

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

**STATE OF NEW YORK, STATE OF
CONNECTICUT, STATE OF NEW
JERSEY and COMMONWEALTH
OF MASSACHUSETTS,**)

Plaintiffs,)

v.)

**UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY and
MARIANNE L. HORINKO, ACTING
ADMINISTRATOR,**)

Defendants.)

Civ. No. _____

**COMPLAINT FOR
DECLARATORY
AND INJUNCTIVE RELIEF**

PRELIMINARY STATEMENT

1. The States of New York, Connecticut and New Jersey and the Commonwealth of Massachusetts (“the States”) seek declaratory and injunctive relief against the U.S. Environmental Protection Agency and its Acting Administrator, Marianne L. Horinko (collectively “EPA”), for failing to comply with statutory obligations imposed by the Food Quality Protection Act (“FQPA”) upon EPA’s mandated review of the permitted levels of chemical pesticide residues on food. In the FQPA, Congress directed EPA to apply an additional tenfold margin of safety to account for the special susceptibility of infants and children to pesticides when establishing tolerances for pesticide residues on food. However, EPA has failed to do so, endangering the health of infants and children.

2. The FQPA allows EPA to apply a smaller safety factor “only if, on the basis of reliable data, such margin will be safe for infants and children.” 21 U.S.C. § 346a(b)(2)(C). EPA

has failed to apply the tenfold safety factor when establishing tolerances for alachlor, chlorothalonil, methomyl, metribuzin and thiodicarb, among other pesticide chemicals, in the absence of reliable data demonstrating that application of a smaller factor will be safe for infants and children.

3. The States seek (a) a declaration that EPA's determinations to establish and leave in place residue tolerances for these pesticides violate the provisions of the FQPA, and (b) an injunction vacating such tolerances and directing EPA to complete the tolerance assessment process in compliance with the requirements of the FQPA. While EPA has failed to apply the tenfold safety factor for a number of additional pesticide chemicals to date, the States seek relief at this time only for these five pesticides which are widely used on children's food.

JURISDICTION AND VENUE

4. The States' claims for relief arise under Section 408 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a (that section being known as the Food Quality Protection Act or FQPA); the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y; and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706.

5. This Court has jurisdiction over the matters raised under 7 U.S.C. § 136n and 28 U.S.C. §§ 1331 and 1346. Venue is proper under 28 U.S.C. § 1391(e).

PARTIES

6. The States of New York, Connecticut and New Jersey and the Commonwealth of Massachusetts are sovereign states and bring this action on behalf of themselves and, as parents patriae, on behalf of the children and infants of the States of New York, Connecticut and New Jersey and the Commonwealth of Massachusetts.

7. Children are exposed to pesticides when they consume pesticide residues in their food and drinking water, and are further exposed in their homes and schools through contact with pesticides present in carpeting, furniture, toys and soil. The determinations being challenged involve pesticides currently used on foods consumed by children living in the plaintiff States. The States have broad interests in ensuring that the health of their resident children is preserved by proper application of federal public health law by the defendants. Through state-funded medical facilities, schools and insurance programs, the States have direct sovereign and economic interests in the health of their resident citizens.

8. The United States Environmental Protection Agency (EPA) is the agency of the United States responsible for the regulation of pesticides and the protection of public health from pesticide risk and exposure.

9. Marianne L. Horinko is the Acting Administrator of EPA and is sued in her official capacity.

STATUTORY FRAMEWORK

10. The sale and use of pesticides is closely regulated by the detailed requirements of two federal statutes and the regulations promulgated thereunder. First, in order to be sold or

distributed in the United States, a pesticide must be registered pursuant to the provisions of FIFRA, 7 U.S.C. §§ 136-136y. In order to register a pesticide, FIFRA requires the EPA Administrator to determine that “it will perform its intended function without unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C). FIFRA defines “unreasonable adverse effects on the environment” as including “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21 [the FQPA].” 7 U.S.C. § 136(bb). Thus, to be registered under FIFRA, a pesticide use must meet the safety standard of the FQPA.

11. The FQPA provides that “the Administrator 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). The FQPA further provides that “[t]he term ‘safe,’ with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined 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 there is reliable information.” 21 U.S.C. § 346a(b)(2)(A)(ii).

12. The FQPA further provides that, “[i]n establishing, modifying, leaving in effect or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors . . . (v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity; (vi) . . . exposure from other non-occupational sources; . . . [and] (vii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.” 21

U.S.C. § 346a(b)(2)(D).

13. The FQPA also includes specific requirements for EPA to consider the special susceptibility of infants and children when establishing, modifying, revoking or leaving in effect a pesticide tolerance. The Administrator “shall assess the risk of the pesticide chemical residue based on – (I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population; (II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults . . . ; and (III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity.” 21 U.S.C. § 346a(b)(2)(C). The Administrator “shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.” Id.

14. To further account for the potential special toxicity of a chemical to infants and children, the FQPA provides that “an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure *shall* be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue *only if, on the basis of reliable data, such margin will be safe for infants and children.*” 21 U.S.C. § 346a(b)(2)(C) (emphasis supplied).

FACTUAL BACKGROUND

National Research Council Findings

15. Congress unanimously passed the FQPA in 1996, largely in response to the 1993 publication of the report of a special committee of the National Research Council (“NRC”).¹ The NRC’s report, *Pesticides in the Diets of Infants and Children*, concluded that pesticide exposure has a qualitatively different impact on the developing body systems of infants and children, and that food consumption patterns of infants and children differ significantly from those of the rest of the population. These factors, the report concluded, must be considered in determining safe levels of pesticide exposure.

16. Among other recommendations, the NRC report specifically recommended application of an additional tenfold safety factor in establishing pesticide residue tolerances on food to account for the unique susceptibility of infants and children. In other words, the exposure considered acceptable should be an extra ten times lower than would result from EPA’s usual methodology, in order to protect children and infants.

The Tolerance Setting Process

17. A pesticide tolerance is the amount of residue, expressed in parts per million, that is permitted for each pesticide for each commodity on which it is used. The tolerance depends upon the toxicity of the chemical and the anticipated exposure of various age groups from eating that food.

¹The National Research Council is jointly administered by the National Academies of Sciences and Engineering and the Institute of Medicine. The Committee on Pesticide Residues in the Diets of Infants and Children was established within the NRC in 1988 at the direction of Congress.

18. In enacting the FQPA, Congress required EPA to review the safety of all pesticide tolerances pursuant to a schedule set forth in the statute. 21 U.S.C. § 346a(q)(1). Section 346a(q) requires EPA to reassess one-third of such tolerances by August 3, 1999; the next one-third by August 3, 2002; and the final one-third by August 3, 2006. In performing such reassessments, EPA issues an Interim Reregistration Eligibility Determination (“Interim RED”) as to each chemical reviewed, followed by a final Reregistration Eligibility Determination (“RED”).

19. In determining whether to establish, revoke, increase, decrease, or leave in place a residue tolerance for food use of a pesticide, the EPA estimates the anticipated aggregate exposure to the pesticide -- from the food in question, other foods, and other sources of exposure -- and compares it to the acceptable dose (called the “reference dose”), taking into account toxicological data and application of safety factors to account for uncertainties. If the anticipated exposure is less than the reference dose, the risk is considered acceptable and the tolerance may be left in place. If the anticipated exposure exceeds 100% of the reference dose, the exposure must be reduced by reducing the tolerance. As the EPA has stated, “[e]xposure must be less than 100% of the FQPA adjusted reference dose to be considered below EPA’s level of concern.” Thiodicarb RED, December 1998, p. vii.

20. If EPA concludes in the final RED that a tolerance shall be left in effect, no further agency action is taken with respect to such tolerance. Thus, the tolerances that are retained in a RED constitute final agency action with respect to those tolerances.

Absence of Data Mandated by the FQPA

21. The FQPA requires EPA to consider the cumulative effect of exposure to pesticides

with a “common mechanism of toxicity.” 21 U.S.C. § 346a(b)(2)(D)(v). As set forth below, EPA has not undertaken such assessments for the five pesticides at issue. Indeed, EPA has initiated (but not completed) cumulative risk assessments for only two classes of pesticides, organophosphates and triazines, that have been determined to share common mechanisms of toxicity. In addition, there are other classes of pesticides, such as carbamates, for which EPA has yet to commence cumulative risk assessments. For most other pesticides, EPA has yet formally to determine whether they share a common mechanism of toxicity.

22. The FQPA also requires EPA to consider the special neurological susceptibility of infants and children. 21 U.S.C. § 346a(b)(2)(C). In 1999, EPA announced that it was going to require registrants of neurotoxic pesticides to conduct developmental neurotoxicity studies and submit the results to EPA. On information and belief, only seven such studies have been received to date, and no such studies have been conducted for alachlor, chlorothalonil, methomyl, metribuzin or thiodicarb.

23. In addition, the FQPA requires EPA to consider whether a pesticide has an effect that mimics estrogen or has other endocrine effects. 21 U.S.C. § 346a(b)(2)(D)(vii). The FQPA also specifically requires EPA to establish an endocrine screening program to assess the endocrine effects of all pesticide chemicals. 21 U.S.C. §346a(p). EPA just recently released its proposed design for the endocrine screening program (67 Fed. Reg. 79611, December 30, 2002). The actual endocrine effects assessments for individual pesticide chemicals will not be completed in the near future.

Criticisms of EPA’s Tolerance Setting Process

24. The State of New York, through the Office of its Attorney General, has provided

comments to the EPA on the reregistration of a number of individual pesticide chemicals and related determinations of the EPA, including the preliminary Cumulative Risk Assessment for Organophosphate Pesticides and the Consideration of the FQPA Safety Factor in Cumulative Risk Assessment. In these comments, the State of New York has repeatedly pointed out the failure of EPA to properly implement the FQPA's requirement for application of an additional tenfold safety factor for the protection of infants and children in the absence of reliable data that a lesser margin is safe.

25. On information and belief, numerous other entities have submitted comments critical of EPA's tolerance setting process, including its repeated failure to apply the tenfold safety factor in the absence of reliable data that a lesser margin is safe.

26. In addition to submitting written comments, the New York Office of Attorney General met with EPA staff in August 2002 to express its numerous concerns regarding EPA's tolerance setting process. EPA did not indicate it would alter its practices with respect to those concerns.

27. Criticism of EPA's failure to apply the full tenfold safety factor has also been leveled by EPA's own expert advisors, the Scientific Advisory Panel ("SAP"). On information and belief, EPA has never sought the SAP's comments with respect to application of the tenfold safety factor. Nonetheless, at the SAP's meeting in June 2002 to review certain predetermined issues arising in the organophosphate cumulative risk assessment, the panel's members on their own initiative raised this issue. The SAP entered into their minutes statements criticizing EPA on its failure to retain the tenfold factor in the cumulative risk assessment. A majority of the 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.”

Declaratory Judgment Action

28. An actual controversy has arisen between the parties concerning the pesticide residue tolerances that are the subject of this suit, and the plaintiffs are entitled to a declaration that those tolerances are arbitrary and capricious and violate the FQPA, 21 U.S.C. §346a(b)(2)(C), as well as injunctive relief.

FIRST CAUSE OF ACTION

EPA VIOLATED THE FQPA IN REASSESSING THE TOLERANCES FOR ALACHLOR

29. EPA issued the final RED for alachlor in December 1998, retaining the pre-existing tolerances for alachlor for 33 food uses. Alachlor is an herbicide used for weed control on corn, soybeans, peanuts and other crops. EPA has classified alachlor as a likely carcinogen at high doses. Alachlor is listed as a developmental toxin in the United States Toxic Release Inventory. According to the National Institute of Environmental Health Sciences, alachlor is suspected of causing endocrine disruption. EPA estimates that between 30 and 45 million pounds of alachlor are applied annually to crops in the United States.

30. EPA acknowledged in the RED (p. vi) that alachlor is structurally similar to four other pesticides, and that alachlor may be grouped with other pesticides of the chloroacetanilide class that cause the same health effects. However, EPA “has not yet completed its assessment of whether or not these chemicals actually have a common mechanism of toxicity.” Alachlor RED, p. vi.

31. In reassessing the tolerances for alachlor, EPA reduced the required tenfold safety factor for the protection of infants and children to one, in effect removing the safety factor altogether.

32. The EPA calculated in the RED that alachlor exposure via food residues equals 33% of the reference dose for non-nursing infants less than one year old, 17% for children aged one to six, and 12% for children aged seven to twelve, when the reference dose is calculated using a safety factor of one. If the full tenfold factor had been applied as the FQPA requires, anticipated exposure from food would amount to 330% of the reference dose for infants, 170% for children one to six and 120% for children seven to twelve.

33. EPA did not have reliable data on which to base a deviation from the tenfold factor in that, among other things, it lacked data on: cumulative risk of pesticides with a common mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA.

34. EPA's tolerance reassessment for alachlor violated FIFRA and the FQPA in that the tenfold safety factor was removed in the absence of reliable data that such removal will be safe for infants and children. EPA's action is arbitrary, capricious, and not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

SECOND CAUSE OF ACTION

EPA VIOLATED THE FQPA IN REASSESSING THE TOLERANCES FOR CHLOROTHALONIL

35. EPA issued the final RED for chlorothalonil in April 1999, retaining the pre-existing

tolerances for chlorothalonil for 37 food uses. Chlorothalonil is a broad spectrum pesticide registered for a wide variety of uses, including as a mildewicide in paint, and as a treatment for a variety of crops, including bananas, broccoli, carrots, corn, peaches, peanuts, potatoes, soybeans, squash and tomatoes. Chlorothalonil is classified by EPA as a likely carcinogen. Approximately 15 million pounds of chlorothalonil are applied to U.S. crops annually.

36. The EPA acknowledged in the RED that chlorothalonil is a member of the polychlorinated fungicide class of pesticides, and may have a common mechanism of toxicity with other members of that class including hexachlorobenzene, pentachlorophenol, and pentachloronitrobenzene. However, “the Agency does not presently have the data or methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way” and “for purposes of this document, the Agency has not assumed that chlorothalonil has a common mechanism of toxicity with other substances.” Chlorothalonil RED, pp. 100-101.

37. In reassessing the tolerances for chlorothalonil, EPA reduced the required tenfold safety factor for the protection of infants and children to one, in effect removing the safety factor altogether.

38. The EPA calculated in the RED that chlorothalonil exposure via food residues equals 60% of the reference dose for non-nursing infants less than one year old and children aged one to six, and 32% for the U.S. population in general, when the reference dose is calculated using a safety factor of one. If the full tenfold factor had been applied as the FQPA requires, anticipated exposure from food would amount to 600% of the reference dose for infants and for children one to six and 320% for the U.S. population in general.

39. EPA did not have reliable data on which to base a deviation from the tenfold factor in that, among other things, it lacked data on: cumulative risk of pesticides with a common mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA.

40. EPA's tolerance reassessment for chlorothalonil violated FIFRA and the FQPA in that the tenfold safety factor was reduced in the absence of reliable data that the lesser factor will be safe for infants and children. EPA's action is arbitrary, capricious, and not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

THIRD CAUSE OF ACTION

EPA VIOLATED THE FQPA IN REASSESSING THE TOLERANCES FOR METHOMYL

41. EPA issued the final RED for methomyl in December 1998, retaining the pre-existing tolerances for methomyl for 70 food uses. Methomyl is an insecticide used on a wide variety of crops, including apples, beans, broccoli, corn, grapes, oats, oranges, peaches, peanuts, pears, soybeans, tomatoes and wheat. The EPA estimates that 8.5 million pounds of methomyl are applied annually to U.S. crops.

42. Methomyl operates by inhibiting production of cholinesterase and is therefore a neurotoxin. Upon issuing the RED, EPA required the manufacturer to submit additional neurotoxicity studies (RED, p. 122), but postponed the requirement for a developmental neurotoxicity study (RED, p. 24).

43. Methomyl is a methyl carbamate and therefore likely to share a common mechanism

of toxicity with other carbamate pesticides. However, EPA “does not have, at this time, available data to determine whether methomyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this assessment, therefore, the Agency has not assumed that methomyl has a common mechanism of toxicity with other substances.” Methomyl RED, p. vi.

44. In reassessing the tolerances for methomyl, EPA reduced the required tenfold safety factor for the protection of infants and children to three.

45. The EPA calculated in the RED that methomyl exposure via food residues equals 67% of the reference dose for non-nursing infants less than one year old, 62% for children aged one to six, and 34.6% for the general U.S. population, when the reference dose is calculated using a safety factor of three. If the full tenfold factor had been applied as the FQPA requires, anticipated exposure from food would amount to 224% of the reference dose for infants, 207% for children one to six and 115% for the general population.

46. EPA did not have reliable data on which to base a deviation from the tenfold factor in that, among other things, it lacked data on: cumulative risk of pesticides with a common mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA.

47. EPA’s tolerance reassessment for methomyl violated FIFRA and the FQPA in that the tenfold safety factor was removed in the absence of reliable data that such removal will be safe for infants and children. EPA’s action is arbitrary, capricious, and not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

FOURTH CAUSE OF ACTION

EPA VIOLATED THE FQPA IN REASSESSING THE TOLERANCES FOR METRIBUZIN

48. EPA issued the final RED for metribuzin in February 1998, retaining the pre-existing tolerances for metribuzin for 25 food uses. Metribuzin is an herbicide used at a variety of sites including on the following food crops: carrots, potatoes, soybeans, sugarcane, tomatoes and wheat. Metribuzin is listed as a developmental and reproductive toxin by the United States Toxic Release Inventory. EPA estimates that five million pounds of metribuzin are applied annually to U.S. crops.

49. The EPA “does not have at this time, available data to determine whether metribuzin has a common mechanism of toxicity with other substances,” and therefore, “[f]or the purposes of this tolerance action, . . . EPA has not assumed that metribuzin has a common mechanism of toxicity with other substances.” Metribuzin RED, p. iv.

50. In reassessing the tolerances for metribuzin, EPA reduced the required tenfold safety factor for the protection of infants and children to one, in effect removing the safety factor altogether.

51. The EPA calculated in the RED that metribuzin exposure via food residues equals 62% of the reference dose for non-nursing infants less than one year old, 75% for children aged one to six, and 36% for the general U.S. population when the reference dose is calculated using a safety factor of one. If the full tenfold factor had been applied as the FQPA requires, anticipated exposure from food would amount to 620% of the reference dose for infants, 750% for children one to six, and 360% for the general population.

52. EPA did not have reliable data on which to base a deviation from the tenfold factor in that, among other things, it lacked data on: cumulative risk of pesticides with a common mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA.

53. EPA's tolerance reassessment for metribuzin violated FIFRA and the FQPA in that the tenfold safety factor was removed in the absence of reliable data that such removal will be safe for infants and children. EPA's action is arbitrary, capricious, and not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

FIFTH CAUSE OF ACTION

EPA VIOLATED THE FQPA IN REASSESSING THE TOLERANCES FOR THIODICARB

60. EPA issued the final RED for thiodicarb in December 1998, retaining the pre-existing tolerances for thiodicarb for 4 food uses. Thiodicarb is an insecticide that is used on corn, soybeans and other crops. EPA has classified thiodicarb as a probable human carcinogen. EPA estimates that 1 to 2.2 million pounds of thiodicarb are applied to U.S. crops annually.

61. The EPA "does not have at this time, available data to determine whether thiodicarb has a common mechanism of toxicity with other substances," and therefore, "[f]or the purposes of this tolerance action, . . . EPA has not assumed that thiodicarb has a common mechanism of toxicity with other substances." Thiodicarb RED, p. vi.

62. Thiodicarb is a cholinesterase inhibitor and therefore a neurotoxin. EPA acknowledged in the RED that neurotoxicity studies for thiodicarb are lacking, and "would have

yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the central and peripheral nervous system which are not presently available for evaluation.”

Thiodicarb RED, pp. v.

63. In reassessing the tolerances for thiodicarb, EPA reduced the required tenfold safety factor for the protection of infants and children to three.

64. The EPA calculated in the RED that thiodicarb exposure via food residues equals 43% of the reference dose for non-nursing infants less than one year old, 104% for children aged one to six,² and 68% for the general U.S. population when the reference dose is calculated using a safety factor of three. If the full tenfold factor had been applied as the FQPA requires, anticipated exposure from food would amount to 143% of the reference dose for infants, 347% for children one to six, and 227% for the general population.

65. EPA did not have reliable data on which to base a deviation from the tenfold factor in that, among other things, it lacked data on: cumulative risk of pesticides with a common mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA.

66. EPA’s tolerance reassessment for thiodicarb violated FIFRA and the FQPA in that the tenfold safety factor was removed in the absence of reliable data that such removal will be safe for infants and children. EPA’s action is arbitrary, capricious, and not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

²EPA admitted in the RED that the reference dose for this age group was “slightly exceeded,” but stated that “the chronic risk from exposure to thiodicarb from food sources is not of concern.” Thiodicarb RED, p. vii.

PRAYER FOR RELIEF

WHEREFORE, the States request that the Court:

- a. Declare that EPA has violated the FQPA, 21 U.S.C. § 346a(b)(2)(C), by failing to apply the full tenfold safety factor in reassessing tolerances for alachlor, chlorothalonil, methomyl, metribuzin and thiodicarb in the absence of reliable data establishing that a lesser factor will be safe for infants and children.
- b. Issue an injunction vacating EPA's tolerances, and ordering EPA to apply the full tenfold safety factor in reassessing tolerances, for the named pesticides.
- c. Grant such additional relief as the Court deems just and proper.

Dated: September 15, 2003

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