energy. The Administrator of the office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedure; and related management system practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This event establishes a safety zone therefore paragraph (34)(g) of the Instruction applies.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary section 165.T09–055 is added as follows:

§ 165.T09–055 Safety Zone; Oswego Harborfest 2007, Oswego, NY.

(a) *Location.* The following area is a temporary safety zone: All waters of Lake Ontario, Oswego, NY within a thousand foot radius of position 43°28′10″ N, 076°31′04″ W. [DATUM: NAD 83].

(b) *Enforcement period.* This regulation will be enforced from 9 p.m. to 10 p.m. on July 28, 2007.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo, or his on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf. The on-scene representative of the Captain of the Port Buffalo will be aboard either a Coast Guard or Coast Guard Auxiliary vessel.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(5) Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo or his on-scene representative.

Dated: July 3, 2007.

S.J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. E7–13844 Filed 7–17–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0050; FRL–8135–3]

Alachlor, Chlorothalonil, Metribuzin; Denial of Objections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: In this order, EPA denies objections to an order denying a petition requesting the modification or revocation of the pesticide tolerances for alachlor, chlorothalonil, and metribuzin, established under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The petition was filed on December 17, 2004, by the States of New York, California, Connecticut, and Massachusetts. The petitioners claimed that EPA had improperly removed an additional safety factor for the protection of infants and children from the risk assessments for these pesticide tolerances and that inclusion of this safety factor rendered the tolerances unsafe. EPA issued an order denying that petition, in part, on August 2, 2006. On October 2, 2006, New York, Connecticut, and Massachusetts filed objections to EPA's denial order.

DATES: This final order is effective July 18, 2007. Supplemental objections, as described in Unit VII.C., may be submitted on or before September 17, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0050. To access the electronic docket, go to http://www.regulations.gov, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Public Docket, in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Terria Northern, Special Review and Reregistration Division, (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–7093; e-mail address: *northern.terria@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities that are potentially affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr.* You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. Can I File an Objection or Hearing Request?

EPA is permitting supplemental objections to be filed under section 408(g) of the FFDCA concerning one issue described in Unit VII.C. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0050 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 17, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0050, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 204607–0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Introduction

A. What Action Is the Agency Taking?

In this order, EPA denies objections to an order denying a petition requesting the modification or revocation of the pesticide tolerances for alachlor, chlorothalonil, and metribuzin, among other pesticides, established under section 408 of the FFDCA. The petition was filed on December 17, 2004, by the States of New York, California, Connecticut, and Massachusetts (''the States'') (Ref. 1). The States contended that EPA is lacking data for each of the challenged pesticides on developmental neurotoxicity, endocrine effects, and/or cumulative effects of exposure to pesticides with a common mechanism of toxicity. This lack of data, the States argued, mandates that EPA must retain the statutory additional tenfold (10X) safety factor for the protection of infants and children. The States further alleged that once the 10X safety factor is retained, the challenged tolerances no longer meet the safety standard under FFDCA section 408 and must be modified or revoked.

On August 2, 2006, EPA denied the petition with regard to alachlor, chlorothalonil, and metribuzin. (71 FR 43906, August 2, 2006). As to alachlor and metribuzin, EPA denied the petition because the tolerances for these pesticides would continue to meet the safety standard even if the additional 10X safety factor sought by the States is applied. For chlorothalonil, EPA denied the petition on the ground that there is reliable data on chlorothalonil showing that the additional 10X safety factor is not needed to protect the safety of infants and children. The petition is still pending before EPA as to two other pesticides, methomyl and thiodicarb.

On October 2, 2006, objections were filed to EPA's denial order by the States of New York, Connecticut, and Massachusetts (although California did not join the objections, for simplicity, the objectors are still referred to as the ''States'' in this order). (Ref. 2) The objections renew the States' claim that EPA has unlawfully removed the children's 10X safety factor and also argue that EPA has ''manipulated'' exposure assessments in making its safety determination. It is these objections that are addressed in today's order.

B. What Is the Agency's Authority for taking this Action?

The procedure for filing objections to tolerance actions and EPA's authority for acting on such objections is contained in section 408(g) of the FFDCA and regulations at 40 CFR part 178. (21 U.S.C. 346a(g)).

III. Statutory and Regulatory Background

A. Statutory Background

1. *In general.* EPA establishes maximum residue limits, or ''tolerances,'' for pesticide residues in food under section 408 of the FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is ''adulterated'' under section 402 of the FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration and the U.S. Department of Agriculture. Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (''FQPA''), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, tolerance reassessment requirements, and the estrogenic substances screening program.

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), (7 U.S.C. 136 et seq.). While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution, (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated by EPA if the tolerance is ''safe.'' (21 U.S.C. 346a(b)(2)(A)(i)). ''Safe'' is defined by the statute to mean 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)). Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

> 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) Available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.. . . .
>
> (viii) 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)(v), (vi) and (viii)). In its first denial order, EPA explained in detail the risk assessment process it follows in making safety determinations under these statutory provisions. (71 FR at 43908–43910).

Section 408(b)(2)(C) requires EPA to give special consideration to risks posed to infants and children. Specifically, this provision states that EPA:

> shall assess the risk of the pesticide chemical based on- . . .
>
> (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 effects of *in utero* exposure to pesticide chemicals; 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)(i)(II) and (III)).

This provision further directs that ''[i]n the case of threshold effects, . . . 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.'' (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to ''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.'' (Id.). [The additional safety margin for infants and children is referred to throughout this order as the ''children's safety factor.''] EPA's policy regarding implementation of the children's safety factor provision is described in the first denial order. (71 FR at 43910, 43918–43919).

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, the rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)). Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any affected party has 60 days to file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1)).

4. *Tolerance reassessment and FIFRA reregistration.* The FQPA requires, among other things, that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. (21 U.S.C. 346a(q)). In this reassessment, EPA is required to review existing pesticide tolerances under the new ''reasonable certainty that no harm will result'' standard set forth in section 408(b)(2)(A)(i). (21 U.S.C. 346a(b)(2)(A)(i)). This reassessment was substantially completed by the August, 2006 deadline. Tolerance reassessment is generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. (7 U.S.C. 136a–1). Reassessment and reregistration decisions are generally combined in a document labeled a Reregistration Eligibility Decision (''RED'').

5. *Estrogenic substances screening program.* Section 408(p) of the FFDCA creates the estrogenic substances screening program. (21 U.S.C. 346a(p)). This provision gives EPA 2 years from enactment of the FQPA to ''develop a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.'' (21 U.S.C. 346a(p)(1)). This screening program must use ''appropriate validated test systems and scientifically relevant information.'' (Id.). Once the program is developed, EPA is required to take public comment and seek independent scientific review of it. Following the period for public comment and scientific review, and not

later than 3 years following enactment of the FQPA, EPA is directed to ''implement the program.'' (21 U.S.C. 346a(p)(2)).

The scope of the estrogenic screening program was expanded by an amendment to the Safe Drinking Water Act (SDWA) passed contemporaneously with the FQPA. That amendment gave EPA the authority to provide for the testing, under the FQPA estrogenic screening program, ''of any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance.'' (42 U.S.C. 300j–17).

The steps taken by EPA in implementing the endocrine screening program are described in the first denial order. (71 FR at 43910–43911, 43920–43921).

B. Evaluating the Safety of Tolerances through the Use of Risk Assessment Including the Use of Safety Factors

In the order denying the petition, EPA explained its risk assessment process for assessing the safety of tolerances in great detail. (71 FR at 43908–43910). That level of detail is not repeated here; however, a brief summary of the risk assessment process with an emphasis on how safety factors are incorporated into the process is included below for the convenience of the reader.

Evaluation of the safety of a pesticide tolerance includes both examination of the pesticide's toxicity and the amount of exposure to the pesticide. EPA principally evaluates a pesticide's toxicity by attempting to establish safe levels of exposure for humans with regard to the adverse effects seen in animal studies conducted with the pesticide. Safe levels of exposure are established by first identifying the doses in animal studies at which no adverse effects were seen, and then dividing these dose levels with safety factors to provide an extra measure of protection for humans. Traditionally, EPA has used 2 safety factors of 10 when establishing a safe human dose level based on animal studies. One factor of 10 is applied to account for potentially increased sensitivity of humans vis-a-vis the test animals and a second factor of 10 is used to account for variable sensitivity in humans. (71 FR at 43909). The FQPA imposed a presumptive additional ten-fold factor to provide extra protection for infants and children.

Having derived a safe dose level for humans, EPA then compares this dose level to aggregate human exposure to the pesticide. EPA follows a tiered approach in assessing exposure to pesticide residues. EPA initially uses the very conservative (health-protective) assumption that all food that legally may contain residues of a pesticide actually does contain such residues at the maximum legal level (Tier 1). Only if this analysis suggests that exposure may be a concern does EPA undertake the more resource-intensive effort of refining its exposure assessment to produce a more realistic estimate of exposure. In the first level of refinement of its worst case assessment, EPA incorporates data on the percentage of a crop treated with a pesticide and/or data on anticipated residues in food from crop field trials (Tier 2). Further refinements rely heavily on pesticide residue monitoring data of food in commerce and may include information from residue decline and degradation studies and studies evaluating the effect of commercial and consumer practices such as washing, cooking, and peeling on pesticide residues (Tiers 3–4). (Ref. 3; 71 FR at 43909–43910).

IV. The Challenged Tolerances

In its first denial order, EPA presented detailed information on the pesticides whose tolerances are at issue. (71 FR at 43911–43912). This information is briefly summarized below.

Alachlor. Alachlor is a selective herbicide used in agriculture for the control of broadleaf weeds and grasses. Alachlor is registered under FIFRA for use on corn, soybeans, sorghum, peanuts, and beans and 37 FFDCA tolerances are currently associated with those uses. (40 CFR 180.249). In December 1998, EPA released a RED for alachlor finding it eligible for reregistration. (Ref. 4). The RED also reassessed alachlor's tolerances concluding that 22 met the requirements of section 408 but that 16 would have to be revised or revoked. (Id. at 184–187; Ref. 5 at 13–14). (The current number of tolerances for alachlor and the other two pesticides may not match the number of reassessed tolerances due to subsequent actions to establish or revoke tolerances as well as to a generic administrative action amending tolerance nomenclature. (68 FR 39428, July 1, 2003)). In making its safety determination as to alachlor, EPA removed the 10X children's safety factor based on its determination that (1) the toxicology database was complete; (2) the toxicology data showed no evidence of neurotoxicity and thus there was no need for a developmental neurotoxicity study for alachlor; (3) the toxicology data showed no evidence of increased susceptibility in the young; and (4) the exposure estimate was unlikely to understate exposure to infants and children. (Ref. 4 at 50).

Chlorothalonil. Chlorothalonil is a broad spectrum, non-systemic protectant pesticide mainly used as a fungicide to control fungal foliar diseases of vegetable, field, and ornamental crops. In connection with these uses there are 66 FFDCA tolerances currently established for chlorothalonil. (40 CFR 180.275). In April 1999, EPA released a RED for chlorothalonil finding it eligible for reregistration so long as various uses were prohibited and numerous risk mitigation steps were taken. (Ref. 6 at v–vi). The RED also reassessed chlorothalonil's tolerances concluding that all met the requirements of section 408 except one that would have to be raised. Further, an additional tolerance was found to be necessary in connection with one use site. (Id. at 171–174; Ref. 5 at 58–59). Except as to acute risks, EPA removed the 10X children's safety factor for chlorothalonil based on its determination that (1) the toxicology database was complete; (2) the toxicology data showed no evidence of increased susceptibility in the young; and (3) the exposure estimate was unlikely to understate exposure to infants and children. (Ref. 6 at 170; 66 FR 56233, 56242, November 7, 2001). Because a chlorothalonil acute study did not identify a dose with no adverse effects, EPA retained an additional FQPA safety factor of 3X in assessing acute risks. (Ref. 6 at 23).

Metribuzin. Metribuzin is a herbicide used on a wide range of sites, including vegetable and field crops, turf grasses (recreational areas), and non-crop areas, to selectively control certain broadleaf weeds and grassy weed species. In connection with these uses there are 61 FFDCA tolerances currently established for metribuzin (40 CFR 180.332).

In February 1999, EPA released a RED for metribuzin finding it eligible for reregistration based on various risk mitigation steps proposed by the registrant. (Ref. 7 at iv). The RED also reassessed metribuzin's tolerances concluding that 22 met the requirements of section 408 but that 38 would have to be revised or revoked. (Id. at 101–107; Ref. 5 at 187–188). EPA removed the 10X children's safety factor for metribuzin based on its determination that the toxicology database was complete and it showed no evidence of increased susceptibility in the young. (Ref. 7 at 51).

V. Prior Proceedings

A. The Petition to Modify or Revoke

The States' petition requested that EPA modify or revoke all of the tolerances for alachlor, chlorothalonil, methomyl, metribuzin, and thiodicarb. (Ref. 1 at 1). These tolerances must be modified or revoked, the States asserted, because they do not meet the safety standard in section 408 of the FFDCA. (Id. at 2). The States argued that the tolerances are unsafe because EPA's latest safety conclusion for these tolerances did not include the full 10X children's safety factor and, if that full 10X safety factor is included, EPA cannot make the required reasonable certainty of no harm determination.

The States claimed that ''as a matter of law'' the full 10X children's safety factor must be retained for each of these pesticides because of missing data concerning developmental neurotoxicity, endocrine effects, and/or cumulative effects of pesticides having a common mechanism of toxicity. It is ''legally impermissible,'' the States asserted, if any of these data are absent for EPA to conclude that there are ''reliable data'' to choose an additional safety factor other than 10X. (Id. at 2, 5, 9, 11).

As statutory support for this allegation, the States cited several provisions in section 408. First, as to developmental neurotoxicity, the States pointed to section 408(b)(2)(C)'s requirement that EPA assess the risk to children based on ''available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults . . . .'' The States noted that EPA has announced that it plans to require developmental neurotoxicity (''DNT'') studies on all pesticides that are neurotoxic. (Ref. 1 at 10 citing 64 FR 42945, August 6, 1999). Second, as to endocrine effects, the States cited both the provision in section 408(b)(2)(D)(vii) requiring consideration of ''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'' and the requirement in section 408(p) for EPA to develop and implement an endocrine screening program. Finally, with regard to cumulative effects, the States referenced the provision in section 408(b)(2)(D)(v) requiring consideration of ''available data on the cumulative effects of such residues and other substances that have a common mechanism of toxicity,'' and the requirement in section 408(b)(2)(C) mandating that EPA assess the risk to children based on similar considerations.

B. EPA's Denial of the Petition

Following consideration of the petition and comments received on the petition, EPA issued an order on August 2, 2006, denying the requested revocation as to alachlor, chlorothalonil, and metribuzin. (71 FR 43906, August 2, 2006). EPA did not address the requested revocation of methomyl and thiodicarb tolerances because those tolerances are still being evaluated as part of the tolerance reassessment program. The reasons for denying the petition are described below.

1. *Alachlor and metribuzin.* The States' petition was denied as to alachlor and metribuzin because EPA found that, even if it accepted as accurate the States' claim that it should have retained the 10X children's safety factor for these pesticides, the States had not shown that the tolerances were unsafe. (71 FR at 43916). As to alachlor, the States had based their conclusion that alachlor would be unsafe if an additional 10X factor was applied relying on an unrefined risk estimate in the alachlor RED. EPA pointed out, however, that ''the RED also contained a revised risk assessment for alachlor that showed the highest aggregate risk estimate to be that exposure of children aged 1–6 is 4 percent of the [maximum safe dose],'' and that ''incorporating an additional 10X safety factor into such a risk estimate would increase the risk estimate to no greater than 40 percent of the [maximum safe dose], or still well within the safe level.'' (Id.).

A similar conclusion was reached as to metribuzin. (Id.). Again, the States had relied upon a risk estimate based on an unrefined exposure assessment to argue that application of the additional 10X safety factor would show that the metribuzin tolerances are unsafe. EPA showed that a slight refinement of the exposure and risk assessment made the requested retention of the additional 10X safety factor irrelevant to the safety determination. EPA made clear that, in moving from an unrefined, worst case exposure assessment to a more refined assessment, it had still taken a very conservative, health-protective approach to estimating exposure. An example is the manner in which EPA incorporated monitoring data on the level of metribuzin residues in potatoes into the exposure assessment. Data from the U.S. Department of Agriculture had shown that only 1 out of 1,472 samplings of potatoes revealed any detectable residue of metribuzin. ''Nonetheless, in its risk assessment, EPA assumed that all potatoes contained metribuzin at the level found in that one sample (0.05 parts per million).'' (Id. at 43917).

Therefore, EPA did not evaluate the merits of the States' claim that the 10X children's safety factor should have been retained for alachlor and metribuzin. Instead it denied the petition as to these two pesticides because the petition, even if its claims were accepted as true, did not demonstrate that the pesticide tolerances were unsafe.

2. *Chlorothalonil.* Based on its conclusion that application of an additional 10X safety factor to the chlorothalonil risk assessment may have raised a safety issue, EPA evaluated the merits of the States' claims that EPA should have retained the 10X children's safety factor for chlorothalonil. The States had argued that the children's safety factor must be retained for chlorothalonil due to the lack of data on cumulative effects and potential endocrine disruption. Further, although the States did not specifically claim that EPA should retain the children's safety factor due to a lack of developmental neurotoxicity data on chlorothalonil, its general allegations could be read as suggesting as much.

As to developmental neurotoxicity data, EPA pointed out that it only required such data for pesticides that were neurotoxins. The States, EPA found, had made no plausible argument that developmental neurotoxicity data were needed for non-neurotoxic pesticides nor had they alleged that chlorothalonil was neurotoxic. Further, EPA confirmed that its review of the chlorothalonil database did not show chlorothalonil to be neurotoxic. Accordingly, EPA rejected the States' claim that data bearing on developmental neurotoxicity were needed for chlorothalonil. (Id. at 43919).

The States contended that data was lacking on cumulative effects due to EPA's finding that chlorothalonil was a member of a related group of chemicals. In response, EPA reviewed the data on chlorothalonil and these chemicals and concluded that chlorothalonil did not share a common mechanism of toxicity with these chemicals, and thus combined exposure to chlorothalonil and these chemicals would not produce cumulative effects. Therefore, EPA found that no additional data was needed on potential cumulative effects from exposure to chlorothalonil and these chemicals. (Id. at 43922).

On endocrine effects data, the States' entire argument was that because EPA had not obtained data under the

endocrine screening program on chlorothalonil it was legally obligated to retain the 10X children's safety factor. EPA responded that the States had misread the statute and not considered the factual information bearing on chlorothalonil. The children's safety provision, EPA noted, does not impose rigid rules regarding retaining the children's safety factor if particular pieces of data are missing. Rather, EPA pointed out that the safety provision gives EPA the discretion to evaluate the completeness of the database and determine if reliable data are available to choose an additional safety factor different than 10X that is protective of the safety of children. Nothing in the endocrine screening provision or its legislative history, EPA concluded, overturned this discretion granted EPA under the children's safety provision. (Id. at 43920). Further, EPA took into account that its existing data requirements for pesticides included testing very similar to that which had been proposed for use in the endocrine screening program. A review of the relevant test data for chlorothalonil showed that chlorothalonil is not an endocrine disruptor. EPA concluded that it had adequate reliable data on chlorothalonil's potential to cause endocrine effects to determine that it was safe to remove the children's safety factor. (Id. at 43921).

Given its conclusion - based on interpretation of the statute as well as a thorough review of all of the extensive test data on chlorothalonil - that adequate, reliable data were available on developmental toxicity, cumulative effects, and endocrine effects, EPA rejected the States' claim that EPA was required to retain the 10X children's safety factor for chlorothalonil. Because the States' argument that the chlorothalonil tolerances are unsafe and must be revoked was based entirely on retention of the 10X children's safety factor, EPA denied its petition to revoke these tolerances.

VI. The States' Objections

On October 2, 2006, three of the four petitioning States (New York, Connecticut, and Massachusetts) filed objections to EPA's denial of their petition. (Ref. 2). EPA finds the objections to be somewhat unclear. To the best of its understanding, EPA believes the objecting States are making four separate, but related, objections.

First, the States take issue with EPA's denial of the petition as to alachlor and metribuzin based on the conclusion that application of the children's safety factor for these pesticides would not change the determination on these pesticides' safety. The States claim that EPA made its determination on the need for the children's safety factor based on the size of the risk posed by these pesticides as opposed to the ''merits.'' (Id. at 7).

Second, the States claim that EPA ''manipulated'' exposure data using ''statistical sleight-of-hand techniques'' to make pesticide exposure levels appear to be lower. (Id. at 2, 5). The objected-to techniques are reliance on data showing the percent of a crop treated with a pesticide and data showing the effect of food processing on residue amounts. The States argue that ''EPA's use of such techniques are [sic] counter to the intent of the FQPA to protect infants and children from unsafe exposure to pesticides.'' (Id. at 5).

Third, the States renew their claim that EPA lacks data on endocrine disruption. The States allege that ''[e]ndocrine disruption was not considered in the FQPA assessment because EPA does not yet have in place the endocrine disruption screening program that was required by the FQPA to have been completed by 1999.'' (Id. at 3). Additionally, the States argue that EPA has ignored ''the growing body of evidence that the effects of endocrine disrupting chemicals can be associated with very low doses, especially if exposure occurs in vulnerable stages such as fetal development.'' (Id. at 4).

Finally, the States argue that EPA removed the children's safety factor for these pesticides despite lingering uncertainty concerning their safety. As support for the assertion of uncertainty, the objecting States cite to EPA's description of the adverse effects seen in animal studies with several of the pesticides. (Id. at 7–8).

The States do not include in their objections any of the claims in their petition regarding lack of data on developmental neurotoxicity or cumulative effects.

VII. EPA's Response to the Objections

For the reasons stated below, EPA denies each of the four objections lodged by the States. EPA's response to objections is necessarily circumscribed by the scope of the objections. Section 408 contains a mandatory exhaustion provision which requires that issues be presented and resolved by EPA in administrative proceedings prior to judicial review. (21 U.S.C. 346a(g) and (h)). This exhaustion requirement is designed to ''bring the agency's experience to bear on a contested question'' and make a full record on the dispute to aid in any judicial review of EPA's action. *Nader* v. *US EPA*, 859 F.2d 747, 753–54 (9th Cir. 1988). EPA cannot bring its experience to bear or make a record on challenges that have not been made. To ensure that EPA can evaluate the challenges that are made, the statute requires that objections ''specif[y] with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor,'' and EPA's regulations make clear that for an objection to be properly presented it must explain ''with particularity . . . [its] basis . . . .'' (40 CFR 178.25(a)(2)). For EPA to go beyond the specific arguments raised in objections, or to treat vague allegations as a general challenge to an EPA decision, and address matters not raised with particularity would undermine the purpose for exhaustion and merely invite objectors to improperly raise issues on judicial review which had not been exhausted before the Agency.

A. Addressing the ''Merits'' of the Children's Safety Factor Determination for Alachlor and Metribuzin

For alachlor and metribuzin, EPA denied the States' petition because grounds for the petition (failure to retain the children's safety factor) did not support the relief requested (revocation of the tolerances). The States object to this determination arguing that EPA should not decide whether to apply the children's safety factor based on the risks posed by a pesticide but instead based on the ''merits.'' Although EPA does not disagree with the general thrust of this proposition, EPA does not believe it has any relevance to EPA's decision on the petition as to alachlor and metribuzin. In responding to the States' petition, EPA did not decide whether the children's safety factor should be retained for alachlor and chlorothalonil. To the contrary, EPA simply assumed that the State's contention on the children's safety factor was correct for the purpose of determining whether it affected the safety determination. When it became clear the State's contention (that the children's safety factor should be retained) did not support their claim that the tolerances were unsafe, EPA denied the petition for failing to show the tolerances were unsafe.

EPA believes it is appropriate for it to refuse to adjudicate the merits of claims where it can be shown that the claims - even if true -- do not justify the relief requested. In related circumstances, the Supreme Court has refused to require agencies to undertake such an ''exercise in futility.'' (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621 (1973) (upholding FDA's authority to deny an administrative hearing on a

new drug application when the hearing requestor had not offered any evidence showing the statutory standard for approval could be met)). EPA has enshrined this principle in its regulations governing objections and requests for hearings by providing that hearings will not be granted as to ''factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.'' (40 CFR 178.32(b)(3)).

Accordingly, EPA denies the objection that it was required to determine whether the children's safety factor should be applied for alachlor and metribuzin on the ''merits.'' EPA is not required to adjudicate issues that, even if substantiated, would not support the relief requested in the petition.

B. Use of Data on Percent Crop Treated and Residue Reduction from Processing

1. *Overview/failure to raise issue in petition.* The States object to the lawfulness of EPA's reliance on percent crop treated information and food processing factors in assessing the risk to the three pesticides. According to the States, reliance on percent crop treated data runs ''counter to the intent of the FQPA to protect infants and children from unsafe exposure to pesticides . . . because EPA's methods have resulted in a failure to address individual exposures.'' (Ref. 2 at 5, 6). Individuals are not protected, the States contend, when EPA, in estimating pesticide exposure, takes percent crop treated data into account by assuming that consumers eat a mixture of pesticide-treated and untreated food and thus are exposed to an average of the residues on the treated and untreated commodities. This approach, the States argue, spreads a pesticide's exposure - by a ''statistical sleight-of-hand'' -- over the entire population instead of focusing on the individuals who eat the treated commodities. The States assert that if EPA's approach was applied to the enforcement of drunk driving laws, highway patrol officers could not make drunk driving arrests based on an individual driver's blood alcohol level but instead would have to examine the average blood alcohol levels of all drivers. As to the effect of food processing on residue levels, the States allege that EPA assumes that reductions in pesticide residues that occur as a result of food processing will also occur in unprocessed raw foods. Finally, they also assert that EPA has limited data on food processing's effect on residue levels.

As an intial matter, EPA believes that such an objection is improper, for the most part, as beyond the scope of the denial order. The objection is appropriate, if at all, only as to EPA's decision as to metribuzin, and even then, only as to reliance on percent crop treated data. Objections must be made with ''particularity [as to] the provisions of the . . . order deemed objectionable . . . .'' (21 U.S.C. 346a(g)(2)). The FFDCA's tolerance revocation procedures are not some sort of ''game,'' whereby a party may petition to revoke a tolerance on one ground, and then, after the petition is denied, file objections to the denial based on an entirely new ground not relied upon by EPA in denying the petition. (See *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978)).

Although it is clear on the face of the alachlor and chlorothalonil REDs that EPA relied on percent crop treated and processing data and factors in assessing the chronic risk these pesticides posed, (Ref. 4 at 56, 83–83; Ref. 6 at 28–31), the States did not once mention a concern with the lawfulness of this practice in their petition to revoke tolerances. Understandably, given the States' silence regarding reliance on percent crop treated data and processing factors, EPA did not address this issue in its denial order as to alachlor and chlorothalonil. To the contrary, EPA's denial order for these pesticides was based on other grounds. For chlorothalonil, EPA denied the States' claim that EPA must retain the 10X children's safety factor by rejecting the States' arguments that the safety factor must be retained because of missing data on neurotoxicity, endocrine effects, and cumulative effects. As to alachlor, the denial order was based on an even more narrow ground - that the States had failed to show that retention of the 10X children's safety factor would render the alachlor tolerances unsafe. The States' error, EPA pointed out, was in misreading the RED's explicit conclusions on the size of the alachlor risk. The only issue, therefore, that the order resolved was what the RED stated with regard to the risk of alachlor. Accordingly, because the denial order as it pertains to alachlor and chlorothalonil did not address reliance on percent crop treated data and processing factors, the States' objection to use of percent crop treated data and processing factors is not an objection to the ''provisions of the . . . order.'' (21 U.S.C. 346a(g)(2)).

Arguably, the States' objection to the use of percent crop treated data is timely and appropriate as to reliance on percent crop treated data for metribuzin because EPA relied on percent crop treated data for the first time in denying the petition as to that pesticide. However, as with alachlor and chlorothalonil, there does not appear to be any basis for the processing factor objection as to metribuzin. Not only does the metribuzin RED discuss processing data that was relied upon, but also the only processing factors used in the revised risk assessment cited in the petition denial were factors used to increase estimated exposure values in processed food. (Ref. 7 at 26, 102; Ref. 8 at 5). Notably, the only specific processing factor cited in the objections as problematic is a processing factor that pertains to a different pesticide (chlorothalonil) and was used to show residues were reduced upon food processing. (Ref. 2 at 6).

Turning to the merits, for the reasons explained below, EPA finds the States' objection to the use of percent crop treated data and processing factors to be without basis. In brief, EPA concludes that:

i. It has ample legal authority to consider percent crop treated data and food processing factors in making a safety determination under section 408 of FFDCA;

ii. Reliance on percent crop treated data in risk assessment is not inconsistent with protection of individuals and was used in a conservative fashion in estimating metribuzin exposure; and

iii. Processing factors are only applied to processed foods.

2. *Legal authority.* It is not clear from the States' objections as to whether they are arguing that EPA may never use percent crop treated and food processing data in estimating pesticide exposure or whether EPA has used it in an impermissible fashion with regard to the challenged pesticide tolerances. To the extent that the States are contending that the ''intent of the FQPA'' bars EPA as a legal matter from relying on percent crop treated information and processing data factors in estimating pesticide exposure and risk, they are mistaken. Such an interpretation is contrary to the plain language of the statute.

Section 408(b)(2)(D)(vi) directs that EPA ''shall consider, among other relevant factors -- . . . available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue . . . .'' (21 U.S.C. 346a(b)(2)(D)). The extent of use of a pesticide and the degree to which a pesticide residue degrades or concentrates during processing are clearly relevant information

''concerning aggregate exposure levels of consumers.'' Further, Congress expressly recognized in the FQPA that this type of information is relevant and appropriate to a FQPA safety analysis. The statute, as amended by the FQPA, contains special provisions placing certain requirements upon EPA when it relies upon percent crop treated data in chronic risk assessments or anticipated residue data. (21 U.S.C. 346a(b)(2)(E) and (F)). Anticipated residue data is a term of art encompassing, among other things, data on the effect food processing has on pesticide residue levels. (70 FR at 46731–46732; Ref. 9) This term was in use by EPA well before such language was adopted in the FQPA. (Ref. 10; see, e.g., 54 FR 33044, 33045, August 11, 1989).

Given this clear legal authority, the States' vague allegations that the use of percent crop treated data or processing factors runs counter to the intent of the FQPA are meritless.

3. *Use of percent crop treated data and individual exposure.* The States' claim that EPA's use of percent crop treated data is not protective of individuals appears to be based on a lack of understanding of (1) the differences between acute and chronic risks and (2) the different techniques EPA uses for incorporating percent crop treated information into risk assessments. At times, EPA uses percent crop treated data in estimating exposure for both chronic and acute risk assessments. Such data, however, is used in a different manner in these assessments due to the differences in how acute and chronic exposures may result in harm. Moreover, as to both acute and chronic risk, EPA is concerned with the risk to an individual within major, identifiable population subgroups and incorporates percent crop treated data in a manner consistent with that concern. Further explanation of this approach is provided below.

With a chronic risk, EPA is concerned with adverse effects that occur from the cumulative effect of repeated exposures over an extended time period (i.e., generally a period of 1 year or more for dietary exposure). The focus for a chronic exposure assessment is not on the level of any one exposure or even the variation in exposure from day-to-day so much as the general level of the continuing exposure. Thus, in estimating chronic pesticide exposure, EPA uses average daily pesticide exposure over the appropriate time period. In estimating average daily pesticide exposure, EPA takes into account that, given the national distribution of food in the United States, over a chronic timeframe a person will consume food from a mixture of sources—regional, national, and international—as well as food grown at different times of the growing season. It is likely, therefore, that to the extent a food commodity is not uniformly treated with a given pesticide, the consumer will over time be exposed to a fairly representative sample of treated and untreated commodities. Accordingly, in refined exposure estimates for chronic pesticide exposures, EPA generally averages dietary pesticide exposure from a food based on the percentage of that food that has been treated with the pesticide. For example, if the estimated residue value for a pesticide on treated blueberries is 1 part per million (ppm) and half of the blueberry crop is treated, EPA would estimate the chronic pesticide exposure level from blueberries using the assumption that all blueberries contain 0.5 ppm of the pesticide (i.e., treated blueberries bear 1 ppm pesticide residues and over time a person gets an equal mixture of treated and untreated blueberries). EPA has long used percent crop treated data in this manner in chronic risk assessments and Congress explicitly recognized the appropriateness of this method of estimating pesticide exposure in the FQPA. (21 U.S.C. 346a(b)(2)(F)).

With acute hazards, EPA is concerned with an adverse effect that can result from a single pesticide exposure or pesticide exposure over a single day to an individual. Thus, acute pesticide exposure assessments are designed to measure or estimate the maximum amount of residue that may be present in a single commodity serving or meal. EPA's traditional method of using percent crop treated data in chronic risk assessments is problematic for acute risk assessments because it masks the highest levels of pesticide residues expected in food by averaging residue values from treated and untreated commodities in estimating pesticide exposure. For this reason, EPA, up until the mid–1990's, did not use percent crop treated data in acute risk assessments. Instead, for acute risk assessments, EPA assumed that all commodities for which a pesticide had a tolerance contain residues at the tolerance level. That changed, however, with the introduction in the last decade of probabilistic risk assessment analysis.

Probabilistic analysis, when used in pesticide exposure/risk assessment, is ''a statistical method where the range of exposures to pesticide residues and the probability of exposure to any particular level is quantified.'' (Ref. 3 at 22). Probabilistic exposure assessments are particularly helpful in realistically estimating pesticide exposure levels from short-term exposures (e.g., a single meal) where there are multiple variables affecting pesticide exposure levels. For pesticide exposures from food these variables can include:

i. Several different foods may be consumed in differing amounts;

ii. The consumed foods may or may not have been treated with the pesticide in question; and

iii. Foods that are treated may have a wide range of residue levels.

Integral to probabilistic analysis of pesticide exposure is information on differing consumption patterns among individuals, the range of the levels of pesticide residue in treated food, and the percent of food that has been treated with a pesticide. Importantly, information on percent crop treated is not used in a probabilistic analysis to average residue levels between treated and untreated crops but rather solely to determine ''the probability of [an individual] encountering a treated commodity.'' (Ref. 11 at 14). Thus, percent crop treated information is used in a fundamentally different fashion in probabilistic acute risk assessments than in non-probabilistic chronic risk assessments. (The Agency currently does not use probabilistic techniques for chronic risk assessment due to limitations in its food consumption database.)

The States' challenge to EPA's use of percent crop treated data for metribuzin is flawed because the States attack the appropriateness of the exposure estimate for a chronic risk assessment based on concerns more applicable to acute risk. The States argue that the adjustment of residue values by the percentage of the treated crop understates exposure of individual children because ''if a child is eating treated carrots, he or she is consuming carrots that all contain pesticide residues . . . .'' (Ref. 2 at 5). EPA generally agrees that if the concern is acute risk, it would be inappropriate to estimate acute exposure for non-blended commodities by multiplying the expected residue value in a food (e.g., carrots) by an estimate of the percent of carrots treated with the pesticide. Acute exposure assessments should be designed to identify actual exposures that can occur to an individual at a single meal or in a single day. For metribuzin (and alachlor and chlorothalonil as well), however, EPA used percent crop treated data only for estimating chronic pesticide exposure and risk. For chronic dietary risk, it is generally exposure over a period of at least 1 year that matters and over such a time period a person is likely to