPA made the following determination:

12 Taking into account both the risks and benefits of azinphos-methyl use, the  
13 Agency has determined that all uses of azinphos-methyl are ineligible for  
reregistration based on their currently approved labeling.

14 AZM IRED Cover Letter at 3.

15 42. EPA divided the AZM uses that posed post-application worker risks of concern  
16 into three categories based on EPA's benefits assessments. First, EPA proposed the immediate  
17 cancellation of 28 uses that have little use and/or low benefits. Second, EPA determined that the  
18 benefits did not outweigh the risks posed by seven uses that it found have moderately high  
19 benefits. However, EPA decided to allow a four-year phase-out of these uses to facilitate an  
20 orderly transition to alternative pest control products, provided certain mitigation measures are  
21 implemented. For these first two categories combined, EPA found: "Of the currently registered  
22 uses of azinphos-methyl, the Agency has determined that 35 are not eligible for reregistration  
23 based on risk concerns for workers and the environment." AZM IRED at 71. Third, EPA  
24

1 decided that eight uses that it found had significant grower benefits are eligible for a time-limited  
2 four-year re-registration, provided certain mitigation measures are implemented. These re-  
3 registrations would expire at the end of October 2005, unless EPA granted an extension.

4 43. For the phased-out and time-limited uses, interim mitigation to address ecological  
5 and worker risks includes eliminating or restricting aerial applications on many sites, reducing  
6 the rate and number of applications per season, extending REIs and PHIs, and requiring the  
7 maximum personal protective clothing. AZM IRED at 67. EPA did not require closed cabs or  
8 closed mixing and loading systems for mixing, loading, and applying AZM, even though MOEs  
9 for open cab and open mixing and loading scenarios were less than 20 for many re-registered  
10 uses.

11 44. In May 2002, EPA entered into a Memorandum of Agreement with registrants of  
12 AZM products, which provides for the immediate, voluntary cancellation of uses of AZM on 23  
13 crops, the amendment of labels to impose additional restrictions, and the cancellation of seven  
14 crop uses in 2005. Under the agreement, the time-limited registration of AZM for ten continued  
15 crop uses, representing approximately one million pounds or more in annual usage, will expire  
16 on October 31, 2005, unless the registrants submit further data and EPA extends the  
17 registrations. In the AZM agreement, EPA reversed its IRED decision to phase out uses on  
18 almonds, walnuts, and pistachios over four years, by making these uses eligible for a four-year  
19 re-registration that can be renewed. In July 2004, the registrants submitted applications to extend  
20 the time-limited registrations for the ten uses.

21 2. *EPA's 2006 Decision to Phase-Out AZM Over Six Years*

22 45. In January 2004, plaintiffs filed this lawsuit challenging the AZM and phosmet  
23 IREDs. In February 2005, this Court denied defendant EPA's motion to dismiss on jurisdictional  
24 grounds. After EPA certified and supplemented the administrative records for the two IREDs,



1 plaintiffs filed a motion for summary judgment in July 2005.

2 46. Plaintiffs and EPA entered into a Settlement Agreement, finalized in January  
3 2006, in which EPA committed to propose publicly its decision with respect to extending AZM  
4 and phosmet registrations for the remaining uses and to consider new comments as well as the  
5 comments and scientific evidence previously submitted by plaintiffs and others in making final  
6 decisions for these two pesticides. The Settlement Agreement established deadlines for EPA's  
7 proposed and final re-registration determinations for AZM and phosmet. EPA repeatedly missed  
8 these deadlines, forcing the parties to renegotiate the timetable for the required determinations.

9 47. In December 2005, EPA released revised worker and ecological risk assessments  
10 and grower impact assessments for the remaining AZM uses. The revised worker risk  
11 assessment found that "MOEs for mixer/loader/applicators using open cab airblast exceed EPA's  
12 level of concern." Revised Occupational Exposure and Risk Assessment for AZM at 20 (June 6,  
13 2006). Several of the remaining uses exceed EPA's level of concern even using closed cab  
14 airblast equipment. Id. For apples, pears, and nuts, the MOEs are less than 20 for open cab  
15 airblast applications. Id. at 21 (MOE of 18 for apples, pears, and crabapples; 14 for almonds,  
16 pistachios, and walnuts). Except for some application methods using maximum engineering  
17 controls, all ten remaining AZM uses posed risks of concern to mixers, handlers, and applicators.  
18 Id. With the exception of the nut crops, the remaining AZM uses pose risks of concern to post-  
19 applications workers. Id. at 28. For apple and pear harvesting, the MOE is as low as 7 at the  
20 current REI of 14 days, and it would take 44-103 days to bring the MOE to acceptable levels. Id.

21 48. EPA prepared revised grower impact assessments for the remaining AZM uses.  
22 These assessments reviewed the respective costs, yields, and crop quality using AZM and  
23 various pest control alternatives. Even for apples, the largest AZM use, EPA concluded that the  
24

1 overall impact on grower revenue would be relatively small. The costs of shifting to alternatives  
2 were a fraction of the costs predicted in the 2001 benefits assessment. With minimal costs,  
3 growers could shift to less toxic alternatives that would result in little or no loss in yield or  
4 quality. EPA refused to consider an alternative scenario that depended on organic pest control  
5 methods, despite recognizing the premium that organic fruit commands and the growing organic  
6 market.

7 49. EPA's revised ecological risk assessment documented risks of concern to both  
8 aquatic and terrestrial wildlife taking into account the mitigation imposed in the 2001 IRED.  
9 AZM is very highly toxic to fish, birds, mammals, and beneficial insects, such as honey bees,  
10 and the estimated environmental exposures from all remaining AZM uses exceed known toxicity  
11 thresholds for these species. Five water bodies are violating water quality standards due to AZM  
12 contamination. Recent U.S. Geological Survey monitoring detected AZM concentrations in 14  
13 watersheds that exceed levels of concern for aquatic species. AZM has been linked to numerous  
14 fish and honey bee kills. In response to a lawsuit compelling EPA to evaluate AZM's effects on  
15 threatened and endangered salmon and steelhead, EPA found that AZM is likely to adversely  
16 affect 25 out of 26 listed salmon and steelhead populations. Use of AZM on apples poses the  
17 most significant ecological risks, although EPA also noted ecological risks of concern for the  
18 remaining uses of AZM on pears, blueberries, cherries and nuts.

19 50. On June 9, 2006, EPA proposed to phase out five remaining AZM uses in 2007  
20 and the other five uses in 2010. On November 16, 2006, EPA made its final decision regarding  
21 the remaining AZM uses, which lengthened the phase-out period for the crops posing the  
22 greatest worker and ecological risks, and weakened the worker, bystander, and environmental  
23 protections that had been proposed to be in place during the phase-out period. For example,  
24

1 AZM uses on apples, pears, blueberries, cherries, and parsley would be phased out in 2012  
2 instead of 2010, and the nut uses would be extended to 2009 rather than 2007. In terms of  
3 mitigation, EPA reduced the proposed 100-foot buffer zones around water to 60 feet, although it  
4 required the buffers to be vegetated. EPA abandoned proposed medical monitoring of post-  
5 application workers and decided instead to require a worker education program.

6 51. For all ten AZM uses, EPA found both worker and ecological risks of concern  
7 that could not be eliminated with mitigation. For example, while far longer REIs could eliminate  
8 risks of concern to workers, growers had indicated that AZM would no longer serve its function  
9 with REIs long enough to bring the risks down to acceptable levels. While risks of concern for  
10 open air cab airblast applications could be mitigated to acceptable levels by requiring closed  
11 cabs, EPA did not consider imposing this mitigation in either the proposed or final AZM  
12 decision.

13 52. For all ten uses, EPA found available, efficacious alternatives that would have  
14 comparable pest control effectiveness with relatively insignificant changes in yield, quality, or  
15 cost. EPA found that the risks posed to both workers and the environment outweigh the  
16 economic benefits to growers of using AZM on all of the remaining crops. While this finding  
17 forms the predicate for the decision not to re-register these AZM uses beyond the phase-out  
18 dates, the bulk of the final decision emphasizes the near-term benefits of AZM for the fruit and  
19 nut crops and the obstacles to shifting to alternatives.

20 53. EPA did not balance the risks and benefits of requiring enclosed cabs that could  
21 reduce unacceptable risks to workers mixing, loading, or applying AZM.

22 54. EPA based its decision to extend AZM uses for lengthy phase-out periods solely  
23 on the economic benefits of AZM and the growers' desires to avoid shifting to alternatives. EPA  
24

1 inappropriately minimized the risks to workers in authorizing the continued AZM uses when  
2 worker risks are greater than EPA's established risk of concern threshold. EPA failed to account  
3 for the risks, economic costs, and hardships to bystanders, communities, families of farm  
4 workers, and the environment in finding that economic benefits outweigh the risks posed by  
5 AZM.

6 55. EPA justified allowing AZM uses on apples, pears, cherries, and blueberries  
7 during a lengthy phase-out period because some countries lack import tolerances for some of the  
8 alternative pesticides. However, for apples, the leading foreign markets have tolerances for the  
9 primary alternatives to AZM, and all the foreign markets have tolerances for at least one  
10 alternative. Mexico has tolerances in place for all the main alternatives for apples and pears;  
11 Japan has tolerances for all the cherries alternatives. EPA's grower impact assessments did not  
12 evaluate the economic impact of having only one or two of the lesser foreign markets  
13 unavailable if import tolerances are not in place in the near future. Nor did the grower impact  
14 assessments fully evaluate the time it is likely to take to obtain sufficient import tolerances to  
15 avoid extensive disruptions in U.S. exports of the particular crops. Instead, EPA recites a worst  
16 case estimate of losses if all foreign markets were to become unavailable for apple exports.

17 56. EPA also sought to justify a lengthy phase-out because developing effective  
18 alternative pest control practices using new pesticides often takes several seasons to perfect.  
19 This contention is inapplicable to some of the alternative pest control methods, and EPA did not  
20 link the contention to particular alternatives and assess the extent of the economic dislocation  
21 that would likely result.

22 57. Despite noting that the worker risks are significant, EPA sought to minimize them  
23 by claiming that no incident or monitoring data reveal large-scale environmental or worker  
24

1 poisoning impacts. EPA relied on the lack of monitoring data even though EPA does not require  
2 monitoring that would document such impacts. EPA also relied on the lack of reported incidents  
3 even though EPA has long recognized that worker poisoning incidents are vastly under-reported  
4 and under-diagnosed. EPA has established methods for determining whether worker and  
5 ecological risks are of concern. These methods documented risks of concern for the remaining  
6 AZM uses. In the final AZM decision, EPA sought to minimize the findings produced using  
7 these established methods of assessing worker and ecological risks without employing any other  
8 scientifically valid assessment methods.

9 58. EPA also justified the lengthy phase-out because it will require additional  
10 mitigation measures during the phase-out period. EPA will not, however, require mitigation that  
11 will reduce worker and ecological risks to acceptable levels.

12 59. EPA decided to authorize the continued use of five AZM uses for six more years  
13 and three nut crop uses for three more years based on the economic costs to growers of shifting  
14 to alternatives and the growers' desires to avoid making that shift on a more accelerated basis.  
15 EPA did not account for and incorporate into the balancing the full costs to workers, their  
16 families, bystanders, communities, and the environment.

17 B. Phosmet

18 60. Phosmet is another highly toxic organophosphate insecticide, first registered for  
19 use in the United States in 1966. Prior to the 2001 IRED, approximately one million pounds of  
20 phosmet were used each year on a variety of fruit, nut, grape, berry, and vegetable crops.

21 *1. 2001 IRED for Phosmet*

22 61. In the 2001 IRED for phosmet, EPA concluded that workers face risks of concern  
23 for many phosmet uses. Phosmet IRED at 51-52. The MOEs for workers who mix and load  
24 phosmet for aerial applications are between 27 and 94 for intermediate exposures. Phosmet

1 IRED at 21-26. These risks exceed EPA’s cutoff for unacceptable risks of a MOE less than 100.

2 62. Workers face even greater post-application risks from harvesting, thinning, and  
3 irrigating activities, which result in MOEs that are lower than 10, an order of magnitude greater  
4 risk than EPA’s level of concern. Phosmet IRED at 32-43. Even with additional mitigation  
5 measures, such as protective clothing, engineering controls, and reducing the number and rates of  
6 applications, “residual risks are still of concern.” Phosmet IRED at 42-43. The MOEs would be  
7 less than 20 for some worker activities on apples, crabapples, apricots, nectarines, peaches,  
8 pears, plums/prunes, highbush blueberries, and grapes. *Id.* at 43, 52. More specifically, the  
9 MOEs are less than 20 for workers harvesting or thinning apples and stone fruits and less than 10  
10 for workers who enter blueberry and grape fields for harvesting, pruning, girding, and turning  
11 activities. *Id.* at 33-34. It would take 19 and 34 days for the MOE to reach the 100 target for  
12 high-exposure activities on apples in the eastern and western United States respectively, 30 days  
13 for apricots, peaches, and nectarines, 37 days for pears, 34 days for grapes, and 28 days for high-  
14 bush blueberries. *Id.* at 62-77.

15 63. In the 2001 IRED, EPA “determined that phosmet products, unless labeled and  
16 used as specified in this document, would present risks inconsistent with FIFRA.” Phosmet  
17 IRED at 41.

18 64. EPA required maximum personal protective equipment for handlers, including  
19 double-layered clothing, chemical-resistant headgear, and a respirator, but did not require closed  
20 cabs. Airblast applications using open cabs pose risks of concern for many uses. EPA did not  
21 include mixer/handler/applicator risks in its 2001 benefits assessments for phosmet.

22 65. To mitigate risks to post-application workers, EPA extended REIs for many  
23 crops. For nine crops, EPA could not mitigate the post-application workers’ risks to acceptable  
24

1 levels. EPA found that these residual risks are still of concern and that they are high enough that  
2 they would outweigh benefits if the benefits changed. Phosmet IRED at 42-43. These nine  
3 crops are blueberries, peaches, nectarines, apples, pears, plums, prunes, grapes, and apricots.  
4 EPA re-registered these nine uses but provided for REIs to increase by October 30, 2006, unless  
5 the registrant demonstrates that shorter intervals pass muster under FIFRA. Phosmet IRED at  
6 42-43, 52-53. The longer REIs would not eliminate the worker risks of concern, but they would  
7 raise the MOEs to approximately 70. *Id.* at 43.

8         66. In an October 2001 Memorandum of Agreement with EPA, the Gowan Company  
9 agreed to amend the phosmet labels to incorporate the language required in the IRED. EPA  
10 agreed not to initiate cancellation or suspension proceedings. The Gowan Company also agreed  
11 to submit data by October 30, 2005, on worker exposure to phosmet, the feasibility of using  
12 gloves to reduce exposure, and the benefits and use patterns of phosmet. EPA would then  
13 evaluate the data to determine whether to modify or maintain the REIs specified in its 2001  
14 phosmet IRED.

15                 2. *EPA's 2007 Decision to Reduce Phosmet Re-Entry Intervals and Forgo*  
16                 *Other Worker and Bystander Protections to Eliminate Risks of Concern.*

17         67. Pursuant to the January 2006 Settlement Agreement with plaintiffs, EPA issued a  
18 proposed phosmet decision for public comment on June 9, 2006. EPA proposed to revert to the  
19 REIs currently on the labels or to extend the REIs only slightly and far less than the post-2006  
20 REIs deemed appropriate in the 2001 IRED for the nine phosmet uses. The proposed REIs for  
21 apples, peaches, nectarines, pears, plums, and prunes would be extended from the pre-2006 REI  
22 of three days to seven days. These extended REIs are at least three times shorter than the REIs  
23 that would achieve an MOE of 70 that EPA had adopted in the 2001 IRED for post-2006.  
24 Compared to the status quo, the grape REI would remain the same, the apricot REI would be

1 extended from three to 14 days, and the blueberries REI would be extended from one to three  
2 days. All of the REIs proposed by EPA were far shorter than those adopted in the 2001 IRED  
3 for post-2006, which ranged from 23 to 29 days for these crops. Based on refined assessments,  
4 EPA concluded that the extended REIs for blueberries and grapes would eliminate risks of  
5 concern for short-term exposure, that intermediate risks from blueberries are unlikely given the  
6 low volume of use, and the intermediate worker risks for grapes would be an MOE of 41. Under  
7 the proposed REIs, the short-term MOE would be 47 for plums and prunes, 47 for pears,  
8 peaches, and nectarines (with an intermediate MOE of 11), 44 for some high-contact activities on  
9 apricots, and 37 for high-exposure activities on apples.

10 68. On January 18, 2007, EPA adopted a final phosmet decision that largely tracked  
11 the proposal. However, EPA backtracked from the proposal by reducing the REI for apples and  
12 peaches east of the Rockies to four days from the seven-day proposed REI, by reducing the  
13 apricot REI to seven days from the proposed 14-day REI, by reducing the blueberries to one day  
14 from the three-day proposed REI, and by allowing aerial applications to apple, pear, peach,  
15 nectarine, apricot, plum, and prune orchards despite potential risks of concern to bystanders.  
16 While the proposal would have largely eliminated risks of concern to workers from blueberry  
17 applications, the final decision adopts an REI with an MOE of less than 100, thereby posing  
18 worker risks of concern.

19 69. Throughout the phosmet decision, EPA stated that it remained concerned about  
20 the low MOEs that denote worker risks of concern for these phosmet uses. The phosmet  
21 registrant had submitted a biomonitoring study in November 2005, but EPA determined that the  
22 study had numerous technical flaws and that it could not be considered in the phosmet decision  
23 because one of the study subjects was a minor and EPA's regulations prohibit consideration of  
24



1 studies that intentionally dose minors. EPA is requiring the registrant to submit additional  
2 biomonitoring data and has represented that it will refine its worker risk assessment based on that  
3 data and any other new information in 2008.

4 C. 2001 IRED for Chlorpyrifos

5 70. Chlorpyrifos is an organophosphate insecticide, first registered for use in the  
6 United States in 1965. It is one of the most widely used organophosphate insecticides in the  
7 United States. Approximately 21-24 million pounds of active ingredient were used annually  
8 from 1987-1998 on approximately 8 million acres. Chlorpyrifos is used on a wide variety of  
9 food and feed crops. Corn is the largest agricultural use in terms of total pounds. Crops with a  
10 high percentage of total acres treated with chlorpyrifos include Brussels sprouts, cranberries,  
11 apples, broccoli, and cauliflower. Like AZM and phosmet, chlorpyrifos inhibits the body's  
12 ability to produce cholinesterase and causes poisoning of exposed workers.

13 71. EPA issued an IRED for chlorpyrifos in 2001. In the 2001 IRED, EPA found that  
14 "[o]ccupational exposure to chlorpyrifos is of concern to the Agency" with respect to mixers,  
15 loaders, and applicators. Chlorpyrifos IRED at x. EPA specifically identified the following  
16 exposures as posing risks of concern: mixing/loading liquids for aerial/chemigation and  
17 groundboom application; mixing wettable powder for groundboom application, aerial  
18 application, and application by backpack sprayer; high-pressure handwand, and hand-held  
19 sprayer or duster. Id. EPA found that most chlorpyrifos uses pose unreasonable adverse effects  
20 to health and the environment, but that with the required mitigation, many agricultural uses  
21 would be eligible for re-registration. However, it identified various occupational risk scenarios  
22 that would still be below the target MOE of 100, even with all feasible PPE or engineering  
23 controls. Chlorpyrifos Facts at 3 (Feb. 2002).

24 72. Airblast applications in open cabs pose risks of concern to workers. For airblast

1 applications, the Chlorpyrifos IRED states that “[t]he biological monitoring results indicate that  
2 open cabs are insufficient.” Chlorpyrifos IRED at 77. Mitigation can eliminate these risks of  
3 concern. Specifically, the MOEs for enclosed cabs for airblast applications and for groundboom  
4 tractor applications exceed 100. Id. While the amended label language requires enclosed  
5 cockpits for pilots for aerial applications, and prohibits human flaggers, it fails to require  
6 enclosed cabs for motorized ground application equipment. Instead, it requires personal  
7 protective equipment (“PPE”) for mixers and loaders, consisting of a combination of long-  
8 sleeved shirt, long pants, socks, shoes, coveralls, chemical resistant-apron, footwear, and/or  
9 gloves, chemical-resistant headgear of overhead exposures, and a NIOSH-approved respirator.  
10 Id. at 99-102. The amended label language provides that: “when handlers use closed systems or  
11 closed cab motorized ground application equipment in a manner that meets the requirements  
12 listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 C.F.R.  
13 § 70.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the  
14 WPS.” Chlorpyrifos IRED at 103 (liquid formulations); IRED at 104 (wetable powder and  
15 granular formulations). The same pattern is replicated for non-WPS uses. Id. at 109-12.

16 73. Post-application risks are generally at “acceptable” levels with the required REIs  
17 and PHIs. An exception is the 24-hour REI for sweet corn, which results in an MOE of 83.  
18 Post-application risks to greenhouse/nursery workers were not assessed due to a lack of data:  
19 “Additional use information, i.e., timing of application relative to postapplication activities,  
20 greenhouse DFR data, and biological monitoring data to develop transfer coefficients for various  
21 greenhouse/nursery activities are required.” Id. at 85, 86. Even without sufficient data, EPA  
22 noted that risks are of concern for pruning, transplanting, and burlap/balling. Nonetheless, EPA  
23 noted that chlorpyrifos is an important chemical for industry and allowed the current REI of 24  
24

1 hours to remain in effect until acceptable data indicate that it should be changed. Id. at 86.

2 74. EPA conducted no benefits assessments for chlorpyrifos. It explored no  
3 alternatives scenarios to determine whether growers could achieve comparable yields and quality  
4 with alternatives. It never compared the costs of chlorpyrifos use and available alternatives. It  
5 therefore had no basis for finding that benefits outweigh risks. The IRED contains two  
6 conclusory risk-benefit statements. First, it states that, with the required changes, “risks will be  
7 mitigated to acceptable levels taking into account the benefits of chlorpyrifos use where  
8 appropriate.” Id. at 61. Second, a single recitation appears after EPA reviews the various  
9 scenarios that pose risks to workers that are less than an MOE of 100. “Taking into account the  
10 strengths and weaknesses of the risk assessment and the benefits of chlorpyrifos use, EPA has  
11 determined that the uses listed above are eligible for reregistration with the designated mitigation  
12 and confirmatory data.” Id. at 85. Nothing in the IRED provides data or a reasoned basis for  
13 these assertions.

14 75. The IRED reveals other harmful effects of chlorpyrifos that need to be taken into  
15 account in a risk-benefit balancing analysis under FIFRA. For example, chlorpyrifos is highly  
16 toxic to bees, id. at 50, it has been associated with bird and fish kills, id. at 60, monitoring in the  
17 1990s revealed widespread and persistent occurrence in aquatic areas throughout the United  
18 States, id. at 51, and chlorpyrifos has been detected at levels that exceed water quality criterion,  
19 id. at 52. EPA’s ecological risk assessment found surface water contamination, and ecological  
20 risks of concern from single applications to small mammals, birds, fish, aquatic invertebrates for  
21 nearly all outdoor uses with multiple applications increasing the risks and prolonging the  
22 exposures. Id. at 3, 44. While the IRED imposed some mitigation for environmental effects, in  
23 April 2003, EPA found that chlorpyrifos is likely to adversely effect 19 threatened or endangered  
24

1 salmon and steelhead populations throughout Oregon, Washington, and California. These  
2 findings trigger EPA's duties under the Endangered Species Act to mitigate these adverse effects  
3 through an ESA consultation, which EPA has not yet done.

4 76. In its 2006 decision, EPA determined that the cumulative risk assessment and the  
5 requirements of the FQPA did not necessitate revisiting the 2001 IRED. The 2001 IRED  
6 identified numerous uncertainties in the data pertaining to various worker risks, but EPA did not  
7 address any of those uncertainties when it made its 2006 chlorpyrifos determination.

#### 8 CAUSES OF ACTION

##### 9 CLAIM ONE: EPA ACTED ARBITRARILY, CAPRICIOUSLY, 10 AND IN VIOLATION OF FIFRA BY SUBJECTING WORKERS 11 TO EXCESSIVE RISKS FROM AZM FOR SIX MORE YEARS

11 77. Paragraphs 12-76 are realleged as though set out in full.

12 78. In order to register a pesticide, the Administrator must determine that the  
13 pesticide, when used in accordance with the label and widespread and commonly recognized  
14 practice, "will not generally cause unreasonable adverse effects on the environment."  
15 7 U.S.C. § 136a(c)(5). FIFRA defines "unreasonable adverse effects on the environment" to  
16 mean "any unreasonable risk to man or the environment, taking into account the economic,  
17 social, and environmental costs and benefits of the use of any pesticide . . . ." 7 U.S.C.  
18 § 136(bb).

19 79. The registrant bears the burden of proving that a pesticide use satisfies FIFRA's  
20 registration standard. The registrant bears this burden at all times. EPA cannot re-register a  
21 pesticide use unless the registrant has met its burden with respect to that use.

22 80. In 2001, EPA determined that the ten remaining AZM uses are eligible only for a  
23 four-year time-limited registration. EPA believed that effective alternatives would be available  
24 at the end of the four-year period. EPA has now determined that efficacious alternatives are

1 available for the remaining AZM uses. Based on this finding, AZM is ineligible for re-  
2 registration. The growers have already had five years to shift to the alternatives that exist and are  
3 efficacious. By allowing continued use of AZM when efficacious alternatives exist, EPA has  
4 shifted the burden of proof away from the registrants and has violated FIFRA. For example,  
5 EPA accepted growers' claims that it would take time to shift to alternatives without requiring  
6 specific supporting evidence. EPA also relied on potential impacts to foreign markets without  
7 documenting the extent to which and length of time that specific markets might be unavailable  
8 for U.S. exports.

9 81. EPA has established a level of protection for worker risks based on margins of  
10 exposure ("MOEs"). EPA has determined that workers are exposed to unacceptable risks when  
11 the MOE is less than a threshold value of 100. In its human health risk assessments for AZM,  
12 EPA concluded that the remaining uses of AZM result in an MOE of less than 100 and thereby  
13 create unacceptable risks to workers. Many of the AZM uses result in risks that are far lower,  
14 sometimes an order of magnitude lower, than an MOE of 100. In allowing continued use of  
15 AZM over the next six years, EPA minimized the worker and ecological risks of concern  
16 determined using EPA's standard risk assessment methods by claiming that no incident or  
17 monitoring data reveal large-scale environmental or worker poisoning impacts. It is irrational for  
18 EPA to rely on the lack of monitoring data when EPA does not require monitoring that would  
19 document such impacts. It is also irrational for EPA to rely on the lack of reported incidents  
20 when EPA has long recognized that worker poisoning incidents are vastly under-reported and  
21 under-diagnosed. It is arbitrary for EPA to discount or minimize risk findings derived using its  
22 standard risk assessments methods, particularly where EPA employed no other scientifically  
23 valid assessment methods and it sought evidence that generally does not exist.

1           82.     EPA has no regulation or policy establishing a uniform process for assessing  
2 benefits of pesticide uses that pose risks of concern. Expert bodies, such as the National  
3 Academy of Sciences, have recommended that EPA develop such a policy to avoid arbitrary and  
4 unprincipled risk-benefit decisionmaking under FIFRA. In the absence of such a regulation or  
5 policy, EPA staff compiled information on the benefits of AZM uses that pose risks of concern  
6 on an ad hoc basis.

7           83.     EPA conducted grower impact assessments to determine whether the benefits  
8 from continued uses of AZM outweigh the risks these pesticides pose to workers and the  
9 environment. These assessments revealed significantly lower crop production benefits from  
10 AZM than the 2001 benefits assessments. The new grower impact assessments revealed that  
11 most of the economic benefits to growers identified in 2001 had disappeared with the emergence  
12 of efficacious alternative pest control methods.

13           84.     The 2005 grower impact assessments over-estimate the benefits of AZM because  
14 they failed to consider the costs of exposing workers to high poisoning risks, as well as the costs  
15 of exposing farm worker children to adverse health effects from continued use of these  
16 pesticides. EPA failed to consider the environmental costs of continued use of AZM, such as  
17 contamination of water bodies, impacts on bees, and impacts on threatened and endangered  
18 species. Had EPA considered the benefits of avoiding health risks to workers, their families, and  
19 communities, as well as the costs of environmental degradation, the benefits of the continued  
20 uses of AZM would likely be outweighed by the risks. None of the pest control alternatives  
21 considered by EPA addressed the costs to workers from exposures during mixing, loading, and  
22 applying AZM or of other mitigation in addition to what EPA is requiring during the phase-out  
23 period. EPA refused to consider organic production as an alternative even though organic  
24

1 markets are growing and organic produce command a premium price. Had EPA considered  
2 mixing, loading, and applicator risks and organic production alternatives, the risks from the  
3 continued AZM uses would likely outweigh the benefits.

4 85. To determine whether a pesticide use presents “unreasonable adverse  
5 environmental effects,” FIFRA requires EPA to “tak[e] into account the economic, social, and  
6 environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb). In the final  
7 AZM decision, EPA accounted for the economic benefits of the pesticides to growers, but failed  
8 to take into account the full social and environmental costs. EPA acted arbitrarily and  
9 capriciously in violation of FIFRA and the Administrative Procedure Act (“APA”), 5 U.S.C.  
10 § 706(2)(A), by making AZM re-registration decisions based on its one-sided grower impact  
11 assessments.

12 86. EPA acted arbitrarily, capriciously, and contrary to FIFRA, in violation of the  
13 APA, by failing to consider and incorporate into its assessments: (1) the costs to workers, their  
14 employers, their children, and society of adverse health effects from continued use of AZM;  
15 (2) the full environmental costs of continued use of AZM; and (3) any comparison of the benefits  
16 and costs of particular pesticide uses.

17 87. EPA’s finding that the worker and ecological risks of AZM uses on the remaining  
18 fruit and nut crops are outweighed by AZM’s benefits lacks supporting evidence, runs counter to  
19 evidence in the record, and is devoid of a rational explanation. EPA has authorized particularly  
20 hazardous AZM uses, such as airblast applications using open cabs, aerial applications on  
21 blueberries, and REIs that subject workers to risks far greater than EPA threshold level for risks  
22 of concern, without specific evidence that the benefits outweigh each of these risks.

1 CLAIM TWO: EPA ACTED ARBITRARILY, CAPRICIOUSLY, AND IN  
2 VIOLATION OF FIFRA IN ABANDONING PROTECTIVE MITIGATION FOR  
WORKERS FROM PHOSMET USES THAT POSE WORKER RISKS OF CONCERN

3 88. Paragraphs 12 through 76 are realleged as though set out in full.

4 89. In order to register a pesticide, the Administrator must determine that the  
5 pesticide, when used in accordance with the label and widespread and commonly recognized  
6 practice, “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C.  
7 § 136a(c)(5). FIFRA defines “unreasonable adverse effects on the environment” to mean “any  
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 . . . .” 7 U.S.C. § 136(bb).

10 90. The registrant bears the burden of proving that a pesticide use satisfies FIFRA’s  
11 registration standard. The registrant bears this burden at all times. EPA cannot re-register a  
12 pesticide use unless the registrant has met its burden with respect to that use. In allowing the  
13 phosmet uses without adequate mitigation to eliminate or significantly reduce worker risks of  
14 concern, EPA shifted the burden of proof and failed to require the registrant to prove that these  
15 uses satisfy FIFRA’s unreasonable adverse effects standard. Specifically, EPA accepted the  
16 growers’ claims that additional worker safeguards would be infeasible without specific  
17 supporting evidence. EPA also rejected specific mitigation measures that would have afforded  
18 workers greater protection without scrutinizing their risks and benefits as required by FIFRA.

19 91. EPA found that nine phosmet uses pose risks of concern to workers without  
20 additional mitigation. Some risks are posed by open cab airblast applications. While those risks  
21 could be mitigated by requiring the use of closed cabs, EPA did not impose such mitigation. It  
22 provided no defensible rationale for continuing to allow open cab airblast applications. EPA did  
23 not conduct grower impact assessments or risk-benefit balancing that addressed requiring closed  
24 cabs. EPA acted arbitrarily, capriciously, and contrary to FIFRA in allowing open cab airblast



1 applications of phosmet that pose risks of concern to workers.

2 92. EPA has established a level of protection for worker risks based on margins of  
3 exposure (“MOEs”). EPA has determined that workers are exposed to unacceptable risks when  
4 the MOE is less than a threshold value of 100. EPA has concluded that nine phosmet uses result  
5 in an MOE of less than 100 and thereby create unacceptable risks to workers. EPA allowed  
6 these phosmet uses without the extended post-2006 REIs that EPA had previously deemed  
7 necessary. In doing so, EPA minimized the worker and ecological risks of concern determined  
8 using EPA’s standard risk assessment methods by claiming that no incident or monitoring data  
9 reveal large-scale environmental or worker poisoning impacts. It is irrational for EPA to rely on  
10 the lack of monitoring data when EPA does not require monitoring that would document such  
11 impacts. It is also irrational for EPA to rely on the lack of reported incidents when EPA has long  
12 recognized that worker poisoning incidents are vastly under-reported and under-diagnosed. It is  
13 arbitrary for EPA to discount or minimize risk findings derived using its standard risk  
14 assessments methods, particularly where EPA employed no other scientifically valid assessment  
15 methods and it sought evidence that generally does not exist.

16 93. EPA has no regulation or policy establishing a uniform process for assessing  
17 benefits of pesticide uses that pose risks of concern. Expert bodies, such as the National  
18 Academy of Sciences, have recommended that EPA develop such a policy to avoid arbitrary and  
19 unprincipled risk-benefit decisionmaking under FIFRA. In the absence of such a regulation or  
20 policy, EPA staff compile information on the benefits of phosmet uses that pose risks of concern  
21 on an ad hoc basis.

22 94. EPA conducted grower impact assessments to determine the benefits to growers  
23 of retaining phosmet without the post-2006 REIs that EPA had previously deemed to be  
24

1 necessary. For some crops, such as apples, the grower impact assessment revealed significantly  
2 lower crop production benefits from phosmet than the 2001 benefits assessments. Most of the  
3 economic benefits to growers identified in 2001 had disappeared with the emergence of  
4 efficacious alternative pest control methods.

5 95. The 2005 grower impact assessments over-estimate the benefits of phosmet  
6 because they failed to consider the costs of exposing workers to high poisoning risks, as well as  
7 the costs of exposing farm worker children to adverse health effects from continued use of  
8 phosmet. EPA failed to consider the environmental costs of continued use of phosmet, such as  
9 contamination of water bodies, impacts on bees, and impacts on threatened and endangered  
10 species. Had EPA considered the benefits of avoiding health risks to workers, their families, and  
11 communities, as well as the costs of environmental degradation, the benefits of the continued  
12 uses of phosmet would likely be outweighed by the risks. None of the pest control alternatives  
13 considered by EPA addressed the costs to workers from exposures during mixing, loading, and  
14 applying the pesticides or of other mitigation in addition to what EPA is requiring during the  
15 phase-out period. Had EPA considered mixing, loading, and applicator risks, the risks from the  
16 continued phosmet uses would likely outweigh the benefits.

17 96. To determine whether a pesticide use presents “unreasonable adverse  
18 environmental effects,” FIFRA requires EPA to “tak[e] into account the economic, social, and  
19 environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb). EPA  
20 accounted for the economic benefits of the pesticides to growers, but failed to take into account  
21 the full social and environmental costs. EPA acted arbitrarily and capriciously in violation of  
22 FIFRA and the APA by making phosmet re-registration decisions based on one-sided  
23 assessments of the impacts to growers of shifting to alternative pest control methods.  
24

1           97.     EPA acted arbitrarily, capriciously, and contrary to FIFRA, in violation of the  
2     APA, by failing to consider and incorporate into its assessments: (1) the costs to workers, their  
3     employers, their children, and society of adverse health effects from continued use of phosmet;  
4     (2) the full environmental costs of continued use of phosmet; and (3) any comparison of the  
5     benefits and costs of particular pesticide uses.

6           98.     As a principal rationale for finding that the benefits of phosmet uses on apples and  
7     pears outweighs the risks, EPA raises the specter of greater regulation of phosmet pushing  
8     growers to use more AZM. EPA had before it expert evidence that such a shift is unlikely in the  
9     Pacific Northwest because growers lack confidence in phosmet's ability to control key pests and  
10    phosmet would cost more than newer alternatives. EPA acted contrary to this evidence. EPA  
11    also did not balance the risks and benefits of these phosmet uses without additional worker  
12    safeguards after AZM is no longer on the market. However, the re-registration of phosmet is not  
13    a time-limited authorization but rather continues until it is superseded by a new EPA registration  
14    determination. EPA first registered phosmet in 1966 and did not undertake the first re-  
15    registration until 2001. Once EPA completes the re-registration of pesticides required by the  
16    current statutory deadlines, FIFRA calls for reviews of pesticide registrations with a goal of  
17    completing such reviews every 15 years. 7 U.S.C. § 136a(g)(1). Since the phosmet re-  
18    registration is likely to remain in place long after AZM is off the market, EPA erred by not  
19    assessing the risks and benefits of retaining phosmet uses without longer REIs or closed cabs  
20    once AZM is no longer a viable alternative.

21                   CLAIM THREE: EPA ACTED ARBITRARILY, CAPRICIOUSLY,  
22                   AND IN VIOLATION OF FIFRA IN RE-REGISTERING CHLORPYRIFOS  
                          USES THAT POSE RISKS OF CONCERN TO WORKERS

23           99.     Paragraphs 12 through 76 are realleged as though set out in full.

24           100.    In order to register a pesticide, the Administrator must determine that the

1 pesticide, when used in accordance with the label and widespread and commonly recognized  
2 practice, “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C.  
3 § 136a(c)(5). FIFRA defines “unreasonable adverse effects on the environment” to mean “any  
4 unreasonable risk to man or the environment, taking into account the economic, social, and  
5 environmental costs and benefits of the use of any pesticide . . . .” 7 U.S.C. § 136(bb).

6 101. The registrant bears the burden of proving that a pesticide use satisfies FIFRA’s  
7 registration standard. The registrant bears this burden at all times. EPA cannot re-register a  
8 pesticide use unless the registrant has met its burden with respect to that use. EPA re-registered  
9 chlorpyrifos uses that pose risks of concern to risks without mitigating those risks to acceptable  
10 levels or requiring the registrant to prove that the uses satisfy FIFRA’s unreasonable adverse  
11 effects standard.

12 102. The Chlorpyrifos IRED contains two conclusory risk-benefit statements. First, it  
13 states that, with the required changes, “risks will be mitigated to acceptable levels taking into  
14 account the benefits of chlorpyrifos use where appropriate.” IRED at 61. Second, a single  
15 recitation appears after EPA reviews the various scenarios that pose risks to workers that are less  
16 than an MOE of 100: “Taking into account the strengths and weaknesses of the risk assessment  
17 and the benefits of chlorpyrifos use, EPA has determined that the uses listed above are eligible  
18 for reregistration with the designated mitigation and confirmatory data.” IRED at 85. EPA  
19 conducted no risk-benefit balancing as required by FIFRA to support these conclusory  
20 statements. Nothing in the IRED provides data or a reasoned basis to support these statements.

21 103. Under FIFRA’s risk-benefit standard, benefits must outweigh risks (considering  
22 all risks and benefits) in order for worker risks of concern to be allowed. EPA has no regulation  
23 or policy establishing a uniform process for assessing benefits of pesticide uses that pose risks of  
24

1 concern. Expert bodies, such as the National Academy of Sciences, have recommended that  
2 EPA develop such a policy to avoid arbitrary and unprincipled risk-benefit decisionmaking under  
3 FIFRA. In the absence of such a regulation or policy, EPA staff compile information on the  
4 benefits of pesticides that pose risks of concern on an ad hoc basis.

5 104. For AZM and phosmet, when EPA found that mitigation would not reduce worker  
6 risks to acceptable levels (MOEs greater than 100), it conducted benefits and grower impacts  
7 assessments. EPA conducted no benefits or grower impact assessments for chlorpyrifos. It  
8 explored no alternative pest control scenarios to determine whether growers could achieve  
9 comparable yields and quality with alternatives. It never compared the costs of chlorpyrifos use  
10 and available alternatives. It therefore had no basis for finding that benefits outweigh risks. Nor  
11 did EPA otherwise document the benefits of allowing continued chlorpyrifos uses that pose risks  
12 of concerns to workers and the environment. Without evidence documenting specific benefits  
13 from each such use, EPA cannot conduct the risk-benefit balancing directed by FIFRA. Under  
14 FIFRA, EPA cannot allow worker risks of concern without determining that clearly documented  
15 benefits outweigh those risks.

16 105. To determine whether a pesticide use presents “unreasonable adverse  
17 environmental effects,” FIFRA requires EPA to “tak[e] into account the economic, social, and  
18 environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb). EPA acted  
19 arbitrarily and capriciously in violation of the FIFRA and the APA by making chlorpyrifos re-  
20 registration decisions without taking into account the full social and environmental costs of the  
21 risks posed by the pesticide uses. EPA acted arbitrarily, capriciously, and contrary to FIFRA, in  
22 violation of the APA, by failing to take into account: (1) the costs to workers, their employers,  
23 their children, and society of adverse health effects from continued use of chlorpyrifos; (2) the  
24

1 full environmental costs of continued use of chlorpyrifos; and (3) any comparison of the benefits  
2 and costs of particular pesticide uses.

3 PRAYER FOR RELIEF

4 WHEREFORE, plaintiffs pray that this Court:

5 A. Declare that EPA acted arbitrarily, capriciously, and contrary to FIFRA in  
6 allowing continued uses of AZM;

7 B. Declare that EPA acted arbitrarily, capriciously, and contrary to FIFRA in  
8 reducing mitigation for worker risks posed by the nine phosmet uses for which EPA had adopted  
9 extended post-2006 REIs and for authorizing continued phosmet uses without other safeguards to  
10 protect workers from risks of concern;

11 C. Declare that EPA acted arbitrarily, capriciously, and contrary to FIFRA in re-  
12 registering chlorpyrifos uses that pose risks of concern to workers;

13 D. Order EPA to make new re-registration eligibility decisions for AZM, phosmet,  
14 and chlorpyrifos on an expeditious basis.

15 E. Award plaintiffs their costs and attorneys' fees in this action pursuant to the Equal  
16 Access to Justice Act, 28 U.S.C. § 2412; and

17 F. Grant such other and further relief as the Court may deem just and proper.

18 Respectfully submitted this 2<sup>nd</sup> day of February, 2007.

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