Final rules concerning the manner in which the FMS will administer the collection of nontax Federal debts after the merger of TROP with TOP were published by the FMS in the **Federal Register** on August 28, 1998 (63 FR 46140) (codified at 31 CFR Part 285.2) effective for refunds payable after January 1, 1998. The regulations in this document provide an ending effective date for § 301.6402–6 to accommodate the beginning effective date of the FMS regulations. Accordingly, § 301.6402–6 does not apply to refunds payable after January 1, 1998.

Final rules concerning the manner in which the FMS will administer the collection of past-due support payments were published by the FMS in the **Federal Register** on December 30, 1998 (63 FR 72092) (codified at 31 CFR Part 285.3), effective for refunds payable after January 1, 1999. The regulations in this document provide an ending effective date for § 301.6402–5 to accommodate the beginning date for the full merger of TROP with TOP. Accordingly, § 301.6402–5 does not apply to refunds payable after January 1, 1999.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking that preceded these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Beverly A. Baughman of the Office of Assistant Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 301.6402–5 is amended by adding paragraph (h) to read as follows:

§ 301.6402–5 Offset of past-due support against overpayments.

* * * * *

(h) Effective dates. This section applies to refunds payable on or before January 1, 1999. For the rules applicable after January 1, 1999, see 31 CFR part 285.

Par. 3. Section 301.6402–6 is amended by revising paragraph (n) to read as follows:

§ 301.6402–6 Offset of past-due, legally enforceable debt against overpayment.

* * * * *

(n) *Effective dates.* This section applies to refunds payable under section 6402 after April 15, 1992, and on or before January 1, 1998. For the rules applicable after January 1, 1998, see 31 CFR part 285.

Bob Wenzel,

Deputy Commissioner of Internal Revenue

Approved: August 25, 1999.

Jonathan Talisman,

Deputy Assistant Secretary of Treasury.

[FR Doc. 99–23083 Filed 9–3–99; 8:45 am]

BILLING CODE 4830–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300916; FRL–6380–7]

RIN 2070–AB78

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 combined residues of the insecticide 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 grapes at 0.02 parts per million (ppm), peppers at 0.02 ppm, and cotton gin byproducts at 0.15 ppm; makes permanent tolerances for citrus, hops, potatoes, meat and meat by-products, milk, and cotton seed which were previously time limited (expiring September 1, 1999); and clarifies that permanent tolerances have previously been established for almond hulls at 0.10 ppm and wet apple pomace at 0.10 ppm. Novartis Crop Protection, Inc. requested these tolerance actions under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 7, 1999. Objections and requests for hearings, identified by docket control number OPP–300916, must be received by EPA on or before November 8, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300916 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9423; and e-mail address: harris.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300916. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

This regulation addresses three tolerance actions concerning avermectin B_1 and its delta-8,9-isomer.

A. New Tolerances

In the **Federal Register** of August 11, 1997 (62 FR 42980) (FRL–5736–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 7F4844) for tolerance by Merck Research Laboratories, PO Box 450, Hillsborough Rd, Three Bridges, NJ. The petition was later transferred to Novartis Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419. There were no comments received in response to the notice of filing.

The initial petition requested that 40 CFR 180.449 be amended by establishing a tolerance for combined residues of the insecticide 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 grapes, raisins, and other grape-derived food items at 0.02 ppm and chili peppers at 0.01 ppm. The petition was subsequently revised to express the tolerance as simply peppers (combining the proposed chili peppers with the existing 0.01 ppm bell pepper tolerance) and raising the level to 0.02 ppm to harmonize the tolerance with international residue limits. In addition, the petition was also revised to express the proposed tolerance as simply grapes at 0.02 ppm since residue data showed that separate, higher tolerance levels were not needed for raisins and other grape-derived food items as expressed in the original petition.

Section 408(b)(2)(A)(i) of the 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) 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) 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 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).

B. Conversion of Certain Tolerances from Time-limited to Permanent

In the **Federal Register** of July 29, 1999 (64 FR 41112) (FRL–6095–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP) by Novartis Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419 to convert certain time limited tolerances due to expire September 1, 1999 to permanent tolerances and to add a new tolerance for a feed commodity. There were no comments received in response to the notice of filing.

The petition referenced pesticide petitions PP 8F3592, 7F3500, 4E4419 and 5F4508. It requested that 40 CFR 180.449 be amended by establishing permanent tolerances for combined residues of the insecticide 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 the agricultural commodities cattle, fat at 0.015 ppm; cattle, meat byproducts at 0.02 ppm; cattle, meat at 0.02 ppm; citrus, dried pulp at 0.10 ppm; citrus, oil at 0.10 ppm; citrus, whole fruit at 0.02 ppm; cotton seed at 0.005 ppm; cotton gin by-products at 0.15 ppm; hops, dried at 0.20 ppm; milk at 0.005 ppm; and potatoes at 0.005 ppm.

With the exception of cotton gin by-products, these tolerances were previously established as time-limited tolerances with an expiration date of September 1, 1999 (see **Federal Register** of March 24, 1997 (62 FR 13833) (FRL–5597–7) to allow for resolution of the following three issues:

1. The petitioner had to submit field residue trial data for cotton gin byproducts and the EPA had to reevaluate dietary risk with respect to secondary residues in meat and milk. These data were submitted; the review is discussed later in this rule. As a result of this review, the July 29, 1999 notice proposed the new tolerance for cotton gin byproducts at 0.15 ppm.

2. The EPA needed to fully review the Monte Carlo analysis for acute dietary risk submitted by the petitioner (especially the anticipated residues and percent of crop treated data used). This review was conducted as part of the tolerance assessment for grapes and peppers.

3. The EPA needed to fully review the indoor residential risk assessment submitted by the petitioner. This review was conducted as part of the tolerance assessment for grapes and peppers. Since all three issues have been satisfactorily addressed, the petitioner is seeking to make the tolerances permanent.

C. Clarification: Certain Feed Tolerances Previously Established

In the **Federal Register** of April 10, 1996 (61 FR 15900) (FRL–5361–9), EPA issued a final rule pursuant to section 409(e) of the FFDCA, 21 U.S.C. 348(b) announcing permanent tolerances under 40 CFR 186.300 for combined residues of the insecticide 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 the processed feed commodities apples, wet pomace at 0.10 ppm and almonds, hulls at 0.10 ppm. This regulation also established permanent tolerances under 40 CFR 180.449 on the raw agricultural commodities almonds at 0.005 ppm; apples at 0.020 ppm; and walnuts at 0.005 ppm.

Although that final rule listed tolerances for both raw agricultural commodities and feed commodities, the 1996 edition of 40 CFR parts 150–189 (revised as of July 1, 1998), and subsequent editions, listed only the tolerances for the raw agricultural commodities and did not list the feed commodities established by this regulation. With this current regulation the Agency is clarifying that tolerances have been legally in effect since April 10, 1996 for the processed feed commodities apples, wet pomace at 0.10 ppm and almonds, hulls at 0.10 ppm. Due to amendments to the FFDCA by the FQPA, all (i.e. raw, processed, and feed commodity) tolerances for avermectin B_1 and its delta-8,9-isomer are now listed in the same section of 40 CFR (180.449).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of avermectin B_1 and its delta-8,9-isomer and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of the insecticide 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 on grapes at 0.02 ppm and peppers at 0.02 ppm. EPA's assessment of the dietary 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 this unit.

1. *Acute toxicity/skin sensitization*. The following summarizes the acute toxicity of technical grade avermectin B_1: the acute oral LD_{50} is 13.6 milligrams/kilogram (mg/kg) (toxicity category I); the acute dermal LD_{50} is 2,000 mg/kg (toxicity category III); acute inhalation requirements were waived; primary eye irritation results show the chemical to be very irritating exhibiting corneal opacity, conjunctivitis, and iritis (toxicity category II); primary skin irritation results show slight irritation (toxicity category III); dermal sensitization results are negative.

2. *Subchronic toxicity*. In a 14-Week Oral Toxicity Study in Rats, groups of 15 male and 15 female Charles River CD rats were gavaged with 0, 0.1, 0.2, or 0.4 mg/kg/day of C–076 (avermectin B_1). The rats had previously been exposed *in utero* to avermectin B_1 at doses of 0, 0.01, 0.2, or 0.4 mg/kg/day. No toxic signs or deaths were noted in any of the treatment groups. Body weight gain was increased in the rats dosed at 0.4 mg/kg/day. There were no treatment-related ophthalmologic changes, clinical pathology anomalies, gross or histopathologic lesions, or changes in organ weights. The No Observable Adverse Effect Level (NOAEL) is > 0.4 mg/kg/day, the highest dose tested.

An 18–Week Oral Toxicity Study in Dogs resulted in a NOAEL of 0.25 mg/kg/day with the Lowest Observed Adverse Effect Level (LOAEL) being 0.5 mg/kg/day based on body tremors, one death, liver pathology, and decreased body weight.

3. *Chronic toxicity/ongogenicity/carcinogenicity*. In a Combined Chronic Toxicity/Oncogenicity Study in Rats, the oncogenic potential was negative up to 2.0 mg/kg/day, the highest dose tested (HDT). The high dose was increased to 2.5 mg/kg/day between weeks 10 and 13. The high-dose is considered the Maximum Tolerated Dose (MTD). The systemic NOAEL is 1.5 mg/kg/day (mid-dose). The LOAEL is 2.0 mg/kg/day based on tremors in both sexes. A mid-dose female that had tremors was found to have received a dose of about 2.5 mg/kg/day (based on actual food consumption and body weight data). No pathological lesions could be found to explain the tremors.

In a Carcinogenicity Study in Mice, oncogenic potential was negative up to 8 mg/kg/day, the HDT. The high-dose (8 mg/kg/day) is considered the MTD. The systemic NOAEL is 4 mg/kg/day. The LOAEL is 8 mg/kg/day based on increased incidence of dermatitis in males, an increased incidence of extra-medullary splenic hematopoiesis in males, increased mortality in males, and tremors and body weight decrease in females.

In a 53–Week Oral Toxicity Study in Dogs, the NOAEL is 0.25 mg/kg/day, and the LOAEL is 0.50 mg/kg/day based on a high incidence of mydriasis (dilatation of the pupil of the eye) in males and females.

4. *Developmental and reproductive toxicity*. In a Developmental Toxicity Study in Rats, groups of 25 female CRCD rats were mated, then dosed by gavage with technical MK-0936 (avermectin B_1) at 0 (vehicle control), 0.4, 0.8, or 1.6 mg/kg/day on gestation days 6 through 19. The lack of any maternal or developmental toxicity demonstrates that the doses selected for this study were too low to establish a LOAEL. The maternal and developmental NOAELs are > 1.6 mg/kg/day (the HDT).

In a Developmental Toxicity Study in Rabbits, the maternal NOAEL is 1.0 mg/kg/day, and the maternal LOAEL is 2.0 mg/kg/day based on decreased body weights, food consumption, and water consumption. The developmental NOAEL is 1.0 mg/kg/day, and the Developmental LOAEL is 2.0 mg/kg/day based on cleft palate, clubbed foot, and delayed ossification of sternebrae, metacarpals, and phalanges.

In a 2–generation Reproduction Study in Rats, the systemic and reproductive NOAELs are ≥ 0.40 mg/kg/day. The developmental NOAEL is 0.12 mg/kg/day, and the developmental LOAEL is 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings.

In a Special Developmental Toxicity Study in CF-1 Mice, a genotypic susceptibility to cleft palate was seen

following *in utero* exposure of avermectin B_1 delta 8-9 isomer (an isomeric photodegradation product found in plants). P-glycoproteins are large proteins (150–180 kDa) found in the cell membranes of animals ranging from sponges to humans. Groups of 12 P-glycoprotein molecules span the lipid bilayer to form pores that protect the cell by secreting toxic chemicals (such as the avermectins) at the expense of ATP.

The CF-1 mouse strain is unique in that it contains a spontaneous mutation in the P-glycoprotein gene resulting in heterogeneity in the expression of the protein, a component of the blood-brain and blood-placental barrier. Mice with a ± or -/- genotype have decreased expression of this protein. A decrease in expression of the P-glycoprotein in both the gastrointestinal tract and brain increased the sensitivity of CF-1 mice to avermectin toxicity by increasing its absorption. Because the protein is also a component of the placental-blood barrier, it was hypothesized that a deficiency of this protein in the placenta may increase the sensitivity of the fetus to the avermectins. In this exploratory developmental toxicity study, the role of fetal P-glycoprotein genotype in the development of cleft palate in CF-1 mice was investigated.

Heterozygous (±) male and female mice for P-glycoprotein expression were mated. The dams were dosed by gavage with 1.5 mg/kg/day of the test article on gestation days 6–15, inclusive. The pups had the typical 1:2:1 Mendelian expression of P-glycoprotein deficiency (+/+, ±, and -/-, respectively).

There was a clear correlation between fetal P-glycoprotein genotype and cleft palate incidence. Cleft palate was observed in 97% of fetuses with the -/- genotype, 41% of fetuses with the ± genotype, and none of the fetuses with the +/+ genotype. It was postulated that placental P-glycoprotein limited the potential of the test article to induce cleft palate in the fetuses, presumably by regulating the amount of test material allowed to cross the placental barrier into the developing fetus.

The literature contains no mention of P-glycoprotein deficiency in humans, and several scientists who are researching P-glycoprotein confirmed this. Since there is no known human correlate for P-glycoprotein deficiency, the CF-1 mouse should not be used for assessing the risk of human exposure to avermectins. Although several developmental toxicity studies were performed using CF-1 mice, they are inappropriate for regulatory purposes.

5. *Mutagenicity*. The available studies clearly indicate that avermectin B_1, delta-8,9-isomer (a plant metabolite), and the polar photolysis degradates are not mutagenic in microbial systems. While avermectin B_1 has the potential to damage DNA, the lack of an *in vitro* mutagenic or clastogenic effect correlates well with the lack of an oncogenic effect in rat or mouse long-term feeding studies and also with the absence of significant reproductive or developmental toxicity attributable to a mutagenic mode of action (i.e., decreased total implants or increased resorptions).

6. *Metabolism*. In a metabolism study in rats, two metabolites were identified, 2,4-OH-ME-B_{1a}, and 3″desmethyl avermectin B_{1a} (3″DM-B_{1a}). No bioaccumulation was seen in rat tissues.

7. *Neurotoxicity*. There are no neurotoxicity or developmental neurotoxicity studies of avermectin B_1. However, neurotoxicity was observed in other oral toxicity studies. A chronic study in dogs resulted in mydriasis at 0.50 mg/kg/day. A chronic/oncogenicity study in rats resulted in tremors in both sexes at the LOAEL of 2.0 mg/kg/day. A chronic/carcinogenicity study in mice resulted in tremors in females at the LOAEL of 8 mg/kg/day. In an 18–week study in dogs signs, seen at 0.50 mg/kg/day included mydriasis, whole body tremors, ataxia (lack of coordination), muscular tremors, and ptyalism (excessive flow of saliva). In a 10–day developmental toxicity study in CF-1 mice, hunched back and marked tremors were observed after 6–7 days dosing at 0.3 mg/kg/day in the diet. In a reproduction study in rats, spastic movements of the limbs and muscular tremors of the entire body were seen in lactating pups, but not in the dams, at 0.4 mg/kg/day. In a reproduction study in rats, whole body tremors, ataxia, ptyalism, and ocular and/or nasal discharges were seen in dams dosed at 2.0 mg/kg/day (no mention of neurotoxicity in the pups). In two developmental toxicity studies in CF-1 mice, death was preceded by tremors, then coma.

B. Toxicological Endpoints

1. *Acute toxicity*. An acute dietary Reference Dose (RfD) of 0.0025 mg/kg was based on data from a 1–year dog study. The NOAEL is 0.25 mg/kg/day, and the LOAEL is 0.50 mg/kg/day based on mydriasis which was observed after 1 week of dosing. An uncertainty factor of 100 was used to account for interspecies extrapolation (10x) and intraspecies variability (10x).

2. *Short- and intermediate-term toxicity*. Short- and intermediate-term dermal and inhalation NOAELs are derived by route-to-route extrapolation of the oral NOAEL of 0.25 mg/kg/day based on mydriasis after 1 week of dosing in a 1–year dog study. Dermal absorption is considered to be 1% based on a monkey study that found dermal absorption to be less than 1% (rounded up to 1% for analysis purposes). Oral and inhalation absorption are both assumed to be 100%.

3. *Chronic toxicity*. EPA has established the RfD for avermectin B_1 and its delta-8,9-isomer at 0.0012 mg/kg/day. This Reference Dose (RfD) is based on a 2–generation reproduction study in rats. The developmental NOAEL is 0.12 mg/kg/day, and the developmental LOAEL is 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings. An uncertainty factor of 100 was used to account for interspecies extrapolation (10x) and intraspecies variability(10x).

The long-term dermal NOAEL is a route-to-route extrapolation of the oral NOAEL of 0.12 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings in a 2–generation reproduction study in rats. Dermal absorption is considered to be 1% based on a monkey study that found dermal absorption to be less than 1% (rounded up to 1% for analysis purposes).

The long-term inhalation NOAEL is a route-to-route extrapolation from the oral NOAEL of 0.12 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings in a 2–generation reproduction study in rats. Oral and inhalation absorption are both assumed to be 100%.

4. *Carcinogenicity*. The Agency has classified avermectin B_1 as a Cancer Group E chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.449) for the combined residues of the insecticide 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 a variety of raw agricultural commodities. Permanent tolerances include almonds (0.005 ppm); almonds, hulls (0.10 ppm); apples (0.020 ppm); apples, wet pomace (0.10 ppm); celery

(0.05 ppm); cucurbits (0.005 ppm); head lettuce (0.05 ppm); pears (0.02 ppm) bell peppers (0.01 ppm) strawberry (0.02 ppm); fresh tomatoes (0.01 ppm); walnuts (0.005 ppm). The following time limited tolerances are due to expire September 1, 1999: cattle, fat (0.015 ppm); cattle, meat (0.02 ppm); cattle, meat by products (0.02 ppm); citrus, dried pulp (0.10 ppm); citrus, oil (0.10 ppm); citrus, whole fruit (0.02 ppm) cotton seed (0.005 ppm); dried hops (0.2 ppm); milk (0.005 ppm); potatoes (0.005 ppm). The following Section 18 time limited tolerances will expire January 31, 2,000: basil (0.05 ppm); celeriac (0.05 ppm) spinach (0.05 ppm). Finally, a section 18 time limited tolerance for avocado (0.02 ppm) will expire September 20, 2,000. All of these tolerances (i.e. both permanent and time-limited) were included in the dietary risk analysis. Risk assessments were conducted by EPA to assess dietary exposures from avermectin B_1 and its delta-8,9-isomer as follows:

Section 408(b)(2)(E) 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 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. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of crop treated (PCT) for assessing chronic dietary risk only if the Agency can make the following three findings: (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; (2) that the exposure estimate does not underestimate exposure for any significant subpopulation group; and (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 percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used the following information to conduct a dietary exposure analysis. The maximum PCT is used for acute dietary exposure estimates and represents the highest levels to which an individual could be exposed. It is unlikely to underestimate an individual's acute dietary exposure. The weighted average percent crop treated is used for chronic dietary exposure and reasonably represents a person's dietary exposure over a lifetime. It is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, so that an individual is unlikely to be exposed to more than the average percent crop treated over a lifetime. For each crop in the dietary (food only) model the following percent crop treated values were used for the acute and chronic analyses (respectively): almond 100%, 100%; apple 6.1%, 1.9%; avocado 100%, 100%; basil 100%, 100%; cantaloupe 5%, 1.3%; celeriac 100%, 100%; celery 60%, 49%; citrus, other 43%, 32%; cotton 4.8%, 3.2%; cucumber 100%, 31%; grapefruit, juice and peel 60.9%, 46%; grapefruit, peeled fruit 43%, 46%; grape 14%, 14%; hops 100%, 84%; lemon, juice and peel 34.4%, 17%; lemon, peeled fruit 43%, 17%; head lettuce 28%, 22%; lime, juice and peel 63.2%, 32%; lime, peeled fruit 43%, 32%; melons 5%, 1.3%; orange, juice and peel 36.3%, 28%; orange, peeled fruit 43%, 28%; pear 75%, 56%; peppers 15%, 6.3%; potato 5%, 0.3%; spinach 18%, 8.9%; squash 100%, 31%; strawberry 47%, 42%; tangelo 43%, 57%; tangerine, juice 74.3%, 53%; tangerine, fresh 43%, 53%; tomato 8%, 3.7%; walnut 100%, 100%; watermelon 5%, 1.3%. For fresh, peeled citrus a weighted average (43%) was calculated pooling all types of citrus; this value was used in the analysis of chronic dietary exposure from citrus.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, 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. However, since the risk assessment includes forecast estimates of usage of avermectin B_1 on the new crops being added, the petitioner must seek permission from the Agency to expand usage beyond these estimates (specifically, 14% crop treated for grapes, 15% crop treated for peppers). Before the petitioner can increase production of product for treatment of greater than 115,500 acres for grapes (14% of 825,000 total U.S. acres grown) or 17,850 acres for peppers (15% of 119,000 total U.S. acres grown), permission from the Agency must be obtained. 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.

i. *Acute exposure and risk*. 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. The registrant has submitted an acute dietary exposure assessment using probabilistic ''Monte Carlo'' modeling incorporating anticipated residue and percent of crop treated refinements to calculate the Anticipated Residue Contribution (ARC). EPA has examined the assumptions made in conducting the analysis for the following crops: celery, strawberry, citrus, tomato, and pear, apple, grape, and pepper. EPA found the analysis adequate with the exception of the acute RfD; the analysis was not conducted with the current acute population adjusted dose (PAD) of 0.00025 mg/kg/day. Residue Data Files (RDF) and percent crop treated were used on all but a few low consumption food items. Reduction factors for fractionation and processing were utilized for citrus and pome fruit. Monitoring data were not used for mixed/blended commodities.

EPA was able to further refine the acute dietary estimate from food by using updated PCT data, resetting the processing factor for dried potatoes to 1 which reflects the non-concentration of

avermectin B_1 in potato processed commodities, correcting the residue files above to use one half the level of detection or one half the level of quantification, where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, the analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin B_1 residues from the raw agricultural commodity, EPA will use the reduction factor for apples in the analysis. Some of the resulting high-end exposure estimates are listed below.

The resulting calculations are presented below as a percent of the acute population adjusted dose (%PAD). The PAD is the reference dose (acute or chronic) adjusted for (divided by) the FQPA safety factor. EPA is generally concerned with acute exposures that exceed 100% of the acute RfD/PAD. The risk estimate should be viewed as highly refined. Additional refinement of the almond, basil, cotton seed, hops and walnut residue estimates using RDF's and PCT would be unlikely to reduce risk estimates significantly. In making a safety determination for this tolerance, EPA is taking into account this refined acute exposure assessment.

TABLE 1.— ACUTE DIETARY (FOOD ONLY) RISK FOR SELECTED POPULATION GROUPS

Subgroup	ARC (mg/kg)	PAD (%)
U.S. Population	0.000088	4
All infants (< 1 yr.)	0.000111	44
Nursing infants (< 1 yr.)	0.000112	45
Non-nursing infants (< 1 yr.)	0.000117	47
Children (1–6 yrs.)	0.000176	70
Children (7–12 yrs.)	0.000085	34
Females (13+ yrs. pregnant, non-nursing)	0.000054	22
Females (13+ yrs. nursing)	0.000093	37
Females (13–19 yrs. non-pregnant, non-nursing)	0.000061	24
Females (13–50 yrs.)	0.000070	28
Males (13–19 yrs.)	0.000051	2

ii. *Chronic exposure and risk.* In conducting this chronic dietary (food only) risk assessment, EPA used anticipated residues and percent crop-treated data for many crops. This chronic dietary (food only) exposure should be viewed as a highly refined risk estimate; further refinement using additional percent crop-treated values would not result in a significantly lower dietary exposure estimate. Thus, in making a safety determination for this tolerance, EPA is taking into account this refined chronic exposure assessment. EPA is generally concerned with exposures that exceed 100% of the chronic RfD/PAD. The existing avermectin B_1 tolerances result in an ARC that is equivalent to the following percentages of the RfD or PAD depending on the subpopulation:

TABLE 2.—CHRONIC DIETARY (FOOD ONLY) RISK FOR SELECTED POPULATION GROUPS

Subgroup	ARCFOOD (mg/kg)	PAD (%)
U.S. Population	0.000008	< 1
U.S. Population - autumn season	0.000008	7
Northeast region	0.000008	7
Western region	0.000009	7
Pacific region	0.000009	7
Non-hispanic other	0.000008	7
All infants (< 1 yr.)	0.000016	14
Nursing infants (< 1 yr.)	0.000009	7
Non-nursing infants (< 1 yr.)	0.000020	17
Children (1-6 yrs.)	0.000016	13
Children (7–12 yrs.)	0.000010	8
Females (13+ yrs. nursing	0.000008	6
Males (20+ years)	0.000007	<1

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants, children, females 13+, nursing; (3) the other subgroups for which the percentage of the RfD/PAD occupied is greater than that occupied by the subgroup U.S. population; and (4) other subgroups of regulatory interest.

2. *From drinking water.* Avermectin B_1 is moderately persistent and non-mobile. It is not expected to reach surface or ground water in significant quantities. It is stable to hydrolysis at pH 5, 7, and 9. It is also moderately persistent in aerobic soil (topsoil) with half-lives of 37–131 days. The major pathways of avermectin B_1 dissipation are binding to soil and sediment, degradation in aerobic soil, and photolysis in water. In shallow, well-mixed surface water with no suspended sediments, avermectin B_1 degraded rapidly with a photodegradation half-life of 3 days. However, in most surface waters, suspended sediments and lack of mixing would decrease the rate of photodegradation significantly. In water, avermectin B_1 residues would be tightly bound to sediment, reducing aqueous concentrations. There are no Maximum Contaminant Levels (MCL) or Health Advisories (HA) established for avermectin B_1 residues in drinking water.

To calculate exposure and risk from avermectin B_1 in drinking water, the EPA analysis first used screening models to calculate Estimated Environmental Concentrations (EECs) for groundwater (screening concentration in ground water (SCI-GROW2)) and surface water (generic expected environmental concentration (GENEEC)). A refined model (Pesticide Root Zone Model-EXAMS (PRZM-EXAMS)) was then run on surface water (refined models do not exist for ground water but given the screening results it is unlikely that the EECs for ground water would change significantly). The resulting EECs were then compared to the Drinking Water Level of Concern (DWLOC) for various population groups to determine acute and chronic risk.

The screening model SCI-GROW2 was used to calculate EECs for avermectin B_1 in ground water from use in grapes, peppers, and strawberries. Strawberries were analyzed since they represent the highest avermectin B_1 use rate for any crop. These EECs were 0.0015, 0.0015, and .002 µg/L for grapes, peppers, and strawberries, respectively.

PRZM-EXAMS was used to perform a refined assessment of EECs for avermectin B_1 in surface drinking water. Use sites modeled were grapes grown with grassed middles in New York and strawberries grown on black plastic mulch in Florida. Peppers were not modeled because the application rate is lower than that for strawberries. Crop specific consecutive PRZM-EXAMS simulations were conducted to evaluate the cumulative probability distribution for peak, 4–day, 21–day, 60–day, and 90–day EECs. PRZM-EXAMS EECs for avermectin B_1 were 0.18 and 0.88 µg/L for peak values and 0.16 and 0.57 µg/L for 90–day for grape and strawberries, respectively.

EPA decided to rely on the strawberry model to assess aggregate risk since strawberries were considered a higher exposure scenario (four applications per season allowed for strawberries vs. three applications for peppers or two applications for grapes). However, EPA noted that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin B_1 on black plastic compared to soil. In order to refine the model in the future, the Agency will require the registrant, as a condition of product registration, to conduct additional tests on the effects of plastic mulch on surface water pesticide concentrations.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit of a pesticide's concentration in drinking water in light of total aggregate exposure to that pesticide in food and through residential uses. A DWLOC will vary depending on the toxic endpoint, consumption, and body weight. Different populations will have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, the DWLOC is used as a point of comparison against conservative model estimates of potential pesticide concentration in water. DWLOC values are not regulatory standards for drinking water.

Acute and chronic exposure and risk. No monitoring data of ground water and surface water are available for avermectin B_1. The SCI-GROW2 modeling data for the grape and chili pepper uses resulted in maximum concentrations in ground water of 0.0015 µg/L for both acute and chronic exposure. Refinements using PRZM–EXAMS indicate a peak EEC in surface water at 0.88 µg/L and a 90–day EEC at 0.57 µg/L. The modeling data were compared to the results of the following equations used to calculate acute and chronic DWLOC for avermectin B_1 in ground and surface water. Additionally, as a result of the retention of the FQPA Safety Factor, EPA considered the PAD for females 13+, infants, and children to be 0.00025 and 0.00012 mg/kg/day for acute and chronic exposure, respectively. For all other populations (e.g. U.S. population, Hispanics, adult males), exposures will be compared to the acute and chronic PADs, 0.0025 and 0.0012 mg/kg/day, respectively.

DWLOC's are calculated as follows: Acute = (acuteRfD/10) - (acute food (mg/kg/day)) × (bodyweight) / consumption (L) × 10^{-3} mg/µg. Chronic = (RfD/10) - (chronic food (mg/kg/day)) × (bodyweight)/consumption (L) × 10^{-3} mg/µg. The 2 liters (L) of drinking water consumed/day by adults and the 1 L per day consumed by children are default assumptions used by the EPA. The Agency's default body weights for the U.S. population and males is 70 kg and for females, 60 kg. EPA's default body weight for children is 10 kg. There are no chronic residential exposures to avermectin B_1.

The results indicate that the exposure to avermectin B_1 in drinking water derived from ground water using SCI-GROW modeling data are below the calculated DWLOC for all population subgroups of concern from use of avermectin B_1 in grapes, peppers and strawberries. Exposure to avermectin B_1 in drinking water derived from surface water using the refined estimates from PRZM-EXAMS and using the results for the crop with the highest use rate (strawberries) the modeled exposure data are below the calculated DWLOC for all population subgroups of concern except for the acute exposure for children 1–6 yrs where the modeled exposure concentration slightly exceeds the DWLOC (0.88 vs. 0.74 µg/L).

Despite this slight exceedance, EPA believes that acute exposure to avermectin from drinking water will not pose an unacceptable risk to human health. Neither surface nor ground water models used by EPA were designed specifically for estimating concentrations in drinking water. There are significant uncertainties in both the toxicology used to derive the DWLOC and the exposure estimate from the PRZM–EXAMS model. EPA has compensated for these uncertainties by using reasonable high-end assumptions. Given this approach, the Agency does not attach great significance to such a small difference. However, EPA may do additional analyses and, as a condition of product registration, the Agency will require the registrant to submit (1) data on the effects of plastic mulch on surface water pesticide concentrations and (2) data characterizing the effectiveness of various types of drinking water treatment on removing avermectin. These data are expected to confirm that the actual concentration of avermectin in drinking water is less than the level of concern for all sub-populations.

3. *From non-dietary exposure.* Avermectin B_1 and its delta-8,9-isomer is currently registered for use on the following residential non-food sites: residential lawns for fire ant control, and residential indoor crack & crevice for cockroaches. Registered residential uses may result in short-term to intermediate exposures. However, based on current use patterns, chronic exposure (6 or more months of continuous exposure) to avermectin B_1 is not expected.

i. *Short and intermediate exposure and risk--residential lawn applications.* For exposure of residential applicators, three scenarios used were: (a) granular bait dispersed by hand, (b) belly grinder-granular open pour-mixer/loader/applicator (MLAP) and (c) push type granular MLAP. Short- and Intermediate-term total MOEs (dermal + inhalation) are greater than 1,000 and therefore do not exceed EPA's level of concern.

For postapplication exposure from treated lawns, EPA default assumptions such as dermal transfer coefficient (Tc), exposure time (ET), hand surface area (SA), ingestion frequency (FQ), residue dissipation, and ingestion rates were used. These defaults were used to estimate postapplication exposure to children and adults from treated lawns. The application rate (AR) used for this assessment is based on the label for Affirm Fire Ant Insecticide (0.011% avermectin B_1). The label recommends a broadcast application rate on lawns of 1 lb of product/acre (1.1E–4 lb ai/acre). This is maximum rate for all registered lawn uses. A margin of exposure (MOE) of 1,000 or greater is required for the most sensitive subgroups. All lawn postapplication MOEs exceeded this value and are therefore not of concern. The dermal short- and intermediate-term MOEs for adults and children are 83,000 and 86,000, respectively. The oral hand-to-mouth short- and intermediate-term MOEs for children are 14,000 and 6,500, respectively. The oral incidental ingestion short- and intermediate-term MOEs for children are 610,000 and 290,000, respectively.

ii. *Short and intermediate exposure and risk--residential indoor crack and crevice uses.* For residential applicators, exposure and risk estimates for homeowners applying crack and crevice baits were estimated using the EPA DRAFT Standard Operating Procedure (SOP) for Residential Exposure Assessments (12/18/97).

The amount of active ingredient (ai) handled was based on the assumption that one 30 gram package of Whitmire Avert Prescription Bait Prescription Treatment 310 (0.05% ai) would be applied in a day. The unit exposure from the EPA default wettable powder, open mixing and loading scenarios was used as a surrogate for estimating dermal and inhalation exposure to residential applicators. The short- and intermediate-term MOEs for dermal and inhalation exposure are each 12 million, which does not exceed EPA's level of concern.

For estimating postapplication exposure and risk from indoor treatment, two postapplication exposure studies were conducted with crack and crevice products containing avermectin B_1: (1) Evaluation of Avert Prescription Treatment 310 Residual Study in Air, Food and on Surfaces, dated November 8, 1990 and (2) Evaluation of Indoor Exposure to a Crack and Crevice Application of Whitmire Avert Crack and Crevice Prescription Treatment 310 and Prescription TC 93A Bait, dated October 27, 1995. The 1990 study reported measured avermectin B_1

concentrations in wipe and air samples up to 7 days following the application. The 1995 study reported non-detect values for all air and surface residue (cotton cloth dosimeters) samples taken.

The EPA noted that neither study met 100% of the Pesticide Assessment Guideline criteria. Among other shortcomings, the 1990 study did not report the amount of avermectin B_1 applied. However, subsequent documentation provided by the study director stated that the application rate in the 1990 study was at least three times greater than the normal label rate.

To be conservative, EPA decided that the values from the 1990 study would be used for this risk assessment. EPA default assumptions for dermal Tc, ET, SA, FQ, inhalation rates, and ingestion rates were used. These defaults were used to estimate children's postapplication exposure to the product Avert Prescription Treatment 310 (dry flowable cockroach bait). According to Table A–1 of the SOP's for Residential Exposure Assessments, the method used for estimating children's postapplication exposure is believed to produce a central to high-end estimate of exposure.

Based on the information available on the study, the air and surface residue values taken from the 1990 study were divided by a factor of 3 to account for the exaggerated application rate used in the study. The avermectin B_1 residue value reported for horizontal residues immediately after the application (4.2E–07 mg/cm^2) was divided by a factor of 3 (1.4E–6 mg/cm 2) and then used to estimate children's dermal and hand-to-mouth exposure. A linear regression analysis was performed on the reported air concentrations at 0 (immediately after), 1, 3 and 7 days after the application to determine the average concentration for the first 21 hours following the application. The analysis indicated an average concentration of avermectin B_1 at 6.4E–04 mg/m^3 (4% dissipation, adjusted R2 = 0.986 for log-transformed data). This value was divided by a factor of 3 (2.1E–4 mg/m^3) and then used to estimate children's inhalation exposure.

The Short- and intermediate-term dermal MOE for children's postapplication dermal is 78,000. The short- and intermediate-term oral MOE for children's postapplication oral hand-to-mouth is 12,000. The short- and intermediate-term inhalation MOE for children's postapplication inhalation is 2,400.

The risk from children's post application exposure to crack and crevice products containing avermectin B_1 does not exceed EPA's level of concern. Avert Prescription Treatment 310 is a dust formulation that is intended for the application to crack and crevices only. Other formulations for similar crack and crevice products (i.e., gels, granulars, pressurized liquids, etc.) will have less migration from the treated area and are expected to result in lower risk from dermal, oral, and inhalation postapplication exposure.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether avermectin B_1 and its delta-8,9-isomer has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, avermectin B_1 and its delta-8,9-isomer 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 and its delta-8,9-isomer 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population including Infants and Children

In examining aggregate exposures, FQPA directs EPA to consider available information concerning exposures from the residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from ground or surface water), and exposure through pesticide use in gardens, lawns or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *Acute risk.* Acute aggregate exposure takes into account acute dietary food and water exposure. The registrant submitted an acute dietary exposure analysis using probabilistic ''Monte Carlo'' modeling. EPA has examined the assumptions made in conducting the analysis and has recalculated the assessment using the submitted acute file, the correct acute RfD, updated PCT data, correcting the residue files above to use one half the Level of Detection (LOD) or one half the Level of Quantitation (LOQ) where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, EPA's analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin B_1 residues from the raw agricultural commodity, EPA used the reduction factor for apples in the analysis. The dietary (food only) acute %PAD range from 45% for nursing infants < 1 year old to 70% for children 1–6 yrs. This risk estimate should be viewed as highly refined since it used anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis. The acute dietary exposure does not exceed EPA's level of concern.

Avermectin B_1 is a moderately persistent but non-mobile compound in soil and water environments. The SCI-GROW modeling data for avermectin B_1 for drinking water derived from ground water sources resulting from use on grapes and peppers indicate levels less than OPP's DWLOC for acute exposure. Using the refined PRZM-EXAMS modeling data for drinking water derived from surface water sources resulting from use on strawberries (the crop with the maximum use rate) also indicates levels less than OPP's DWLOC for acute exposure in all populations with the exception of children 1–6 years old where the peak EEC of 0.88 µg/L slightly exceed this subgroup's acute DWLOC (0.74 µg/L).

Despite this slight exceedance, EPA believes that acute exposure to avermectin from drinking water will not pose an unacceptable risk to human health. Neither surface nor ground water models used by EPA were designed specifically for estimating concentrations in drinking water. There are significant uncertainties in both the toxicology used to derive the DWLOC and the exposure estimate from the PRZM-EXAMS model. EPA has compensated for these uncertainties by using reasonable high-end assumptions. Given this approach, the Agency does not attach great significance to such a small difference. However, EPA may do additional analyses and, as a condition of product registration, the Agency will require the registrant to submit (1) data

on the effects of plastic mulch on surface water pesticide concentrations and (2) data characterizing the effectiveness of various types of drinking water treatment on removing avermectin. These data are expected to confirm that the actual concentration of avermectin in drinking water is less than the level of concern for all sub-populations.

2. *Chronic risk.* Chronic aggregate exposure takes into account chronic exposure via food, water, and residential uses. Since there is no chronic residential exposure to avermectin B_1 only food and water contributed to chronic risk.

Using the exposure assumptions described in this notice, EPA has concluded that aggregate exposure to avermectin B_1 and its delta-8,9-isomer from food will utilize < 1% of the PAD for the U.S. population and will utilize from 6% to 17% of the PAD for infants and children (depending on specific subgroup). The major identifiable subgroup with the highest aggregate exposure is non-nursing infants with 17% of the chronic PAD. EPA generally has no concern for exposures below 100% of the RfD/PAD because the RfD/PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

Avermectin B_1 is a moderately persistent, but non-mobile compound in soil and water environments. The modeling data for avermectin B_1 indicate chronic water residue levels less than OPP's DWLOC's. EPA does not expect aggregate chronic exposure to avermectin B_1 will pose an unacceptable risk to human health.

3. *Short- and intermediate-term risk.* Short-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term residential uses which include dermal, inhalation, and oral exposures. For children's post-application exposure from crack and crevice uses, the worst case exposure scenario, risks do not exceed EPA's level of concern. The residential uses that were aggregated with chronic dietary food and water are from lawn and crack and crevice uses and include: (1) Adult dermal exposure from the highest adult residential applicator scenario (3.4E–7 mg/kg/day from belly grinder granular open pour) and crack and crevice applicator scenario (2.1E–8 mg/kg/day) with exposure from post-application activities (3.0E–6 mg/kg/day), and inhalation from turf and crack and crevice (3.9E–7 mg/kg/day). (2) Children's oral exposure from turf and crack and crevice hand-to-mouth, with turf incidental ingestion (3.8E–5 mg/kg/day), dermal exposure from turf and crack and crevice (6.1E–6 mg/kg/day), and inhalation exposure from crack and crevice (1.1E–4 mg/kg/day).

Using the exposures above, EPA calculated the short-term DWLOCs. The DWLOC of 8.2 µg/L for the U.S. population is greater than the water EEC's. The DWLOC for infants/children (0.77 µg/L) is greater than the PRZM-EXAMS chronic value of 0.57 µg/L. EPA does not expect aggregate short-term exposure to avermectin B_1 will pose an unacceptable risk to human health.

The worst case intermediate-term exposures to avermectin B_1 for adults are the same as those described above for short-term exposures. Using the exposures above, EPA calculated the adult intermediate-term DWLOC of 8.2 µg/L, which is greater than the water EEC's. EPA does not expect aggregate intermediate-term exposure to avermectin B_1 will pose an unacceptable risk to adult human health.

The worst case intermediate-term exposures to avermectin B_1 for infants and children are the same as those described above. Since the short- and intermediate-term NOAELs are the same, the DWLOC is also equal to the 0.77 µg/L short-term value. Again, given the 0.57 µg/L PRZM-EXAMS value, EPA is not concerned with the residues in drinking water. EPA does not expect aggregate intermediate-term exposure to avermectin B_1 will pose an unacceptable risk to human health.

4. *Aggregate cancer risk for U.S. population.* EPA classified avermectin B_1 as a Cancer Group E chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, infants, or children from aggregate exposure to avermectin B_1 and its delta-8,9-isomer residues.

E. Determination of Safety for Infants and Children

1. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of avermectin B_1 and its delta-8,9-isomer, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the database unless EPA determines 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

2. *Developmental toxicity studies.* Studies are discussed in Unit III.A.4 of this preamble.

3. *Reproductive toxicity study.* Studies are discussed in Unit III.A.4 of this preamble.

4. *Pre- and postnatal sensitivity.* There was evidence of increased susceptibility to the offspring following pre- and postnatal exposure to avermectin B_1 in the 2–generation reproduction study in rats.

5. *Conclusion.* There is a complete toxicity database for avermectin B_1 and its delta-8,9-isomer and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. The Agency is retaining the 10–fold safety factor for increased susceptibility of infants and children for this pesticide and is applying it to females 13+, infants, and children population subgroups for acute, chronic, and residential exposure.

The 10x Safety Factor is being retained because:

(1) There was evidence of increased susceptibility to the offspring following pre- and postnatal exposure to avermectin B_1 in the two-generation reproduction study in rats.

(2) There is evidence of neurotoxicity manifested as clinical signs of neurotoxicity in mice, rats, and dogs in developmental, reproduction, chronic and/or carcinogenicity studies in mice, rats and/or dogs.

(3) There is concern for Structure Activity Relationship: ivermectin induced cleft palate in fetal rats, and cleft palate and clubbed forefoot in fetal rabbits.

(4) EPA determined that a developmental neurotoxicity study in rats is required for avermectin B_1. This study could provide additional information on potential increased susceptibility, effects on the development of the fetal nervous system, as well as the functional development of the young.

(5) There is concern for post-application exposure to infants and children in treated areas, including incidental hand-to-mouth ingestion of the pesticide.

IV. Other Considerations

A. Metabolism In Plants and Animals

Plant metabolism data have been previously submitted on cotton seed, citrus, and celery. In addition, a report titled ''Comparative Degradation of Avermectin B_{1a} in Cotton Leaf, Citrus Fruit, Celery, and *In Vitro*'' was submitted. The proposed use in this petition on grapes and chili peppers specifies multiple applications up to a maximum application rate on grapes of 32 fl oz/A/season (0.038 lb ai/A/season) and on peppers of 48 oz/A/season (0.057 lb ai/A/season). Previously, the metabolism components have been examined from radio-labeled avermectin B_1 on celery (10 applications at 7 day intervals for a total equivalent of 1.0 lb ai/A/season), radio-labeled avermectin B_1 on cotton (3 applications at 50 to 89 day intervals for a total equivalent of 0.60 lb/A/season), and exaggerated application rates to citrus (30X, 2.25 lb ai/A). The available metabolism data on cotton, celery, and citrus represent a wide enough range of crop matrices, growth modes, and use rates. It is unlikely that application of avermectin B_1 to grapes and chili peppers will result in new degradation compounds that have not previously been produced and subjected to toxicity testing. EPA concludes that the metabolism data are sufficient (a) to support the proposed use on grapes and chili peppers and (b) to support the recommended tolerance on cotton gin byproducts. The residues of concern in/on grapes, chili pepper, and cotton gin byproduct commodities are the parent compound (avermectin B_{1a} and B_{1b}) and its delta-8,9-isomer.

Since there are no grape or chili pepper animal feed items of regulatory concern, a discussion of animal metabolism is not germane to petition PP 7F4844.

Animal metabolism data were not submitted in conjunction with cotton petition (PP 7F3500). However, the metabolism of avermectin in goat and rat has been reviewed. From these studies, it was determined that the residues of concern in ruminants are avermectin B_{1a} and B_{1b} and their delta-8,9-isomers. This conclusion was based upon a feeding level of 1.0 mg/goat/day of ^{3}H-avermectin. An additional metabolite (24-hydroxymethyl avermectin B_{1a}) was identified and is potentially of toxicological significance, but was not included in the tolerance expression because of its presence at low levels. However, EPA notes that if the livestock dietary burden is increased and the tolerances for residues in meat and milk need to be raised, then the 24-hydroxymethyl metabolite may need to be included in the tolerance expression and appropriate enforcement methods would need to be developed. Furthermore, an additional animal metabolism study using ^{14}C-avermectin would be needed if the expected ruminant dietary burden exceeded the dose level in the previously submitted goat metabolism study. EPA concludes the available ruminant metabolism study is adequate to support the proposed tolerances for avermectin on cotton gin byproducts.

Cotton gin byproducts are not a poultry feed item. Therefore a discussion of metabolism and secondary residues in poultry commodities is not pertinent to petition PP 7F3500.

B. Analytical Enforcement Methodology

The registrant has used the analytical procedure designated Method 91–1 for data gathering purposes in these grape and chili pepper field trials for avermectin B_1 and its delta-8,9-isomer. Acceptable independent method validations (ILV) were submitted for both commodities. The samples are extracted with acetonitrile/water/hexane, cleaned up with an aminopropyl column, and derivatized with trifluoroacetic anhydride. Quantitation of the residues of interest is accomplished by high performance liquid chromatography (HPLC) with fluorescence detector. The LOQ varies from .001 ppm for grapes to .004 ppm for chili peppers. Method 91–1 is adequate for data collection purposes. Method 91–1 is somewhat similar to the registrant's method for hops, Method M–036.2, which has been submitted for inclusion in FDA's PAM II. Since they are similar, Method M–036.2 is adequate for tolerance enforcement.

Residues of avermectin B_1 and 8,9-Z avermectin B_1 in cotton gin byproducts were determined using a modification of Method M–078. Samples are extracted with a methanol-water mixture. The avermectins are partitioned into hexane and the hexane extract is purified/concentrated on an NH2 SPE column. The purified extract is derivatized with trifluoroacetic anhydride. The derivatized avermectins are analyzed by reversed phase HPLC with fluorescence detection. The avermectin B_{1a} standard is used to calculate the concentration of avermectin B_{1a} + 8,9-Z avermectin B_{1a} and avermectin B_{1b} + 8,9-Z avermectin B_{1b} in/on the sample. The modifications made to Method M–078 included using a higher HPLC flow rate, preparing the standard solutions at different concentrations, centrifuging the samples with emulsions after shaking, and using equipment, apparatus, and chemical manufacturers which were different from those specified in the method. The limit of detection (LOD) is 0.001 ppm; the LOQ is 0.002 ppm. The method was validated by fortifying control gin trash samples and analyzing them concurrently with the treated and control samples. Method M–078 is very similar to the registrant's method for hops, Method M–036.2, which has been submitted for inclusion in FDA's PAM II. Since they are very similar and method recovery is good, Method M–078 is adequate for enforcement purposes.

Merck Method 32A is available for enforcing avermectin tolerances in bovine tissues and milk. This method has been published in PAM II (Method II).

Avermectin B_1 is not recovered using FDA multi-residue protocol A described in PAM I.

C. Magnitude of Residues

The residue field trial data on grapes submitted with this petition are adequate to support the proposed use. The highest residue found on grapes at the 28–day pre-harvest interval (PHI) was 6.7 ppb (0.007 ppm). This supports the tolerance of 0.02 ppm proposed by the registrant.

The residue field trial data on chili peppers submitted with this petition are adequate to support the proposed use. The highest residue found on chili peppers at the 7– day PHI was < 5 parts per billion (ppb) (< 0.005 ppm). This supports the tolerance of 0.01 ppm on peppers proposed by the registrant. However, the originally submitted Section F lists chili peppers not peppers. In order to harmonize with international residue limits discussed below, the Section F was revised to express the tolerance as 0.02 ppm on peppers.

The grape processing study and existing storage stability database are adequate to support the proposed tolerance on juice. The highest residues found on commodities of regulatory concern were < 2 ppb (< 0.002 ppm) in juice. This supports the requested tolerance of 0.02 ppm on grape juice. However, since the processing study shows that avermectin B_1 does not concentrate in juice, a tolerance on grape juice is not required.

Starting with raw grapes bearing residues of 10 ppb, the highest avermectin B_1 residues found on raisins were 10.2 ppb (0.01 ppm). The results of the raisin storage stability study indicate that the residues in raisins could have been as high as 20 ppb (2x concentration factor, based on < 50% recoveries). Using this concentration factor and the highest grape field trial value of 0.007 ppm, residues in raisins would be 0.014 ppm versus the grape tolerance of 0.02 ppm. Therefore, even taking into account the poor recoveries from the raisin storage stability study, a tolerance for raisins is not necessary. Since tolerances are not needed for processed grape food items, the Section F was revised to express the tolerance as grapes.

There are no chili pepper processed food items; therefore a discussion of processed food items is not germane to this action.

Since there are no grape or pepper animal feed items of regulatory interest, secondary avermectin B_1 residues in meat, milk, poultry, and eggs will not be increased by the proposed tolerances for these crops.

To support the tolerance on cotton gin byproducts, the petitioner has submitted the results of eight field trials on cotton using the maximum labeled rate. The existing storage stability database is adequate to support the cotton gin byproduct analyses. The highest residue level obtained was 0.101 ppm. The PHI was slightly longer than that specified on the label, however. The label specifies a PHI of 20 days; the PHI used in the field trails was 25 days. EPA has concluded that the data support the establishment of a tolerance of 0.15 ppm for the residues of avermectin in/on cotton gin byproducts.

Since cotton gin byproducts are a feed item for some livestock an analysis was performed to calculate the dietary burden in these animals. Cotton gin byproducts are not a feed item for poultry or swine; these commodities were not included in the analysis. Cotton gin byproducts can comprise up to 20% of the diets of both beef and dairy cattle. The following animal feed items are associated with commodities with avermectin registrations: almond hulls, wet apple pomace, dried citrus pulp, cotton seed, potato culls, and potato waste. Of these commodities, cotton seed meal is the only highly nutritive one. The others mainly provide fiber to the diet. Cotton seed meal will be distributed to all parts of the country, but the others will not. Therefore, it is reasonable to construct a dietary burden with cotton seed meal and only one of the other ''esoteric'' feed items. Wet apple pomace would contribute the highest residues to the diet, therefore a dietary burden was constructed using cotton seed meal and apple pomace. The feeding study was done at 3 different feeding levels: 0.010 ppm, 0.030 ppm, and 0.10 ppm. The dietary burden constructed with cotton seed and apple pomace is essentially the same as the highest feeding level: 0.10 ppm. The established tolerances are adequate to cover this dietary burden. As the tolerances will not change, it is not necessary to perform a dietary exposure analysis. EPA concludes that residues present in animal commodities will not increase over current levels. Therefore, it is not necessary to increase the established tolerances for animal commodities. Furthermore, the establishment of a tolerance for cotton gin byproducts does not affect risk to human health as animal commodity tolerances will not be affected by the establishment of this tolerance.

D. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRL) for avermectin B_1 on grapes, grape processed commodities. Therefore, international harmonization is not an issue for the action on grapes.

There are no Canadian or Mexican MRLs for avermectin B_1 on peppers. There is a Codex MRL for avermectin B_{1a}, B_{1b}, (*Z*)-8,9-avermectin B_{1a}, and (*Z*)-8,9-avermectin B_{1b} on sweet peppers at 0.02 ppm. The regulable residues for the U.S. and Codex are identical. In order to harmonize with this MRL, the Section F was revised to express the tolerance for avermectin B_1 and its delta-8.9-isomer as 0.02 ppm on peppers.

There are no Codex, Canadian, or Mexican MRLs for avermectin B_1 on cotton gin by-products. Therefore, international harmonization is not an issue for cotton gin by-products. A Codex MRL has been established for cotton seed: 0.01 ppm. This MRL differs from the proposed permanent tolerance for cotton seed: 0.005 ppm.

E. Rotational Crop Restrictions

Review of the results of the confined rotational crop study indicated that avermectin B_1 residues accumulated in some rotational crops at levels up to 10 – 12 ppb. However, the radioactivity was due to polar degradates that were of little toxicological concern as compared to the parent compound avermectin B_1 and/or the delta-8,9-isomer. Therefore, the requirements for field rotational crop studies have been waived.

V. Conclusion

Therefore, the tolerance is established for combined residues of the insecticide 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 grapes at 0.02 ppm, peppers at 0.02 ppm, and cotton gin byproducts at 0.15 ppm. Furthermore, the following tolerances which were previously time-limited (expiring September 1, 1999) are now made permanent: cattle, fat at 0.015 ppm; cattle, meat byproducts at 0.02 ppm; cattle, meat at 0.02 ppm; citrus, dried pulp at 0.10 ppm; citrus, oil at 0.10 ppm; citrus, whole fruit at 0.02 ppm; cotton seed at 0.005 ppm; hops, dried at 0.20 ppm; milk at 0.005 ppm; and potatoes at 0.005 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-300916 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 November 8, 1999.

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 (1900), Environmental Protection Agency, 401 M St. SW. Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St. SW. Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission be labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' (cite). For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW. Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP–300916, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW. Washington, DC 20460. In person or by courier, bring a copy to the location of the PRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 file format 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. Regulatory Assessment Requirements

This final rule establishes tolerances under section 408(d) of the 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). 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 346a(b)(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). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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 rule in the **Federal Register**. This 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: August 31, 1999.

Richard P. Keigwin, Jr.,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.449 is amended by revising paragraph (a) to read as follows:

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

(a) *General.* Tolerances are established for the combined residues of the insecticide 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 the following commodities:

Commodity	Parts per million
Almonds	0.005
Almond, hulls	0.10
Apples	0.020
Apples, pomace (wet)	0.10
Cattle, fat	0.015
Cattle, mbyp	0.02
Cattle, meat	0.02
Celery	0.05
Citrus, dried pulp	0.10
Citrus, oil	0.10
Citrus whole fruit	0.02
Cotton gin by-products	0.15
Cotton seed	0.005
Cucurbits (cucumbers, mellons, and squashes)	0.005
Grapes	0.02
Hops, dried	0.20
Lettuce, head	0.05
Milk	0.005
Pears	0.02
Peppers	0.02
Potatoes	0.005
Strawberry	0.02
Tomatoes, fresh	0.01
Walnuts	0.005

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[FR Doc. 99–23194 Filed 9–3–99; 8:45 am]

BILLING CODE 6560–50–F

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1806, 1813, 1815, 1835, 1852, and 1872

Implementing Foreign Proposals to NASA Research Announcements on a No-Exchange-of-Funds Basis

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Interim rule with request for comments.

SUMMARY: This is an interim rule to revise the NASA FAR Supplement (NFS) to conform the handling of foreign proposals under NASA Research Announcements (NRAs) with that under Announcements of Opportunity (AOs).

DATES: *Effective Date:* This rule is effective September 7, 1999.

Applicability Date: This rule applies to NRAs and AOs issued on or after September 7, 1999.

Comment Date: Comments should be submitted to NASA at the address shown below on or before November 8, 1999.

ADDRESSES: Interested parties should submit written comments to: Celeste Dalton, NASA Headquarters Office of Procurement, Contract Management Division (Code HK), Washington, DC 20546. Comments may also be submitted by email to celeste.dalton@hq.nasa.gov.

FOR FURTHER INFORMATION CONTACT: Celeste Dalton, (202) 358–1645, email: *celeste.dalton@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

NASA uses NRAs and AOs to solicit research proposals from both U.S. and non-U.S. sources. Because of NASA's policy to conduct research with foreign entities on a cooperative, no-exchange-of-funds basis, NASA does not normally fund foreign research proposals or foreign research efforts that are part of U.S. research proposals. Rather, cooperative research efforts are normally implemented via international agreements between NASA and the foreign entity involved. Thus, foreign proposers, whether as primary proposers or as participants in U.S. research efforts, are expected to arrange for financing for their portion of the research. This rule will implement NASA's policy for NRAs and make it consistent with the existing policy for AOs contained in NASA FAR Supplement (NFS) Part 1872, which requires foreign research to be implemented on a no-exchange-of-funds basis. Additional changes are made to NFS Part 1872 for consistency in the treatment of foreign proposals under NRAs and AOs. Treatment of late proposals under NRAs and AOs is clarified and subcontracting plans (when applicable) are added to the items required of selectees under NRAs. Other editorial changes are made to revise several references to the NASA Office of External Relations.

B. Regulatory Flexibility Act

NASA certifies that this interim rule will not have a significant economic impact on a substantial number of small business entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), because it only affects small business entities in the rare circumstance when such entities team with a foreign entity in response to an NRA.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the NFS do not impose any recordkeeping or information collection requirements, or collections of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

D. Interim Rule

In accordance with 41 U.S.C. 418(d), NASA has determined that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This action is necessary to ensure that NRAs reflect NASA's policy that foreign research be implemented on a no-exchange-of-funds basis, and that foreign proposals received in response to NRAs are handled in accordance with the existing policy for AOs contained in NFS Part 1872. However, pursuant to Public Law 98–577 and FAR 1.501, public comments received in response to this interim rule will be considered in the formation of the final rule.