PETITION OF NEW YORK, CALIFORNIA, CONNECTICUT AND MASSACHUSETTS FOR MODIFICATION OF TOLERANCES FOR PESTICIDE CHEMICAL RESIDUES ESTABLISHED IN REREGISTRATION ELIGIBILITY DETERMINATIONS FOR THE FOLLOWING CHEMICALS:

Alachlor EPA 738-R-98-020 (40 CFR § 180.249)
Chlorothalonil EPA 738-R-99-004 (40 CFR § 180.275)
Methomyl EPA 738-R-98-021 (40 CFR § 180.253)
Metribuzin EPA 738-R-97-006 (40 CFR § 180.332)
Thiodicarb EPA 738-R-98-022 (40 CFR § 180.407)[1]

TO: **Michael O. Leavitt, Administrator**
United States Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

DATE: **December 17, 2004**

I. INTRODUCTION

Pursuant to 21 USC § 346a(d) and 40 CFR Part 180, the States of New York, California, and Connecticut and the Commonwealth of Massachusetts ("petitioners" or "petitioner States") request the issuance of a regulation or regulations modifying or revoking all the pesticide residue tolerances established for alachlor, chlorothalonil, methomyl, metribuzin and thiodicarb in the

[1] Regulations listing the tolerances for each of the five named pesticides do not in all cases reflect the tolerances established in the respective Reregistration Eligibility Determinations ("REDs"). The tolerances challenged herein are those established in the REDs. An EPA determination announced in a RED constitutes final agency action regardless of whether it results in a change in regulation. See, State of New York et al. v. United States Environmental Protection Agency, No.03 Civ.7155 (S.D.N.Y. July 29, 2004 [Lynch, J.]), slip op. at 9-11. A copy of Judge Lynch's decision granting defendants' motion to dismiss is attached hereto as Exhibit 1.

Three of the petitioner States herein were also plaintiffs in this litigation. While the decision dismissing the States' action was not appealed, the consolidated case, NRDC, et al. v. Leavitt, et al., No. 03 Civ. 7176 (GEL), raising the same issue among others, is on appeal to the Second Circuit Court of Appeals (Notice of Appeal filed October 1, 2004).

respective Reregistration Eligibility Determination ("RED") for each of those pesticide chemicals, so as to reflect proper application of the additional tenfold safety factor for the protection of infants and children required by the Food Quality Protection Act ("FQPA"). 21 USC § 346a(b)(2)(C). In establishing the subject tolerances, EPA failed to apply the additional tenfold safety factor, which legally can only be reduced or eliminated when, "on the basis of reliable data, such [lesser] margin will be safe for infants and children." Id. With respect to these tolerances, EPA reduced or eliminated the required safety factor even though it lacked data specifically required by the FQPA to be considered in all EPA tolerance reassessment decisions. The absence of these data made it impossible and legally impermissible for EPA to determine that application of a smaller factor would be "safe for infants and children" with respect to these pesticide chemicals. Therefore the full tenfold safety factor should have been applied.

This petition is brought on behalf of the petitioner States and on behalf of the infants and children residing in each petitioner State who are not receiving the full protective benefit of the FQPA statutory requirements. Children are exposed to pesticides when they consume pesticide residues in their food and drinking water, and are further exposed to pesticides applied in and around their homes and schools and in public places. The pesticides that are the subject of this petition are currently used on foods consumed by children living in the petitioner States. The petitioner States bear the costs of health problems arising from pesticide exposures through increased burden on publicly-funded health care and insurance programs. EPA's failure to apply the protections of the FQPA ignores Congress's clear mandate and unnecessarily jeopardizes children's health.

II. APPLICATION OF 21 USC § 346a(d) TO THE CLAIMS OF THE PETITION

The petition process of 21 USC § 346a(d) has been determined by EPA and the federal courts to be an appropriate vehicle for obtaining the relief sought here. In State of New York et al. v. United States Environmental Protection Agency, No. 03 Civ. 7155 (S.D.N.Y. July 29, 2004), the plaintiffs challenged EPA's reassessment of tolerances for the same five pesticide chemicals named in this petition, because, *inter alia*, the full tenfold safety factor for the protection of infants and children was not applied. The plaintiffs sought (a) a declaratory judgment that EPA's determinations violated the FQPA, and (b) an injunction vacating such tolerances and directing EPA to complete the reassessments in full compliance with the FQPA.[2]

The defendant EPA moved to dismiss for lack of subject matter jurisdiction. EPA argued that

> [e]ach of the issues raised by plaintiffs in their lawsuits – from the alleged improper removal of the additional safety factor for the protection of infants and children to use of the Calendex risk modeling tool [raised by other plaintiffs in the consolidated case] – could have been and still could be included in a petition under section 408(d) [21 USC § 346a(d)].[3]

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[2] State of New York et al. v. United States Environmental Protection Agency, No. 03 Civ. 7155 (S.D.N.Y. July 29, 2004), Complaint for Declaratory and Injunctive Relief dated September 15, 2003, attached hereto as Exhibit 2, at 2.

[3] Id., Memorandum of Law in Support of Defendants' Motion to Dismiss the Complaints dated February 6, 2004, attached hereto as Exhibit 3, at 17.

Although the plaintiffs argued that this petition process was designed to be used by manufacturers seeking changes to tolerances on technical grounds, Judge Lynch held that "plaintiffs' demand for vacatur and remand is tantamount to a request for modification or revocation."[4] The Court thus ruled that the plaintiffs' challenge was the proper subject of a petition to modify tolerances pursuant to 21 USC § 346a(d)(1). See slip op. at 16-22. Judge Lynch reasoned:

> [Subsections (d) and (g) of 21 USC §346a are both] drafted in the broadest possible terms. . . . Subsection (d) permits "any person" to petition for an existing tolerance (or exemption) to be established, modified, or revoked. Neither provision restricts the grounds on which petitions or objections may be filed, limits them to challenges based on disagreement with the specific tolerance level set in a particular reassessment determination, or specifies that challenges to the methods used in establishing specific tolerances will not be entertained. *On the contrary, the statute provides an expansive administrative appeal process for review of tolerance reassessments.*

Id. at 21 - 22 (citation omitted; emphasis supplied). The court further found that "the statute nowhere requires that a petitioner under subsection (d) must propose a particular tolerance level – it requires merely that the petition ask the tolerance to be changed or revoked." Id.

The requirements for a petition to establish, modify or revoke a tolerance are set forth in Section 346a(d)(2). They are listed in detail for a petition to "establish" a tolerance. 21 USC § 346a(d)(2)(A). However, with respect to the requirements of a petition to modify or revoke a tolerance, the statute only provides that "[t]he Administrator may by regulation establish the requirements for information and data to support [such] a petition." 21 USC § 346a(d)(2)(B). The Administration has done so in a regulation codified at 40 CFR § 180.32, "Procedure for

[4] Id., slip op. at 22.

amending and repealing tolerances or exemptions from tolerances." That rule provides that the Administrator may propose the issuance of a regulation amending or repealing a tolerance on his own initiative or "on request from an interested person furnishing reasonable grounds therefor." It further provides:

> Reasonable grounds shall include . . . an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to the toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its amendment or repeal.

Id.

The petitioner States base this petition, not on facts related to new uses or new data, but rather on the legal argument that EPA has violated the FQPA's clear mandate. Plaintiffs in the recent State of New York litigation pointed out that they are not among the industry participants to whom this EPA regulation is apparently intended to apply, and cannot realistically make the factual assertions specified.[5] The Court nonetheless held, as EPA argued, that the States' legal arguments were properly addressed in a petition. The Court thus implicitly held that a petition to modify a tolerance may be based on grounds other than the types of facts set forth in the rule. Under EPA's argument and the Court's ruling, therefore, this petition sets forth legally cognizable grounds for modifying and/or revoking the subject pesticide tolerances. These arguments must now be addressed by EPA.

[5] Id., State Plaintiffs' Memorandum of Law in Opposition to Defendants' and Intervenors' Motions to Dismiss dated April 6, 2004, attached as Exhibit 4, at 11-13.

III. STATUTORY BACKGROUND

In 1996, Congress unanimously passed the FQPA, 21 USC § 346a. This unusual unanimity by Congress on an environmental matter was largely in response to the 1993 publication of the report of a special committee of the National Research Council ("NRC") which highlighted the inadequacy of existing EPA practice for protecting children's health.[6] 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. The report noted that data on pesticide exposures reflected "the current regulatory emphasis on average adult consumption patterns"[7] and criticized EPA's practice of establishing tolerances "to ensure compliance with good agricultural practice" rather than basing them "primarily on health considerations."[8] The report concluded that "[t]o ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances . . . incorporat[ing] the use of improved estimates of exposure and more relevant toxicology."[9] In debating the enactment of

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[6]National Research Council, *Pesticides in the Diets of Infants and Childre*n. Washington, DC; National Academy Press, 1993. The 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.

[7]Id. at 5.

[8]Id. at 2.

[9]Id. at 8.

the FQPA, Congress repeatedly cited the NRC Report[10] and in adopting the new law expressly mandated the Report's 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.

The FQPA's "General Rule" for pesticide tolerances is 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 USC § 346a(b)(2)(A)(I). The FQPA 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 USC § 346a(b)(2)(A)(ii).

The FQPA further specifies the factors bearing on tolerance decisions.

> In 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 USC § 346a(b)(2)(D) (emphasis added).

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[10] E.g., *Food Quality Protection Act of 1995: Hearings on H.R.1627 Before the Subcommittee on Department Operations, Nutrition, and Foreign Agriculture of the House Committee on Agriculture*, 104th Cong. 13 (May 16, 1995); *Food Quality Protection Act of 1995; Hearings on H.R. 1627 Before the Subcommittee on Health and Environment of the House Committee on Commerce,*104th Cong. 9 (June 7 and 29, 1995).

In addition to these general requirements, the FQPA mandates three additional steps that EPA must follow to address the heightened sensitivity of children and infants: EPA must (1) consider additional information specific to the risks posed to infants and children, (2) make a special finding, and (3) impose an extra margin of safety.

First, 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 USC § 346a(b)(2)(C) (emphasis added).

Second, 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," and in addition shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." Id.

Third, 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." This additional safety factor is mandatory except in very narrow circumstances. The FQPA provides that "[n]otwithstanding 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 USC § 346a(b)(2)(C) (emphasis supplied).

Thus, in sum, the FQPA mandates application of the full tenfold safety factor unless "reliable data" supports a determination that use of a lesser factor "will be safe" for infants and children. Since the statute requires that a tolerance safety determination include consideration of the cumulative effects of chemicals with a common mechanism of toxicity, the special neurological susceptibility of infants and children as reflected in developmental neurotoxicity studies, and information concerning endocrine effects, in the absence of these data, the narrow exception to the tenfold safety factor mandate does not and cannot apply. When EPA fails to apply this safety factor, as with the pesticides that are the subject of this petition, it is illegally and unnecessarily endangering children's health.

IV. ABSENCE OF STATUTORILY-REQUIRED DATA

As explained above, among the factors that EPA is required to consider in the tolerance reassessment process are: the cumulative effects of exposure to pesticide chemicals with a common mechanism of toxicity; the effects of exposure to a pesticide upon neurological development in infants and children; and endocrine disruptor effects. EPA has recognized these requirements by taking initial steps toward developing data on these factors. However, the data have yet to be produced and were not considered in reassessing the tolerances at issue in this petition.

A. Cumulative Effects of Exposure

The FQPA requires EPA to consider the cumulative effect of exposure to pesticides with a "common mechanism of toxicity." 21 USC § 346a(b)(2)(D)(v). EPA has identified five classes of pesticides that share a common mechanism of toxicity: organophosphates; triazines; thiocarbamates and dithiocarbamates; –methyl carbamates; and chloroacetanilides.[11] EPA has initiated (but not completed) a cumulative risk assessment for only one class, organophosphates.[12] Common mechanism of toxicity determinations for the other four classes were made in 2001 and 2002, but cumulative risk assessments for these classes have yet to be undertaken.[13] For most pesticides, EPA has not yet formally determined whether they share a common mechanism of toxicity.

B. Developmental Neurotoxity

The FQPA also requires EPA to consider the special neurological susceptibility of infants and children. 21 USC § 346a(b)(2)(C). In 1999, EPA announced that it was going to require registrants of all neurotoxic pesticides to conduct developmental neurotoxicity studies and submit the results to EPA.[14] On information and belief, only seven such studies have been received to date, and none of them relate to alachlor, chlorothalonil, methomyl, metribuzin or

[11] See generally "Other Cumulative Risk Assessments," at http://www.epa.gov/pesticides/cumulative/other_cum_assessments.htm (last updated July 14, 2004).

[12] The Preliminary Cumulative Risk Assessment for Organophosphates was issued in December, 2001 (66 FR 67249), and the Revised Cumulative Risk Assessment for Organophosphates was issued in June 2002 (67 FR 41993). The New York Office of the Attorney General submitted comments on both documents, in both cases objecting to the reduction of the additional tenfold safety factor in the cumulative risk assessment. Exhibits 5 and 6.

[13] See fn 11.

[14] 64 FR 42945 (August 6, 1999).

thiodicarb.

C. Endocrine Effects

In addition, the FQPA requires EPA to consider whether a pesticide has an effect that mimics estrogen or has other endocrine effects. 21 USC § 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 USC §346a(p). EPA has only taken the first preliminary step in meeting this requirement, by releasing its proposed design for the required endocrine screening program.[15] Actual endocrine effects assessments have not been performed for *any* individual pesticide chemicals.

Thus, EPA has made final tolerance reassessment determinations for the subject pesticide chemicals in the absence of data and studies which the FQPA expressly requires EPA to consider when making such determinations. Petitioners submit that in the absence of this statutorily-required data, EPA cannot, as a matter of law, conclude that there are "reliable data" on which to base a deviation from the mandated application of the tenfold safety factor. Therefore, the subject tolerances must be recalculated to reflect the application of the full tenfold safety factor

[15]67 FR 79611 (December 30, 2002). See EPA webpage, "Endocrine Disruptor Screening Program," http://www.epa.gov/oppfod01/cb/csb_page/updates/endocrin.htm (last updated July 2, 2004). The New York Office of the Attorney General commented on the proposed design of the Screening Program, criticizing it, *inter alia*, for the failure to include a reasonable time line for the actual commencement and completion of the program. See Exhibit 7. The webpage lists this Notice as the most recent step in the program.

for the protection of infants and children.

V. EPA'S REPEATED FAILURE TO APPLY THE FULL TENFOLD FACTOR

EPA's misapplication of the FQPA's safety factor requirement extends beyond the reassessment determinations challenged herein. In comments to EPA on the reregistration of a number of other pesticide chemicals and related determinations of EPA, the State of New York, through the Office of its Attorney General, has repeatedly criticized EPA for failing to apply the additional tenfold safety factor for the protection of infants and children in the absence of reliable data that a lesser margin is safe.[16] In particular, these comments have argued that it is legally impermissible for EPA to conclude it had "reliable data" when it completes its tolerance reassessment without having obtained the data and studies expressly required by the statute. Comments submitted by other entities have also criticized EPA's repeated failure to apply the tenfold safety factor in the absence of reliable data demonstrating that a lesser margin is safe.[17]

EPA's own expert advisors, the Scientific Advisory Panel ("SAP"), have also criticized EPA for its failure to apply the full tenfold safety factor. 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

[16]See Exhibits 8 - 13.

[17]For example, the Natural Resources Defense Council raised this issue in comments on lindane, azinphos-methyl, chlorpyrifos, endosulfan, the EPA Safety Factor Policy Document, and the Cumulative Risk Assessment for Organophosphates, among others.

apply 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."[18]

VI. CLAIMS FOR MODIFICATIONS/REVOCATIONS OF TOLERANCES

In the absence of data required by the FQPA to be considered in the tolerance reassessment process, as specified below, petitioners request modification of the following specified tolerances to reflect full application of the additional tenfold safety factor for the protection of infants and children, as required by the statute.

A. Alachlor

EPA issued the final RED for alachlor in December 1998, reassessing tolerances for use of alachlor on 38 commodities. Six tolerances were increased, 27 were left in place, and five were revoked. Exhibit 15, Alachlor RED, pp. 185-87. 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.

[18]Exhibit 14, Scientific Advisory Panel (SAP) Report, July 19, 2002. Transmittal of Meeting Minutes (No. 2002-03) of the Meeting held June 26-27, 2002, at 10.

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." Exhibit 15, Alachlor RED, p. vi. Subsequent to the issuance of the RED, EPA issued a common mechanism of toxicity determination for chloroacetanilides, including alachlor.[19]

[19]The announcement of EPA's Common Mechanism of Toxicity Determination for N-methyl Carabamates and for Chloroacetanilides is found at http://www.epa.gov/oppfead1/cb/csb_page/updates/commechs.htm (last updated July 18, 2001). The comment period for this determination expired on September 10, 2001.

Despite the fact that alachlor is a neurotoxin and EPA has required developmental neurotoxicity studies for all neurotoxins,[20] EPA waived the requirement for a developmental neurotoxicity study in setting tolerances for alachlor. Exhibit 15, Alachlor RED, p. 49.

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.

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. Such unacceptably high risk would require a reduction in the residue tolerance.

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. In order to comply with the FQPA and assure the protection of infants and children, the tolerances for alachlor must be recalculated applying the full tenfold safety factor.

B. Chlorothalonil

EPA issued the final RED for chlorothalonil in April 1999, reassessing tolerances for use

[20]See fn. 15 supra and accompanying text.

of chlorothalonil on 38 commodities. One tolerance was increased and 37 were left in place. Exhibit 16, Chlorothalonil RED, pp. 173-74. 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, as well as for lawns and gardens. Chlorothalonil is classified by EPA as a likely carcinogen. Approximately 15 million pounds of chlorothalonil are applied to U.S. crops annually.

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. Exhibit 16, Chlorothalonil RED, p. 100. 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." Id. p. 101. EPA has not yet issued a determination that polychlorinated fungicides share a common mechanism of toxicity.

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.

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. Such unacceptably high risk would require a reduction in the residue tolerance, even without accounting for non-dietary exposures.

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 and endocrine disruptive effects, as required by the FQPA. In order to comply with the FQPA and assure the protection of infants and children, the tolerances for chlorothalonil must be recalculated applying the full tenfold safety factor.

C. Methomyl

EPA issued the final RED for methomyl in December 1998, reassessing tolerances for use of methomyl on 80 commodities. One tolerance was increased, 65 were left in place, four were reduced, and seven uses were revoked (three were left "to be determined"). Exhibit 17, Methomyl RED, pp. 106-11. 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. EPA estimates that 8.5 million pounds of methomyl are applied annually to U.S. crops.

Methomyl is a methyl carbamate and therefore likely to share a common mechanism of toxicity with other carbamate pesticides. Indeed, subsequent to EPA's issuance of the RED for methomyl, EPA determined that the N-methyl carbamates share a common mechanism of toxicity.[21] However, at the time the methomyl RED was issued, EPA did "not have, at this time,

[21] See fn. 19, supra.

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." Exhibit 17, Methomyl RED, p. vi.

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 (Id. p. 122), but postponed a determination as to whether a developmental neurotoxicity study would be required (Id. p. 24). EPA subsequently required the submission of developmental neurotoxicity studies for all neurotoxic pesticides.[22]

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

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. Such unacceptably high risk would require a reduction in the residue tolerance.

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

[22]See fn. 14, supra, and accompanying text.

mechanism of toxicity; developmental neurotoxicity; and endocrine disruptive effects, all as required by the FQPA. In order to comply with the FQPA and assure the protection of infants and children, the tolerances for methomyl must be recalculated applying the full tenfold safety factor.

D. Metribuzin

EPA issued the final RED for metribuzin in February 1998, reassessing tolerances for use of metribuzin on 60 commodities. Three tolerances were increased, 22 were left in place, and five uses were revoked (30 were left "to be determined"). Exhibit 18, Metribuzin RED, pp. 104-07. Metribuzin is an herbicide used for weed control in a variety of circumstances, including on rights-of-way and in landscaping, as well as 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.

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." Exhibit 18, Metribuzin RED, p. iv.

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.

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. Such unacceptably high risk would require a reduction in the residue tolerance, even without accounting for non-dietary exposures.

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 and endocrine disruptive effects, as required by the FQPA. In order to comply with the FQPA and assure the protection of infants and children, the tolerances for metribuzin must be recalculated applying the full tenfold safety factor.

E. Thiodicarb

EPA issued the final RED for thiodicarb in December 1998, reassessing tolerances for use of thiodicarb on five commodities. Two tolerances were left in place, two tolerances were reduced and one use was revoked. Exhibit 19, Thiodicarb RED, pp. 90-91. 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.

Thiodicarb is a carbamate and shares a common mechanism of toxicity with other carbamate pesticides, such as methomyl. However, EPA stated in the RED that it "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."

Exhibit 19, Thiodicarb RED, p. vi.

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." Exhibit 19, Thiodicarb RED, p. v.

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

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,[23] 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. Such unacceptably high risk would require a reduction in the residue tolerance.

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. In order to comply with the FQPA and assure the protection of infants and children, the tolerances for thiodicarb must be recalculated applying the full tenfold safety

[23]EPA 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." Exhibit 19, Thiodicarb RED, p. vii.

factor.

CONCLUSION

Based on the foregoing, petitioners request the issuance of a regulation or regulations modifying or revoking all the pesticide residue tolerances established for alachlor, chlorothalonil, methomyl, metribuzin and thiodicarb, reflecting for each tolerance application of the full additional tenfold safety factor for the protection of infants and children.

CERTIFICATION

The undersigned certifies that, to the best of her knowledge and belief, the information presented in this petition is true and correct.

Respectfully submitted,

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Exhibits

1. State of New York et al. v. United States Environmental Protection Agency, No.03 Civ.7155 (S.D.N.Y. July 29, 2004) (slip opinion).

2. Complaint for Declaratory and Injunctive Relief in State of New York et al. v. United States Environmental Protection Agency, No.03 Civ.7155 (S.D.N.Y. July 29, 2004)

3. Memorandum of Law in Support of Defendants' Motion to Dismiss the Complaint in State of New York et al. v. United States Environmental Protection Agency, No.03 Civ.7155 (S.D.N.Y. July 29, 2004)

4. State Plaintiffs' Memorandum of Law in Opposition to Defendants' and Intervenors' Motion to Dismiss in State of New York et al. v. United States Environmental Protection Agency, No.03 Civ.7155 (S.D.N.Y. July 29, 2004)

5. Letter from Office of the Attorney General of the State of New York to EPA docket on Preliminary Cumulative Risk Assessment for Organophosphates, OPP-34250, dated March 15, 2002.

6. Letter from Office of the Attorney General of the State of New York to EPA docket on Revised Cumulative Risk Assessment for Organophosphates, OPP-2002-0110/2002-0230, dated September 9, 2002.

7. Letter from Office of the Attorney General of the State of New York to EPA docket on Endocrine Disruptor Screening Program, OPP-2002-0066, dated February 26, 2003.

8. Letter from Office of the Attorney General of the State of New York to EPA docket on Thiabendazole Risk Assessment, OPP-34244, dated September 28, 2001

9. Letter from Office of the Attorney General of the State of New York to EPA docket on Lindane Risk Assessment, OPP-34239, dated October 29, 2001.

10. Letter from Office of the Attorney General of the State of New York to EPA docket on Azinphos-methyl Risk Assessment, OPP-34248, dated November 13, 2001.

11. Letter from Office of the Attorney General of the State of New York to EPA docket on Endosulfan Risk Assessment, OPP-34242, dated December 10, 2001.

12. Letter from Office of the Attorney General of the State of New York to EPA docket on Chlorpyrifos IRED, OPP-34203G, dated January 30, 2002 (without exhibits).

13. Letter from Office of the Attorney General of the State of New York to EPA docket on Safety Factor Policy Document, OPP-00759, dated April 29, 2002.

14. Scientific Advisory Panel (SAP) Report, July 19, 2002. Transmittal of Meeting Minutes (No. 2002-03) of the Meeting held June 26-27, 2002.

15. Alachlor Reregistration Eligibility Decision, December 1998, selected pages.

16. Chlorothalonil Reregistration Eligibility Decision, April 1999, selected pages.

17. Methomyl Reregistration Eligibility Decision, December 1998, selected pages.

18. Metribuzin Reregistration Eligibility Decision, February1998, selected pages.

19. Thiodicarb Reregistration Eligibility Decision, December 1998, selected pages.