

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE COUNCIL,)
PESTICIDE ACTION NETWORK NORTH AMERICA,)
THE BREAST CANCER FUND,)
PHYSICIANS FOR SOCIAL RESPONSIBILITY,)
NEW YORK PUBLIC INTEREST RESEARCH GROUP,)
FARMWORKER LEGAL SERVICES OF NEW YORK,)
CITIZENS CAMPAIGN FOR THE ENVIRONMENT,)
NEIGHBORHOOD NETWORK RESEARCH CENTER,)
CITIZENS' ENVIRONMENTAL COALITION,)
MID-HUDSON CATSKILL RURAL AND)
MIGRANT MINISTRY, and)
ENVIRONMENTAL ADVOCATES OF NEW YORK,)

Plaintiffs,)

v.)

MARIANNE LAMONT HORINKO, ACTING)
ADMINISTRATOR, UNITED STATES)
ENVIRONMENTAL PROTECTION AGENCY,)
and UNITED STATES ENVIRONMENTAL)
PROTECTION AGENCY,)

Defendants.)

No: 03 CV 7176 (GEL)

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. In this lawsuit, eleven medical, health, environmental, religious, and farmworker protection organizations challenge the U.S. Environmental Protection Agency's (EPA's) unlawful failure to protect the public, and particularly infants and children, from the substantial health threats posed by five high-risk pesticides. Some of these pesticides are so toxic that a teaspoon can cause acute poisoning in people, resulting in seizures and coma. One is so potent that EPA says to protect against acute toxicity, a toddler should not be exposed to an amount weighing less than a single grain of salt per day. Lower

doses over time may cause neurological damage, learning disabilities, behavioral problems, and cancer. Yet EPA has decided to allow continued use of these chemicals on food and in or near the homes, schools, playgrounds, parks, and workplaces of Plaintiffs' members and their children.

2. This suit seeks to breathe life into Congress' unanimous overhaul of the nation's pesticide laws in the Food Quality Protection Act of 1996 (FQPA), in response to a 1993 National Academy of Sciences study finding that EPA's pesticide program was not adequately protecting the health of infants and children. Through the FQPA, Congress required EPA to review the safety of all pesticides used on food crops, and, for the first time in any environmental law, specifically ordered EPA to assure the safety of infants and children.
3. In response to this mandate, EPA has dragged its feet, forcing the Natural Resources Defense Council (NRDC) and others to sue the agency for its failure to meet its FQPA statutory deadlines. (The deadline suit was ultimately settled through a Consent Decree, *NRDC v. Whitman*, No. 99-3701 WHA, 2001 WL 1221774 (N.D.Cal. Sept. 24, 2001)). EPA now has made many pesticide decisions under FQPA, but has repeatedly failed to comply with the clear Congressional mandate to protect the health of our most vulnerable citizens, our infants and children. *See generally* Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 Admin. L. Rev. 103 (Winter 2001).
4. This case specifically challenges EPA's failure to carry out the dictates of the FQPA to protect Plaintiffs' members, and particularly their infants and children, from the health threats posed by five high risk pesticides: diazinon, disulfoton, oxydemeton methyl,

alachlor, and captan. It also challenges EPA for unlawfully making final decisions using a secret, proprietary, “black box” computer model unavailable for public review or analysis.

5. Plaintiffs therefore seek declaratory and injunctive relief against defendants EPA and Marianne Lamont Horinko, Acting Administrator of the EPA (collectively, EPA), for failing to comply with their statutory obligations to protect children, workers, and others from unsafe exposure to the pesticides diazinon, disulfoton, oxydemeton-methyl, alachlor, and captan under the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the FQPA.

JURISDICTION AND VENUE

6. This case arises under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a, section 4 and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136a-1, and sections 701 through 706 of the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. This action is brought to address defendants’ violations of federal law.
7. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, over federal questions arising under 21 U.S.C. § 346a (FFDCA), 7 U.S.C. § 136n (FIFRA), 28 U.S.C. § 1346 (United States as defendant), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief).
8. No other statute grants any other court exclusive jurisdiction over this matter.
9. Venue is proper in the District Court for the Southern District of New York pursuant to 28 U.S.C. §§ 1391(e) & 1402.

THE PARTIES

10. Plaintiff the Natural Resources Defense Council (NRDC) is a non-profit, environmental membership organization with more than 465,000 members nationwide, including more than 41,000 members in the state of New York. NRDC maintains headquarters in New York City and additional offices in Washington D.C., Los Angeles, and San Francisco. NRDC's membership and staff of lawyers, scientists, and other environmental specialists have a long-standing interest in improving the regulation of pesticides and other toxic chemical residues in food, air, and water. NRDC seeks to ensure that pesticide regulation is protective of the public health and in compliance with governing statutes. NRDC has litigated major cases seeking to require EPA to comply with its legal obligations to protect the public from pesticides, and has actively participated in the development, enforcement, and reform of pesticide laws and pesticide regulation for over two decades.
11. Plaintiff Pesticide Action Network North America (PANNA) is a San Francisco-based organization that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than 60 countries. For more than 20 years, PANNA has worked to replace hazardous, unnecessary pesticide use with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education, and access to pesticide data and analysis, policy development, and coalition support to over 170 affiliated organizations in North America. PANNA has approximately 300 individual members and affiliate organizations in New York.

12. Plaintiff The Breast Cancer Fund (TBCF) is a non-profit organization based in San Francisco and formed in 1992 to accelerate the response to the breast cancer crisis. TBCF's mission is to identify and advocate for the elimination of the environmental and other preventable causes of breast cancer. TBCF pursues its mission through public education, prevention, and public policy initiatives that, among others, aim to uncover the environmental links to breast cancer and eliminate preventable causes of the disease. TBCF mobilizes the public and secures the institutional changes and legislative reforms necessary to eliminate the environmental links to breast cancer. TBCF has 50,000 supporters across the country.
13. Plaintiff Physicians for Social Responsibility (PSR) is a national non-profit organization whose 26,000 members are physicians, other healthcare and public health professionals, and citizens concerned about threats to human health. PSR seeks to educate the medical community and the public about the links between environmental exposures and human health, and to promote preventive, precautionary policy solutions to protect public health. PSR maintains a national office in Washington, D.C. and some 40 local chapters across the country, including chapters in New York City and Albany, NY. PSR has more than 2,800 members throughout the state of New York.
14. Plaintiff New York Public Interest Research Group, Inc. (NYPIRG) is a non-profit membership organization formed in 1973 dedicated to protecting the environment and public health, supporting consumer rights, and improving government administration. NYPIRG maintains headquarters in New York City and additional offices in Albany, Buffalo, Huntington, Syracuse and on twenty college campuses across New York. NYPIRG has successfully campaigned for a wide range of pesticide right-to-know and

use reduction policies in New York, including the Pesticide Reporting Law of 1996, the Pesticide Neighbor Notification Law of 2000, and numerous local laws and ordinances. NYPIRG's pesticide project has conducted extensive research, public education, coalition-building, and media outreach to raise public awareness about pesticide use patterns in New York.

15. Plaintiff Farmworker Legal Services of New York, Inc. (FLSNY) is a statewide law project that provides legal assistance to migrant and seasonal farmworkers including dairy and packing shed workers. Since 1996, FLSNY represents all farmworkers regardless of immigration status. FLSNY operates two offices, one in New Paltz for the Hudson Valley and Long Island, and one in Rochester for Central, Northern, and Western New York. FLSNY engages in extensive outreach to migrant labor camps and other sites used to house migrant labor, and holds community legal education sessions for farmworkers several nights a week during the season from early May until mid-November. FLSNY works to protect farmworkers' rights under EPA Worker Protection Standards, to address civil rights violations, and to provide education and representation to farmworkers on a wide range of issues.
16. Plaintiff Citizens Campaign for the Environment (CCE) is a not-for-profit, grassroots environmental organization working to protect public health and to conserve the land and water resources of New York State, coastal Connecticut and the nation. CCE has 80,000 members throughout New York and Connecticut. CCE was founded in 1985 as a grassroots organization dedicated to bringing citizens into the policy-making process as well as advocating for better laws, regulations, and practices that lead to improvements in land and water quality and the elimination of human exposure to dangerous substances

and agents in the environment. CCE has led numerous campaigns to educate the public about the health risks posed by household and lawn pesticides. In addition, CCE has conducted several legislative campaigns to protect the public from the harmful effects of pesticides.

17. Plaintiff Neighborhood Network Research Center, Inc. (Neighborhood Network), is a non-profit membership organization with an office in Massapequa, New York, working on issues that impact suburban communities. The Neighborhood Network has more than 15,000 members and supporters, all of whom live on Long Island, New York. The Neighborhood Network has a long history of advocacy regarding the environmental and public health concerns of chemical pesticide use, and publishes an annual report detailing the health and environmental hazards associated with pesticides and providing advice on non-chemical pest control products. The organization also conducts educational forums on effective lawn care without chemical pesticides.
18. Plaintiff Citizens' Environmental Coalition (CEC) is a statewide grassroots environmental organization in New York working to eliminate pollution by empowering people. Started in 1983 by a small group of people concerned about local pollution, CEC has grown to have 14,000 individual and 110 organizational members in New York State, with offices in Albany, Buffalo and Seneca Falls, New York. CEC organizes strategic campaigns, coalition building, and public education to promote toxic use reduction and pollution clean-up.
19. Plaintiff Mid-Hudson Catskill Rural and Migrant Ministry (RMM) is a multi-faith organization serving rural and migrant people in New York, through youth

empowerment, education, and accompaniment programs. These efforts include work with farmworkers and their families related to pesticide exposure.

20. Plaintiff Environmental Advocates of New York (EANY) is a non-profit environmental organization with over 7,000 individual members and 130 organizational members. Through advocacy, coalition building, citizen education, and policy development, EANY works to safeguard public health and preserve New York's unique natural heritage. EANY also advances multi-state and national initiatives that have an impact on New York's environment and environmental health. EANY promotes state legislation to ban aesthetic use of pesticides, address the risks of urban pesticide use, improve farmworker safety, phase out pesticide use by state agencies, and improve local control of pesticide use.
21. Plaintiffs bring this action on their own behalf and on behalf of their members and their members' children. Plaintiffs' members and their children are exposed to pesticides in food and drinking water; through rainwater, fog, spray drift, and post-application drift; and in schools, homes, and workplaces through contact with water, counters, tables, flooring, carpeting, lawns, playgrounds, pets, toys, and contaminated soil. For instance, Plaintiffs' members and their children can be exposed because of close proximity to pesticide use in their homes, schools, workplaces, or places of recreation. Many of Plaintiffs' members are farmworkers or live near active farms, and their children are especially heavily exposed to pesticides when these toxic chemicals are applied to fields near their homes, schools, food and water sources, and locations where the children play.
22. The health of Plaintiffs' members and their children is placed at increased risk by EPA's actions permitting unsafe levels of diazinon, disulfoton, oxydemeton methyl, alachlor,

and captan in the food supply and environment. The requested declaratory and injunctive relief mandating that EPA comply with its statutory obligations would remedy these harms. Plaintiffs have an interest in having EPA properly implement its statutory mandates under the FFDCA and the APA in a manner that protects human health – especially children’s health – from unsafe exposure to diazinon, disulfoton, oxydemeton-methyl, alachlor, and captan.

23. Defendant Environmental Protection Agency, a federal agency of the United States, is charged with the responsibility for the implementation and administration of the relevant provisions of the FFDCA and FIFRA.
24. Defendant Marianne Lamont Horinko is the Acting Administrator of the Environmental Protection Agency. She is sued in her official capacity.

RELEVANT STATUTORY PROVISIONS

25. Federal regulation of pesticides is accomplished primarily under two interrelated statutes – FIFRA and the FFDCA. The Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996), substantially amended FIFRA and the FFDCA in 1996 by mandating that health-based and child-protective standards drive decisions about acceptable levels of pesticide residues in the food supply and the environment.
26. FIFRA requires that pesticides must be registered to be sold or distributed in the United States. 7 U.S.C. § 136a. FIFRA section 4, as amended in 1988, requires EPA to complete a review and reregistration of previously registered pesticides; this reregistration process is currently ongoing. 7 U.S.C. § 136a-1. Under FIFRA sections 3 and 4, EPA may not register or reregister a pesticide unless the chemical will perform its

intended function without causing any “unreasonable adverse effects on the environment.” 7 U.S.C. §§ 136a(c)(5)(C), 136a-1(g)(2)(C).

27. The FFDCA authorizes EPA to set tolerances (*i.e.*, maximum allowable levels) for pesticide residues in food, or to grant exemptions from the requirement to have a tolerance. 21 U.S.C. §§ 346a(b) & (c). EPA may “establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe.” 21 U.S.C. § 346a(b)(2)(A)(i).
28. Under the FFDCA safety standard, EPA may not set a pesticide residue tolerance unless the agency first finds that there is “a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue,” including “all anticipated dietary exposures” and “all other exposures” for which reliable information exists. 21 U.S.C. §§ 346a(b)(2)(A)(ii) & (c)(2)(A)(ii). Tolerances also must ensure to a reasonable certainty that “no harm will result to infants and children from aggregate exposure. . . .” 21 U.S.C. § 346a(b)(2)(C)(ii)(I).
29. Any pesticide chemical residue in or on a food is deemed unsafe unless a tolerance or exemption is in effect and the residue is in compliance with that tolerance or exemption. If a pesticide is used on more than one food crop, a separate tolerance must be established for each crop.
30. Under the FFDCA, EPA must review the safety of all existing tolerances in a process known as tolerance reassessment. 21 U.S.C. § 346a(q). EPA frequently makes these tolerance reassessment determinations through the mechanism of a “Reregistration Eligibility Decision,” or RED, a document that also plays a role in the FIFRA reregistration process.

31. Before a pesticide can be reregistered under FIFRA, EPA must conclude that use of the pesticide will not result in a food residue or aggregate exposure from all sources (including air and water) that violates the FFDCAs safety standard. 7 U.S.C. §§ 136(bb)(2), 136a(c)(5)(C) & (D), 136a-1(g)(2)(C) & (D).
32. If EPA concludes following a tolerance reassessment that an existing tolerance must be modified or revoked, further administrative action is necessary to effect the change. *See* 21 U.S.C. §§ 346a(q); 346a(e); & 346a(g). But if EPA concludes that an existing tolerance meets the safety standard and can be left in place, the tolerance is considered reassessed, no further administrative action will follow, and the tolerance reassessment is final. When it makes a determination to leave a tolerance in place, EPA counts the tolerance as reassessed for purposes of compliance with 21 U.S.C. § 346a(q)(1). *See, e.g.,* 67 Fed. Reg. 35,991, 35,993 (May 22, 2002) (“In this notice, EPA identifies several categories of non-contributor tolerances and considers these tolerances reassessed for purposes of FQPA section 408(q) as of today’s date.”).

BACKGROUND

I. THE HARMFUL PESTICIDES AT ISSUE.

33. Diazinon, disulfoton, and oxydemeton methyl are highly toxic organophosphate pesticides that target the nervous system. Organophosphates are a class of chemicals developed for use as nerve agents during World War II. Organophosphate pesticides act by inhibiting acetylcholinesterase (AChE) – an important nervous system enzyme that plays a crucial role in regulating neurotransmission. AChE inhibition can cause nausea, dizziness, confusion, respiratory paralysis, and, in extreme cases, death.

34. Diazinon is a broad spectrum organophosphate insecticide used on a wide variety of agricultural crops and in homes. The thirteen million pounds of diazinon applied annually to crops, homes, lawns, and gardens pose significant risks to agricultural workers, consumers, and the environment. EPA's recent final approval of unsafe levels of diazinon on a number of foods is a serious threat to public health. Diazinon acts to disrupt normal function of the nervous system. Mild or moderate acute exposures can cause headache, dizziness, weakness, nausea, diarrhea, breathing difficulty, feelings of anxiety, constriction of the pupils of the eye, and blurred vision. Some studies indicate that pesticides like diazinon may have long-term effects on the brain, interfering with memory and concentration. In deciding to maintain the challenged tolerances, EPA failed to consider diazinon's toxicity to the brain or nervous system of developing fetuses, infants, or children, despite requiring the manufacturer to conduct and submit such toxicity tests, and despite the fact that organophosphates are known to be potent poisons to the developing brain and nervous system. In addition to human toxicity, diazinon is very toxic to birds, fish, and honeybees. Because it is so toxic, an agreement has been reached between EPA and the companies that sell diazinon to cancel residential uses indoors and on lawns by December 2004. However, agricultural uses of this dangerous chemical will continue.
35. Disulfoton is a toxic organophosphate insecticide. Almost five million pounds are applied annually in the United States, primarily on agricultural crops, but also around the home on shrubs and flowers, rose bushes, and outdoor potted plants. Exposure to disulfoton occurs from breathing contaminated air, drinking contaminated water, and eating contaminated food. Depending on the amount of disulfoton that enters the body,

disulfoton causes effects on the nervous system, including narrowing of the pupils, vomiting, diarrhea, drooling, difficulty breathing, tremors, convulsions, and, in extreme cases, death. Some studies indicate that pesticides like disulfoton may have long-term effects on the brain, interfering with memory and concentration. In deciding to maintain the challenged tolerances, EPA failed to consider disulfoton's toxicity to the brain or nervous system of developing fetuses, infants, or children, despite requiring the manufacturer to conduct and submit such toxicity tests, and despite the fact that organophosphates are known to be potent poisons to the developing brain and nervous system. EPA has determined that disulfoton poses a risk for human health (especially to workers who apply disulfoton), but nevertheless allows its continued use.

36. Oxydemeton methyl is a broad spectrum organophosphate insecticide used on vegetables, fruit trees, and nut crops. Approximately two hundred thousand pounds are used annually in the United States. Like all organophosphate pesticides, it acts in humans and wildlife to disrupt normal function of the brain and nervous system. Exposure can cause a variety of health effects, including headache, confusion, blurred vision, weakness, tremors, nausea, diarrhea, and difficulty breathing. Some studies indicate that pesticides like oxydemeton-methyl may have long-term effects on the brain, interfering with memory and concentration. In deciding to maintain the challenged tolerances, EPA failed to consider oxydemeton methyl's toxicity to the brain or nervous system of developing fetuses, infants, or children, despite requiring the manufacturer to conduct and submit such toxicity tests, and despite the fact that organophosphates are known to be potent poisons to the developing brain and nervous system. Although it is known that

oxydemeton-methyl is very toxic, the company that sells it has provided very little data to the EPA to evaluate its long-term effects.

37. Alachlor has been used as an herbicide for weed control in the United States since 1969. Twenty-nine to forty-five million pounds per year are used in the United States, predominantly on corn, soybeans, and sorghum. In high doses, alachlor may increase the risk of cancer, and is thought to disrupt hormonal systems. EPA has determined that even when it is used according to the legal label instructions, it causes significant pollution to surface and ground water, and is highly toxic to freshwater fish and aquatic plants.
38. Captan is a fungicide used on a variety of fruit and vegetable crops as well as on ornamental plants. Four to seven million pounds per year are used in the United States. More than half of the apples and almonds in the United States are treated with this chemical, as are nearly all the strawberries, and it is also used by home gardeners. Captan is also used as a preservative in paints, wallpaper paste, plastic, and for treating some textiles and leather. Although captan apparently is not very acutely poisonous to humans, it can cause significant irritation of the eyes and skin. Most worrisome, captan causes DNA mutations in some laboratory tests, and also causes cancer in both mice and rats. As a result, captan is classified as a probable carcinogen by EPA and as “known to cause cancer” by the State of California. Captan is very toxic to fish and other aquatic organisms, and is also very poisonous to honeybees.
39. EPA’s final approval of unsafe levels of diazinon, disulfoton, oxydemeton methyl, alachlor, and captan on a number of foods is a serious threat to public health.

II. THE FQPA TENFOLD SAFETY FACTOR

40. The House and Senate passed the FQPA unanimously in 1996, in large part because of the findings of an influential 1993 National Academy of Sciences (NAS) report, *Pesticides in the Diets of Infants and Children*. The 1993 NAS report found that EPA's existing approach to regulating pesticides failed to address the unique vulnerabilities of infants and children to the adverse effects of pesticides, including the likelihood that infants and children are both more susceptible and more highly exposed to pesticides.
41. One of the FQPA's most important provisions to protect children – incorporated into the FFDCFA – is that it requires EPA to use an additional tenfold margin of safety in its tolerance risk assessments to protect infants and children. Under the FFDCFA, EPA must maintain an additional tenfold margin of safety in its risk assessments to “take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” 21 U.S.C. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety “*only if*, on the basis of reliable data, such margin will be safe for infants and children.” *Id.* (emphasis added).
42. The safety factor provision requires EPA, in making tolerance decisions, to assume that a particular pesticide used on food is ten times more toxic to children than adults, unless reliable data show that use of a different uncertainty factor will be safe for infants and children.
43. In ensuring that the statutory safety standard is met for infants and children, EPA must base its tolerance decision on available information about a number of relevant factors:

“food consumption patterns unique to infants and children;” “special susceptibility of infants and children to pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure;” and the “cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity.” 21 U.S.C. §§ 346a(b)(2)(C)(i)(I-III).

44. If there are no data or where there are gaps in data – either for particular toxic effects, for age-specific patterns of food-consumption, or for particular routes of pesticide exposure – there cannot be “reliable data” sufficient to overturn the statutory presumption of an additional tenfold safety factor to protect infants and children.
45. For each of the pesticides that are the subject of this complaint – diazinon, disulfoton, oxydemeton methyl, alachlor, and captan – EPA has waived the statutory tenfold safety factor even though reliable data do not exist to prove that a less protective margin of safety is safe for infants and children. This is contrary to EPA’s obligation under the FFDCA to maintain the full tenfold safety factor unless the Agency has affirmative evidence that justifies departing from that safety level.

A. Absence of Developmental Neurotoxicity Tests

46. Organophosphate insecticides, including diazinon, disulfoton, and oxydemeton-methyl, are poisonous to the nervous system of insects by design, and are also poisonous to the human nervous system and brain. EPA has determined that organophosphates are among the pesticides that pose the greatest risk to public health. Organophosphate pesticide residues are frequently detected in the foods most commonly found in children’s diets, and in and around their homes from use to control insects in homes and gardens.

47. Developmental neurotoxicity (DNT) tests are used to assess toxicity to the developing brain and nervous system. In its 1993 report *Pesticides in the Diets of Infants and Children*, the NAS cited strong evidence that pesticide exposures may disrupt the normal development of a child's brain and nervous system, and more conclusive evidence has since been published supporting this finding. The developing nervous system is exquisitely sensitive to exposure to neurotoxins, which can irrevocably alter developing neurological connections and thereby negatively impact people for the rest of their lives.
48. Studies by EPA scientists show that DNT testing is more sensitive than other studies in measuring the effects of exposure on proper development of the brain and nervous system, and therefore DNT testing is most appropriate for protecting children's health. DNT testing is essential for assessing pesticide effects, not only as a measure of toxicity to the developing brain and nervous system, but also as a measure of developmental and reproductive effects generally.
49. EPA has required DNT studies through data call-ins for many individual pesticides and classes of pesticides, including diazinon, disulfoton, oxydemeton-methyl and all other organophosphates. *See, e.g.*, 64 Fed. Reg. 42,945 (Aug. 6, 1999) (announcing a data call-in for DNT testing for approximately 140 neurotoxic pesticides, including the organophosphate class of pesticides). Through a data call-in notice sent to pesticide manufacturers on September 10, 1999, EPA required the submission of DNT studies for 34 organophosphate pesticides.
50. On information and belief, to date EPA has received DNT data for just 10 of 34 organophosphate pesticides. Of these, data are only publicly available for three chemicals. Where there are data available, they show infants and children may be

dramatically more sensitive and susceptible to pesticide exposure. For example, for the pesticide dimethoate, the DNT study reports that rat pups are at least 30 times more sensitive than adults.

51. If EPA has required DNT testing for a particular pesticide but the testing was not completed before EPA published final tolerance reassessments for the pesticide, the absence of or failure to include DNT results constitutes a significant toxicity data gap. The absence of DNT data – particularly for organophosphates and other insecticides specifically designed to be neurotoxic – requires that EPA retain the additional tenfold safety factor to protect infants and children. EPA’s requirement of DNT testing demonstrates the Agency’s acknowledgment of critical data gaps; EPA therefore lacks reliable data to prove safety without such studies.

B. Absence of Non-Dietary Exposure Data for Infants and Children

52. Infants and children are exposed to pesticides through significant non-dietary sources. These sources include pesticides in the home, in schools, in yards, parks, and playgrounds, and in both indoor and outdoor air. No integrated database exists within EPA to collect and collate data on pesticide exposure through non-dietary contaminated media, including indoor and outdoor air, surface water, soil, and household dust. Pesticide residue and exposure data are virtually never considered by EPA in the kind of detail necessary to support quantitative calculations of exposure to fetuses, infants, and children through all routes and at all critical stages of development.
53. EPA ignores or minimizes data on non-dietary exposure. In addition, EPA’s assessments of non-dietary exposure rely on unrealistic assumptions that underestimate exposure. For

diazinon, for example, EPA assumed that there is zero residential exposure to that pesticide because it will no longer be registered for any home uses after December 2004. However, data shows that significant residues of non-residential pesticides, including diazinon, are tracked into the home, particularly in agricultural areas where diazinon is used extensively and routinely drifts far from the application site.

54. The absence of non-dietary exposure data for infants and children constitutes a significant exposure data gap. While EPA can and must make estimates of these non-dietary exposures based upon the best available information, these exposure gaps make it impossible for the Agency to have “reliable data” to overturn the tenfold safety factor. The absence of non-dietary exposure data for infants and children requires that EPA retain the additional tenfold safety factor to protect infants and children. There is a lack of reliable data for EPA to demonstrate the safety of departing from the tenfold safety factor in the absence of a proper analysis of non-dietary exposure.

C. Failure to Consider Exposures from Pesticide Drift

55. Pesticide drift is a significant source of pesticide exposure for people living near pesticide application sites, and reliable information exists on the extent and magnitude of such exposures.
56. Pesticide drift is comprehensively defined as any airborne movement of pesticides off the target application site, and can occur both during an application and for many days afterward.
57. “Spray drift” occurs during and soon after a pesticide application, when winds or application equipment blow spray droplets, gas-phase pesticides, or particles away from

the application site. In a recent proposal to update and refine pesticide label language related to spray drift, EPA acknowledged that all pesticide spray applications are accompanied by some spray drift. *See* EPA, Pesticide Registration Notice 2001-X, *Spray and Dust Drift Label Statements for Pesticide Products*. Spray drift can travel for miles and can lead to exposure by contaminating lawns, parks, picnic areas, and even indoor spaces where people may come in contact with contaminated surfaces. Children are particularly susceptible to these types of exposures because they spend more time on the ground and have a greater propensity to put potentially contaminated objects in their mouths.

58. “Post-application drift” occurs after application is complete and can result from either volatilization of applied pesticides from plant or soil surfaces or from wind-driven transport of pesticide-contaminated dust particles away from the application site. Air monitoring studies conducted by the California Air Resources Board (ARB) indicate that post-application volatilization drift typically peaks between 4 and 24 hours after the start of an application for volatile and semi-volatile pesticides and may persist for days above levels of concern. The ARB has been publishing these air monitoring studies since 1986.
59. Available monitoring data show that, for volatile and semi-volatile pesticides, post-application drift typically accounts for 80 to 95% of the total off-site airborne movement. For non-volatile pesticides, spray drift and wind-driven transport of pesticide-contaminated dust particles are the major mechanisms of airborne transport.
60. In its risk assessment process for the five pesticides that are the subject of this complaint, EPA did not assess exposures due to spray drift and post-application drift – from either

inhalation or drift-related residue on lawns, in homes, or elsewhere – even though it admits that drift is all but unavoidable in pesticide spray or dust applications.

61. A pesticide's potential for post-application drift can be correlated with its physicochemical properties and atmospheric conditions. Researchers have used publicly available air-monitoring data and the known physicochemical properties of pesticides to develop an algorithm to estimate the rate of pesticide volatilization from treated fields. This model provides an estimate of peak concentrations downwind from an application site. This work was published in a peer-reviewed journal, *see* J.E. Woodrow et al., *Correlation Techniques for Estimating Pesticide Volatilization Flux and Downwind Concentrations*, 31 Environ. Sci. Technol. 523 (1997), and Plaintiff PANNA gave a presentation to EPA staff in May 2002 highlighting this work and extending it to include additional pesticides evaluated between 1996 and 2002. The model provides a means to estimate near-field, post-application drift exposures for all pesticides currently registered in the United States.
62. People are exposed to pesticide drift through one of several mechanisms, including by breathing air containing pesticide vapors, particles, or droplets, or by contacting surfaces onto which pesticide drift has deposited or condensed. Spray drift and post-application drift can be sources of both of these types of exposures.
63. Residents of rural communities and suburban communities bordering farmland are frequently exposed to drift from agricultural pesticides through these two exposure routes. Urban residents are also exposed to drift from non-agricultural use of pesticides applied to roadsides, lawns, gardens, and homes.

64. Recently-published research in the peer-reviewed literature evaluated air monitoring data and pesticide use reporting data to estimate the number of people at risk of adverse effects from exposures to airborne pesticides through ambient air at locations somewhat distant from pesticide applications but in an area of high use for the pesticide in question. *See S. Lee et al., Community Exposures to Airborne Agricultural Pesticides in California: Ranking of Inhalation Risks*, 110 *Env. Health Persp.* 1175 (2002). The researchers estimated that hundreds of thousands of people are potentially at risk of adverse effects from exposures to pesticides in ambient air in California alone.
65. Plaintiff PANNA has evaluated available near-field air monitoring data and compared measured air concentrations of post-application drift to published EPA reference doses for several pesticides, including diazinon and captan. The data show that pesticide concentrations in air near application sites commonly exceed EPA-determined “safe” concentrations for volatile pesticides.
66. Plaintiff PANNA has provided EPA with the results of this work for multiple pesticides on several occasions, including in several formal comment letters to EPA and in a presentation to EPA staff.
67. Pesticides sprayed outdoors are transported into homes, where children may be exposed to residues on floors, carpets, toys, and other surfaces contaminated with spray and dust drift. Pesticides also appear in fog; analysis of fog samples has revealed more than a dozen different pesticides. Ambient air monitoring data show that people are frequently exposed to many pesticides simultaneously in the air that they breathe. The toxicological effects of exposure to multiple chemicals through drift are unknown.

68. Ample evidence exists in the peer-reviewed toxicology and epidemiology literature to suggest that living in areas of high pesticide use or in homes where pesticides are used increases the risk of many types of cancers, stillbirths, spontaneous abortion, reproductive failures, and neurological disease. *See, e.g.,* Susan Kegley et al., *Secondhand Pesticides: Airborne Pesticide Drift in California*, at 9-13 (2003).
69. EPA fails to consider available and significant data on pesticide drift as a source of pesticide exposure. EPA's failure to consider pesticide drift exposure data for infants and children constitutes a significant exposure data gap. This pesticide drift exposure data gap requires that EPA retain the additional tenfold safety factor to protect infants and children.

D. Absence of Data on Farm Children's Exposure

70. Children living in agricultural communities are heavily exposed to pesticides. *See* discussion of farm children at Section III, *infra*. Farm children are an identifiable subgroup of the population with unique exposure patterns and sensitivities to pesticides.
71. Farm children come in contact with pesticides through residues from their parents' skin and clothing, soil and dust tracked into their homes, contaminated soil and other surfaces in areas where they play, food eaten directly from the fields, drift from agricultural pesticide applications, contaminated well water, and breastmilk. Furthermore, farm children often accompany their parents to work in the fields, raising their potential for pesticide exposures even higher.

72. In the absence of an assessment of farm children's unique and heightened exposures and sensitivities, EPA lacks reliable data to ensure safety and therefore must retain the additional tenfold safety factor to protect infants and children.

E. Absence of a No-Observed-Effect-Level

73. One objective of pesticide toxicity studies is to discover if there is a dose of the pesticide that causes no effects. This dose is referred to as the "no-observed-effects-level," or "NOEL." Occasionally, toxicity studies submitted to EPA fail to identify any such dose, and instead can only point to a "lowest-observed-adverse-effect-level," or "LOAEL." "Lowest-observed-adverse-effects" are often based on crude toxicological endpoints, such as dramatic loss of organ weight, and are not necessarily designed to correlate with the vulnerable points in embryonic development. Even worse, a LOAEL could simply represent the lowest dose that the pesticide registrant chose to test. A LOAEL may therefore be a dose high enough to elicit significant harmful effects, and is not as protective or meaningful as a NOEL.
74. If the results of a study reveal only a LOAEL and no NOEL for a particular endpoint, that constitutes a significant toxicity data gap. By relying only on a LOAEL for certain endpoints, EPA has an insufficient scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental or reproductive harm because of pesticide exposure. Acknowledging this deficiency, EPA typically applies a three-fold safety factor to compensate for the use of a LOAEL instead of a NOEL.

75. The FQPA’s legislative history clarifies the statutory intent that regulatory decisions be made on the basis of the NOEL. *See* H.R. Rep. No. 104-669, Part 2, at 43, presented to the House on July 23, 1996.
76. The absence of a NOEL for a toxicity study constitutes a significant toxicity data gap. This toxicity data gap requires that EPA retain the additional tenfold safety factor to protect infants and children.

III. FARM CHILDREN

77. The FFDCA requires that EPA consider exposure not just to consumers as a whole, but also to “major identifiable subgroups of consumers.” 21 U.S.C. § 346a(b)(2)(D). In reassessing tolerances, EPA must consider, among other relevant factors, “available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers); . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers);” and “available information concerning the variability of the sensitivities of major identifiable subgroups of consumers.” 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii). The 1993 NAS report *Pesticides in the Diets of Infants and Children* found – and Congress recognized in enacting the FQPA – that there are certain subpopulations of people who are likely to be far more heavily exposed or far more susceptible to pesticide toxicity than are average people.
78. The children of farmworkers and those that live on or near farms (“farm children”) are a major identifiable subgroup of consumers under these statutory provisions. In

reassessing tolerances, EPA is required to consider the unique dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure of farm children.

79. Plaintiffs NRDC, TBCF, PANNA, PSR and several dozen other organizations filed a petition in October 1998, requesting that EPA designate farm children as a major identifiable subgroup and population at special risk under the FQPA. *See* NRDC et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup and Population at Special Risk to be Protected under the Food Quality Protection Act*, Oct. 22, 1998 (hereafter “NRDC, *Farm Children Petition*”). EPA has failed to respond to this petition.
80. More than 320,000 children under the age of six live on farms in the United States. In addition, many hundreds of thousands of children play or attend schools on or near agricultural land, and others have family members who work on farms or handle pesticides as part of their jobs. The nation’s two and a half million farmworkers have approximately one million children living in the United States. *See* NRDC, *Farm Children Petition*, at 1.
81. Children living in agricultural communities are heavily exposed to pesticides, whether or not they work in the fields. Farm children come in contact with pesticides through residues from their parents’ skin and clothing, soil and dust tracked into their homes, contaminated soil and other surfaces in areas where they play, food eaten directly from the fields, drift from aerial spraying, contaminated well water, and breastmilk. Furthermore, farm children often accompany their parents to work in the fields, raising their potential for pesticide exposures even higher. *See id.* at 2-3.

82. Citing data from the Department of Labor, the U.S. General Accounting Office has reported that seven percent of farmworkers with children five years old or younger took their children with them, at least sometimes, when they worked in the fields. *See* U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children*, (RCED-00-40), March 14, 2000, at 6 (hereafter “GAO, *Safety of Farmworkers and Their Children*”).
83. Children age ten or older may and do work on large farms, and children of any age may and do work on their parents’ farms or on small farms. There are an estimated 400,000 to 800,000 children farmworkers in the United States. *See* Human Rights Watch, *Fingers to the Bone: United States Failure to Protect Child Farmworkers*, June 2000, at 10, 16-22. In a recent survey of 88 Colorado farmworkers, 40 began working before they were 18 years old, including several younger than 10. *See* Cassillas Pesticide Action Project, *Hidden Costs: Farm Workers Sacrifice their Health to Put Food on Our Tables*, August, 2002, at 4.
84. Farm children have very high rates of exposure to pesticides compared to other groups of people in the country. Many of the children with the greatest pesticide exposures are from migrant farmworker families. Seventy-eight percent of farmworkers are Hispanic, and sixty-eight percent of farmworker children live below the poverty line. *See* NRDC, *Farm Children Petition*, at 2-3, 8-9.
85. Children have unique exposure patterns and sensitivities to pesticides. Per pound of body weight, children eat, drink, and breathe more than adults. Children also engage in more frequent hand-to-mouth contact, and therefore have higher rates of oral exposure from

objects, dust, or soil. *See id.* at 3; GAO, *Safety of Farmworkers and Their Children*, at 17.

86. Infants and children can be exposed through unusual routes not normally encountered by adults, such as ingestion of turf and soils outside the house and dust on floors and toys inside. The GAO has found that crawling, sitting, and lying on contaminated surfaces may also increase exposure rates of farm children to pesticides. *See GAO, Safety of Farmworkers and Their Children*, at 17.
87. The GAO has concluded that, “[b]ecause young children’s internal organs and bodily processes are still developing and maturing, their enzymatic, metabolic, and immune systems may provide less natural protection than those of an adult.” *Id.*
88. Farm children are also exposed to pesticides in utero, when pregnant farmworker women are exposed at work, or when pregnant residents of rural areas are exposed via contaminated drinking water, drift, or contamination of the home by family members who work with pesticides. The FFDCA requires EPA to consider available information concerning “effects of in utero exposure to pesticide chemicals” when conducting tolerance reassessments. 21 U.S.C. § 346a(b)(2)(C)(i)(II). Maternal exposures between conception and birth are relevant to both reproductive and developmental toxicity. Any prenatal exposure to the fetuses of farmworkers must be considered in reassessing tolerances.
89. Farm children are a population at special risk, whose exposures and health status serve as an indicator of potential problems for other population groups. Protection of farm children would ensure a greater level of confidence in protection for the rest of the population.

90. Plaintiffs NRDC, TBCF, PANNA, PSR and others have presented EPA with reliable data regarding farm children's exposure to pesticides from house dust, indoor air, pesticide drift from agricultural pesticide applications, and soil around homes, schools, and parks. Plaintiffs NRDC, TBCF, PANNA, and PSR have also presented EPA with reliable data regarding the increased susceptibility of farm children to pesticide exposure.
91. In the 1998 petition to EPA, and in a series of comments filed on proposed EPA actions with respect to specific pesticides, Plaintiffs NRDC, TBCF, PANNA, PSR and other organizations repeatedly urged the agency to consider extensive scientific data showing that children whose parents are farmworkers, and other children who live on or near farms, are far more heavily exposed to pesticides than average consumers. EPA has not only failed to respond to this petition, it has refused to protect these children from their heavy exposure when reassessing tolerances, even where Plaintiffs or other groups have provided specific data for a specific pesticide indicating that farm children are more exposed than most consumers.
92. EPA must consider data regarding farm children's dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure in conducting tolerance reassessment. 21 U.S.C. § 346a(b)(2)(D). If reliable data are lacking, EPA must apply the statutory 10-fold safety factor and require the pesticide chemical registrants to secure the necessary data.

IV. LEGAL FOOD MUST BE SAFE FOOD

93. The FFDCA provides that EPA "may establish or leave in effect a tolerance . . . only if the Administrator determines that the *tolerance* is safe. The Administrator shall modify

or revoke a tolerance if the Administrator determines it is not safe.” 21 U.S.C.

§346a(b)(2)(A)(i) (emphasis added).

94. EPA routinely approves tolerances even when its own data show that it is unsafe for a child to be exposed to pesticides at the level allowed by the tolerance. In particular, EPA bases its estimates of the likely levels of exposure to pesticides on a limited set of data from limited sampling of food items, and generally concludes that the existing levels in the food supply are far below the tolerance. EPA then often approves a tolerance if the *predicted* level of exposure is deemed safe, even if exposure at the tolerance level is known to be unsafe and extremely hazardous.
95. As part of the process of assessing dietary risk, EPA calculates the “acute Population Adjusted Dose” (aPAD) and “chronic Population Adjusted Dose” (cPAD). The aPAD and cPAD characterize the Agency’s view of the dietary dose of a pesticide that can safely be consumed. Based on Plaintiffs’ calculations, EPA frequently sets a tolerance at a level significantly higher than the aPAD or cPAD.
96. Thus, in many cases the enforceable tolerance permits food to be sold lawfully with pesticide residues far higher than safe levels. EPA routinely sets tolerances at levels ten times higher than the safe level. This is analogous to setting the speed limit at 600 miles per hour, and declaring it safe because most people will probably drive 60 mph. Permitting a gap between the safe level and the tolerance puts consumers at risk in several ways.
97. First, EPA’s exposure estimates ignore localized sources of produce and are therefore based on incomplete and biased data. A significant number of consumers purchase produce at farmers’ markets, farm stands, and in farm fields at “you-pick” farming

operations. Almost two million people buy vegetables and fruits from nearly thirteen thousand farmers at more than two thousand community-based farmers' markets and farm stands in the United States. Based on EPA's assumptions, consumers who purchase vegetables and fruit at farmers' markets or other similar sources are more likely to consume food with pesticide chemical residues at or near the tolerance level. There may be unaccounted-for differences in the length of time between pesticide application and consumption between those who purchase produce through farmers' markets or similar sources and those who purchase produce in grocery stores.

98. Furthermore, pesticide use patterns do not remain constant. As EPA limits the use of a pesticide on certain foods, the use of other pesticides on those same foods may increase because of the regulatory restrictions or market pressures on the alternatives. Therefore, EPA's predictions about the level of pesticide exposure that will result from a given tolerance are likely to be inaccurate. By leaving a gap between the tolerance and the safe level, EPA's actions permit increased use of pesticides up to the tolerance level.
99. Finally, allowing a tolerance above the safe level can increase the risk from imported food. When the measured dietary exposure level exceeds the aPAD or cPAD level of dietary risk, EPA frequently fails to reduce the tolerance level, and thus fails to require that exposure will be below the risk limit. Instead, EPA may simply make technical changes to the instructions on the pesticide label, and assume that those changes will have the prospective effect of reducing exposure down to the safe level. For example, EPA might lengthen the "pre-harvest interval" (PHI) – the amount of time after pesticide application before the crop is harvested, in the hope that this will cause pesticide residue

levels in food to drop and dietary exposure to go down as well. However, these requirements need not be followed by pesticide producers and users *abroad*.

100. Accordingly, these domestic actions do not do anything to make it more likely that imported food will have pesticide residues at a “safe” level below the applicable tolerance. When EPA sets the legal tolerance at a level far above the safe level for the pesticide, imported food (grown, for example, during pest infestations or bad weather in developing countries that have few or no meaningful restrictions on pesticide use) may contain far higher levels of the pesticide than estimated based upon limited monitoring data by EPA. Such pesticide-laden foods that exceed EPA’s own safety level still could be legally imported despite exceedingly high, even dangerous pesticide residues, because of the agency practice of setting tolerances above agency-defined safe levels.

V. PERCENT OF CROP TREATED

101. The FFDCA provides that EPA may adjust the presumed exposure to a pesticide in food for chronic health effects based upon the percent of the crop that is treated with that pesticide. The statute states, “the Administrator may, when assessing *chronic* dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical,” if the Administrator makes four specific findings about data reliability. 21 U.S.C. § 346a(2)(F) (emphasis added). This provision, by its terms, does not apply to *acute* dietary risks.
102. In assessing whether exposure to a pesticide may cause harm to a person, it is logical to consider the percent of crop treated to ascertain whether a person is exposed to residues that could cause chronic problems because a person’s diet in the long term is likely to be

made up of food from a variety of locations and sources. The percent of crop treated is mostly meaningless in determining what level of pesticide residue could cause acute harm, however, because what matters is the amount a person can safely eat in a single serving.

103. Despite the statutory limitation of percent of crop treated adjustments to chronic toxins, EPA improperly applied the percent of crop treated adjustment to assess the acute toxicity of four of the pesticides that are the subject of this complaint – captan, diazinon, disulfoton, and oxydemeton methyl.

VI. THE CALENDEX AGGREGATE EXPOSURE MODEL

104. The FFDCA requires that EPA assess aggregate exposure to pesticide residues, defined as exposure through all sources for which reliable information exists. 21 U.S.C. §§ 346a(b)(2)(A)(ii) & (c)(2)(A)(ii). To conduct aggregate exposure assessments for some pesticides, EPA has used the Calendex Aggregate Exposure Model: a confidential and proprietary computer program unavailable for public review.
105. Calendex is a secret model that is not available to outside scientists for independent scrutiny. The Calendex model is a “black box,” inside which are hidden assumptions and calculations that drive the bulk of the results of aggregate exposure assessments.
106. No public peer review of this confidential model has been able to guarantee its scientific validity. *See Report of the FIFRA Scientific Advisory Panel Meeting on September 28, 2000, at 19* (“At this time, the Panel is in no position to make a detailed validation of the many models and assumptions in CalendexTM”). An EPA panel of science advisors was

provided so little information about the Calendex model that “they could not verify, refute, or validate Calendex.” *Id.* at 17.

107. On information and belief, EPA used the Calendex model to conduct exposure assessments for the organophosphate pesticides, including diazinon, disulfoton, and oxydemeton methyl.
108. EPA’s choice of an exposure model is an important decision, with real-world consequences. Different models may use different assumptions about peoples’ activities and about the quantity of chemicals to which individuals are exposed in varied environments. By accounting for input differently, alternate models may produce dramatically different output estimates. Risk assessments typically require scientists to extrapolate from experimental doses to environmental levels, from one exposure route to another (such as ingestion, inhalation, or dermal exposures), from one exposure pattern to another, and from small samples to larger and more heterogeneous populations. Depending on the model chosen, these extrapolations may be made in different ways, and one model may be much less health-protective than another. This inherent uncertainty invites “model shopping,” as EPA has itself observed.
109. NRDC has requested that EPA either disclose sufficient information about the Calendex model and the assumptions incorporated in it to provide a meaningful public understanding of how it works, or perform exposure assessments using a non-proprietary and publicly available model. EPA has failed to respond to these requests.
110. EPA may not legally rely on the Calendex model without providing substantial detail about its built-in assumptions and calculation methodologies; the Agency’s authority to use a model to predict pesticide residue exposures is not unqualified. *See* 7 U.S.C. §

136h(d). EPA has failed to explain the assumptions and methodology used in preparing Calendex, and has failed to provide enough information to the public about the underlying facts supporting the model to demonstrate that the Agency has engaged in reasoned decisionmaking.

THE CHALLENGED ACTIONS

I. ORGANOPHOSPHATE TOLERANCES

111. In a series of Federal Register notices between May 22 and September 5, 2002, EPA published final tolerance reassessments for 118 pesticide tolerances for uses of the organophosphate pesticides diazinon, disulfoton, and oxydemeton methyl. *See* 67 Fed. Reg. 35,991 (May 22, 2002) (30 tolerance reassessments for oxydemeton methyl and 13 for disulfoton); 67 Fed. Reg. 46,972 (July 17, 2002) (18 tolerance reassessments for oxydemeton methyl and 9 for disulfoton); 67 Fed. Reg. 52,988 (Aug. 14, 2002) (effective July 23, 2002) (3 tolerance reassessments for oxydemeton methyl and 6 for disulfoton); 67 Fed. Reg. 56,557 (Sept. 5, 2002) (effective July 31, 2002) (26 tolerance reassessments for diazinon); 67 Fed. Reg. 56,555 (Sept. 5, 2002) (effective July 31, 2002) (13 tolerance reassessments for diazinon).
112. EPA stated that each one of these tolerance reassessment decisions was final agency action, and stated that “these tolerances will be maintained regardless of the outcome of the [organophosphate] cumulative assessment and any potential regulatory action taken as a result of that assessment. Accordingly, EPA believes it is appropriate to consider these tolerances reassessed for the purposes of FQPA section 408(q) as of today’s date.... The Agency’s assessment of these tolerances is effectively complete and the tolerances

are considered reassessed.” *See* 67 Fed. Reg. at 35,993; 67 Fed. Reg. at 46,974; 67 Fed. Reg. at 52,990; 67 Fed. Reg. at 56,558-59; 67 Fed. Reg. at 56,556. EPA counted each of these tolerance reassessments as final and complete when announcing that it had met its legal obligations under the FQPA, 21 U.S.C. §346a(q), to reassess two-thirds of all existing tolerances – approximately 6,400 tolerances out of more than 9,700 – by August 3, 2002.

113. Many of Plaintiffs’ members and their children are exposed to these organophosphate pesticides through their food, drinking water, and other sources.

II. REREGISTRATION ELIGIBILITY DECISIONS

114. EPA approved the Reregistration Eligibility Decision (RED) for the pesticide alachlor on September 30, 1998, and for captan on September 30, 1999. In each of these REDs, announced in the Federal Register, EPA concluded that a number of existing tolerances for each pesticide met the FFDCA safety standard and could therefore be left in place. *See* EPA, Alachlor RED, EPA 738-R-98-020 (Dec. 1998) at 185-187; 64 Fed. Reg. 11,870 (March 10, 1999) (alachlor); EPA, Captan RED, EPA 738-R-99-015 (Nov. 1999) at 66-72; 64 Fed. Reg. 67,902 (Dec. 3, 1999) (captan). These tolerances are considered fully reassessed, no further administrative action will follow, and the tolerance reassessments are final. EPA counted each of these tolerance reassessments as final and complete for purposes of satisfying a statutory deadline, set forth in 21 U.S.C. § 346a(q), that has since passed.
115. Many of Plaintiffs’ members and their children are exposed to these pesticides through their food, drinking water, and other sources.

CLAIMS FOR RELIEF

COUNT ONE

IN FINAL TOLERANCE REASSESSMENT ACTIONS, EPA FAILED TO INCLUDE THE FULL REQUIRED TENFOLD SAFETY FACTOR DESPITE SIGNIFICANT DATA GAPS WITH RESPECT TO EXPOSURE AND TOXICITY TO INFANTS AND CHILDREN, AND DESPITE POTENTIAL PRE- AND POST-NATAL TOXICITY.

116. Plaintiffs hereby incorporate all preceding paragraphs as if fully set forth herein.
117. The FFDCA provides that EPA must maintain an additional tenfold margin of safety in its risk assessments for individual pesticides to “take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” 21 U.S.C. § 346a(b)(2)(C). EPA can use a different margin of safety “only if, on the basis of reliable data, such margin will be safe for infants and children.” *Id.*
118. EPA published final tolerance reassessments for 146 pesticide tolerances for uses of alachlor, captan, and the organophosphate pesticides diazinon, disulfoton, and oxydemeton methyl. For each of these pesticides, EPA failed to apply the full tenfold safety factor required by the FFDCA, despite one or more significant data gaps with respect to exposure and toxicity to infants and children, and despite potential pre- and post-natal toxicity. These data gaps and evidence of pre- and post-natal toxicity demonstrate that EPA lacked sufficient data to justify departing from the tenfold safety factor.
119. In reassessing these pesticide tolerances, EPA failed to consider important non-dietary exposure routes for millions of infants and children. Infants and children are exposed to these pesticides in homes, schools, yards, parks, playgrounds, indoor and outdoor air,

soil, and dust. The absence of non-dietary exposure data for infants and children constitutes a significant exposure data gap. EPA has insufficient reliable data to justify lifting the presumptive tenfold safety factor because of gaps in data on exposure to these pesticides through these non-dietary sources.

120. In reassessing these pesticide tolerances, EPA also failed to consider data concerning exposure from both spray drift and post-application drift from application of pesticides. Plaintiff NRDC has presented EPA with reliable data concerning exposure to organophosphates and to alachlor through drift and fog. Plaintiff PANNA has presented EPA with reliable data concerning exposure to post-application drift. EPA's failure to assess or consider exposure through drift constitutes a significant exposure data gap that precludes removal of the presumptive tenfold safety factor.
121. In reassessing these pesticide tolerances, EPA also failed to take into consideration the unique exposure and vulnerabilities of farm children. NRDC and others have presented EPA with reliable data concerning the take-home exposure of children to organophosphate and alachlor residues that have been tracked in to homes. EPA's failure to assess or consider farm children's exposure constitutes a significant exposure data gap that precludes removal of the presumptive tenfold safety factor.
122. The results of the alachlor dermal toxicity study reveal only a LOAEL and no NOEL. The failure to discern a no-observed-effects-level constitutes a significant toxicity data gap for alachlor that prevents EPA from modifying the presumptive tenfold safety factor.
123. For the organophosphate pesticides, EPA expressly stated that developmental neurotoxicity testing is required and necessary to assess the risks posed by each pesticide. EPA published final tolerance reassessments for diazinon, disulfoton, or oxydemeton

methyl even though the required DNT studies had not been completed or submitted to the Agency. These critical data gaps make it impossible to fully assess the neurotoxic effects of these pesticides to fetuses, infants, and children. It is therefore impossible to find that there are reliable data to overturn the presumptive tenfold safety factor for the tolerances reassessed for each of these pesticides.

124. The EPA Scientific Advisory Panel (SAP) issued a report on July 19, 2002 that faulted the Agency for failing to apply the full tenfold margin of safety for all organophosphate insecticides. Specifically, the report said, “[a] majority of the Panel members who commented on the Agency decision of an appropriate FQPA safety factor disagreed with the Agency’s proposal to deal with the FQPA requirements to ensure protection of infants and children by selective application of a 3X safety factor. These Panel members concluded that the confidence with the available data was not sufficient to assure adequate protection with less than the 10X FQPA safety factor.”
125. EPA’s failure to apply the required tenfold safety factor in reassessing tolerances for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan violates the FFDCA, 21 U.S.C. § 346a(b)(2)(C), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), constitutes arbitrary and capricious agency action, and agency action not in accordance with law under the APA, 5 U.S.C. § 706, and subjects Plaintiffs, their members, and their members’ children to continued risk of harm from exposure to potentially dangerous chemicals.

COUNT TWO

IN FINAL TOLERANCE REASSESSMENT ACTIONS, EPA REFUSED TO PROTECT FARM CHILDREN AS A MAJOR IDENTIFIABLE SUBGROUP OF CONSUMERS UNDER THE FFDCA.

126. Plaintiffs hereby incorporate all preceding paragraphs as if fully set forth herein.

127. The FFDCA requires that EPA consider exposure to “major identifiable subgroups of consumers.” 21 U.S.C. § 346a(b)(2)(D). In reassessing tolerances, EPA must consider, among other relevant factors, “available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers); . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers);” and “available information concerning the variability of the sensitivities of major identifiable subgroups of consumers.” 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii).
128. Farm children are a major identifiable subgroup of consumers under the FFDCA.
129. EPA published final tolerance reassessments for 146 pesticide tolerances for uses of alachlor, captan, and the organophosphate pesticides diazinon, disulfoton, and oxydemeton methyl. For each of these pesticides, EPA did not consider farm children as a major identifiable subgroup. EPA refused to consider available information concerning the consumption patterns and exposure levels of farm children.
130. Plaintiffs NRDC, TBCF, PANNA, PSR and several dozen other organizations filed a petition with EPA in October 1998, requesting that the Agency designate farm children as a major identifiable subgroup under the FFDCA. EPA has never responded to this petition.
131. Plaintiff NRDC submitted reliable data to EPA concerning the exposure of farm children to a number of these pesticides individually, including alachlor and diazinon, and to the organophosphates as a class generally.

132. In comments regarding a number of these pesticides individually, including diazinon, Plaintiff NRDC requested that EPA designate farm children as a major identifiable subgroup under the FFDCA.
133. EPA's refusal to consider the dietary consumption patterns, aggregate exposure levels, and variability of sensitivities of farm children as a major identifiable subgroup when reassessing these pesticide tolerances for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan violates the FFDCA, 21 U.S.C. § 346a(b)(2)(D), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), constitutes arbitrary and capricious agency action, and agency action not in accordance with law under the APA, 5 U.S.C. § 706, and subjects Plaintiffs, their members, and their members' children to continued risk of harm from exposure to potentially dangerous chemicals.

COUNT THREE

IN FINAL TOLERANCE REASSESSMENT ACTIONS, EPA FAILED TO REGULATE BASED ON EXPOSURE TO PESTICIDE CHEMICAL RESIDUES AT THE TOLERANCE LEVEL AND ESTABLISHED TOLERANCES AT UNSAFE LEVELS.

134. Plaintiffs hereby incorporate all preceding paragraphs as if fully set forth herein.
135. The FFDCA provides that EPA "may establish or leave in effect a tolerance . . . only if the Administrator determines that the *tolerance* is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. §346a(b)(2)(A)(i) (emphasis added). The tolerance is the enforceable limit, and a tolerance that is higher than the level that is safe undercuts the law's enforcement mechanism.
136. Of the final tolerance reassessments that EPA published for the organophosphate pesticides diazinon and disulfoton, Plaintiffs calculate that at least 11 of them exceed

EPA's safe level for children's exposure. This includes tolerances for diazinon on cherry, cucumber, grape, lettuce, melon, spinach, winter squash, and tomato; and tolerances for disulfoton on broccoli, cabbage, and lettuce.

137. Each of these 11 tolerances is set at a level higher than the corresponding aPAD, adjusted to reflect a 20kg child eating a 100g dose of the food. Therefore, a child eating this amount of the listed foods may be exposed to these organophosphates at levels far higher than EPA's safe level for acute dietary effects.
138. EPA's failure to guarantee that legal food will be safe food based on exposure to pesticide chemical residues at the tolerance level violates the FFDCA, 21 U.S.C. §§ 346a(b)(2)(A), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), constitutes arbitrary and capricious agency action, and agency action not in accordance with law under the APA, 5 U.S.C. § 706, and subjects Plaintiff, its members, and its members' children to continued risk of harm from exposure to these potentially dangerous chemicals.

COUNT FOUR

IN FINAL TOLERANCE REASSESSMENT ACTIONS, EPA IMPROPERLY ASSESSED ACUTE DIETARY RISK, BY REDUCING PRESUMED RISK BASED ON PERCENT OF CROP TREATED DATA.

139. Plaintiffs hereby incorporate all preceding paragraphs as if fully set forth herein.
140. The FFDCA authorizes EPA to consider the percent of crop treated "when assessing *chronic* dietary risk . . . only if the Administrator" makes four specific rulings about data reliability. 21 U.S.C. § 346a(b)(2)(F) (emphasis added). The law nowhere allows EPA to use data concerning the percent of crop treated to assess *acute* dietary risk.
141. EPA published final tolerance reassessments for 120 pesticide tolerances for uses of the pesticides captan, diazinon, disulfoton, and oxydemeton methyl.

142. In conducting these tolerance reassessments, the acute exposure analysis for each chemical was adjusted for the percent of each crop estimated to be treated, in violation of the FFDCA.
143. In examining the acute harm resulting from a single exposure to any of these pesticides, it is irrelevant whether a large or small percentage of the crop was treated with that pesticide. Any amount of a crop treated with one of these pesticides at a level causing acute harm could not ensure a “reasonable certainty of no harm.”
144. EPA’s failure to account for the full amount of the acute dietary risk posed by these pesticides violates the FFDCA, 21 U.S.C. § 346a(b)(2)(F), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), constitutes arbitrary and capricious agency action, and agency action not in accordance with law under the APA, 5 U.S.C. § 706, and subjects Plaintiff, its members, and its members’ children to continued risk of harm from exposure to potentially dangerous chemicals.

COUNT FIVE

IN FINAL TOLERANCE REASSESSMENT ACTIONS, EPA ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO LAW, RELIED ON A CONFIDENTIAL, PROPRIETARY, INDUSTRY-DEVELOPED MODEL TO ASSESS EXPOSURE, AND REFUSED TO PROVIDE AN OPPORTUNITY FOR PUBLIC REVIEW OF THE ASSUMPTIONS AND METHODOLOGY SUPPORTING THAT MODEL.

145. Plaintiffs hereby incorporate all preceding paragraphs as if fully set forth herein.
146. EPA published final tolerance reassessments for 118 pesticide tolerances for uses of the organophosphate pesticides diazinon, disulfoton, and oxydemeton methyl.
147. On information and belief, in conducting tolerance reassessments for these pesticides, EPA relied on the confidential, proprietary Calendex model to assess exposure to these pesticides, and refused to provide an opportunity for public review of the assumptions

built in to the model. This violates FIFRA's requirement that "[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide . . . , and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, . . . shall be available for disclosure to the public." 7 U.S.C. § 136h(d). It also constitutes arbitrary and capricious agency action, an abuse of discretion, and is contrary to law, in violation of the APA, 5 U.S.C. §706, and deprives Plaintiffs and their members of the ability to meaningfully participate in EPA's assessment of exposure to potentially dangerous chemicals.

REQUEST FOR RELIEF

In the absence of injunctive relief, Plaintiffs and their members will continue to be unlawfully exposed to hazardous chemicals in their food and environment at a significant risk of irreparable harm to their personal health and safety.

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment providing for the following relief, in addition to reasonable attorneys' fees and costs, and such other additional relief that the Court deems appropriate:

COUNT ONE

148. A declaratory judgment that EPA has failed to act in accordance with the FFDCA, 21 U.S.C. § 346a(b)(2)(C), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), and has acted in a manner that is arbitrary, capricious, and contrary to law, by failing to apply the full

tenfold safety factor in reassessing tolerances for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan.

149. An injunction vacating EPA's tolerance reassessment actions for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan and ordering EPA to apply the full tenfold safety factor required by the FFDCA in reassessing tolerances for these pesticides, pursuant to a court-ordered timetable, to take into account significant data gaps with respect to exposure and toxicity to infants and children and potential pre- and post-natal toxicity.

COUNT TWO

150. A declaratory judgment that EPA has failed to act in accordance with the FFDCA, 21 U.S.C. § 346a(b)(2)(D), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), and has acted in a manner that is arbitrary, capricious, and contrary to law, by failing to consider the unique vulnerabilities and exposures of farm children as a major identifiable subgroup of consumers in reassessing tolerances for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan.
151. An injunction vacating EPA's tolerance reassessment actions for diazinon, disulfoton, oxydemeton methyl, alachlor, and captan and ordering EPA to consider the unique vulnerabilities and exposures of farm children as a major identifiable subgroup of consumers in reassessing tolerances for these pesticides, pursuant to a court-ordered timetable.

COUNT THREE

152. A declaratory judgment that EPA has failed to act in accordance with the FFDCA, 21 U.S.C. § 346a(b)(2)(A), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), and has acted in a

manner that is arbitrary, capricious, and contrary to law, by reassessing tolerances at unsafe levels for the organophosphate pesticides diazinon and disulfoton.

153. A preliminary and permanent injunction vacating EPA's tolerance reassessment actions and ordering EPA to reassess tolerances for these pesticides, pursuant to a court-ordered timetable, at a level that is safe for infants and children.

COUNT FOUR

154. A declaratory judgment that EPA has failed to act in accordance with the FFDCA, 21 U.S.C. § 346a(b)(2)(F), and FIFRA, 7 U.S.C. § 136a-1(g)(2)(E), and has acted in a manner that is arbitrary, capricious, and contrary to law, by failing to calculate acute dietary risk without regard for the percent of crops treated when reassessing tolerances for the pesticides captan, diazinon, disulfoton, and oxydemeton methyl.

155. A preliminary and permanent injunction vacating EPA's tolerance reassessment actions and ordering EPA to calculate acute dietary risk without regard for the percent of crops treated when reassessing tolerances for these pesticides, pursuant to a court-ordered timetable.

COUNT FIVE

156. A declaratory judgment that EPA's reliance on the confidential and proprietary Calendex model to assess pesticide exposure in conducting final tolerance reassessments for the organophosphate pesticides diazinon, disulfoton, and oxydemeton methyl is arbitrary, capricious, contrary to law, an abuse of discretion, and violates FIFRA, 7 U.S.C. §136h(d).

157. An injunction vacating EPA's tolerance reassessment actions for diazinon, disulfoton, and oxydemeton methyl and ordering EPA to perform its exposure assessments using a publicly-available model or data when reassessing tolerances for these pesticides.

Respectfully submitted,

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