adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, PHMB may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method(s)

An analytical method for food is not needed. Food contact sanitizers are typically regulated by state health departments to ensure that the food industry is using these products in compliance with regulations in 40 CFR 180.940. The end use solution that is applied to the food contact surface is analyzed not food items that may come into contact with the treated surface. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. The solution can be analyzed by use of the spectrophotometric method.

C. Existing Tolerances

There is no existing tolerance or exemption from tolerance for PHMB.

D. International Tolerances

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for any food uses at this time.

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 18, 2007.

Betty Shackleford,

Acting Director, Antimicrobials Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1280 is added to subpart D to read as follows:

§ 180.1280 Poly(hexamethylenebiguanide) hydrochloride (PHMB) exemption from the requirement of a tolerance.

Poly(hexamethylenebiguanide) hydrochloride (PHMB)(CAS Reg. No. 32289–58–0) is exempt from the requirement of a tolerance for residues of the antimicrobial in or on all food commodities when the residues are the result of the lawful application of a food contact surface sanitizer containing PHMB at 550 parts per million (ppm).

[FR Doc. E8–189 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0300; FRL–8346–3]

Zeta-cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of zeta-cypermethrin and its inactive R-isomers in or on Citrus (dried pulp, fruit and oil); oilseed commodities (seeds of borage, castor oil plant, Chinese tallow tree, crambe, cuphea, echium, euphorbia, evening primrose, flax, gold of pleasure, hare's-ear mustard, jojoba,

lesquerella, lunaria, meadowfoam, milkweed, mustard, niger seed, oil radish, poppy, rose hip, sesame, Stokes aster, sweet rocket, tallowwood, tea oil plant, and vernonia); oilseed, refined oils (refined oils of castor oil plant, Chinese tallowtree, euphorbia, evening primrose, jojoba, niger seed, rose hip, stokes aster, tallowwood, tea oil plant and vernonia); okra; rice, wild; and safflower, seed. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also deletes time-limited flax seed tolerances which are made redundant and unnecessary by establishment of the permanent tolerance on flax seed.

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, 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–2007–0300. 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 website 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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-5218; e-mail address: *stanton.susan@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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be 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 EPA's tolerance regulations at 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?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation 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–2007–0300 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 as required by 40 CFR part 178 on or before March 10, 2008.

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 this copy, identified by docket ID number EPA–HQ–OPP–2007–0300, 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 20460–0001.
- *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. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237-35242) (FRL–8133–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7132 and PP 6E7133) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540-6635. The petitions requested that 40 CFR 180.418 be amended by establishing tolerances for combined residues of the insecticide zeta-cypermethrin, S-cyano(3-phenoxyphenyl) methyl (±)-cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate and its inactive R-isomers, in or on the following food commodities: PP 6E7132 - Rice, wild, grain at 1.50 parts per million (ppm); okra at 0.20 ppm;

safflower, seed at 0.20 ppm; and PP 6E7133 - Fruit, citrus, group 10 at 0.25 ppm; citrus, dried, pulp at 0.50 ppm; and citrus, oil at 0.90 ppm. That notice referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of October 24, 2007 (72 FR 60369-60371) (FRL–8150–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7255) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540-6635. The petition requested that 40 CFR 180.418 be amended by establishing tolerances for combined residues of the insecticide zeta-cypermethrin, S-cyano(3-phenoxyphenyl) methyl (±)-cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate and its inactive R-isomers, at 0.2 ppm in or on the following commodities: borage, seed; castor oil plant, seed; Chinese tallowtree, seed; crambe, seed; cuphea, seed; echium, seed; euphorbia, seed; evening primrose, seed; flax, seed; gold of pleasure, seed; hare's ear mustard, seed; jojoba, seed; lesquerella, seed; lunaria, seed; meadowfoam, seed; milkweed, seed; mustard, seed; niger seed, seed; oil radish, seed; poppy, seed; rose hip, seed; sesame, seed; Stokes aster, seed; sweet rocket, seed; tallowwood, seed; tea oil plant, seed; and vernonia, seed. That notice referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received from a private citizen on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. below.

Based upon review of the data supporting the petition, EPA has revised the tolerance levels for citrus commodities and determined that a separate tolerance is needed for refined oils derived from several of the proposed oilseed crops. The reason for these changes is explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' 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.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of zeta-cypermethrin and its inactive R-isomers on Borage, seed at 0.2 ppm; Castor oil plant, refined oil at 0.4 ppm; Castor oil plant, seed at 0.2 ppm; Chinese tallowtree, refined oil at 0.4 ppm; Chinese tallowtree, seed at 0.2 ppm; Citrus, dried pulp at 1.8 ppm; Citrus, oil at 4.0 ppm; Crambe, seed at 0.2 ppm; Cuphea, seed at 0.2 ppm; Echium, seed at 0.2 ppm; Euphorbia, refined oil at 0.4 ppm; Euphorbia, seed at 0.2 ppm; Evening primrose, refined oil at 0.4 ppm; Evening primrose, seed at 0.2 ppm; Flax, seed at 0.2 ppm; Fruit, citrus, group 10 at 0.35 ppm; Gold of pleasure, seed at 0.2 ppm; Hare's-ear mustard, seed at 0.2 ppm; Jojoba, refined oil at 0.4 ppm; Jojoba, seed at 0.2 ppm; Lesquerella, seed at 0.2 ppm; Lunaria, seed at 0.2 pm; Meadowfoam, seed at 0.2 ppm; Milkweed, seed at 0.2 ppm; Mustard, seed at 0.2 ppm; Niger seed, refined oil at 0.4 ppm; Niger seed, seed at 0.2 ppm; Oil radish, seed at 0.2 ppm; Okra at 0.2 ppm; Poppy, seed at 0.2 ppm; Rice, wild, grain at 1.5 ppm; Rose hip, refined oil at 0.4 ppm; Rose hip, seed at 0.2 ppm; Safflower, seed at 0.2 ppm; Sesame, seed at 0.2 ppm; Stokes aster, refined oil at 0.4 ppm; Stokes aster, seed at 0.2 ppm; Sweet rocket, seed at 0.2 ppm; Tallowwood, refined oil at 0.4 ppm; Tallowwood, seed at 0.2 ppm; Tea oil plant, refined oil at 0.4 ppm; Tea oil plant, seed at 0.2 ppm; Vernonia, refined oil at 0.4 ppm; and Vernonia, seed at 0.2 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

Zeta-cypermethrin is an enriched version of the synthetic pyrethroid insecticide cypermethrin. Cypermethrin [(±) α-cyano-(3-phenoxyphenyl)methyl (±)-cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] is a racemic mixture of eight isomers (each with percentages of 11-14%). Zeta-cypermethrin consists primarily of the four isomers with the ''S'' configuration at the cyano-bearing carbon. While cypermethrin and zeta-cypermethrin are separate active ingredients, each registered in separate end-use products, they are considered together in this risk assessment due to the close similarity of their uses, toxicity, and chemical characteristics.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by cypermethrin/zeta-cypermethrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Zeta-cypermethrin: Human Health Risk Assessment for Section 3 Use of Zeta-cypermethrin on Citrus (Crop Group 10), Oilseeds (proposed Crop Group 20, except cottonseed), Safflower, Wild Rice and Okra*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES** and is identified as document ID number EPA–HQ–OPP–2007–0300-0006 in that docket.

The toxicity data for zeta-cypermethrin indicate one major target for this chemical: the neuromuscular system. There may be some liver effects as well; however, these may be an adaptive response. The neuromuscular effects (tremors, gait abnormalities, and decreases in motor activity) occur mainly in oral studies in the dog and the rat. Similar effects were observed in a rat inhalation study conducted with cypermethrin. As with other pyrethroids, the neuromuscular effects appear to be transient acute effects and do not appear to increase in severity with increasing duration of exposure.

Studies on zeta-cypermethrin, in addition to those on cypermethrin,

show that it is not a developmental or reproductive toxicant. In the prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity up to the highest dose tested. Maternal toxicity was observed in these studies in the form of decreased body weight gain and food consumption and/or clinical signs of neurotoxicity such as gait abnormalities. In the multi-generation reproduction studies in rats, offspring toxicity was observed at the same treatment level that resulted in parental systemic toxicity. There did not appear to be any increases in severity of toxicity for the pups in these studies. In the developmental neurotoxicity (DNT) study, there was limited evidence of increased susceptibility of the offspring. No toxicity was observed in the maternal animals at the highest dose tested, while decreased body weight, decreased subsession motor activity, and changes in brain morphometry were seen in the offspring at this same dose. With the available toxicity database at this time, there is no evidence of endocrine disruption.

EPA has classified cypermethrin/zeta-cypermethrin as a possible human carcinogen, based on an increased incidence of lung adenomas and combined adenomas plus carcinomas in female mice. The presence of common benign tumors (lung adenomas) in one species (mice) and one sex (female), with no increase in the proportion of malignant tumors or decrease in the time-to-tumor occurrence, together with the lack of mutagenic activity, was not considered strong enough evidence to warrant a quantitative estimation of human cancer risk. The point-of-departure selected for deriving the chronic reference dose will account for all chronic effects as well as potential cancer effects.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty factors (UFs) is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for zeta-cypermethrin/cypermethrin used for human risk assessment can be found at *http://www.regulations.gov* at pages 25-26 in the document *Zeta-cypermethrin: Human Health Risk Assessment for Section 3 Use of Zeta-cypermethrin on Citrus (Crop Group 10), Oilseeds (proposed Crop Group 20, except cottonseed), Safflower, Wild Rice and Okra* in docket ID number EPA–HQ–OPP–2007–0300.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cypermethrin/zeta-cypermethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing cypermethrin/zeta-cypermethrin tolerances in 40 CFR 180.418. Cypermethrin and zeta-cypermethrin are registered for use on some of the same commodities; however, when both are applied to the same crop in the same year, the maximum seasonal rate may not exceed the maximum seasonal rate for cypermethrin when used alone. Therefore, EPA has not assumed that residues of both cypermethrin and zeta-cypermethrin would appear on the same crop. EPA assessed dietary exposures from cypermethrin/zeta-cypermethrin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues. For crops with both cypermethrin and zeta-cypermethrin tolerances, the higher of the two tolerances was assumed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA calculated anticipated residues for most commodities. Anticipated residues were based on USDA Pesticide Data Program (PDP) monitoring data or crop field trial data and in many cases were further adjusted to reflect actual percent crop treated (PCT) estimates. For crops with both cypermethrin and zeta-cypermethrin registrations, the higher of the two PCT estimates was assumed. EPA assumed 100 PCT for all of the new uses. Anticipated residues were calculated for livestock commodities using the residue data from livestock feeding studies in conjunction with anticipated dietary burdens from consumption of cypermethrin/zeta-cypermethrin treated feed items. Projected PCT (PPCT) estimates were used in these calculations for certain recently registered feed items (alfalfa hay, other hay and pasture/rangeland grasses), since reliable PCT estimates based on historical usage are not yet available.

iii. *Cancer*. As discussed above in Unit III.A., EPA has classified cypermethrin/zeta-cypermethrin as a possible human carcinogen (Group C), based on an increased incidence of lung adenomas and combined adenomas plus carcinomas in female mice. EPA determined that the Chronic Reference Dose (cRfD) would be protective of any cancer risk posed by zeta-cypermethrin because the cRfD of 0.06 milligrams/kilogram/day (mg/kg/day) (based on a NOAEL of 6 mg/kg/day) used for risk assessment is significantly lower than the dose of 1,600 ppm (approximately 229 mg/kg/day) at which tumors were observed; the NOAEL for tumor induction is 400 ppm (approximately 57 mg/kg/day). EPA also took into account that the benign tumors (lung adenomas) were observed in one species (mice) and one sex (female), with no increase in the proportion of malignant tumors or decrease in the time-to-tumor

occurrence. Together with the lack of mutagenic activity, there was not strong enough evidence to warrant a quantitative estimation of human cancer risk. Therefore, the cRfD is considered protective of both non-cancer and cancer effects and a separate cancer exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• *Condition a.* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

• *Condition b.* The exposure estimate does not underestimate exposure for any significant subpopulation group.

• *Condition c.* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information in the chronic dietary exposure assessment as follows:

PCT estimates for existing uses: broccoli 6%, cabbage 3%, carrots 1%, cauliflower 13%, collards 9%, celery 1%, corn (field and sweet) <1%, cotton 5%, garlic 13%, kale 13%, lettuce (head and leaf) 26%, mustard greens 8%, onions 15%, peanuts <1%, pecans 9%, sorghum <1%, soybeans <1%, spinach 2%, tomato 1%, turnip greens 4% and wheat <1%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% except for those situations in which the average PCT is less than one. In those cases <1% is used as the average. In most cases, EPA uses available data from U. S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA used Projected PCT (PPCT) estimates for animal feed items: alfalfa hay 3%, other hay 1% and pasture/rangeland <1%.

EPA estimates PPCT for a new pesticide use by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with the new insecticide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for the PCT data because they are publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the estimated PPCT for these three crops could be exceeded include pest resistance concerns, relative efficacies, pest prevalence and other factors. All such relevant information that is currently available to EPA has been considered for zeta-cypermethrin on alfalfa hay, other hay and pasture/rangeland. It is unlikely that the actual PCT for zeta-cypermethrin will exceed the estimated PPCT for this chemical on each of these three sites during the next 5 years.

The Agency believes that the three conditions listed in this Unit have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cypermethrin/zeta-cypermethrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for cypermethrin/zeta-cypermethrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of cypermethrin/zeta-cypermethrin. Further information regarding EPA's drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of cypermethrin/zeta-cypermethrin for acute exposures are estimated to be 1.04 parts per billion (ppb) for surface water and 0.0036 ppb for ground water. The EECs for chronic exposures are estimated to be 0.013 ppb for surface water and 0.0036 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1.04 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of

value 0.013 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cypermethrin/zeta-cypermethrin is currently registered for the following residential non-dietary sites: as an indoor surface or spot/crack and crevice treatment; and as a granular broadcast or spot application for lawns. EPA assessed residential exposure using the following assumptions:

There is a potential for short- and intermediate-term dermal and inhalation exposure of homeowners applying products containing cypermethrin/zeta-cypermethrin in indoor (surface or crack and crevice treatments) and outdoor (lawn treatment) settings. The outdoor use on lawns, considered the worst case residential handler exposure scenario, was used to assess residential handler exposure and risk. A dermal endpoint of concern for adults was not identified in the toxicology database for cypermethrin/zeta-cypermethrin; therefore, only the inhalation route of exposure was assessed for residential applicators.

There is also a potential for short- and intermediate-term dermal and inhalation post-application exposure of adults and short- and intermediate-term dermal, inhalation and incidental oral post-application exposure of children from entering areas treated with cypermethrin/zeta-cypermethrin. As noted above, a dermal endpoint of concern for adults was not identified in the toxicology database for cypermethrin/zeta-cypermethrin. In addition, EPA has determined in previous residential assessments that indoor and outdoor inhalation exposures are negligible, due in part to the low vapor pressure of cypermethrin/zeta-cypermethrin; therefore, EPA only assessed post-application dermal and incidental oral exposure of children to cypermethrin/zeta-cypermethrin in indoor and outdoor settings.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Cypermethrin/zeta-cypermethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids interact with sodium channels, there are multiple types of sodium channels and it is currently unknown whether the pyrethroids have similar effects on all channels. Nor do we have a clear understanding of effects on key downstream neuronal function e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. Information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism can be found on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty factors (UFs) and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The pre- and postnatal toxicology database for cypermethrin/zeta-cypermethrin includes rat and rabbit developmental toxicity studies, a two-generation reproduction toxicity study in rats and a developmental neurotoxicity (DNT) study in rats. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or rabbits or offspring following exposure to cypermethrin/zeta-cypermethrin in the developmental toxicity and reproduction studies.

In the DNT study, there was limited evidence of increased susceptibility of the offspring. No toxicity was observed in the maternal animals at the highest dose tested, while decreased body weight, decreased subsession motor activity, and changes in brain morphometry were seen in the offspring at this same dose. An in-depth analysis of the effects seen in the pups revealed that these effects were of low concern because:

i. Body weight decreases were seen only during late lactation (postnatal days 13 to 21) when the pups are potentially exposed to higher levels of the chemical via both milk and feed.

ii. The decreases in motor activity were not considered biologically significant because they were seen only in the subsession data (not in total or ambulatory counts), only in one sex (females), only on postnatal day 21 (not in measurements taken at three other time periods), and the differences did not reach statistical significance.

iii. The sole brain morphometric change (increased mean vertical thickness of the cortex) was determined to occur in isolation, only in female pups on day 21, and was not considered biologically significant because when the values of individual treated animals were compared with individual control animals, the incidence and magnitude of the change suggested a low concern.No statistically or biologically significant changes were seen in any other brain areas in male or female pups at any time period.

Based on these factors, the limited susceptibility seen in the DNT was determined to be of low concern, and there are no residual uncertainties for pre- and/or postnatal neurotoxicity.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for cypermethrin/zeta-cypermethrin is complete.

ii. There is no evidence that cypermethrin/zeta-cypermethrin results in increased qualitative or quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iii. Although there is limited evidence of increased susceptibility of the offspring in the DNT study, the degree

of concern for pre- and/or postnatal toxicity is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment utilizes tolerance level residues and 100 PCT. The chronic dietary food exposure assessment utilizes anticipated residues that are based on reliable field trial or PDP monitoring data. The chronic assessment also utilizes PCT data for many registered commodities that have been verified by the Agency, as well as high-end PPCT estimates for animal feed items that are unlikely to be exceeded during the next 5 years. Conservative ground and surface water modeling estimates were used. Similarly, conservative residential SOPs were used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cypermethrin/zeta-cypermethrin.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cypermethrin/zeta-cypermethrin will occupy 53% of the aPAD for children, 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cypermethrin/zeta-cypermethrin from food and water will utilize 3.0% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use pattern, chronic residential exposure to residues of cypermethrin/zeta-cypermethrin is not expected.

3. *Short- and intermediate-term risk*. Short-term and intermediate-term aggregate exposure take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cypermethrin/zeta-cypermethrin is currently registered for uses that could result in short- and intermediate-term residential exposures and the Agency has determined that it is appropriate to aggregate chronic food and water and short- or intermediate-term exposures for cypermethrin/zeta-cypermethrin. Since the cypermethrin/zeta-cypermethrin endpoints and points of departure (NOAELs) are identical for short- and intermediate-term exposures, in this case the aggregate MOEs for short- and intermediate-term exposure are the same.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 7,500 for the overall U.S. population and 8,600 for females 13 to 49 years old, using handler exposure estimates based on indoor surface uses of cypermethrin/zeta-cypermethrin. Aggregate MOEs for infants and children are estimated to be 220 and 160, respectively, based on post-application exposures following indoor surface treatments with cypermethrin/zeta-cypermethrin. The indoor surface treatment scenario was used in the aggregate assessment, since this scenario resulted in the highest estimated exposures and is, therefore, protective of all post-application exposures. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses.

5. *Aggregate cancer risk for U.S. population*. Cypermethrin/zeta-cypermethrin has been classified as a ''Group C'' (possible human) carcinogen, based on an increased incidence of lung adenomas and combined adenomas plus carcinomas in female mice. As explained above, risk assessments based on the endpoint selected for the chronic population adjusted dose (cPAD) are considered to be protective of any potential carcinogenic risk from exposure to cypermethrin/zeta-cypermethrin. Based on the results of the chronic risk assessment discussed above in Unit III.E.2., EPA concludes that cypermethrin/zeta-cypermethrin is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cypermethrin/zeta-cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement analytical methodology for cypermethrin and zeta-cypermethrin residues is available in PAM Volume II. PAM Volume II lists Methods I and II for the determination of residues of cypermethrin *per se* in or on plant and livestock commodities, respectively. Both are gas chromatography (GC) methods with electron capture detection and have undergone successful Agency method tryout. Method I has a detection limit of 0.01 ppm and Method II has detection limits of 0.005 ppm for milk and 0.01 ppm for livestock tissues. These methods are not stereo-specific; thus, no distinction is made between residues of cypermethrin (all eight stereoisomers) and zeta-cypermethrin (an enriched isomer form of cypermethrin).

B. International Residue Limits

There are no specific Codex maximum residue limits (MRLs) for zeta-cypermethrin, but there are Codex MRLs for cypermethrin. Codex has an MRL of 2.0 ppm for cypermethrin on citrus, an MRL of 0.2 ppm on oilseeds and an MRL of 0.5 ppm on edible vegetable oils. The 0.2 ppm U.S. tolerances on safflower and other oilseeds are harmonized numerically with the current Codex MRL of 0.2 mg/kg on oilseeds, although the latter is based on cypermethrin instead of zeta-cypermethrin. EPA is not recommending an increase in the U.S. citrus tolerance of 0.35 ppm or the tolerance on refined oils of 0.4 ppm to harmonize numerically with the Codex MRLs on citrus and edible vegetable oils, because the latter are expressed in terms of cypermethrin, which requires higher application rates and residues than zeta-cypermethrin to be efficacious.

C. Response to Comments

Comments were received from a private citizen objecting to the sale of zeta-cypermethrin anywhere in this country on the basis that it is a ''possible human carcinogen''. EPA considered the carcinogenic potential of zeta-cypermethrin in its risk assessment and determined that it did not pose a cancer risk. Comments received contained no scientific data or other substantive evidence to rebut this conclusion or the Agency's finding that there is a reasonable certainty that no

harm will result from aggregate exposure to cypermethrin/zeta-cypermethrin from the establishment of these tolerances. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63096-63098 (October 29, 2004) for the Agency's previous responses to these objections.

V. Conclusion

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: (1) Increased the tolerance level for Fruit, citrus, group 10 from 0.25 ppm to 0.35 ppm; for Citrus, dried pulp from 0.5 ppm to 1.8 ppm; and for Citrus, oil from 0.9 ppm to 4.0 ppm; and (2) Determined that a separate, higher tolerance of 0.4 ppm should be established for specific refined oils. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* and the results of citrus and oilseed processing studies. EPA also revised the commodity term for Safflower to read ''Safflower, seed'' to agree with the recommended commodity term in the Office of Pesticide Program's Food and Feed Commodity Vocabulary.

Therefore, tolerances are established for combined residues of zeta-cypermethrin, S-cyano(3-phenoxyphenyl)methyl(±)(cis-trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate and its inactive R-isomers, in or on Borage, seed at 0.2 ppm; Castor oil plant, refined oil at 0.4 ppm; Castor oil plant, seed at 0.2 ppm; Chinese tallowtree, refined oil at 0.4 ppm; Chinese tallowtree, seed at 0.2 ppm; Citrus, dried pulp at 1.8 ppm; Citrus, oil at 4.0 ppm; Crambe, seed at 0.2 ppm; Cuphea, seed at 0.2 ppm; Echium, seed at 0.2 ppm; Euphorbia, refined oil at 0.4 ppm; Euphorbia, seed at 0.2 ppm; Evening primrose, refined oil at 0.4 ppm; Evening primrose, seed at 0.2 ppm; Flax, seed at 0.2 ppm; Fruit, citrus, group 10 at 0.35 ppm; Gold of pleasure, seed at 0.2 ppm; Hare's-ear mustard, seed at 0.2 ppm; Jojoba, refined oil at 0.4 ppm; Jojoba, seed at 0.2 ppm; Lesquerella, seed at 0.2 ppm; Lunaria, seed at 0.2 pm; Meadowfoam, seed at 0.2 ppm; Milkweed, seed at 0.2 ppm; Mustard, seed at 0.2 ppm; Niger seed, refined oil at 0.4 ppm; Niger seed, seed at 0.2 ppm; Oil radish, seed at 0.2 ppm; Okra at 0.2 ppm; Poppy, seed at 0.2 ppm; Rice, wild, grain at 1.5 ppm; Rose hip, refined oil at 0.4 ppm; Rose hip, seed at 0.2 ppm; Safflower, seed at 0.2 ppm; Sesame, seed at 0.2 ppm; Stokes aster, refined oil at 0.4 ppm; Stokes aster, seed at 0.2 ppm; Sweet rocket, seed at 0.2 ppm; Tallowwood, refined oil at 0.4 ppm; Tallowwood, seed at 0.2 ppm; Tea oil plant, refined oil at 0.4 ppm; Tea oil plant, seed at 0.2 ppm; Vernonia, refined oil at 0.4 ppm; and Vernonia, seed at 0.2 ppm.

Time-limited tolerances were established at 40 CFR 180.418(b) for residues of zeta-cypermethrin in or on flax, meal and seed in connection with FIFRA section 18 emergency exemptions granted by EPA. These time-limited tolerances are no longer necessary, because a permanent tolerance is being established for flax at the same level. Therefore, these time-limited tolerances for residues of zeta-cypermethrin are revoked.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 20, 2007.

Lois Rossi

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.418 is amended by alphabetically adding the following commodities to the table in paragraph (a)(2) and removing the text from paragraph (b) and reserving the paragraph designation and heading to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * *	* *
Borage, seed	0.2
* * *	* *
Castor oil plant, refined oil	0.4
Castor oil plant, seed	0.2
* * *	* *
Chinese tallowtree, refined oil	0.4
Chinese tallowtree, seed	0.2
* * *	* *
Citrus, dried pulp	1.8
Citrus, oil	4.0
* * *	* *
Crambe, seed	0.2
Cuphea, seed	0.2
Echium, seed	0.2
* * *	* *
Euphorbia, refined oil	0.4
Euphorbia, seed	0.2
Evening primrose, refined oil	0.4
Evening primrose, seed	0.2
Flax, seed	0.2
* * *	* *
Fruit, citrus, group 10	0.35
* * *	* *
Gold of pleasure, seed	0.2
* * *	* *
Hare's-ear mustard, seed	0.2
* * *	* *
Jojoba, refined oil	0.4
Jojoba, seed	0.2
Lesquerella, seed	0.2
Lunaria, seed	0.2
Meadowfoam, seed	0.2
* * *	* *
Milkweed, seed	0.2
Mustard, seed	0.2
Niger seed, refined oil	0.4
Niger seed, seed	0.2
* * *	* *
Oil radish, seed	0.2
Okra	0.2
* * *	* *
Poppy, seed	0.2
* * *	* *
Rice, wild, grain	1.5
Rose hip, refined oil	0.4
Rose hip, seed	0.2
Safflower, seed	0.2
Sesame, seed	0.2
* * *	* *
Stokes aster, refined oil	0.4
Stokes aster, seed	0.2
* * *	* *
Sweet rocket, seed	0.2
Tallowwood, refined oil	0.4
Tallowwood, seed	0.2
Tea oil plant, refined oil	0.4
Tea oil plant, seed	0.2
* * *	* *
Vernonia, refined oil	0.4
Vernonia, seed	0.2
* * *	* *

(b) Section 18 emergency exemptions. [Reserved]

* * * * *

[FR Doc. E7–25392 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R8–ES–2007–0026; 92210–1117–0000; ABC Code: B4]

RIN 1018–AU83

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Monterey Spineflower (Chorizanthe pungens var. pungens)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are designating revised critical habitat for the threatened Monterey spineflower (*Chorizanthe pungens* var. *pungens*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 11,055 acres (ac) (4,475 hectares (ha)) fall within the boundaries of this revised critical habitat designation. The revised critical habitat is located in Santa Cruz and Monterey counties, California.

DATES: This rule becomes effective on February 8, 2008.

ADDRESSES: Comments and materials we received, as well as supporting documentation we used in the preparation of this final rule, are available for public inspection, by appointment, during normal business hours at the Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003 (telephone 805–644–1766). The final rule, economic analysis, and more detailed maps are also available on the Internet at *http://www.fws.gov/ventura*.

FOR FURTHER INFORMATION CONTACT: Connie Rutherford, Listing and Recovery Coordinator for Plants, Ventura Fish and Wildlife Office (see **ADDRESSES**), (telephone 805–644–1766, ext. 306; facsimile 805–644–3958). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

It is our intent to discuss only those topics directly relevant to the designation of revised critical habitat in this rule. For more detailed background information on the appearance, seed ecology, habitat requirements, and the historical and current distribution of *Chorizanthe pungens* var. *pungens*, refer to the proposed revised critical habitat designation published in the **Federal Register** on December 14, 2006 (71 FR 75189), and the previous final designation of critical habitat for *C. p.* var. *pungens* published in the **Federal Register** on May 29, 2002 (67 FR 37498). Additional information on *C. p.* var. *pungens* is also available in the final listing rule published in the **Federal Register** on February 4, 1994 (59 FR 5499).

Chorizanthe pungens var. *pungens* is an annual species in the buckwheat family (Polygonaceae). It is a low-growing herb that is soft-hairy and grayish or reddish in color, with white- to rose-colored flowers. It produces one seed per flower, and depending on the vigor of an individual plant, dozens to over one hundred seeds can be produced (Abrams 1944, F35–1; Fox *et al.* 2006, pp. 162–163). Seed dispersal in *C. p.* var. *pungens* is likely facilitated by hooked spines on the structure surrounding the seed. In the *Chorizanthe* genus, these are believed to attach to passing animals and disperse seed between plant colonies and populations (Reveal 2001, unpaginated). Wind also disperses seed within colonies and populations.

Previous Federal Actions

On May 29, 2002, we designated critical habitat for *Chorizanthe pungens* var. *pungens* on approximately 18,829 acres (ac) (7,620 hectares (ha)) of land in Santa Cruz and Monterey counties, California (67 FR 37498). In March 2005, the Homebuilders Association of Northern California, *et al.*, filed suit against the Service (CV–013630LKK–JFM) challenging final critical habitat rules for several species, including *Chorizanthe pungens* var. *pungens*. In March 2006, a settlement was reached that requires the Service to re-evaluate five final critical habitat designations, including critical habitat designated for