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

consume a mixture of treated and untreated commodities.

For the same reason, the States' drunk driving hypothetical is not persuasive. Their hypothetical is somewhat analogous to the situation EPA faces in assessing acute pesticide risk - both the highway patrol officer investigating a suspected drunk driver and EPA in evaluating acute risk from pesticide exposures are interested in ascertaining an individual's actual level of exposure (to alcohol or pesticides, respectively) at a certain point in time. However, the hypothetical has no relevance to chronic pesticide risk assessment - the type of risk assessment involved in the State's objections -- because with chronic pesticide risk it is appropriate for EPA to focus on a person's general pesticide exposure level over an extended period rather than one particular exposure at a single point in time.

The States additionally argue that because ''families purchase food from the same place each week, a family could virtually always eat treated carrots . . . .'' (Ref. 2 at 5). What the States fail to take into account, however, is that, although a family may do its food shopping at the same store week-to-week and even may purchase a bag of carrots every week, from week-to-week the bag of carrots is likely to come not just from a different farm but a different region of the United States due to the national distribution of food commodities. Perishable foods are available on a nearly year-round basis in the United States only because the country's national food distribution network ships foods nationwide from different parts of the country or world as dictated by the differing growing seasons in these areas. For foods such as grains, root crops, or other commodities which have significantly greater storage times, a broad mixing of commodities occurs due to centralization of storage facilities prior to the commodities entering the food distribution network.

The States also fail to take into account the conservative manner that EPA uses percent crop treated data to estimate chronic exposure both generally and with regard to how these data were used for the metribuzin risk assessment. As discussed earlier, EPA uses a tiered approach to assess pesticide exposure in food, starting with a worst case assessment which assumes that all foods with tolerances contain the pesticide at the tolerance level (Tier 1) and then refining those assumptions through a series of tiers that increasingly incorporate data designed to measure residues at the time of consumption. Higher tiers (Tiers 3 and 4) rely heavily on monitoring data of pesticide residues in food sampled either at central food distribution points or in retail locations. Percent crop treated data is commonly introduced in Tier 2 as an initial refinement of worst case assumptions, and that is how it was used in the metribuzin risk assessment. There, EPA conducted primarily a Tier 2 assessment assuming that foods with metribuzin tolerances contained residues at the tolerance level reduced only by the percentage of these foods treated with metribuzin. EPA's experience has been that Tier 2 assessments significantly overstate exposure levels compared to higher tier assessments relying on monitoring data. This is well illustrated by the metribuzin risk assessment. For one crop commodity in that assessment, potatoes, EPA used monitoring data to estimate exposure levels rather than a combination of assuming tolerance level residues diminished only by the percent of the crop treated. The monitoring data showed that only 1 out of 1,472 potato samples had metribuzin residues. In that sample, metribuzin was detected at a level of 0.05 ppm. Conservatively, EPA assumed in its risk assessment that all potatoes contain 0.05 ppm of metribuzin. Despite this conservative approach to the monitoring data, a Tier 2 assessment relying on percent crop treated data and tolerance level residues in potatotes would have produced a much higher exposure estimate than the assessment relying on monitoring data. The tolerance for metribuzin in potatoes is 0.6 ppm. Decreasing that value by the percent crop treated value for metribuzin use on potatotes (70 percent) yields an estimated residue value in potatoes of 0.42 ppm, or almost an order of magnitude higher than the value derived from monitoring data which was used in the metribuzin risk assessment. (Ref. 8). There would have been an even bigger gap between a Tier 2 exposure assessment for potatoes and an assessment relying on monitoring data if EPA had made the reasonable, but still conservative assumption, that all potato samples in which no metribuzin was detected contained metribuzin at half the level of detection for the analytical method (levels of detection ranged from 0.016 to 0.030 ppm). (Ref. 12).

The conservativeness of EPA's metribuzin exposure assessment is further demonstrated by the most recent pesticide monitoring data (for the years 2002 – 2005) on foods for which EPA relied on percent crop treated information (asparagus, barley, carrots, corn (field, sweet, and pop), peas (dried and succulent), sugarcane, tomatoes, and wheat). Over these 4 years, USDA, through its Pesticide Data Program has collected pesticide monitoring data on asparagus, barley, carrots, corn (sweet), peas (succulent), tomatoes, and wheat. Out of 10,313 samples, only 11 showed metribuzin residues. (Ref. 13). These data demonstrate that, for all practical purposes, meaningful levels of metribuzin are nonexistent in food. Thus, EPA's use of percent crop treated data to refine the worst case assumption of all food bearing tolerance level residues in estimating chronic human exposure to metribuzin is very unlikely to have resulted in an understatement of such exposure. The States, for their part, offer no evidence to support their contention that EPA's use of percent crop treated data in the metribuzin risk assessment has led to an underestimate of metribuzin exposure.

Accordingly, the States' objection to the use of percent crop treated information is denied. First, as discussed in Unit VII.B.1., EPA denies this objection as to alachlor and chlorothalonil because it exceeds the scope of denial order and the petition underlying it. Second, as is explained in Unit VII.B.1., to the extent the States are making a legal argument that EPA may never consider percent crop treated data, that argument is defeated by the plain language of the statute. Third, to the extent they are arguing that the manner in which EPA uses percent crop treated data in chronic risk assessments understates pesticide exposures to individuals, their argument is not well-taken because they confuse chronic and acute exposure and risk; they do not take into account that the food distribution system in this country is national in scope; and they do not recognize the conservative fashion in which percent crop treated data was used in the metribuzin risk assessment to estimate exposure. Moreover, the States have offered no evidence to support their speculations about EPA underestimating exposure. Finally, the States have made no challenge to the accuracy of EPA's factual findings with regard to the percent crop treated data on metribuzin.

4. *Use of processing data.* The States object to the use of food processing factors claiming that such factors ''are generally based on limited test data from certain crops and extrapolated to other crops or conditions using a variety of statistical techniques.'' (Ref. 2 at 5). Further, citing to the chlorothalonil RED, the States claim that EPA wrongfully used a processing factor for carrots showing that chlorothalonil residues declined significantly in cooked carrots in estimating exposure to chlorothalonil from raw carrots.

According to the States, EPA erred because ''if a child is eating freshly treated raw carrots, the processing factor should not apply.'' (Ref. 2 at 6). The States imply that it is common practice for EPA to apply processing factors to raw food.

A bit of background might be helpful here. In estimating exposure to pesticide residues in food, EPA uses residue data from commercial food processing studies as well as, on occasion, data from in-home food preparation studies. (Ref. 3). These studies reveal whether commercial or home processing concentrates or reduces pesticide residues. Based on the degree of reduction or concentration of residues in food processing, EPA computes processing factors which when applied to level of residues found in raw foods will calculate the level of residue expected in the food following processing.

Data on the commercial processing of food (e.g., processing apples into apple juice; separating wheat into grain and bran) is routinely required as a part of pesticide registration under FIFRA and the tolerance petition process under the FFDCA. (40 CFR 158.240; Ref. 14). EPA has extensive guidance on the use of such data in pesticide exposure assessments including the appropriateness of extrapolating between data on different commodities. (Refs. 9 and 14). In the absence of commercial processing data, EPA relies on default processing factors in estimating exposure in processed foods. These default processing factors are extremely conservative in that they assume that:

i. Residues are concentrated to the maximum extent physically possible in processed foods, and

ii. When a raw commodity is processed into two separate processed commodities, all of the pesticide in the raw commodity is translocated to both processed commodities.

For example, in estimating residues in processed commodities resulting from the juicing of apples, EPA uses default processing factors that assume that all pesticide residues from the apple concentrate in both the juice and the remaining dry matter, apple pomace, which is fed to animals. (70 FR at 46733–46734). Data on pesticide residue levels following in-home food preparation is not routinely required and reliance on this information is used in risk assessments relatively rarely. Generally, these data are produced by pesticide manufacturers in an attempt to demonstrate that EPA has overstated residues in food as consumed.

The States' objection as to the use of processing factors is replete with problems. First, as noted above, if the States were concerned about the use of processing data in calculating processing factors, those concerns should have been raised in its petition. The REDs for all three pesticides extensively discussed processing data. Second, the States' claim that processing data are ''limited'' is too general and vague to satisfy the regulatory requirement that the basis for objections be stated with ''particularity.'' (40 CFR 178.25(a)(2)). The States neither point to specific data missing on these pesticides nor address the extensive EPA guidance and test guidelines concerning the collection and use of processing data. Third, the States' claim that EPA applies processing factors to raw foods in estimating residue levels in raw foods is specious. In support, the States assert that, in the chlorothalonil RED, EPA used a processing factor that showed a marked reduction of residues during the cooking of carrots to estimate the residues in raw carrots. The States are wrong. As the RED clearly states, the processing factor of 0.005 is for ''all cooked or processed food forms'' of carrots. (Ref. 6 at Table 6). Further, although the printouts from the computer risk assessment runs used to compile the 1998 chlorothalonil RED do not contain a high level of detail, later chlorothalonil risk assessments plainly show that the cooking factor for carrots is only applied to ''cooked'' carrots and not to ''uncooked'' carrots. (Ref. 15). The States, again, cite no basis for their claim to the contrary. The States' objection here is based on nothing more than speculation and incorrect assumptions and is, therefore, denied.

C. Data on Endocrine Effects

The States object to EPA's removal of the children's safety factor for chlorothalonil arguing 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 . . . .'' (Ref. 2 at 3). The States further allege that ''EPA failed to consider other published information on endocrine disruption, and instead has made a unilateral decision to wait for the endocrine disruption program to be established before it can make any determination about endocrine disruption potential.'' (Id.).

These claims have no factual basis. In its order denying the States' petition, EPA described the multiple chlorothalonil studies it had addressing potential endocrine effects and found that chlorothalonil was not an endocrine disruptor. (71 FR at 43921). The States have made no credible challenge to EPA's scientific determination based on this extensive database. Further, the States are simply wrong in claiming that potential endocrine disruption was not considered by EPA.

In reviewing EPA's disposition of the endocrine disruptor issue in its petition denial, EPA has discovered one error in that document. There, EPA stated that the chlorothalonil two-generation reproduction study in rats was conducted ''under the most recent testing guidelines.'' (71 FR at 43921). Although this chlorothalonil study is largely consistent with these testing guidelines it was performed and reviewed by EPA prior to the finalization of the revised guidelines. In light of this misstatement, EPA has once again carefully reviewed the evidence on whether chlorothalonil is an endocrine disruptor. EPA reaffirms its earlier conclusion that chlorothalonil is not an endocrine disruptor for the reasons below.

EPA has extensive data bearing on chlorothalonil's potential to disrupt endocrine systems. For all pesticides that result in residues in foods, EPA reviews numerous studies that bear on a pesticide's potential endocrine effects. (71 FR at 43921). For chlorothalonil, EPA reviewed two complete sets of data on developmental toxicity, reproductive toxicity, subchronic toxicity, chronic toxicity, and cancer. (Ref. 16). Developmental studies evaluate several endpoints susceptible to endocrine influence including effects on maternal animal fertility and pregnancy rates and on pup viability and sex ratios in pups. (71 FR at 43921). The chlorothalonil studies showed no treatment-related effects on any of these endpoints. (Refs. 17, 18, 19, and 20). Subchronic, chronic, and cancer studies must include examination of organs that play a critical role in the endocrine system (e.g., testes, epididymides, uterus, ovaries, mammary glands, and thyroid with parathyroid). These organs are removed, weighed and subjected microscopically to examination for evidence of any pathology. (71 FR at 43921). For chlorothalonil, no effects were seen in these organs in sub-chronic, chronic, and cancer studies involving rats, dogs, and mice. Rather, these studies consistently showed non-endocrine mediated effects on the stomach and kidneys, or on body weight. (Refs. 19, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, and 32).

The most important study for evaluating endocrine effects is the two-generation reproduction study in rats. (71 FR 43921). This study has been proposed by the Endocrine Disruptor Screening Program as the critical study for resolving whether chemicals are endocrine disruptors in mammals. The two-generation reproduction study examines numerous endpoints potentially influenced by the endocrine system including the endocrine-related organs noted above, as well as various reproduction endpoints both with regard to adults and pups. The most recent amendment to the guidelines for the reproduction study recommended expansion of the study to include consideration of the time of vaginal patency and balanopreputial separation in pups and determination of estrous cycle length and sperm enumeration, morphology, and motility in adults. (Ref. 33). Although the most recent chlorothalonil reproduction study was conducted prior to finalization of these amendments to the guideline, it nonetheless addressed all of these endpoints other than examination of adult sperm. Consistent with the other chlorothalonil toxicity studies, the reproduction study reported similar effects on the stomach and kidneys and no effects on the endocrine-related organs. A delay in vaginal patency and balanopreputial separation was noted at the high dose in pups; however, this effect was determined to have been a consequence of body weight decrements during lactation and not an endocrine effect, based on the fact that no differences were seen in mating and reproductive performance between treated and control animals. (Ref. 34). The findings in this study were similar to those in an earlier reproduction study with chlorothalonil. (Ref. 35).

What each of these studies show is that chlorothalonil's toxicity is not endocrine-mediated but rather operates by quite different mechanisms. Chlorothalonil causes a thickening and roughening, including hyperplasia and hyperkeratosis, of the lining (epithelium) of the non-glandular portion of the stomach and adverse effects on the kidney including increased weight and tumors. Chlorothalonil's effects on the stomach are due to irritation of the stomach lining followed by cytotoxicity, necrosis, increased cell proliferation, and restorative hyperplasia. The kidney effects are caused by chlorothalonil's disruption of enzymatic processes in the kidney leading to vacuolar degeneration, rapid cellular regeneration and proliferation, and eventually tumor formation. These effects are not related to the endocrine system. (Ref. 16). In fact, repeated examinations of the primary organs in the endocrine system in chlorothalonil studies have shown no adverse effects. Similarly, chlorothalonil's effect on body weight is a non-specific response not targeting any of the body's organs and thus not endocrine-related. Although data on effects on adult sperm were not collected in the reproduction study, repeated examinations of the testes in that and other studies showed no concern with this organ. Accordingly, EPA reaffirms its prior conclusion that it has sufficient data on the potential of chlorothalonil to cause endocrine effects in the young to remove the additional children's safety factor with regard to this endpoint.

For the first time in this proceeding, the States claim in their objections that EPA ignored ''published data [on endocrine disruption] that suggests that the full 10X factor should be applied . . ..'' (Ref. 2 at 4). Specifically, the States cite to two scientific articles which they claim document ''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 during fetal development.'' (Id.). EPA has several difficulties with this claim. First, for the reasons cited in Units VII.B., EPA questions the appropriateness of raising new factual claims at this stage of the proceedings. Second, the two articles cited are, for the most part, general overview discussions of endocrine disrupting chemicals, and do not show - and the States do not claim they show - that chlorothalonil is an endocrine disruptor.[1] Third, EPA does not understand the relevance the level at which endocrine disruptors cause effects has with regard to a pesticide such as chlorothalonil which has been found not to be an endocrine disruptor.

Accordingly, EPA denies the States' objection concerning endocrine disruptor data. To recap, EPA denied the States' petition which sought the revocation of the chlorothalonil tolerances based on the States' claim that EPA had unlawfully removed the children's safety factor given the alleged absence of data on, among other things, endocrine disruption. EPA explained that:

i. It was not legally compelled to retain the children's safety factor because data on chlorothalonil had not been collected under the endocrine disruptor screening program;

ii. It had adequate data on whether chlorothalonil was an endocrine disruptor; and

iii. Those data showed that chlorothalonil was not an endocrine disruptor. (71 FR at 43919–43921).

In its objections the States make no specific challenge to EPA's factual determination as to the second and third points; rather, they do little other than repeat the assertion presented in their petition that EPA cannot remove the children's safety factor until data is gathered under the endocrine disruptor screening program. EPA, therefore, denies the objections based on the legal and unchallenged factual grounds asserted in its order denying the petition. (See 71 FR at 43906). To the extent the States believe that the misstatement concerning conformance of the chlorothalonil reproduction study to the most recent testing guidelines caused it not to dispute EPA's factual findings, EPA will entertain supplemental objections addressing this factual issue so long as such supplemental objections are filed within 60 days of the date of publication of this order and otherwise meet the requirements governing objections in section 408(g) of FFDCA and 40 CFR part 178.

D. Alleged Uncertainty with Regard to Safety

The States object that there is uncertainty with regard to the safety of each of the pesticides and, for that reason, EPA should have retained the 10X children's safety factor. To demonstrate the alleged uncertainty, the States do nothing more than quote language from EPA's denial order that summarized the toxicological effect findings for chlorothalonil, alachlor, and methomyl. Presumably, the States are contending that the mere fact that at some dose a pesticide can cause an adverse effect in an animal study is sufficient to show a level of uncertainty that bars EPA from exercising its discretion to vary from the tenfold children's safety factor. As explained below, this argument is without a basis. The mere presence of an adverse effect

[1] One of the articles, contains an EPA list of endocrine disruptors which includes chlorothalonil. That list is dated October 24, 1996 and provides no reason for chlorothalonil's inclusion. The article notes that there is ''no doubt this list will change rapidly in the near future. Some of the chemicals on this list will probably be dropped from future consideration and other new ones are expected to be added.'' (Keith, Lawrence H., Environmental Endocrine Disruptors, Pure & Applied Chemistry., Vol. 70,No 12 pp. 2319–2326, at 2321 (1998)). As EPA has detailed in its order on the petition and this order, it has extensive data on chlorothalonil that shows that chlorothalonil is not an endocrine disruptor. As mentioned above, the objectors have provided no factual grounds challenging that determination.

in a toxicology study is insufficient without more factual context to show uncertainty. Because the States do not provide that context, their argument collapses at its inception.

Before addressing the merits of the States' objection, as a preliminary matter, EPA notes that this objection only applies to chlorothalonil and not to methomyl, alachlor, or metribuzin since EPA declined to retain the children's safety factor only as to chlorothalonil. As discussed above, the methomyl petition is still pending before EPA, and as to alachlor and metribuzin EPA did not address the issue of whether the children's safety factor should be retained given that, even if the factor is retained (due to uncertainty or some other reason), the tolerances would still meet the safety standard. Finally, even as to chlorothalonil, EPA questions the appropriateness of this objection given that it is based on arguments not included in the States' petition.

Turning to the merits of the objection-assuming it is properly filed as to chlorothalonil -- the objection can be quickly dismissed. The States are correct to note that the issue of whether there is uncertainty regarding the safety of children is a key consideration in a determination as to whether to retain or modify the children's safety factor. However, the States fail to make a significant argument that there is uncertainty regarding the safety of chlorothalonil. Certainly, the mere repetition of EPA's findings for chlorothalonil on the adverse effects seen in animal studies does not demonstrate uncertainty as to the safety of infants and children.

Adverse effects found in toxicological animal studies with a pesticide comprise just one piece of the complex puzzle informing the evaluation of uncertainty that is critical to the children's safety factor determination. Standing alone, they show little regarding the certainty or uncertainty regarding risks to infants and children. Rather, this certainty or uncertainty, which drives the determination of the children's safety factor, is informed by a weight-of-the-evidence evaluation of many issues including: what effects are seen in animals; what dose levels the effects occurred at; how strong the effects were; whether there was a good dose-response relationship with regard to the effects; how clearly a threshold for the effects have been identified; whether similar or related effects were seen in the same or other species in other studies; whether these effects are seen in adult and young animals, and, if so, at the same or differing levels; and what level of protection against the effects is provided by traditional safety factors. Reliance on a single fact (such as the type of adverse effect seen in an animal study), in isolation, without explanation of how it bears on the ultimate safety factor determination and certainty/uncertainty regarding that determination, is insufficient to state a meaningful challenge to EPA's conclusion on the children's safety factor.

For example, the first adverse effect cited by the States is that ''increased kidney weights and hyperplasia'' were seen in a chlorothalonil chronic rat study and that these effects were used in calculation of a safe dose for that pesticide. That is all the States say with regard to the increased kidney weights and hyperplasia. They do not discuss what dose level the effects occurred at, how significant the effects were, whether a clear no-effect level was identified for the effects, what safety factors were used to protect against the effect in humans, or any of the other issues identified above bearing on EPA's certainty/uncertainty regarding these effects. By itself, the fact that an adverse effect occurred shows little, and the failure of the States to offer any argument as to why such an effect evidences uncertainty renders their objection deficient on its face.

Accordingly, the States' objection that the children's safety factor is required for chlorothalonil due to uncertainty raised by adverse effects is denied. This argument is entirely absent from its petition and is thus not properly raised as an objection. In any event, the objection is denied on the merits for a failure to cite relevant factors or to make a meaningful factual showing on uncertainty.

E. Summary of Findings on the Objections

EPA denies each of the States' four objections for the reasons summarized below:

Objection #1: EPA was required to determine whether the children's safety factor should be applied for alachlor and metribuzin on the ''merits.''

In ruling on a petition to revoke tolerances as unsafe, EPA is not required to resolve substantive issues concerning the children's safety factor if resolution of those issues in the manner sought by the petitioner would not alter the safety determination for the challenged tolerances.

Objection #2: EPA unlawfully relied on percent crop treated data and processing factors to decrease the estimated risks of the challenged pesticide tolerances.

First, this objection is improper as to alachlor and chlorothalonil because the denial order did not rely on percent crop treated data or processing factors in resolving the objections as to these pesticide tolerances. The objection as to use of processing factors is improper as to metribuzin because EPA did not rely on processing factors to decrease metribuzin exposure estimates in the denial order.

Second, as to the objection with regard to the use of percent crop treated data in the metribuzin risk assessment, the plain language of the statute makes clear that EPA may rely on such information and the States' claims that reliance on such data is not protective of individual risk were not substantiated. Additionally, EPA's conservative use of percent crop treated data in the metribuzin risk assessment is unlikely to have underestimated metribuzin exposure and the States have presented no evidence to the contrary.

Third, alternate grounds for denying the States' objection to the use of processing factors include: (1) the States have failed to particularize their criticism of the use of such information and instead rely on vague and unsubstantiated allegations; and (2) the States' claim that EPA uses processing factors to estimate residue levels in raw, unprocessed food is in contravention of clear record evidence, and without any substantiation.

Objection #3: EPA has failed to consider endocrine effects for challenged pesticides because EPA has not obtained data for these pesticides under the endocrine-screening program and because EPA has not considered outside literature bearing on endocrine effects.

First, this objection is improper as to alachlor and metribuzin because the denial order did not resolve any issue regarding endocrine effects as to these two pesticides. This objection is only properly filed as to chlorothalonil.

Second, EPA has considered substantial data on the potential endocrine effects of chlorothalonil and concluded that it is not an endocrine disruptor. The States' objection does not challenge this factual determination. The statute does not require that EPA retain the children's safety factor until the endocrine-screening program is completed.

Third, the States' claim that EPA has not properly considered outside literature on endocrine disruption is denied as going beyond the provisions of the denial order. An alternate ground for denying this argument is that literature cited by the States is general

in nature and does not provide information on chlorothalonil.

Objection #4: Where a pesticide causes adverse effects in animal toxicological studies EPA may not remove the children's safety factor due to lingering uncertainty concerning its safety.

First, this objection is improperly submitted in that the question of whether the mere presence of adverse effects in animal toxicological studies is determinative under the children's safety factor provision was not addressed in the petition denial order.

Second, an alternate ground for denying this objection is that the mere citation of adverse effects is inadequate standing alone to demonstrate uncertainty regarding the safety of a pesticide.

VIII. Judicial Review

This is a final order under FFDCA section 408(g)(2)(C) and is reviewable in the United States Courts of Appeals pursuant to FFDCA section 408(h)(1). (21 U.S.C. 346a(g)(2)(C) and 346a(h)(1)). To the extent supplemental objections are timely filed, as discussed in Unit VII.C., EPA will issue a separate, reviewable order under FFDCA section 408(g)(2)(C) pertaining solely to any such supplemental objections.

IX. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's final order regarding objections filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, (5 U.S.C. 801 et seq.), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

XI. References

1. 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; Chlorothalonil; Methomyl; Metribuzin; Thiodicarb (December 17, 2004) (petition addressed to Michael O. Leavitt, Administrator, United States Environmental Protection Agency).

2. Objection of New York, Connecticut, and Massachusetts to Order Denying Petition to Revoke or Modify Tolerances for Alachlor, Chlorothalonil and Metribuzin (October 2, 2006).

3. Office of Pesticide Programs, U.S. EPA, ''Available Information on Assessing Pesticide Exposure From Food: A User's Guide'' (June 21, 2000).

4. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Reregistration Eligibility Decision: Alachlor (December 1998).

5. U.S. EPA, Permanent Tolerances by Pesticide: Aug. 1996 TIS (August 2002) (available at *http://www.epa.gov/oppsrrd1/tolerance/pdf-files/TolUniv8-05-2002.PDF*).

6. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Reregistration Eligibility Decision: Chlorothalonil (April 1999).

7. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Reregistration Eligibility Decision: Metribuzin (February 1998).

8. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Memorandum from Douglas Dotson to Paula Deschamp, ''Metribuzin Acute and Chronic Dietary Exposure Assessments'' (April 17, 2006).

9. Office of Pesticide Programs, U.S. EPA, ''Guidance For Refining Anticipated Residue Estimates For Use In Acute Dietary Probabilistic Risk Assessment'' (June 15, 2000).

10. U.S. EPA, ''Guidelines for the Use of Anticipated Residues in Dietary Exposure Assessment'' (March 25, 1991).

11. Office of Pesticide Programs, U.S. EPA, ''Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern.'' (March 16, 2000) (available at *http://www.epa.gov/pesticides/ trac/science/trac2b054.pdf*).]

12. Office of Pesticide Programs, U.S. EPA, ''Assigning Values To Nondetected/Non-Quantified Pesticide Residues In Human Health Food Exposure Assessments.'' (March 23, 2000).

13. U.S. Department of Agriculture, Pesticide Data Program (2002 – 2005) (available at *http://www.ams.usda.gov/science/pdp/download.htm* and in the docket).

14. Office of Prevention, Pesticide, and Toxic Substances, U.S. EPA, OPPTS Harmonized Test Guidelines: Series 860 Residue Chemistry Test Guidelines, OPPTS 860.1520 - Processed Food/Feed (August 1996).

15. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Memorandum from J.R. Tomerlein to Dennis McNeilly/Rosemary Kearns, ''Chlorothalonil: Acute and Chronic Dietary Exposure Assessments for a Tolerance on Edible Podded Peas Without a U.S. Registration'' (December 15, 2004).

16. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Memorandum from P.V. Shah to Pete Caulkins, ''HED Response to Questions Raised by SRRD Regarding Chlorothalonil'' (June 22, 2006).

17. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Prenatal Developmental Toxicity Study - Rabbit; Chlorothalonil (1994).

18. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Prenatal Developmental Toxicity Study - Rat; Chlorothalonil (1994).

19. Office of Pesticide and Toxic Substances, U.S. EPA, Memorandum from Alan C. Levy to Cynthia Giles-Parker, ''Chlorothalonil - Reviews of the Following Toxicity Studies: Rat Oncogenicity, Rabbit Teratogenicity, One-Generation Rat Reproduction (rangefinding), Rat Pilot Metabolism With AT-125, Comparison of Dog and Rat Metabolism, and Rat Dermal Metabolism'' (1991).

20. Office of Pesticide and Toxic Substances, U.S. EPA, Memorandum from David L. Ritter to Henry Jacoby, ''EPA Reg. No 677–313 - Review of miscellaneous Toxicity Data'' (1984).

21. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Subchronic Oral Toxicity in Dogs (diet); Chlorothalonil (1994).

22. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): 90–Day Oral Toxicity [diet] - rats; Chlorothalonil (1994).

23. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Subchronic Feeding Neurotoxicity in Rat; Chlorothalonil (2004).

24. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Combined chronic toxicity/carcinogenicity (diet)- rats; Chlorothalonil (1996).

25. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Chronic Toxicity in Dogs (diet); Chlorothalonil (1995).

26. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Carcinogenicity study in mice [feeding]; Chlorothalonil (1995).

27. Office of Pesticides and Toxic Substances, U.S. EPA, Memorandum to Diane Beavers, ''Chlorothalonil (CTN)

and its 4-OH metabolite in almonds, rice, wheat and meat, milk, poultry and eggs. Petition for tolerances'' (1984).

28. Office of Pesticides and Toxic Substances, Memorandum from David Ritter to H. Jacoby, ''EPA Reg.No 50534–7 Data Call in Submission. Chlorothalonil Registration Standard; review of data'' (1986).

29. Office of Prevention, Pesticides, and Toxic Substances, Memorandum from Alan C. Levy to Walter Waldrop/Andrew W. Ertman, ''Chlorothalonil - Review of 30–Day, 90–Day and One–Year Dog Studies (Oral Administration, Gelatin Capsules)'' (1996).

30. Health Effects Division, U.S. EPA, Data Evaluation Report; Ninety Day Mouse Feeding Study; Technical Chlorothalonil (DS–2787) (1983).

31. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Memorandum from Alan C. Levy to Karen Whitby, ''Chlorothalonil - Rereview of a Chronic Dog Study and a Developmental Rat Study; Review of a Dermal Absorption Rat Study'' (1995).

32. Office of Pesticides and Toxic Substances, U.S. EPA, Memorandum from D. Ritter to Lois Rossi, ''EPA No 50534–7 - CX, Submission of additional toxicity data'' (1988).

33. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Health Effects Test Guidelines; OPPTS 870.3800; Reproduction and Fertility Effects (August 1998).

34. Health Effects Division, Office of Pesticide Programs, U.S. EPA, Data Evaluation Record (TXR No: 0052493): Reproduction and Fertility Effects Study - [rat]; Chlorothalonil (1995).

35. Office of Pesticide and Toxic Substances, U.S. EPA, Memorandum from Alan C. Levy to Walter Waldrop/Andrew W. Ertman, ''Chlorothalonil - Two-Generation Reproduction Study in Rats'' (1993).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 1, 2007.

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. E7–13830 Filed 7–17–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260 and 278

[EPA–HQ–RCRA–2006–0097; FRL–8326–1]

RIN 2050–AG27

Criteria for the Safe and Environmentally Protective Use of Granular Mine Tailings Known as ''Chat''

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is promulgating mandatory criteria for the environmentally protective use of chat in transportation projects carried out, in whole or in part, with Federal funds. Specifically, chat used in such transportation projects will be safe and environmentally protective if it is used in asphalt concrete, in slurry seals, microsurfacing, or in epoxy seals for anti-skid on bridge decking. Chat used in such transportation projects will also meet EPA's criteria if it is used in Portland cement concrete, flowable fill, stabilized base, chip seals, or as road base providing, on a case-by-case basis, either: Synthetic Precipitation Leaching Procedure (SPLP, EPA SW–846 Method 1312) tests are conducted on the proposed material and the leachate testing results show that concentrations in the leachate do not exceed the Drinking Water Standards for lead and cadmium and the fresh water chronic National Recommended Water Quality Criterion for zinc of 120 ug/l; or EPA (or a State environmental Agency, if it chooses to do so) has determined, based on a site-specific risk assessment and after notice and opportunity for public comment, that the releases from the chat mixture in its proposed use will not cause an exceedance of the National Primary Drinking Water Standards for lead and cadmium in potential drinking water sources and the fresh water chronic National Recommended Water Quality Criterion for zinc of 120 ug/l in surface water. Furthermore, this rule also establishes a criterion that other uses of chat will be safe and environmentally protective and are acceptable if they are part of, and otherwise authorized by, a State or Federal response action undertaken in accordance with Federal or State environmental laws, with consideration of a site-specific risk assessment. This rule does not require that chat be sized (dry or wet) prior to its use, as long as this rule's criteria are complied with. EPA is also establishing recommended criteria as guidance on the environmentally protective use of chat for non-transportation cement and concrete projects. Finally, the Agency is establishing certification and recordkeeping requirements for all chat, except that under the jurisdiction of the U.S. Department of Interior, Bureau of Indian Affairs (BIA). The chat covered by this rule is from the lead and zinc mining areas of Oklahoma, Kansas and Missouri, known as the Tri-State Mining District.

DATES: This final rule is effective on September 17, 2007.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of September 17, 2007.

ADDRESSES: The public docket for this final rule, Docket ID No EPA–HQ–RCRA–2006–0097, contains the information related to this rulemaking, including the response to comment document. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, *e.g.*, Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Public Reading Room is 202–566–1744, and the telephone number to make an appointment to view the docket is 202–566–0276.

FOR FURTHER INFORMATION CONTACT: Stephen Hoffman, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC, 20460–0002, Mail Code 5306P; telephone number: 703–308–8413; fax number: 703–308–8686; e-mail address: *hoffman.stephen@epa.gov.* Additional information on this rulemaking is also available on the internet at *http://www.epa.gov/epaoswer/other/mining/chat/*.

The contents of this final rule are listed in the following outline

Contents of the Final Rule