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.

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 7, 2005.

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 § 180.950, the table in paragraph (e) is amended by adding alphabetically the following entry to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical Name	CAS No.
* * *	* *
Syrups, hydrolyzed starch, hydrogenated	CAS Reg. No. 68425–17–2
* * *	* *

[FR Doc. 05–2981 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0400; FRL–7695–7]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the 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, in or on avocado at 0.020 ppm; food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts) at 0.01 ppm; herbs, subgroup 19A (except chives) at 0.030 ppm; meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm; mint at 0.010 ppm; plum at 0.010 ppm; plum, prune, dried at 0.025 ppm; vegetable, fruiting, group 8 at 0.020 ppm; and vegetable, leafy, except Brassica, group 4 at 0.10 ppm. These tolerances were requested under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) in petitions filed by Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.), Interregional Research Project Number 4, and Whitmire Micro-Gen Research Laboratories, Inc.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0400. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Thomas C. Harris, Registration Division (7505C), 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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two 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/*.

II. Background and Statutory Findings

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. Note: 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 substantive comments received in response to these notices of filing.

- April 7, 2000, 65 FR 18328, FRL–6499–4, PP 9F5047: This petition was filed by Novartis Crop Protection, Inc. (now Syngenta Crop Protection, Inc.), P.O. Box 18300, Greensboro, NC 27419–8300 for tolerances in or on vegetable, leafy, except Brassica, group 4 at 0.10 ppm; vegetable, fruiting, group 8 at 0.02 ppm (subsequently revised to 0.020 ppm); and plum at 0.01 ppm (subsequently revised to 0.010 ppm). The petition was also subsequently revised to add a tolerance for plum, prune, dried at 0.025 ppm.
- 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 in or on avocado at 0.02 ppm (subsequently revised to 0.020 ppm) and mint tops at 0.01 ppm (subsequently revised to simply mint at 0.010 ppm). Requests for tolerances for additional crops submitted in that petition will be decided at a later date.
- July 28, 2004, 69 FR 45039, FRL–7366–3, PP 2H5642: This petition was filed by Whitmire Micro-Gen Research Laboratories, Inc., 3568 Tree Court Industrial Blvd, St. Louis, MO 63122 for tolerances in or on food products in food handling establishments at 0.001 ppm (subsequently revised to 0.01 ppm). In addition, the petition was subsequently revised to request tolerances for meat and meat byproducts for goat, hog, horse, poultry, and sheep at 0.02 ppm.
- July 28, 2004, 69 FR 45039, FRL–7366–3, PP 3E6557: This petition was filed by Interregional Research Project Number 4, 681 U.S. Hwy 1 South, North Brunswick, NJ 08902–3390 for tolerances in or on herb crop subgroup 19A (except chives) at 0.03 ppm (subsequently revised to 0.030 ppm).

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 the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

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 a tolerance for the 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 or on avocado at 0.020 ppm; food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts) at 0.01 ppm; herbs, subgroup 19A (except chives) at 0.030 ppm; meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm; mint at 0.010 ppm; plum at 0.010 ppm; plum, prune, dried at 0.025 ppm; vegetable, fruiting, group 8 at 0.020 ppm; and vegetable, leafy, except Brassica, group 4 at 0.10 ppm. 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 nature of the toxic effects caused by avermectin B_1 and its delta-8,9-isomer are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	Subchronic feeding study - rats	NOAEL > 0.40 mg/kg/day LOAEL = not established

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3150	Subchronic toxicity - dogs	NOAEL = 0.25 mg/kg/day LOAEL = 0.50 mg/kg/day based on body tremors, one death, liver pathology, decreased body weight
870.3200	21/28–Day dermal toxicity	Study not available
870.3700	Prenatal developmental in rodents - rats	Maternal NOAEL > 1.6 mg/kg/day Maternal LOAEL = not established Developmental NOAEL > 1.6 mg/lg/day Developmental LOAEL = not established
870.3700	Prenatal developmental in rodents - CD-1 mouse	Maternal NOAEL = 1.5 mg/kg/day Maternal LOAEL = 3.0 mg/kg/day based on hind limb splay Developmental NOAEL < 0.75 mg/kg/day Developmental LOAEL = 0.75 mg/kg/day based on cleft palate and hindlimb extension
870.3700	Prenatal developmental in nonrodents - rabbits	Maternal NOAEL = 1.0 mg/kg/day Maternal LOAEL = 2.0 mg/kg/day based on decreased body weight, food consumption and water consumption Developmental NOAEL = 1.0 mg/kg/day Developmental LOAEL = 2.0 mg/kg/day based on cleft palate, clubbed foot, delayed ossification of sternebrae, metacarpals, phalanges
870.3800	2–Generation reproduction and fertility effects - rat	Parental/Systemic NOAEL = 0.40 mg/kg/day LOAEL =not established Reproductive NOAEL = 0.40 mg/kg/day LOAEL = not established Offspring NOAEL = 0.12 mg/kg/day LOAEL = 0.40 mg/kg/day based on increased retinal folds, increased dead pups at birth, decreased viability and lactation indices, decreased pup body weight
870.3800	1–Generation reproduction and fertility effects - rat	Parental/Systemic NOAEL = 1.0 mg/kg/day. LOAEL = 1.5/2.0 based on whole body tremors, ataxia, ptyalis, ocular/nasal discharges and mortality Reproductive NOAEL = 3.0 mg/kg/day Offspring NOAEL < 0.5 mg/kg/day LOAEL = 0.5 mg/kg/day based on decreased pup survival and body weight between days 1–21 and delay in opening of eyes
870.3800	1–Generation reproduction and fertility effects - rat	Parental/Systemic NOAEL = 0.4 mg/kg/day LOAEL = not established Reproductive NOAEL = 0.4 mg/kg/day Offspring NOAEL =0.1 mg/kg/day LOAEL = 0.2 mg/kg/day based on reduced pup weight, spastic movements, delayed incisor eruption
870.3800	1–Generation reproduction and fertility effects - rat	Parental/Systemic NOAEL = 0.4 mg/kg/day LOAEL = not established Reproductive NOAEL = 0.4 mg/kg/day Offspring NOAEL = 0.4 mg/kg/day LOAEL = not established
870.4100	Chronic toxicity - dogs	NOAEL = 0.25 mg/kg/day LOAEL = 0.5 mg/kg/day based on mydriasis, death at 1.0 mg/kg/day
870.4300	Combined chronic toxicity/carcinogenicity - rats	NOAEL = 1.5 mg/kg/day LOAEL = 2.0 mg/kg/day based on tremors No evidence of carcinogenicity
870.4300	Combined chronic toxicity/carcinogenicity - mice	NOAEL = 4.0 mg/kg/day LOAEL = 8.0 mg/kg/day based on increased mortality in males, tremors, body weight decreases in females, dermatitis in males, extramedullary hematopoiesis in spleen of males No evidence of carcinogenicity
870.5100	Gene mutation Ames/*Salmonella E. coli*/mammalian gene mutation assay	Negative both with and without S-9

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5100	Gene mutation Ames/*Salmonella E. coli*/mammalian gene mutation assay	Negative both with and without S-9 up to 3,000 μg/plate
870.5100	Gene mutation Ames/*Salmonella E. coli*/mammalian gene mutation assay	Negative both with and without S-9
870.5300	Gene mutation CHO/HGPRTforward mutation assay	Negative
870.5300	Gene mutation Mammalian cells in culture in V79 cells	Not mutagenic for V79 cells in absence of S-9, but in the presence of S-9 appeared to have a mutagenic potential, provided the test cells had an appropriate level of sensitivity
870.5395	Cytogenetics *in vivo* micronucleus assay - male mice	No chromosomal aberrations in male mice, but females not tested
870.5550	Other effects	Single strand DNA breaks at 0.3 and 0.6 mM in rat hepatocytes *in vitro*, but negative when hepatocytes from rat at LD_{50} dose level was used
non-guideline	Metabolism	69–82% of label is excreted in feces by day 7; $T_{\frac{1}{2}}$ =1.2 days. The reliability of these data is questionable
non-guideline	Metabolism	Avermectin B_{1a} did not bioaccumulate in rat tissues. Half-life slightly longer in females than in males for several tissues
non-guideline	Metabolism	The metabolism of avermectin B_1 in rats results in the formation of 24-OH-Me-B_{1a} and accounts for most of the radiolabeled residues. Avermectin B_{1a} does not bioaccumulate
870.7600	Dermal penetration	Dermal penetration is 1%

Additional data, from studies conducted in CF-1 mice, are also available and were included in a developmental toxicity review conducted by the Agency. However, additional data were submitted by the registrant documenting that the extreme sensitivity of CF-1 mice to abamectin, resulting in developmental toxicity, was due to a genetic lack of p-glycoprotein (a genetic finding specific to the CF-1 mouse strain). EPA has concluded that the CF-1 mouse data are inappropriate for use in risk assessment for abamectin.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the '' default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the Level of Concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to

describe the risk as one in one hundred thousand (1 x 10^5), one in a million (1 x 10^6), or one in ten million (1 x 10^7). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for avermectin B_1 and its delta-8,9-isomer used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AVERMECTIN B_1 AND ITS DELTA-8,9-ISOMER FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population, including infants and children and females 13–50)	NOAEL = 0.25 mg/kg/day UF = 1,000[1] Acute RfD = 0.00025 mg/kg/day	Special FQPA SF= 1 aPAD = acute RfD ÷ FQPA SF= 0.00025 mg/kg/day	1–Year Oral Study in the Dog LOAEL = 0.50 mg/kg/day based on mydriasis seen at week 1 of dosing.
Chronic dietary(all populations)	NOAEL = 0.12 mg/kg/day UF = 1,000[1] Chronic RfD = 0.00012 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF= 0.00012 mg/kg/day	2–Generation reproduction in the rat LOAEL = 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings
Short-term and intermediate-term incidental oral (1 day–6 months)	NOAEL = 0.12 mg/kg/day	Residential LOC for MOE = 1,000[1] Occupational = NA	2–Generation reproduction in the rat LOAEL = 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings
Dermal (all durations)	Oral study NOAEL = 0.12 mg/kg/day (dermal absorption rate = 1%)	Residential LOC for MOE = 1,000[1] Occupational LOC for MOE = 100	2–Generation reproduction in the rat LOAEL = 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings
Inhalation (all durations)	Oral study NOAEL = 0.12 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000[1] Occupational LOC for MOE = 100	2–Generation reproduction in the rat LOAEL = 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings
Cancer (oral, dermal, inhalation)	EPA classified Avermectin B_1 as ''not likely to be carcinogenic to humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

NA = Not Applicable

[1]Includes a 10X FQPA Safety Factor to account for the lack of a DNT study, the steepness of the dose/response curve in several studies, and the severity of effects (death, neurotoxicity, and developmental toxicity) seen at the LOAELs.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.449) for the combined residues of avermectin B_1 and its delta-8,9-isomer, in or on a variety of raw agricultural commodities. Permanent tolerances were previously established for almond; almond, hulls; apple; apple, wet pomace; cattle, fat; cattle, meat byproducts; cattle, meat; celeriac, roots; celeriac, tops; celery; citrus, dried pulp; citrus, oil; citrus; cotton gin byproducts; cotton seed; cucurbits; grape; hop, dried cone; lettuce, head; milk; pear; pepper; potato; strawberry; tomato; walnut. Temporary tolerances were established for avocado, basil, spinach. Risk assessments were conducted by EPA to assess dietary exposures from avermectin B_1 and its delta-8,9-isomer in food as follows:

i. *Acute exposure.* Acute dietary 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 conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model (DEEM™) software with the Food Commodity Intake Database (FCID) and the Lifeline™ model version 2.0), which incorporate food consumption data as reported by respondents in the U.S. Department of Agricultural (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. Percent crop treated and anticipated residues were used.

A highly refined Tier 3 acute dietary exposure assessment was conducted for the general U.S. population and various population subgroups. This was a probabilistic assessment using anticipated residues from the current and previously submitted field trial and market basket data, USDA Pesticide Data Program (PDP) monitoring data, percent crop treated (%CT) estimates for most of the commodities, and default DEEM™ version 7.76 processing factors when monitoring data were not available.

The acute dietary exposure estimates are below EPA's level of concern

(<100% aPAD) at the 99.9th exposure percentile for the general U.S. population (35% aPAD using Lifeline™ and 34% aPAD using DEEM™ software with the FCID and all other population subgroups. The most highly exposed population subgroup is children 1– 2 years old, at 64% aPAD using Lifeline™ and 65% aPAD using DEEM™/FCID. The acute assessment was highly refined; however, inclusion of additional %CT data and modified concentration/processing factors could aid in further refining the acute dietary assessment.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM™/FCID and the Lifeline™ model version 2.0, which incorporate food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. Percent crop treated and anticipated residues were used.

A Tier 2 chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The assumptions of the assessment were anticipated residue estimates, %CT estimates for most of the commodities, and default DEEM™ (version 7.76) processing factors when necessary.

The chronic dietary exposure estimates are below EPA's level of concern (<100% cPAD) for the general U.S. population (4% of the cPAD using both models) and all population subgroups. The most highly exposed population subgroup is children 1–2 years old, at 13% cPAD using Lifeline™ and 14 %cPAD using DEEM™/FCID. The chronic assessment was somewhat refined; inclusion of additional anticipated residues, more %CT information, and modified concentration/processing factors would further refine the chronic dietary assessment.

iii. *Cancer.* A cancer aggregate exposure assessment was not performed because avermectin B_1 is classified as ''not likely to be carcinogenic to humans.''

iv. *Anticipated residue and percent crop treated (PCT) information.* The Agency used the anticipated residues from field trial data, market basket data, PDP monitoring data, and percent crop treated data to conduct a dietary exposure analysis.

Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency believes that the three conditions have been met. With respect to condition 1, EPA finds that the PCT information is reliable and has a valid basis. The Agency has utilized statistical data from a number of public and proprietary sources including USDA/National Agricultural Statistics Service, Doane, Maritz, Kline, and National Center for Food and Agricultural Policy. The following PCT information was used in this analysis: Almonds 21%; apples 9%; avocado 20%; basil 100%; casabas 1%; celeriac 100%; celery 51%; citrus (except orange) 49%; cotton 3%; cress (garden, upland) 1%; eggplant 6%; endive 9%; grape 6%; hops 82%; lettuce 17%; melons (except casabas) 7%; mint 100%; orange 26%; pear 62%; peppers 8%; plum 1%; potato 1%; squash and cucumber 1%; spinach 9%; strawberry 44%; tomato 6%; walnut 2%.

With respect to conditions 2 and 3, the regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing avermectin B_1 and its delta-8,9-isomer in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative) in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative).

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration In Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a

screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water, to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to avermectin B_1 and its degradates they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM and EXAMS models/index reservoir scenario and SCI-GROW models, the EECs of avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative) for acute exposures are estimated to be 0.34 parts per billion (ppb) for surface water and 0.0017 ppb for ground water. The EECs for chronic exposures are estimated to be 0.14 ppb for surface water and 0.0017 ppb for ground 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 use on the following residential non-dietary sites: Residential lawn application for fire ant control and residential indoor crack and crevice application for cockroaches and ants. Because the FQPA requires consideration of aggregate exposure to all likely non-occupational uses, this assessment includes contact with Avermectin B_1 from residential crack and crevice and lawn treatments as the most common and worst-case contributors to such exposures. The MOEs for applicable residential scenarios were calculated using limited exposure monitoring data and the Standard Operating Procedures for Residential Exposure Assessments (Draft, December 18, 1997), along with interim changes presented in Science Advisory Council for Exposure SOP No.11 (February 22, 2001). For the indoor crack and crevice treatment, measured airborne and surface residue data were available to perform an assessment of postapplication inhalation, dermal and incidental oral risks. Combined residential exposures/risks were estimated for adults and for children.

Children's exposure from incidental ingestion of granules on treated lawns was compared to the acute dietary NOAEL of 0.25 mg/kg/day. The exposure/risk from this latter scenario was not combined with other scenarios, nor was it included in the aggregate assessment, because it is considered to be a one-time, episodic event, rather than occurring for several days (or several months).

The MOEs for all residential scenarios are greater than the LOC of 1,000, and therefore, are not of concern.

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 avermectin B_1 and 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 not assumed that avermectin B_1 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 concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

For avermectin B_1 EPA retained the default 10X factor based on the following combination of factors:

- There is residual uncertainty due to a data gap for a developmental neurotoxicity study (DNT), as well as data gaps for acute and subchronic neurotoxicity studies. These studies are required because avermectin B_1 has been shown to be neurotoxic, with multiple neurotoxic clinical signs (including head and body tremors and limb splay) seen in multiple studies with multiple species.
- For several species, the dose-response curve appears to be steep.
- Severe effects were seen at the LOAELs in several studies (death, neurotoxicity, and developmental toxicity).

Although increased susceptibility of the young was observed in several studies, the degree of concern with that susceptibility was judged to be low. Increased susceptibility (qualitative and/or quantitative) was seen in prenatal developmental toxicity studies in CD-1 mice and rabbits following in utero exposure to avermectin B_1. There was also an increase in quantitative and qualitative susceptibility in the rat reproductive toxicity study. The concern for susceptibility seen in the developmental study with rabbits and in the reproductive toxicity study in the rat is low because the lowest NOAEL obtained (0.12 mg/kg/day) was used as the basis for the chronic RfD and other non-dietary risk assessment scenarios, which is protective of all of the developmental/offspring effects seen in those studies. Similarly, the concern for susceptibility seen at the LOAEL in the CD-1 mouse developmental toxicity study is low, since the NOAEL in the rat reproductive toxicity study is lower than the dose at which effects were seen in the CD-1 mouse.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency

calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to avermectin B_1 and its delta-8,9-isomer will occupy 35% of the aPAD for the U.S. population, 32% of the aPAD for females 13 years and older, 62% of the aPAD for all infants (< 1 year old), and 65% of the aPAD for children (1–2 years old). In addition, there is potential for acute dietary exposure to avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative) in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 4 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AVERMECTIN B_1 AND ITS DEGRADATES

Population Subgroup	aPAD (mg/kg)	% aPAD/(Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.00025	35	0.34	0.0017	5.7
All infants (<1 year old)	0.00025	62	0.34	0.0017	0.94
Children (1–2 years old)	0.00025	65	0.34	0.0017	0.88
Children (3–5 years old)	0.00025	62	0.34	0.0017	0.94
Children (6–12 years old)	0.00025	36	0.34	0.0017	1.6
Youth (13–19 years old)	0.00025	29	0.34	0.0017	5.3
Females (13–49 years old)	0.00025	32	0.34	0.0017	5.1
Adults (20–49 years old)	0.00025	27	0.34	0.0017	6.3

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to avermectin B_1 and its delta-8,9-isomer from food will utilize 4.3% of the cPAD for the U.S. population, 5.8% of the cPAD for all infants (< 1 year old), and 14% of the cPAD for children (1 –2 years old). Based upon the use pattern, chronic residential exposure to residues of avermectin B_1 and its delta-8,9-isomer is not expected. In addition, there is potential for chronic dietary exposure to avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative) in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FORCHRONIC (NON-CANCER) EXPOSURE TO AVERMECTIN B_1 AND ITS DEGRADATES

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.00012	4.3	0.14	0.0017	4.0
All infants (<1 year old)	0.00012	5.8	0.14	0.0017	1.1
Children (1–2 years old)	0.00012	14	0.14	0.0017	1.0

TABLE 4.—AGGREGATE RISK ASSESSMENT FORCHRONIC (NON-CANCER) EXPOSURE TO AVERMECTIN B_1 AND ITS DEGRADATES—Continued

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children (3–5 years old)	0.00012	11	0.14	0.0017	1.1
Children (6–12 years old)	0.00012	6.7	0.14	0.0017	1.4
Youth (13–19 years old)	0.00012	4.2	0.14	0.0017	3.5
Females (13–49 years old)	0.00012	4.1	0.14	0.0017	3.5
Adults (20–49 years old)	0.00012	3.7	0.14	0.0017	4.0

3. *Short-term Intermediate- term risk.* Short-term/intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Avermectin B_1 is currently registered for use that could result in short-term/intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term/intermediate-term exposures for avermectin B_1.

Using the exposure assumptions described in this unit for short-term/intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 4,000 for adults and 2,600 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term/intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of avermectin B_1 and its major soil degradates (a mixture of an 8-α-hydroxy and a ring opened aldehyde derivative) in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term/intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM/INTERMEDIATE-TERM EXPOSURE TO AVERMECTIN B_1 AND ITS DEGRADATES

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term/Intermediate-Term DWLOC (ppb)
Adults	4,000	1,000	0.14	0.0017	3.0
Children (1–2 years old)	2,600	1,000	0.14	0.0017	0.56

5. *Aggregate cancer risk for U.S.* population. A cancer aggregate risk assessment was not performed because avermectin B_1 is classified as ''not likely to be carcinogenic 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, and to infants and children from aggregate exposure to residues of avermectin B_1 and its degradates.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Residue analytical method.* Analytical methodologies for enforcement of residues from the use of Avermectin B_1 are available in PAM II for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). These methods are adequate for enforcement of the proposed tolerances.

2. *Multiresidue methods testing.* The 1990 Pestrak data base indicates that Avermectin B_1 and its delta 8,9-isomer are not recovered or not likely to be recovered by Food and Drug Administration multiresidue methods.

B. International Residue Limits

Codex has recommended several Maximum Residue Levels (MRLs) for plant and cattle commodities (Pesticide Residues in Food-1997, Part 1). The Codex residue definition (step 8/CXL) is ''sum of avermectin B_{1a}, avermectin B_{1b}, 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} for plants, and the sum of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} for cattle commodities. The Codex limits of determination (equivalent to EPA's limits of quantitation, (LOQ's)) for plant and livestock commodities are ≤0.01 ppm. (For plants, the LOQ ranges from 0.002 to 0.005 ppm for each of two peaks, one peak representing avermectin B_{1a} and its 8,9-Z-isomer and the other peak representing avermectin B_{1b} and its 8,9-Z-isomer. For cattle meat, the Codex LOQ is 0.01 ppm.) The tolerance expression in Canada for plants is ''avermectin B_{1a}, avermectin B_{1b}, and the 8,9-Z-isomers.'' The tolerance expression in Mexico for plants is avermectina. The Codex and the USA residue definitions are the same for plants. The Codex definition does not include avermectin B_{1b} and 8,9-Z-avermectin B_{1b} for livestock commodities whereas the U.S. does include avermectin B_{1b} and 8,9-Z-avermectin B_{1b} in livestock commodities.

C. Conditions

The following data are required. The product registrations for the above new uses will be conditional and may be

rescinded if this information is not provided.

1. Storage stability data to support the storage interval of prunes and to provide the storage information for prunes. The tolerance is conservatively established using the maximum theoretical concentration factor of 3.5x for plum, prunes, dried. This value will be reevaluated once the required information is supplied.

2. A summary of the procedures for the processing of mint to mint oil.

3. A developmental neurotoxicity study in the rat.

4. Acute and subchronic neurotoxicity studies in the rat.

5. A 28–day inhalation study (following the 90–day inhalation toxicity study protocol). Thorough histopathological evaluation is recommended to assess potential pulmonary toxicity resulting from long-term or repeated exposure.

V. Conclusion

The following current temporary tolerances due to expire on December 31, 2006 are hereby deleted: Avocado at 0.02 ppm, basil at 0.05 ppm, and spinach at 0.05. The following permanent tolerances are also deleted: Celery at 0.05 ppm, head lettuce at 0.05 ppm, pepper at 0.02 ppm, and tomato at 0.01 ppm. In their place, new tolerances without a time limitation are established for the 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, in or on avocado at 0.020 ppm; food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts) at 0.01 ppm; herbs, subgroup 19A (except chives) at 0.030 ppm; meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm; mint at 0.010 ppm; plum at 0.010 ppm; plum, prune, dried at 0.025 ppm; vegetable, fruiting, group 8 at 0.020 ppm; and vegetable, leafy, except Brassica, group 4 at 0.10 ppm.

VI. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0400 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 April 18, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0400, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. 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 final 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 6, 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.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 7, 2005.

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 180.449 is amended as follows.

■ i. By alphabetically adding the following commodities to the table in paragraph (a) to read as follows

■ ii. By removing the entries for the commodities ''Celery''; ''Lettuce, head''; ''Pepper''; and ''Tomato''; in the table in paragraph (a).

■ iii. The text of paragraph (b) is removed and reserved.

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

(a) * * *

Commodity	Parts per million
* * * * *	
Avocado	0.020
* * * * *	
Food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts)	0.01
Goat, meat	0.02
Goat, meat byproducts	0.02
* * * * *	
Herbs, crop subgroup 19A (except chives)	0.030
Hog, meat	0.02
Hog, meat byproducts	0.02
* * * * *	
Horse, meat	0.02
Horse, meat byproducts	0.02
* * * * *	
Mint	0.010
* * * * *	
Plum	0.010
Plum, prune, dried	0.025
* * * * *	
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02
* * * * *	
Vegetable, fruiting, crop group 8	0.020
Vegetable, leafy, except Brassica, crop group 4	0.10
* * * * *	

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

* * * * *

[FR Doc. 05–2985 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0406; FRL–7690–2]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).