(MRLs) for cloquintocet-mexyl on wheat and barley at 0.1 ppm.

F. Determination of Safety and Conclusions

The Agency is granting the requested increase in tolerances for cloquintocet-mexyl and its metabolite on wheat, forage at 0.20 ppm and wheat, hay at 0.50 ppm. The Agency is also granting the requested addition of reference to the active ingredient pyroxsulam for use with the inert ingredient safener cloquintocet-mexyl on wheat. In addition, the Agency is removing the specification of a 1:4 ratio of cloquintocet-mexyl to active ingredient from the existing tolerance expression of 40 CFR 180.560. The specification is not necessary when numerical tolerances are already established.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to residues of cloquintocet-mexyl and its metabolite. Accordingly, EPA finds that the tolerances described above for residues of cloquintocet-mexyl and its metabolite will be safe.

IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to petitions 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).

V. 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: February 20, 2008.

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 180.560 is amended by revising paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2); tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	0.1
Barley, straw	0.1
Wheat, forage	0.2
Wheat, grain	0.1
Wheat, hay	0.5
Wheat, straw	0.1

* * * * *

[FR Doc. E8–4023 Filed 3–4–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0495; FRL–8352–2]

Methoxyfenozide; Pesticide Tolerances and Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide per se; benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide in or on the food commodities acerola; animal feed, nongrass, group 18, forage; animal feed, nongrass, group 18, hay; avocado; bean,

dry, seed; bushberry subgroup 13-07B; canistel; feijoa; grass, forage, fodder and hay, group 17, forage; grass, forage, fodder and hay, group 17, hay; guava; jaboticaba; kurrat; mango; onion, green, subgroup 3-07B; papaya; passionfruit; peanut; peanut, hay; peanut oil; sapodilla; sapote, black; sapote, mamey; star apple; starfruit; vegetable, tuberous and corm, except potato, sub group 1D; and wax jambu. This regulation also establishes time-limited tolerances for indirect or inadvertent residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and indirect or inadvertent combined residues of methoxyfenozide and its metabolites RH-117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid N-tert-butyl-N'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH-151,055 glucose conjugate of RH-117,236; 3,5-dimethyl benzoic acid N-tert-butyl-N-[3 ([beta]-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH-152,072 the malonylglycosyl conjugate of RH 117,236 in or on the food commodities animal feed, nongrass, group 18; grain, cereal, forage, fodder and straw, group 16; grass forage, fodder, and hay, group 17; herb and spice, group 19; vegetable, bulb, group 3-07; vegetable, foliage of legume, group 7; vegetable, leaves of root and tuber, group 2; vegetable, legume, group 6; and vegetable, root and tuber, group 1. Dow AgroSciences LLC and Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The time-limited tolerances will expire on September 30, 2010.

DATES: This regulation is effective March 5, 2008. Objections and requests for hearings must be received on or before May 5, 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–2007–0495. 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 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: Mark Suarez, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0120; e-mail address: *suarez.mark@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 provides 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 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, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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 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–2007–0495 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 May 5, 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 your copies, identified by docket ID number EPA–HQ–OPP–2007–0495, 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 Tolerances

In the **Federal Register** of October 20, 2006 (71 FR 61971) (FRL–8098–6), August 1, 2007 (72 FR 42072) (FRL–8138–1), and October 24, 2007 (72 FR 60367) (FRL–8154–1), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PPs 6E7086, 7E7218, 6F7135, and 0F6201) by, Dow AgroSciences LLC, Zionsville Road -Indianapolis, IN 46268 (PPs 6F7135 and 0F6201) and IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 08540 (PPs 7E7218 and 6E7086). The petitions requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide, methoxyfenozide, in or on the food commodities acerola at 0.4 parts per million (ppm) (PP 7E7218); arionia berry at 3.0 ppm (PP 6E7086); avocado at 0.6 ppm (PP 7E7218); bean, dry, seed at 0.15 ppm (PP 6E7086); blueberry, lowbush at 3.0 ppm (PP 6E7086); buffalo currant at 3.0 ppm (PP 6E7086); bushberry subgroup 13B at 3.0 ppm (PP 6E7086); canistel at 0.6 ppm (PP 7E7218); Chilean guava at 3.0 ppm (PP 6E7086); chive, Chinese, fresh leaves at 5.0 ppm (PP 7E7218); chive, fresh leaves at 5.0 ppm (PP 7E7218); elegans hosta at 5.0 ppm (PP 7E7218); European barberry at 3.0 ppm (PP 6E7086); feijoa at 0.4 ppm (PP 7E7218); fritillaria leaves at 5.0 ppm (PP 7E7218); grass forage, fodder, and hay group 17, forage at 18.0 ppm (PP 6E7086); grass forage, fodder, and hay, group 17, hay at 30.0 ppm (PP 6E7086); guava at 0.4 ppm (PP 7E7218); highbush cranberry at 3.0 ppm (PP 6E7086); honeysuckle at 3.0 ppm (PP 6E7086); jaboticaba at 0.4 ppm (PP 7E7218); jostaberry at 3.0 ppm (PP 6E7086); juneberry at 3.0 ppm (PP 6E7086); kurrat at 5.0 ppm (PP 7E7218); Lady's leek at 5.0 ppm (PP 7E7218); leek at 5.0 ppm (PP 7E7218); leek, wild at 5.0 ppm (PP 7E7218); lingonberry at 3.0 ppm (PP 6E7086); mango at 0.6 ppm (PP 7E7218); native currant at 3.0 ppm (PP 6E7086); nongrass animal feeds, group 18, forage at 35.0 ppm (PP 6F7135); nongrass animal feeds, group 18, hay at 85.0 ppm (PP 6F7135); onion, Beltsville bunching at 5.0 ppm (PP 7E7218); onion, fresh at 5.0 ppm (PP 7E7218); onion, green at 5.0 ppm (PP 7E7218); onion, macrostem at 5.0 ppm (PP 7E7218); onion, tree, tops at 5.0 ppm (PP 7E7218); onion, Welsh, tops at 5.0 ppm (PP 7E7218); papaya at 0.6 ppm (PP 7E7218); passionfruit at 0.4 ppm (PP 7E7218); peanut at 0.02 ppm (PP 6E7086); peanut, hay at 60 ppm (PP 6E7086); peanut oil at 0.09 ppm (PP 6E7086); salal at 3.0 ppm (PP 6E7086); sapodilla at 0.6 ppm (PP 7E7218); sapote, black at 0.6 ppm (PP 7E7218); sapote, mamey at 0.6 ppm (PP 7E7218); sea buckthorn at 3.0 ppm (PP 6E7086); shallot, fresh leaves at 5.0 ppm (PP 7E7218); star apple at 0.6 ppm (PP 7E7218); starfruit at 0.4 ppm (PP 7E7218); vegetable, tuberous and corm, except potato, sub group 1D at 0.02 ppm (PP 6E7086); wax jambu at 0.4 ppm (PP 7E7218). In the petition 0F6201, Dow requested that tolerances that expired on September 30, 2007 be re-established for indirect or inadvertent residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and indirect or inadvertent combined residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its metabolites RH-117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid N-tert-butyl-N'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH-151,055 glucose conjugate of RH-117,236; 3,5-dimethyl benzoic acid N-tert-butyl-N-[3 ([beta]-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH-152,072 the malonylglycosyl conjugate of RH 117,236 in or on the food commodities grain, cereal, forage, fodder, and straw, group 16 at 10.0 ppm; grass forage, fodder, and hay, group 17 at 10.0 ppm; herb and spice, group 19 at 10.0 ppm; nongrass animal feeds crop group 18 at 10.0 ppm; vegetable, bulb, group 3 at 0.2 ppm; vegetable, foliage of legume, group 7 at 10.0 ppm; vegetable, leaves of root and tuber, group 2 at 0.2 ppm; vegetable, legume, group 6 at 0.1 ppm; and vegetable, root and tuber, group 1 at 0.1 ppm. Those notices referenced summaries of the petitions prepared by Dow AgroSciences LLC and IR-4, the registrants, which are available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notices of filing. EPA's response to these comments is discussed in Unit IV.C. The time-limited tolerances will expire on September 30, 2010.

Based upon review of the data supporting the petition, EPA has modified the tolerance expression for the food commodities bean, dry, seed to 0.24 ppm (PP 6E7086); animal feeds, nongrass, group 18, forage to 50.0 ppm (PP 6F7135); animal feeds, nongrass, group 18, hay to 150.0 ppm (PP 6F7135); onions, green, subgroup 3-07B at 5.0 ppm (PP 7E7218); peanut, hay to 55 ppm (PP 6E7086); peanut oil to 0.04 ppm (PP 6E7086). The reason for these changes is explained in Unit IV.D. EPA is also deleting all the tolerances in § 180.544(b) for sorghum and soybean commodities that are no longer needed since they have expired. The deletions under § 180.544(b) are time-limited tolerances that were established under section 18 emergency exemptions that have since expired.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for tolerances for the petitioned-for tolerances for residues of methoxyfenozide on the food commodities named above. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

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.

The toxicology studies conducted with methoxyfenozide demonstrate that it has few or no biologically significant toxic effects at relatively low-dose levels and only mild or no toxic effects at relatively high-dose levels. In subchronic and chronic oral studies in rats, the most toxicologically significant effects were mild anemia and mild effects on the liver, thyroid gland, and adrenal gland. In subchronic and chronic oral studies in dogs, the predominant toxic effect was anemia, which was often accompanied by signs of a compensatory response. Methoxyfenozide is not acutely toxic, not a dermal sensitizer, not neurotoxic, carcinogenic or mutagenic and is not a developmental or reproductive toxicant. There was no evidence for increased susceptibility of rat or rabbit fetuses to *in utero* exposure or rat pups to post-natal exposure to methoxyfenozide. Minimal or no toxic effects were observed in studies in which methoxyfenozide was administered by the dermal or inhalation routes of exposure. Methoxyfenozide is classified as a ''not likely'' human carcinogen.

Specific information on the studies received and the nature of the adverse effects caused by methoxyfenozide 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*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2007–0495 in that docket.

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 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment can be found at *http://www.regulations.gov* in document ''Methoxyfenozide. Human Health Risk Assessment for Proposed Use on Sweet Potato, Blueberry, Dry Bean, Grass, Peanut, Green Onion, Avocado, Guava, Alfalfa and Clover. PC Code:121027, Petition No: 6E7086, 7E7218, and 6F7135. DP Num: 331948, 340540, and 371933'' at page 30 in docket ID number EPA–HQ–OPP–2007–0495.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to methoxyfenozide, EPA considered exposure under the petitioned-for tolerances as well as all existing methoxyfenozide tolerances in 40 CFR 180.544. EPA assessed dietary exposures from methoxyfenozide 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.

No such effects were identified in the toxicological studies for methoxyfenozide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

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 assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer*. Methoxyfenozide is not likely to be carcinogenic to humans; therefore, a cancer exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated*. Anticipated residues/PCT data were not needed to refine the risk assessment so they were not used.

2. *Dietary exposure from drinking water*. Methoxyfenozide is expected to be a ground water and surface water contaminant primarily due to its persistence in the environment.

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 methoxyfenozide for acute exposures are estimated to be 43 parts per billion (ppb) for surface water and 7.43 ppb for ground water. The EECs for chronic exposures are estimated to be 33.1 ppb for surface water and <7.43 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 43 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 33.1 ppb was used to access 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).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to methoxyfenozide and any other substances and methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that methoxyfenozide has a common

mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism 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 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 refered 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 UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is not a concern for prenatal and/or postnatal toxicity resulting from exposure to methoxyfenozide. The prenatal and postnatal toxicology database for methoxyfenozide includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There was no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in the developmental studies; similarly, there was no evidence of increased susceptibility of rat pups following prenatal/postnatal exposure in the 2–generation reproduction study.

3. *Conclusion*. The FQPA SF for the protection of infants and children be removed (i.e. reduced to 1x) for methoxyfenozide for the following reasons:

i. The toxicology database for methoxyfenozide is complete for assessment of potential hazard to infants and children.

ii. Based on weight-of-the-evidence considerations, EPA determined that a developmental neurotoxicity study in rats is not required to support the registration of methoxyfenozide.

iii. In developmental toxicity studies in rats and rabbits, no increased susceptibility in fetuses as compared to maternal animals was observed following *in utero* exposures.

iv. In a 2–generation reproduction study in rats, no increased susceptibility in pups as compared to adults was observed following *in utero* and postnatal exposures.

v. The exposure assessments will not underestimate the potential dietary (food and drinking water) or nondietary exposures for infants and children from the use of methoxyfenozide. The chronic dietary food exposure assessment utilizes tolerance level residues and assumes 100 PCT. Conservative ground water and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by methoxyfenozide.

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 log-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UTs is not exceeded.

1. *Acute risk*. No acute risk is expected from exposure to methoxyfenozide since no acute endpoints were identified for the general U.S. population (including infants and children) or the females 13-50 years old population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to methoxyfenozide from food and water will utilize 56% of the cPAD for the most highly exposed population group, children 1-2 years old. There are no residential uses for methoxyfenozide.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Methoxyfenozide is classified as a ''not likely'' human carcinogen and thus is not expected to pose a cancer risk to humans.

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 methoxyfenozide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high pressure liquid chromatography with mass spectrometry (HPLC/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex, Canadian or Mexican MRLs for methoxyfenozide, so there are no international harmonization issues associated with this action.

C. Response to Comments

Public comments were received from a citizen who objected to the proposed tolerances because ''methoxyfenozide harms fish and birds so that they die'' and also opposes ''any exemption or residue left on plants after use from this product.'' The comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from human or environmental exposure to methoxyfenozide. EPA has responded to similar comments on numerous previous occasions. (January 7, 2005, 70 FR 1349) (October 29, 2004, 69 FR 63083).

D. Explanation of Tolerance Revisions

The tolerances established here have been modified in some instances from the tolerances originally proposed in the notices of filing. These modifications have been based upon specific data, as described in unit IV.D. The data indicate that the requested tolerance on dry beans at 0.15 ppm is not appropriate

since the field trial data indicate that residues could be higher than the tolerance request. Therefore, a more appropriate tolerance is being established for the residues of methoxyfenozide on bean, dry at 0.24 ppm. The data for peanut hay are adequate. EPA's Review indicates that the requested tolerance of 60 ppm is not appropriate. Therefore, a more appropriate tolerance is being established for the residues of methoxyfenozide on peanut, hay at 55.0 ppm. The data for animal feed, nongrass, group 18, forage and hay are adequate. EPA's Review indicates that the requested tolerances are not appropriate. Residue field trial data from representative crops should be analyzed separately and the highest result used for tolerance setting purposes. This was not done. A more appropriate tolerance is being established for the residues of methoxyfenozide on animal feed, nongrass, group 18, forage at 50 ppm, and hay at 150 ppm. The only processed commodities of regulatory concern for this petition are peanut meal and oil. A study was conducted using a 3x exaggerated application rate to the peanut raw agricultural commodity and simulated commercial processing to produce the peanut processed commodities. Results of the study indicate that residues of methoxyfenozide are not expected to concentrate in peanut meal but do concentrate 3x in oil. The requested tolerance level for peanut oil is inadequate. Using the highest average field trial values from the submitted field trial data and the concentration factor for peanut oil, the tolerance level should be 0.04 ppm.

IR-4 petitioned for individual tolerances on green onion, fresh chive leaves, fresh Chinese chive leaves, elegans hosta, fritillaria leaves, kurrat, Lady's leek, leek, wild leek, Beltsville bunching onion, fresh onion, macrostem onion, tree onion tops, Welsh onion tops, and fresh shallot leaves at 5.0 ppm (PP 7E7128) as well as for a tolerance for bushberry subgroup 13B and individual tolerances on aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, honeysuckle, jostaberry, juneberry, lingonberry, native currant, salal, and sea buckthorn (PP 6E7086).

In the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised bulb vegetables group 3. Changes to crop group 3 (bulb vegetables) included adding new commodities, creating subgroups for bulb and green onions, and changing the name of one of the representative commodities from ''onion, dry bulb'' to ''onion, bulb.'' EPA also expanded and revised berries group 13. Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a bushberry subgroup 13-07B consisting of the commodities requested in PP 6E7086 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL–8126–1) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on onion, green, subgroup 3-07B and bushberry subgroup 13-07B.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because:

1. Although the subgroups are new the commodities in the new group were proposed as individual tolerances and the added commodities are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk; and

2. Methoxyfenozide exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action.

V. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on the food commodities acerola at 0.4 ppm; animal feeds, nongrass, group 18, forage at 50.0 ppm; animal feeds, nongrass, group 18, hay at 150.0 ppm; avocado at 0.6 ppm; bean, dry, seed at 0.24 ppm; bushberry subgroup 13-07B at 3.0 ppm; canistel at 0.6 ppm; feijoa at 0.4 ppm; grass, forage, fodder, and hay group 17, forage at 18.0 ppm; grass, forage, fodder, and hay, group 17, hay at 30.0 ppm; guava at 0.4 ppm; jaboticaba at 0.4 ppm; mango at 0.6 ppm; onions, green, subgroup 3-07B at 5.0 ppm; papaya at 0.6 ppm; passionfruit at 0.4 ppm; peanut at 0.02 ppm; peanut, hay at 55 ppm; peanut oil at 0.04 ppm; sapodilla at 0.6 ppm; sapote, black at 0.6 ppm; sapote, mamey at 0.6 ppm; star apple at 0.6 ppm; starfruit at 0.4 ppm; vegetable, tuberous and corm, except potato, sub group 1D at 0.02 ppm; wax jambu at 0.4 ppm.

Time-limited tolerances are established for the indirect or inadvertent residues for methoxyfenozide in or on vegetable, bulb, group 3 at 0.2 ppm; vegetable, leaves of root and tuber, group 2 at 0.2 ppm; and vegetable, root and tuber, group 1 at 0.1 ppm; and the combined residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its metabolites RH-117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid N-tert-butyl-N'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH-151,055 glucose conjugate of RH-117,236; 3,5-dimethyl benzoic acid N-tert-butyl-N-[3([beta]-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH-152,072 the malonylglycosyl conjugate of RH 117,236 in or on the food commodities animal feed, nongrass, group 18 at 10.0 ppm; grain, cereal, forage, fodder and straw, group 16 at 10.0 ppm; grass forage, fodder and hay, group 17 at 10.0 ppm; herb and spice, group 19 at 10.0 ppm; vegetable, foliage of legume, group 7 at 10.0 ppm; and vegetable, legume, group 6 at 0.10 ppm.

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: February 14, 2008.

Donald R. Stubbs,

Acting 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 180.544 is amended by:
■ i. Revising the entries ''canistel''; ''mango''; ''papaya''; ''sapodilla''; ''sapote, black''; ''sapote, mamey''; and ''star apple'' in paragraph (a)(1).
■ ii. Alphabetically adding commodities to the table in paragraph (a)(1).
■ iii. Removing the text from paragraph (b) and reserving the heading.
■ iv. Revising the tables in paragraphs (d)(1) and (d)(2) to read as follows:

§ 180.544 Methoxyfenozide; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Acerola	0.4
* * * * *	
Animal feed, nongrass, group 18, forage	50.0
Animal feed, nongrass, group 18, hay	150.0
* * * * *	
Avocado	0.6
Bean, dry, seed	0.24
* * * * *	
Bushberry subgroup 13-07B	3.0
Canistel	0.6
* * * * *	
Feijoa	0.4
* * * * *	
Grass, forage, fodder and hay, group 17, forage	18.0
Grass, forage, fodder and hay, group 17, hay	30.0
Guava	0.4
* * * * *	
Jaboticaba	0.4
* * * * *	
Mango	0.6
* * * * *	
Onion, green, subgroup 3-07B	5.0
Papaya	0.6
Passionfruit	0.4
* * * * *	
Peanut	0.02
Peanut, hay	55.0
Peanut, oil	0.04
* * * * *	
Sapodilla	0.6
Sapote, black	0.6
Sapote, mamey	0.6
* * * * *	
Star apple	0.6
Starfruit	0.4
* * * * *	
Vegetable, tuberous and corm, except potato, subgroup 1D	0.02
Wax jambu	0.4

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) * * *

(1) * * *

Commodity	Parts per million	Expiration/ revocation date
Vegetable, bulb, group 3-07	0.20	9/30/10
Vegetable, leaves of root and tuber, group 2	0.20	9/30/10
Vegetable, root and tuber, group 1	0.10	9/30/10

(2) * * *

Commodity	Parts per million	Expiration/ revocation date
Animal feed, non-grass, group 18	10.0	9/30/10
Grain, cereal, forage, fodder and straw, group 16	10.0	9/30/10
Grass, forage, fodder and hay, group 17	10.0	9/30/10
Herb and spice, group 19	10.0	9/30/10
Vegetable, foliage of legume, group 7	10.0	9/30/10
Vegetable, legume, group 6	0.10	9/30/10

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0308; FRL–8352–5]

Flumioxazin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of flumioxazin in or on alfalfa, forage; alfalfa, hay; asparagus; bean, dry seed; bushberry subgroup 13-07B; melon, subgroup 9A;