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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 8, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: June 6, 2003.

Alexis Strauss,

Acting Regional Administrator, Region IX.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(314) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(314) New and amended plan for the following agency was submitted on February 21, 2003, by the Governor's designee.

(i) Incorporation by reference.

(A) Santa Barbara County Air Pollution Control District.

(*1*) Emission Inventories, 1-hour ozone maintenance demonstration, commitments to continue ambient monitoring and to track progress, and contingency measures, as contained in the Final 2001 Clean Air Plan adopted on December 19, 2002.

* * * * *

PART 81—[AMENDED]

■ 1. The authority citation for Part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 81.305, the California Ozone (1–Hour Standard) table is amended by revising the entry for the Santa Barbara-Santa Maria-Lompoc Area: to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA—OZONE (1–HOUR STANDARD)

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Santa Barbara-Santa Maria-Lompoc Area:		Attainment.		
Santa Barbara County	August 8, 2003.			
* * *	*	*	*	*

[1] This date is November 15, 1990, unless otherwise noted.

* * * * *

[FR Doc. 03–17210 Filed 7–8–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0220; FRL–7316–6]

Emamectin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of emamectin and its metabolites in or on *Brassica* leafy vegetables (crop group 5); turnip greens; cotton, undelinted seed; cotton gin byproduct; leafy vegetables (except *Brassica*) (crop group 4); fruiting vegetables (crop group 8); and tomato paste. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin and the associated 8,9-Z isomers in or on milk and fat of cattle, goats, hogs, horses, and sheep; meat byproducts, except liver, of cattle, goats, hogs, horses , and sheep; liver of cattle, goats, hogs, horses, and sheep; and meat of cattle, goat, hogs, horses, and sheep. Syngenta Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) , as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 9, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0220, must be received on or before September 8, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001; telephone number: (703) 308–9423; e-mail address: harris.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop Production (NAICS 111, e.g.)
- Animal Production (NAICS 112, e.g.)
- Food Manufacturing (NAICS 311, e.g.)
- Pesticide Manufacturing (NAICS 32532, e.g.)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0220. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 20, 2002 (67 FR 12990) (FRL–6824–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 7F4845) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The original petition requested that 40 CFR 180.505 be amended by establishing a tolerance for combined residues of the insecticide emamectin benzoate, 4′-epi-methylamino-4′-deoxyavermectin B_1 benzoate (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and a maximum of 10% 4′-epi-methlyamino-4′deoxyavermectin B_{1b} benzoate), and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide in or on the raw agricultural commodities fruiting vegetables (except Cucurbits) group at 0.02 parts per million (ppm), *Brassica* leafy vegetables group at 0.025 ppm, leafy vegetables (except *Brassica*) group at 0.1 ppm, cottonseed at 0.025 ppm, cotton gin byproducts at 0.5 ppm.

Based on the EPA analysis of the residue chemistry and toxicological databases, the petition was subsequently revised to express the tolerance as the combined residues of emamectin, (a mixture of a minimum of 90% 4″-epi-methylamino-4″-deoxyavermectin B_{1a} and maximum of 10% 4″-epi-methylamino-4″-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4″-deoxy-4″-epi-amino-avermectin B_{1a} and 4″-deoxy-4″-epi-amino-avermectin B_{1b}; 4″-deoxy-4″-epi-amino avermectin B_{1a} (AB_{1a}); 4″-deoxy-4″-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4″-deoxy-4″-epi-(*N*-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group 4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses, and sheep at 0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 ppm. Note that the tolerance expression in 40 CFR 180.505 is being changed from emamectin benzoate to emamectin since the enforcement method, Method 244–92–3, Revision 1, analyzes residues of emamectin MAB_1 isomers (not emamectin benzoate), 8,9-ZMA, AB_{1a}, MFB_{1a}, and FAB_{1a} in/on crops.

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) of the FFDCA defines ''safe'' to mean that''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory

requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of emamectin, (a mixture of a minimum of 90% 4″-epi-methylamino-4″-deoxyavermectin B_{1a} and maximum of 10% 4″-epi-methylamino-4″-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4″-deoxy-4″-epi-amino-avermectin B_{1a} and 4″-deoxy-4″-epi-amino-avermectin B_{1b}; 4″-deoxy-4″-epi-amino avermectin B_{1a} (AB_{1a}); 4″-deoxy-4″-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4″-deoxy-4″-epi-(*N*-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group 4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses, and sheep at 0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by emamectin are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	Subchronic-Feeding-Rat MK–0243	Systemic Toxicity NOAEL=2.5 mg/kg/day. Systemic Toxicity LOAEL=5 mg/kg/day based on tremors, hindlimb splaying, urogenital staining, histological changes in brain and spinal cord, sciatic and optic nerves and skeletal muscles in males, emaciation, reduced body weight and reduced food consumption in both sexes.
870.3150	Subchronic-Feeding-Dog MK–0243	Systemic Toxicity NOAEL=0.25 mg/kg. Systemic Toxicity LOAEL=0.50 mg/kg based on microscopic pathological signs of neurotoxicity consisting of skeletal muscle atrophy and white matter multifocal degeneration in the brains of both sexes and white matter multifocal degeneration in the spinal cords of males.
870.3200	21–Day Dermal Toxicity-Rat	No Study Available.
870.3700	Developmental Toxicity-Rat MK–0243	Maternal Toxicity NOAEL=2 mg/kg/day. Maternal Toxicity LOAEL=4 mg/kg/day based on a significant trend towards decreased body weight gain during the dosing period. Developmental Toxicity NOAEL=4 mg/kg/day. Developmental Toxicity LOAEL=8 mg/kg/day based on altered growth and an increased incidence of supernumerary rib.
870.3700	Developmental Toxicity-Rabbit MK–0243	Maternal Toxicity NOAEL=3 mg/kg/day. Maternal Toxicity LOAEL=6 mg/kg/day based on a significant trend towards decreased body weight gain during dosing period and increased clinical signs (mydriasis and decreased pupillary reaction). Developmental Toxicity NOAEL=6 mg/kg/day. Developmental Toxicity LOAEL=Not Determined.
870.3800	Reproductive Toxicity-Rat MK–0244	Systemic Toxicity NOAEL=0.6 mg/kg/day. Systemic Toxicity LOAEL=1.8 mg/kg/day based on decreased body weight gain and histopathological changes (neuronal degeneration in the brain and spinal cord) in both sexes and generations. Reproductive Toxicity NOAEL=0.6 mg/kg/day. Reproductive Toxicity LOAEL=1.8 mg/kg/day based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations.

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

Guideline No.	Study Type	Results
870.4100	Chronic-Feeding-Dog MK–0244	Systemic Toxicity NOAEL= 0.25 mg/kg/day. Systemic Toxicity LOAEL=0.5 mg/kg/day based on axonal degeneration in the pons, medulla and peripheral nerves (sciatic, sural, and tibial) in both sexes, clinical signs of neurotoxicity (whole body tremors, stiffness of the hind legs), spinal cord axonal degeneration, and muscle fiber degeneration in females.
870.4100	Chronic Feeding-Rat MK–0244	Systemic Toxicity NOAEL=1.0 mg/kg/day. Systemic Toxicity LOAEL=2.5 mg/kg/day, based on increased incidence of neuronal degeneration in the brain and spinal cord, decreased rearing, and an increased incidence of animals with low arousal.
870.4200	Carcinogenicity-Mouse (78–week) MK–0244	Systemic Toxicity NOAEL=2.5 mg/kg/day. Systemic Toxicity LOAEL=5.0 mg/kg/day for males and 7.5 mg/kg/day for females based on increased mortality, decreased weight gain, neurological signs, and increased incidence of severity of infections. There were no signs of carcinogenicity in this study.
870.4300	Chronic Toxicity/Carcinogenicity-Rat Emamectin	Systemic Toxicity NOAEL=1.0 mg/kg/day. Systemic Toxicity LOAEL=2.5/5.0 mg/kg/day based on marked neural degeneration in the brain and spinal cord of both sexes, brain white matter degeneration in males, and on decreased body weight, body weight gain, and food efficiency in males. There were no signs of carcinogenicity in this study. Note: The initial dose of the high dose group was 5.0 mg/kg/day. Due to unacceptable weight loss and/or tremors occurring at this dose in another concurrent study (TT#91–006–0) during week 9 in males and week 11 in females, the dose was lowered to 2.5 mg/kg/day starting at week 6 in males and week 10 in females.
870.5100	Gene Mutation - *Salmonella* MK–0243 and L–660,599; L–657,831; L–695,638; L–930,905 (photometabolites of MK–0244)	Negative for the induction of reverse gene mutation
870.5300	Gene Mutation in Cultured V–79 Chinese Hamster Lung Cells MK–0243	Negative for the induction of forward gene mutations in Chinese hamster lung fibroblast cells up to a severely cytotoxic nonactivated dose of 0.01mM or a severely cytotoxic S9-activated dose of 0.04mM.
870.5385	Structural Chromosome Aberration-*in vivo* mouse bone marrowMK–0244	Negative for the induction of chromosome aberrations in the bone marrow cells of male CD–1 mice.
870.5500	DNA Damage-Rat hepatocytes MK–0243	Negative for the induction of single strand breaks (SBs) in DNA of rat hepatocytes.
870.6200	Acute Oral Neurotoxicity -Rat MK–0243	A Neurotoxicity NOAEL was not established, since toxic signs of neurotoxicity as well as histological lesions in the brain, spinal cord and sciatic nerve occurred at all doses tested (27.4, 54.8 or 82.2 mg/kg)
870.6200	Subchronic Neurotoxicity-Rat MK–0243	Neurotoxicity NOAEL=1.0 mg/kg/day. LOAEL=5.0 mg/kg/day (highest dose tested) based on mild tremors, posture, rearing, excessive salivation, fur appearance, gait, strength, mobility and righting reflex.
870.6200	2–Week Dietary Neurotoxicity–CD–1 Mice MK–0243	Neurotoxicity NOAEL=2.0 mg/kg/day (highest dose tested). No characteristic neuronal lesions in the brain, spinal cord or sciatic nerve in mice of high dose group (2.0 mg/kg/day).
870.6200	15–day Dietary Neurotoxicity-CF–1 Mice MK–244	Neurotoxicity NOAEL=0.075 mg/kg/day. LOAEL=0.10 mg/kg/day based on tremors observed beginning on day 3, decreases in body weight and food consumption as well as degeneration of the sciatic nerve.

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

Guideline No.	Study Type	Results
870.6200	Dietary Neurotoxicity-CF–1 Mice L–660,599 Supplementary Study	Neurotoxicity NOAEL <0.1 mg/kg/day. One of the low-dose males had tremors, hunched posture and piloerection on day 14.
870.6300	Developmental Neurotoxicity-Rat MK–0244	Maternal Toxicity NOAEL=3.6/2.5 mg/kg/day (highest dose tested). Developmental Neurotoxicity NOAEL=0.10 mg/kg/day (lowest dose tested). The LOAEL is 0.60 mg/kg/day based on the dose-related decrease in open field motor activity in females at postnatal day 17.
870.7485	Metabolism-Rat MAB_{1a}	Radiolabeled MAB_{1a} benzoate is rapidly absorbed, distributed and excreted following oral and i.v. administration. The feces was the major route of excretion in oral and i.v. groups, while <1% of the administered dose was recovered in the urine 7 days post dosing. Tissue distribution and bioaccumulation appeared minimal. The metabolism of MAB_{1a} benzoate appears to involve primarily *N*-demethylation to AB_{1a}. AB_{1a} was the only metabolite detected in the feces while unmetabolized parent compound represented a large amount of the radioactivity.
870.7485	Bioequivalence-Dog MK–0243 solvate/monohydrate	The study demonstrated that MK–0243 benzoate MTBE solvate and MK–0243 benzoate monohydrate were bioequivalent in male dogs following oral administration as indicated by similar plasma levels for the two compounds.
870.7485	Bioequivalence-Dog MK–0243 benzoate/HCL salts	The study demonstrated that benzoate and HCl salts are bioequivalent after oral administration in male beagle dogs.
870.7600	Dermal Absorption-Rhesus Monkey MAB_{1a}, MK–244	Dermal Absorption was approximated at 1.79% of the administered dose.

Key: MK–0243 = hydrochloride (adduct) or salt of emamectin; MK–0244 = benzoic acid (adduct) or salt of emamectin.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

As explained below in Unit III.D.3, EPA determined that the special FQPA SF be reduced to 1x. However, EPA also determined that an additional 3x Modifying Uncertainty Factor (UF_M) is required for application of the endpoint (based on the 15–day mouse neurotoxicity study) to acute- and short-term scenarios, to account for the steepness of the dose-response curve and the severity of effects at the LOAEL (death and neuropathology). A 3x UF_M was judged to be adequate (as opposed to a 10X) because: (1) A NOAEL was established in this study; (2) although the effects of concern are seen after repeated dosing, the NOAEL here is used for a single exposure risk assessment; and (3) the most sensitive endpoint in the most sensitive species is selected. For intermediate- and chronic/long-term scenarios, EPA determined that a 10x UF_M is required to account for steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for long-term risk assessment.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic population adjusted dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of

departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for emamectin used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR EMAMECTIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All populations)	NOAEL = 0.075 mg/kg/day UF = 300 Acute RfD = 0.00025 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD/ FQPA SF = 0.00025 mg/kg/day	15-day mouse LOAEL = 0.1 mg/kg/day based tremors on day 3 of dosing.
Chronic Dietary (All populations)	NOAEL= 0.075 mg/kg/day UF = 1,000 Chronic RfD = 0.000075 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.000075 mg/kg/day	15-day mouse LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Short-Term Incidental Oral (1–30 days)	Toxicological endpoints were not selected since there are no residential uses at the present time and thus no potential exposure via this scenario.		
Intermediate-Term Incidental Oral (1–6 months)	Toxicological endpoints were not selected since there are no residential uses at the present time and thus no potential exposure via this scenario		
Short-Term Dermal (1 to 30 days)	Oral study NOAEL= 0.075 mg/kg/day (dermal absorption rate = 1.8 %)	Occupational LOC for MOE = 300 Residential LOC for MOE: N/A	15–day mouse LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Intermediate-Term Dermal (1 to 6 months)	Oral study NOAEL= 0.075 mg/kg/day (dermal absorption rate = 1.8 %)	Occupational LOC for MOE = 1,000 Residential LOC for MOE: N/A	15–day mouse LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Long-Term Dermal (>6 months)	Long term dermal exposure is not expected and there are no residential uses at the present time. Therefore, quantification of risk is not required.		
Short-Term Inhalation (1 to 30 days)	Oral study NOAEL= 0.075 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = 300 Residential LOC for MOE: N/A	15-day mouse LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Intermediate-Term Inhalation (1 to 6 months)	Oral study NOAEL= 0.075 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = 1,000 Residential LOC for MOE: N/A	15–day mouse LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Long-Term Inhalation (>6 months)	Not required; long term occupational exposure is not expected and there are no residential uses at the present time. Therefore, quantification of risk is not required.		

*The reference to the special FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.505) for the combined residues of emamectin and its metabolites, in or on a variety of raw agricultural commodities and livestock. Tolerances range from 0.002 to 0.05. Risk assessments were conducted by EPA to assess dietary exposures from emamectin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A highly refined, Tier 3, acute dietary exposure assessment was conducted for the general U.S. population and various population subgroups. This was a probabilistic assessment using anticipated residue estimates from the

current and previously submitted field trial data as well as EPA percent crop treated (PCT) estimates for a number of commodities. PCT estimates used were 1% for cotton commodities; 52% for head lettuce; 2.5% for the subgroup 4A (leafy greens); 20% for the subgroup 4B (leaf petioles), the group 5 (*Brassica* leafy vegetables), and peppers; and 11% for tomatoes and its processing commodities. Anticipated residues were used for group 5 (*Brassica* leafy vegetables), group 4 (leafy vegetables (except *Brassica*)), and group 8 (fruiting vegetables). The calculation of anticipated residues for tomatoes (a representative commodity in group 8) used the following approach: For residues of MAB_{1a} and MAB_{1b} which were below the limit of detection (< LOD), calculation was based on the MAB_{1a} and MAB_{1b} ratio of 9:1; a residue value of 0.0005 ppm (½ LOD) for MAB_{1a} and a residue value of 0.000055 ppm (1/9 of the ½ LOD or 1/18 LOD) for MAB_{1b} was reported in the assessment. For residues of L'649 and (L'599 + L'831), a residue value of 0.0005 ppm (the ½ LOD) was reported if residues were below the limit of detection (<LOD). Anticipated residue levels of 0.0003 ppm for milk and skim milk, and 0.0009 ppm for cream were used. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM® (version 7.76) concentration factors were used when necessary.

The acute dietary exposure estimates are below EPA's level of concern (< 100% aPAD) at the 99.9th exposure percentile for the general U.S. population (29% of the aPAD) and all other population subgroups. The most highly exposed population subgroup is children 3–5 years old, at 58% of the aPAD. The acute assessment was highly refined, however, inclusion of additional PCT data and modified concentration/processing factors could aid in further refining the acute dietary assessment.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food-form is summed with the residue consumption estimates for all other food/food-forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup. A somewhat refined Tier 2 chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The assumptions of the assessment were tolerance level residues for all commodities except milk (for which anticipated residue estimates were used), and PCT estimates for a number of commodities. PCT estimates used were 0.4% for cotton commodities; 26% for head lettuce; 1.5% for the subgroup 4A (leafy greens); 10% for the subgroup 4B (leaf petioles), the group 5 (*Brassica* leafy vegetables), and peppers; and 6% for tomatoes and its processing commodities. Anticipated residue levels of 0.0003 ppm for milk and skim milk, and 0.0009 ppm for cream were used. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM® (version 7.76) concentration factors were used when necessary.

The chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population (19% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1–2 years old, at 34% of the cPAD. The chronic assessment was somewhat refined; inclusion of ARs, additional PCT information, and modified concentration/processing factors would further refine the chronic dietary assessment.

iii. *Cancer*. Emamectin is classified as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must 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) of the FFDCA, 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) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as detailed above under Unit III.C.1.i and III.C.1.ii Different PCTs and anticipated residues were used for the acute versus the chronic dietary risk from food and feed uses as explained in these units.

The Agency believes that the three conditions listed in Unit III.C.1.iv have been met. With respect to Condition 1, PCT estimates for existing registrations are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and 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, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. For new uses, PCT

estimates are based on the use of existing alternative insecticides against insects that emmamectin will control. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which emamectin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for emamectin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of emamectin.

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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

Refined (Tier II) surface water concentrations were developed for emamectin and its metabolites with the PRZM/EXAMS model, using an index reservoir scenario for the aerial and ground applications of emamectin on cotton. The model assumes that emamectin is applied at the maximum label rate (0.015 lb active ingredient/acre with a maximum of 0.09 lb active ingredient/acre/season for the dispersable granule; and 0.016 lb active ingredient/acre with a maximum of 0.064 lb active ingredient/acre/season for the emulsifiable concentrate). The results indicate that emamectin and its metabolites have a very low potential to reach surface waters as dissolved species. However, emamectin does have the potential to reach surface water bodies through erosion of soil particles to which the compound is sorbed. One percent of the application rate is assumed to drift from the application site during ground application. For the additional proposed aerial application, 5% of the application rate is assumed to drift from the application site to water bodies.

Surface water and ground water EECs are based on the PRZM/EXAMS and SCI-GROW models respectively. The EECs of emamectin for acute exposure are estimated to be 0.298 parts per billion (ppb) for surface water from aerial application and 0.293 ppb for surface water from ground application. The EEC for chronic exposure is estimated to be 0.080 ppb for surface water. Ground water EECs are based on the Tier I SCI-GROW model. The EEC of emamectin for both acute and chronic exposure is estimated to be 0.006 ppb for ground water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this preamble to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Emamectin is not registered for use on any sites that would result in residential exposure.

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

EPA does not have, at this time, available data to determine whether emamectin 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, emamectin 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 emamectin 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. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. EPA concludedthat there is low concern, and no residual uncertainty, for pre- and/or postnatal toxicity resulting from exposure to emamectin, based on the following:

i. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative evidence of increased susceptibility of rat offspring in the two generation reproduction study, however, an increase in qualitative susceptibility was determined. EPA determined that the concern is low because:

(a) There was a clear NOAEL for offspring toxicity.

(b) Effects unique to offspring (decreased fertility in F_1 adults, and clinical signs (tremors and hind limb extensions during and following lactation)) were seen at the same dose that caused parental systemic toxicity (decreased body weight gain and histopathological lesions in the brain and spinal cord).

(c) The decreased fertility seen in F_1 adults may have been due to histopathological lesions in the brain and central nervous system (seen in both F_0 and F_1 generations), rather than due to a direct effect on the reproductive system.

ii. There is evidence of increased qualitative and quantitative susceptibility in the rat developmental neurotoxicity study, but EPA determined that the concern is low because: Although multiple offsping effects (including decreased pup body weight, head and body tremors, hind limb extension and splay, changes in motor activity and auditory startle) were seen at the highest dose, and no maternal effects were seen at any dose, there was a clear NOAEL for offspring toxicity at the low dose, and the offspring LOAEL (at the mid dose) is based on a single effect seen on only one day (decreased motor activity on PND 17) and no other offspring toxicity was seen at the LOAEL.

3. *Conclusion*. EPA concluded that the toxicology database was complete for FQPA purposes and that there are no residual uncertainties for pre-/post-natal toxicity. Based on the quality of the data, EPA determined that the special FQPA SF should be reduced to 1x. However, as explained in Unit III.3.B. of this preamble, EPA determined that an additional 3x or 10x modifying uncertainty factor should be used for short-term or intermediate-term exposure, respectively. The recommendation for the 1x FQPA SF is based on the following:

- The toxicological database is complete for FQPA assessment.
- The acute dietary food exposure assessment utilizes anticipated residue estimates based on carefully reviewed field trial data and PCT data verified by EPA for several commodities (100% crop treated was assumed for remaining commodities). By using the 99.9th percentile exposure values for comparison to the aPAD, actual risks are not likely to be underestimated.
- The chronic dietary food exposure assessment utilizes tolerance level residue estimates and PCT data verified by EPA for several commodities (100% crop treated was assumed for remaining commodities). This assessment is somewhat refined and based on reliable data that is not likely to underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are no proposed or existing residential uses for emamectin.

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure (at the 99.9th percentile) from food to emamectin will occupy 29% of the aPAD for the U.S. population, 23% of the aPAD for females 13 years and older, 51% of the aPAD for all infants (<1 year old) and 58% of the aPAD for children 3–5 years old. In addition, there is potential for acute dietary exposure to emamectin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO EMAMECTIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.00025	29	0.298	0.006	6.2
All infants (< 1 year old)	0.00025	51	0.298	0.006	1.2
Children (1–2 years old)	0.00025	50	0.298	0.006	1.3
Children (3–5 years old)	0.00025	58	0.298	0.006	1.0
Children (6–12 years old)	0.00025	36	0.298	0.006	1.6
Youth (13–19 years old)	0.00025	27	0.298	0.006	6.4
Adults (20–49 years old)	0.00025	20	0.298	0.006	7.0
Females (13–49 years old)	0.00025	23	0.298	0.006	5.8
Adults (50+ years old)	0.00025	22	0.298	0.006	6.9

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to emamectin from food will utilize 19% of the cPAD for the U.S. population, 17% of the cPAD for females 13 years and older, 9% of the cPAD for all infants (<1 year old) and 34% of the cPAD for children 1–2 years old. There are no residential uses for emamectin that result in chronic residential exposure to emamectin. In addition, there is potential for chronic dietary exposure to emamectin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO EMAMECTIN

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.000075	19	0.080	0.006	2.1
All infants (< 1 year old)	0.000075	9	0.080	0.006	0.68
Children (1–2 years old)	0.000075	34	0.080	0.006	0.49
Children (3–5 years old)	0.000075	31	0.080	0.006	0.52
Children (6–12 years old)	0.000075	23	0.080	0.006	0.58
Youth (13–19 years old)	0.000075	17	0.080	0.006	2.2
Adults (20–49 years old)	0.000075	17	0.080	0.006	2.2
Females (13–49 years old)	0.000075	17	0.080	0.006	1.9
Adults (50+ years old)	0.000075	16	0.080	0.006	2.2

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Emamectin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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

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

5. *Aggregate cancer risk for U.S. population*. Emamectin is classified as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical. Therefore, EPA does not expect it to pose a cancer risk. As a result, a quantitative cancer dietary exposure analysis was not performed.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method (HPLC-fluorescence) for the enforcement of tolerances for residues of emamectin and its metabolites in/on plant commodities has been validated by EPA

and submitted to the FDA for inclusion in the Pesticide Analytical Manual (PAM) Vol. II. In addition, an analytical method (HPLC-fluorescence) for the enforcement of tolerances for residues of emamectin and its metabolites in/on ruminant commodities has been submitted to EPA for review. The ruminant method has been validated by an independent laboratory but EPA validation is required as a condition of registration.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican maximum residue limits on emamectin or its metabolites.

C. Conditions

The following studies must be submitted as conditions for product registrations related to these tolerances: A storage stability study for cotton seed, gin byproducts, and processed commodities which reflect the storage intervals and conditions of the submitted field trial and processing studies; additional storage stability studies to support 19 month storage intervals for bell pepper and tomatoes; a new tomato processing study with tomatoes treated at an exaggerated rate (up to 5x the maximum proposed seasonal application rate); three additional spinach field trials conducted in Regions X, VI, and II (one study each) based on OPPTS Guidelines 860.1500; and a 28–day inhalation study using the CF–1 mouse. In addition, a successful method validation by EPA is required for the high performance liquid chromatography-fluorescence method submitted for residues in ruminant commodities; the registrant is required to make any necessary modifications resulting from the EPA method review.

V. Conclusion

Therefore, the tolerance is established for combined residues of emamectin, (a mixture of a minimum of 90% 4″-epi-methylamino-4″-deoxyavermectin B_{1a} and maximum of 10% 4″-epi-methylamino-4″-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4″-deoxy-4″-epi-amino-avermectin B_{1a} and 4″-deoxy-4″-epi-amino-avermectin B_{1b}; 4″-deoxy-4″-epi-amino avermectin B_{1a} (AB_{1a}); 4″-deoxy-4″-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4″-deoxy-4″-epi-(*N*-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group 4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses , and sheep at 0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 ppm. Note that the tolerance expression in 40 CFR 180.505 is being changed from emamectin benzoate to emamectin since the enforcement method, Method 244–92–3, Revision 1, analyzes residues of emamectin MAB_1 isomers (not emamectin benzoate), 8,9-ZMA, AB_{1a}, MFB_{1a}, and FAB_{1a} in/on crops.

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0220 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 September 8, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 by 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.'' 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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request

with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0220, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 30, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.505 is revised to read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of emamectin, (a mixture of a minimum of 90% 4″-epi-methylamino-4″-deoxyavermectin B_{1a} and maximum of 10% 4″-epi-methylamino-4″-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4″-deoxy-4″-epi-amino-avermectin B_{1a} and 4″-deoxy-4″-epi-amino-avermectin B_{1b}; 4″-deoxy-4″-epi-amino avermectin B_{1a} (AB_{1a}); 4″-deoxy-4″-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4″-deoxy-4″-epi-(*N*-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on the following commodities:

Commodity	Parts per million
Cotton, gin byproduct	0.050
Cotton, undelinted seed	0.025
Tomato, paste	0.150
Turnip, greens	0.050
Vegetable, *Brassica*, leafy, group 5	0.050
Vegetable, fruiting, group 8	0.020
Vegetable, leafy, except *Brassica*, group 4	0.100

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

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

(d) *Indirect and inadvertant residues.* Tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on the following commodities when present therein as a result of the application of emamectin to crops listed in the table to paragraph (a) of this section:

Commodity	Parts per million
Cattle, fat	0.003
Cattle, liver	0.020
Cattle, meat	0.002
Cattle, meat byproducts (except liver)	0.005
Cattle, milk	0.003
Goats, fat	0.003
Goats, liver	0.020
Goats, meat	0.002
Goats, meat byproducts (except liver)	0.005
Goats, milk	0.003
Hogs, fat	0.003
Hogs, liver	0.020
Hogs, meat	0.002
Hogs, meat byproducts (except liver)	0.005
Hogs, milk	0.003
Horses, fat	0.003
Horses, liver	0.020
Horses, meat	0.002
Horses, meat byproducts (except liver)	0.005
Horses, milk	0.003
Sheep, fat	0.003
Sheep, liver	0.020
Sheep, meat	0.002
Sheep, meat byproducts (except liver)	0.005
Sheep, milk	0.003

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0134; FRL–7303–6]

Diallyl Sulfides; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of diallyl sulfides (DADs) in/on garlic, leeks, onions, and shallots. Platte Chemical Company submitted a petition to EPA under section 408(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DADs in/on garlic, leeks, onions, and shallots.

DATES: This regulation is effective July 9, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0134, must be received on or before September 8, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: By mail: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *Benmhend.driss@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:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0134. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://*