Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant negative economic impact on a substantial number of small entities.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 13175 requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

List of Subjects in 40 CFR Part 180

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

Dated: August 4, 2009.

G. Jeffrey Herndon,

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.

§180.910 [Amended]

■ 2. In the final rule published August 9, 2006 (71 FR 45415), and delayed on August 4, 2008 (73 FR 45312), the effective date is delayed from August 9, 2009, to October 9, 2009, for the following amendments to § 180.910: 2.m., n., and cc.

§180.930 [Amended]

■ 3. In the final rule published August 9, 2006 (71 FR 45415), and delayed on August 4, 2008 (73 FR 45312), the effective date is delayed from August 9, 2009, to October 9, 2009, for the following amendments to § 180.930: 4.t., u., and v.

[FR Doc. E9–19057 Filed 8–6–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0806; FRL–8427–7]

Avermectin B_1 and its delta-8,9-isomer; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of avermectin B_1 and its delta-8,9-isomer in or on stone fruit crop group 12, tree nut crop group 14, pistachio, tuberous and corm vegetable crop subgroup 01C, goat fat, hog fat, horse fat, sheep fat, cattle fat, and cattle meat byproducts. Existing tolerances for cattle, fat and cattle, meat byproducts are revised. Existing individual crop tolerances on almond, plum, potato, and walnut are deleted and replaced by the establishment of new crop group tolerances. Existing tolerances on almond, hulls and plum, prune, dried are retained. This regulation also makes a technical correction to correctly express the existing tolerances for mint (replace term ''mint'' with the more specific terms ''peppermint, tops'' and ''spearmint, tops''). Syngenta Crop Protection, Inc. and Y-TEX Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 7, 2009. Objections and requests for hearings must be received on or before October 6, 2009, 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–2008–0806. All documents in the docket are listed in the docket index available at *http://www.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: Thomas C. Harris, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308-9423; e-mail address: *harris.thomas@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 electronically available documents 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 e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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–2008–0806 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 October 6, 2009.

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–2008–0806, 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 Facility'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

As listed below, EPA published notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions in the **Federal Register** requesting that 40 CFR 180.449 be amended by establishing a tolerance for combined residues of the insecticide/miticide avermectin B_1 (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de (1-methylpropyl)-25-(1-methylethyl) avermectin A_1)), and its delta-8,9-isomer, as listed below. Avermectin B_1 is also referred to as abamectin. Each notice included a summary of the petition prepared by the registrant listed. There were no comments received in response to these notices of filing.

September 27, 2000, 65 FR 58080, FRL–6746–4, PP 0F6146. This petition was filed by Novartis Crop Protection, Inc. (now Syngenta Crop Protection, Inc.), P.O. Box 18300, Greensboro, NC 27419–8300 for tolerances of avermectin B_1 and its delta-8,9-isomer in or on grass forage at 0.001 ppm, grass hay at 0.001 ppm, stone fruit crop group 12 at 0.015 ppm, tree nut crop group 14 at 0.005 ppm, pistachio at 0.005 ppm, and the tuberous and corm vegetable crop subgroup 01C at 0.005 ppm. Tolerances for avocado and mint which were also requested in that notice were established earlier (see February 16, 2005, 70 FR 7876).

Based upon EPA review of the data supporting the petition, the petition was subsequently amended to request permanent tolerances for avermectin B_1 and its delta-8,9-isomer at the revised levels as follow: Stone fruit crop group 12 at 0.09 ppm, tree nut crop group 14 at 0.01 ppm, pistachios at 0.01 ppm, tuberous and corm vegetables crop subgroup 01C at 0.01 ppm, goat fat at 0.01 ppm, hog fat at 0.01 ppm, horse fat at 0.01 ppm, and sheep fat at 0.01 ppm. The tolerance requests for grass hay and grass forage were withdrawn pending development of further data on grass hay. Existing individual crop tolerances on almond, plum, potato, and walnut are deleted and replaced by the establishment of new crop group tolerances. Existing tolerances on almond, hulls and plum, prune, dried are retained. The proposed tolerance levels were raised based on EPA's analysis of the residue data, EPA's assessment of the limits of quantitation (LOQs) of the analytical methods, current livestock feed items (OPPTS Guideline 860.100, Table 1 Feedstuffs, June 2008), and/or to coordinate with Codex Maximum Residue Limits (MRLs) (see Unit IV.B.).

December 3, 2008, 73 FR 73648, FRL–8391–3, PP 8F7454. This petition was filed by Y-TEX Corporation, 1825 Big Horn Avenue, P.O. Box 1450, Cody, WY 82414, and proposes to amend the tolerances in 40 CFR 180.449 by increasing the tolerances of avermectin B_1 and its delta-8,9-isomer in or on cattle fat from 0.015 ppm to 0.03 ppm and cattle meat byproducts from 0.02 ppm to 0.06 ppm. These tolerances support use of avermectin in cattle ear tags.

This regulation also makes a technical amendment to correctly express the existing tolerances for mint which were established in the final rule published on February 16, 2005 (70 FR 7876) (FRL-7695-7). That rule listed the tolerance as ''mint'' at 0.010 ppm. The correct terminology is ''peppermint, tops'' at 0.010 ppm and ''spearmint, tops'' at 0.010 ppm.

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....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of avermectin B_1 and its delta-8,9-isomer on stone fruit crop group 12 at 0.09 ppm, tree nut crop group 14 at 0.01 ppm, pistachios at 0.01 ppm, tuberous and corm vegetables crop subgroup 01C at 0.01 ppm, goat fat at 0.01 ppm, hog fat at 0.01 ppm, horse fat at 0.01 ppm, sheep fat at 0.01 ppm, cattle fat at 0.03 ppm, and cattle meat byproducts at 0.06 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Avermection B_1 (also known as abamectin) has high to moderate acute toxicity by the oral route, high acute toxicity by the inhalation route, and low acute toxicity by the dermal route. It is slightly irritating to the skin, but is not an ocular irritant or a dermal sensitizer. In general, the results of available toxicity studies with single or repeated dosing indicate that the main target organ for avermection B_1 is the nervous system, and that decreased body weight is also one of the most frequent findings. There was no observed estrogen, androgen, or thyroid mediated toxicity. Neurotoxicity and developmental effects are detected in multiple studies and species of test animals. The dose/response curve is very steep in several studies, with severe effects (including death and morbid sacrifice) seen at dose levels as low as 0.4 milligrams/kilogram/day (mg/kg/day) and 0.1 mg/kg/day in rats and mice, respectively, following repeated exposures. Increased susceptibility (qualitative and/or quantitative) was seen in prenatal developmental toxicity studies in mice and rabbits, and an increase in quantitative and qualitative susceptibility was also seen in the rat reproductive toxicity studies. Review of acceptable oncogenicity and mutagenicity studies provide no indication that avermection B_1 is carcinogenic or mutagenic.

Specific information on the studies received and the nature of the adverse effects caused by avermectin B_1 and its delta-8,9-isomer 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 document the ''Abamectin, Revised Human Health Risk Assessment for Proposed Uses on Pasture and Rangeland Grass, Stone Fruit Crop Group 12, Tree Nut Crop Group 14, Pistachio, Tuberous and Corm Vegetables Subgroup 01C, and Request for Cattle Ear Tag Use,'' at page 18 in docket ID number EPA–HQ–OPP–2008–0806.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. 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 avermectin B_1 and its delta-8,9-isomer used for human risk assessment can be found at *http://www.regulations.gov* in the document ''Abamectin, Revised Human Health Risk Assessment for Proposed Uses on Pasture and Rangeland Grass, Stone Fruit Crop Group 12, Tree Nut Crop Group 14, Pistachio, Tuberous and Corm Vegetables Subgroup 01C, and Request for Cattle Ear Tag Use,'' at page 25 in docket ID number EPA–HQ–OPP–2008–0806.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to avermectin B_1 and its delta-8,9-isomer, EPA considered exposure under the petitioned-for tolerances as well as all existing avermectin B_1 and its delta-8,9-isomer tolerances in (40 CFR 180.449). EPA assessed dietary exposures from avermectin B_1 and its delta-8,9-isomer 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 United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used a probabilistic distribution of anticipated residues derived from field trial data for all commodities. Default processing factors and maximum surveyed percent crop treated (PCT) were used as available. See Unit C.1.iv. below for full listing of PCTs.

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

used point estimates of anticipated residues derived from field trial data for all commodities. Default processing factors and average surveyed percent crop treated (PCT) were used as available. Also, residues of avermectin B_1 and its delta-8,9-isomer in foods exposed in a food-handling establishment were assumed to be 0.0002 ppm which is one-half the Limit of Detection (LOD). See Unit C.1.iv. below for full listing of PCTs.

iii. *Cancer*. Based on the absence of a significant increase in tumor incidence in two rodent studies, EPA classified avermectin B_1 as ''not likely to be carcinogenic to humans'' and, thus, an exposure assessment for evaluating cancer risk is unnecessary.

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 require pursuant to FFDCA section 408(f)(1) 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 these tolerances.

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 the 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 as follows (average and maximum, respectively):

Commodity	Percent Crop Treated (PCT)	
	Average	Maximum
Almond	50	75
Apple	5	10
Avocado	40	60
Cantaloupe	15	30
Celery	40	65
Cottonseed oil	5	5
Cucumber	5	10
Grape	5	15
Grape, raisin	5	15
Grapefruit	60	80
Honeydew	15	30
Hop	85	100
Lemon	30	50
Lettuce	10	15
Orange	20	40
Pear	65	80
Pepper	25	100
Potato	1	2.5
Pumpkin	2.5	5
Spinach	20	45
Squash	5	10
Strawberry	35	45
Tangerine	40	45
Tomato	15	100
Walnut	5	20
Watermelon	5	10

EPA assumed 100 PCT (both average and maximum) for other crops not listed above, and for all livestock commodities. Maximum PCT was used for analysis of acute exposure while average PCT was used for analysis of chronic exposure.

In most cases, EPA uses available data from the U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is <1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. 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 reliable information on the regional consumption of food to which avermectin B_1 may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for avermectin B_1 and its major soil degradate (a mixture of an 8-alpha-hydroxy and a ring opened aldehyde derivative) in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of avermectin B_1 and its major soil degradate (a mixture of an 8-alpha-hydroxy and a ring opened aldehyde derivative). Further information regarding EPA 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) for surface water and Screening Concentration in

Ground Water (SCI-GROW) models for ground water, the estimated drinking water concentrations (EDWCs) of avermectin B_1 and its major soil degradate (a mixture of an 8-alpha-hydroxy and a ring opened aldehyde derivative) for acute exposures are estimated to be 0.464 parts per billion (ppb) for surface water and 0.00184 ppb for ground water; and for chronic exposures for non-cancer assessments are estimated to be 0.211 ppb for surface water and 0.00184 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 0.464 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.211 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).

Avermectin B_1 is currently registered for the following uses that could result in residential exposures: Residential lawn application for fire ant control, and residential indoor crack and crevice application for cockroaches and ants. EPA assessed residential exposure as follows. Exposure and risk estimates for homeowners applying crack and crevice baits were estimated using the Standard Operating Procedure (SOP) for Residential Exposure Assessments. The unit exposure from the wettable powder, open mixing and loading scenario listed in the SOP for Residential Exposure Assessments was used as a surrogate for estimating dermal and inhalation exposure for an activity that involves the use of a small syringe-type duster to make bait placements along the baseboards and into cracks and crevices. The method used for estimating residential applicator exposure is believed to produce a high-end estimate of 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.''

EPA has not found avermectin B_1 to share a common mechanism of toxicity with any other substances, and avermectin B_1 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that avermectin B_1 does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Increased susceptibility was seen in prenatal developmental toxicity studies in mice and rabbits following *in utero* exposure to avermectin B_1. There was also an increase in susceptibility in the rat reproductive toxicity study and the rat developmental neurotoxicity study.

3. *Conclusion*. EPA has retained an additional FQPA SF for chronic/long-term and short/intermediate-term assessments due to the steepness of the dose-response curve and severity of effects (death) at the LOAEL. For all risk assessments involving repeat exposures, the selected toxicity endpoint is based on the decrease in pup body weight seen in the developmental neurotoxicity study and three reproduction studies in the rat. Although the study identified a NOAEL for the effects observed in the pups, the data clearly indicate that the decrease in pup body weight seen at 0.2 mg/kg/day rapidly progresses to death at the next higher tested dose level (0.4 mg/kg/day) in both reproduction and developmental neurotoxicity studies. The combined data from several reproduction toxicity and developmental neurotoxicity studies have documented a very narrow dose range from NOAEL (0.12 mg/kg/day) to adverse effect (0.2 mg/kg/day) to severe adverse effect (0.4 mg/kg/day). Dose spacing is commonly greater than the 2x between NOAEL and LOAEL here, and the 3x difference between the NOAEL and the dose that induced mortality in the pups in the developmental neurotoxicity study provides little margin of safety for such a severe effect.

Nonetheless, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the 10X FQPA safety (SF) were reduced to 3X for chronic/long term and short/intermediate-term assessments and reduced to 1X for acute assessments. This conclusion is based on the following findings:

i. Retaining an additional 3x FQPA safety factor effectively provides a 10x margin between the dose which causes death (0.4 mg/kg/day) and the NOAEL adjusted by the additional safety factor (0.12 mg/kg/day/3x = 0.04 mg/kg/day). A dose spacing of 10x between a NOAEL and LOAEL is as broad, if not broader, than the dose spacing generally used in animal testing and thus removes the residual concern with the steepness of the dose response curve and the severe effects seen here.

ii. This adjusted point of departure (0.04 mg/kg/day) would also address the concerns for the increased susceptibility seen at higher doses in the two-generation reproduction study in rats (LOAEL = 0.4 mg/kg/day), prenatal developmental study in CD-1 mice (LOAEL = 0.75 mg/kg/day), the prenatal developmental toxicity study in rabbits (LOAEL = 2 mg/kg/day), and the one-generation reproduction study (LOAEL = 0.2 mg/kg/day).

iii. The toxicity database for avermectin B_1 is complete, except for immunotoxicity studies. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. To address the issue of an immunotoxicity data gap and the associated database uncertainty factor, the Agency examined the entire database of avermectin B_1 and determined that an additional uncertainty factor is not needed to account for potential immunotoxicity. Avermectin B_1 has not been found to induce effects associated with immunotoxicity and avermectin B_1 does not belong to a class of chemicals that would be expected to be immunotoxic. Therefore, based on the above considerations, EPA does not believe that conducting a special Harmonized Guideline series 870.7800 immunotoxicity study will result in a NOAEL less than the NOAELs of 0.5 and 0.12 mg/kg/day already set for avermectin B_1 acute and repeated

exposures, respectively. An additional uncertainty factor (UF_{DB}) for database uncertainties associated with immunotoxicity does not need to be applied at this time.

iv. With respect to acute dietary exposure, the endpoint selected for risk assessment is based on mydriasis observed in dogs. The additional 3x factor applied to chronic and other exposure scenarios is not applicable to acute exposure because steepness of the dose and severity of effects were not seen in the studies where mydriasis occurred. In addition, reduced body weight is not considered a single dose effect and would not be appropriate as a toxicity endpoint for acute exposure scenarios.

v. There are no residual concerns with respect to the exposure databases. The chronic and acute dietary food exposure assessment utilizes reliable data on anticipated residues and percent crop treated as well as default processing factors. The dietary drinking water assessment utilized modeling results which included conservative assumptions for the parent and all degradates of concern. Conservative assumptions were used in the water models. Therefore, the water exposure assessment will not underestimate the potential risks for infants and children. Likewise, the use of maximum application rates and central-to-high end inputs results in calculated residential exposures that should not underestimate the risks to infants and children from these requested uses.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure from dietary (food and water) consumption. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to avermectin B_1 and its delta-8,9-isomer will occupy 27% 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 chronic exposure to avermectin B_1 and its delta-8,9-isomer from food and water will utilize 47% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of avermectin B_1 and its delta-8,9-isomer is not expected.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). High-end estimates of residential exposure were used, while average values were used for food and drinking water exposure. Avermectin B_1 is currently registered for uses that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to avermectin B_1 and its delta-8,9-isomer. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 500 for children 1 to 2 years old, the population group receiving the greatest exposure.

4. *Aggregate cancer risk for U.S. population*. Based on the absence of a significant increase in tumor incidence in two rodent studies, EPA classified avermectin B_1 as ''not likely to be carcinogenic to humans'' and it is, therefore, not expected to pose a cancer risk.

5. *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 avermectin B_1 and its delta-8,9-isomer residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods for avermectin B_1 in plant and livestock commodities are available in PAM II. The methods have been validated for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). These methods determine residues in plant and livestock commodities at limits of quantitation of 0.02 ppm for meat and meat byproducts and ≤0.01 ppm for other plant/livestock commodities. The limits of detection of the methods for plant and livestock commodities is 0.001 ppm for each analyte, equivalent to 0.002 ppm for two analyte peaks (i.e., avermectin B_{1a} and its delta-8,9-isomer in one peak and avermectin B_{1b} and its delta-8,9-isomer in the other peak).

The plant methods used for data collection adequately measure the residues of concern. The methods have been validated at 0.001, 0.002, or 0.005 ppm (depending on the commodity and the method) for each of two analyte peaks (avermectin B_{1a} and its delta-8,9-isomer in one peak and avermectin B_{1b} and its delta-8,9-isomer in the other peak), which means that the LOQs of the data collection methods would be 0.002, 0.004 or 0.01 ppm.

The 1990 Pestrak database indicates that avermectin B_1 and its metabolites are not recovered or not likely to be recovered by FDA multiresidue methods. Therefore, the multiresidue methods can not be used to determine residues for dietary exposure assessment and can not be used as the primary enforcement method.

B. International Residue Limits

The Codex tolerance expressions for plants are consistent with the U.S. tolerance expression.

C. Response to Comments

No comments were received to the Notices of Filing.

D. Revisions to Petitioned-For Tolerances

The correct commodity definitions are obtained from the ''Food and Feed Commodity Vocabulary'', which can be found at *http://www.epa.gov/pesticides/foodfeed*. Some proposed tolerance levels were raised based on EPA's analysis of the residue data, EPA's assessment of the limits of quantitation of the analytical methods, current livestock feed items (OPPTS Guideline 860.100, Table 1 Feedstuffs, June 2008), and/or to coordinate with Codex Maximum Residue Limits (MRLs).

V. Conclusion

Therefore, tolerances are established for combined residues of avermectin B_1 (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de (1-

methylpropyl)-25-(1-methylethyl) avermectin A_1)), and its delta-8,9-isomer in/on cattle, fat at 0.03 ppm; cattle, meat byproducts at 0.06 ppm; fruit, stone, group 12 at 0.09 ppm; goat, fat at 0.01 ppm; hog, fat at 0.01 ppm; horse, fat at 0.01 ppm; nut, tree, group 14 at 0.01 ppm; pistachio at 0.01 ppm; sheep, fat at 0.01 ppm; and vegetable, tuberous and corm subgroup 01C at 0.01 ppm.

Existing tolerances for cattle, fat and cattle, meat byproducts are revised. Existing individual crop tolerances on almond, plum, potato, and walnut are deleted and replaced by the establishment of new crop group tolerances. Existing tolerances on almond, hulls and plum, prune, dried are retained. The expression for existing mint tolerances is corrected by deleting the term mint and replacing with peppermint, tops at 0.010 ppm and spearmint, tops at 0.010 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule is not subject to Executive Order 13211, entitled *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 9, 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).

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: July 28, 2009.

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. In § 180.449, the table to paragraph (a) is amended by revising the entries for cattle, fat and cattle, meat byproducts; by removing the entries for almond, plum, mint, potato and walnut; and by adding alphabetically, the remaining entries in the table to read as follows:

180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cattle, fat	0.03
Cattle, meat byproducts	0.06
* * * * *	
Fruit, stone, group 12	0.09
Goat, fat	0.01
* * * * *	
Hog, fat	0.01
* * * * *	
Horse, fat	0.01
* * * * *	
Nut, tree, group 14	0.01
* * * * *	
Peppermint, tops	0.010
Pistachio	0.01
* * * * *	
Sheep, fat	0.01
* * * * *	
Spearmint, tops	0.010
Vegetable, tuberous and corm, subgroup 01C	0.01

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 63

[WC Docket No. 04–36; FCC 09–40]

IP-Enabled Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Commission's rules so that providers of interconnected Voice over Internet Protocol (VoIP) service will be required to comply with the same discontinuance rules as domestic non-dominant telecommunications carriers. These rules protect consumers of interconnected VoIP service from the abrupt discontinuance, reduction or impairment of their service by requiring