27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 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**. 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: May 6, 1999.

Susan B. Hazen,

Acting Director, 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 180.552 is added to subpart C to read as follows:

§ 180.552 Sulfosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide sulfosulfuron, 1–(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl) sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron in or on the raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.005
Cattle, meat	0.005
Cattle, meat by-products	0.05
Goat, fat	0.005
Goat, meat	0.005
Goat, meat by-products	0.05
Horse, fat	0.005
Horse, meat	0.005
Horse, meat by-products	0.05
Milk	0.006
Sheep, fat	0.005
Sheep, meat	0.005
Sheep, meat by-products	0.05
Swine, fat	0.005
Swine, meat	0.005
Swine, meat by-products	0.05
Wheat, forage	4.0
Wheat, grain	0.02
Wheat, hay	0.3
Wheat, straw	0.1

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99–12247 Filed 5–18–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300856; FRL–6079–7]

RIN 2070–AB78

Emamectin Benzoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes 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 (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) (CAS No. 137512–74–4) in or on Brassica, head & stem subgroup (5-A), head lettuce and celery. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 19, 1999. Objections and requests for hearings must be received by EPA on or before July 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300856], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300856], must also be submitted 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, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300856]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 206, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–6100, larocca.george@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1997 (62 FR 35804) (FRL–5722–9), 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) (Pub. L. 104–170) announcing the filing of a pesticide petition (6F4628) for tolerance by Novartis Crop Protection, Inc., P.O Box 18300, Greensboro, NC 27419–8300. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The 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 (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}), in or on Brassica, head & stem subgroup (5-A), head lettuce and celery at 0.025 ppm part per million (ppm). Emamectin benzoate controls a broad spectrum of lepidopterous insects (including beet army worm, diamond back moths, cabbage loopers and fall army worms.

I. Background and Statutory Findings

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).

II. 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 emamectin benzoate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of 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 (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) on Brassica, head & stem subgroup (5-A), head lettuce and celery at 0.025 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 emamectin benzoate are discussed in this unit.

1. Acute toxicology studies classify technical grade emamectin as having moderate acute toxicity and as being a severe eye irritant (Toxicity Category I). Emamectin falls into Toxicity Category 2 and 3 for acute oral and dermal toxicity, respectively. Emamectin did not cause dermal irritation and is not a dermal sensitizer.

2. A 13-week feeding study in rats resulted in a systemic toxicity no observable adverse effect level (NOAEL) of 2.5 mg/kg/day and a systemic toxicity lowest observable adverse effect level (LOAEL) of 5 mg/kg/day, based on tremors, hind limb 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.

3. A 14-week feeding study in dogs resulted in a systemic toxicity NOAEL of 0.25 mg/kg/day and a systemic toxicity LOAEL of 0.50 mg/kg/day, based on microscopic pathological signs of neurotoxicity consisting of skeletal muscle atrophy and white matter multi focal degeneration in the brains of both sexes and white matter multi focal degeneration in the spinal cords of males.

4. A chronic feeding study in rats resulted in a systemic toxicity NOAEL of 1.0 mg/kg/day and a systemic toxicity LOAEL of 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.

5. A chronic feeding study in dogs resulted in a systemic toxicity NOAEL of 0.25 mg/kg/day. The systemic toxicity LOAEL was 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.

6. A 2–year chronic/carcinogenicity study is rats was conducted. The systemic toxicity NOAEL was 1.0 mg/kg/day. The systemic toxicity LOAEL was 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.

7. A 78–week carcinogenicity mouse study resulted in a systemic toxicity NOAEL of 2.5 mg/kg/day and a systemic toxicity LOAEL of 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 and severity of infections. There were no signs of carcinogenicity in this study.

8. A developmental toxicity study in rabbits was conducted. The maternal toxicity NOAEL was 3 mg/kg/day. The maternal toxicity LOAEL was 6 mg/kg/day, based on a significant trend towards decreased body weight gain during the dosing period and increased clinical signs (mydriasis and decreased pupillary reaction). The developmental toxicity NOAEL was 6 mg/kg/day, however, the developmental toxicity LOAEL was not determined.

9. A developmental toxicity study in rats was conducted. The maternal toxicity NOAEL was 2 mg/kg/day. The maternal toxicity LOAEL was 4 mg/kg/day, based on a significant trend towards decreased body weight gain during the dosing period. The developmental toxicity NOAEL was 4 mg/kg/day. The developmental toxicity LOAEL was 8 mg/kg/day, based on altered growth and an increased incidence of supernumerary rib.

10. A 2–generation reproduction study in rats was conducted. The systemic toxicity NOAEL was 0.6 mg/kg/day. The systemic toxicity LOAEL of 1.8 mg/kg/day was based on decreased body weight gain and histopathological changes (neuronal degeneration in the brain and spinal cord) in both sexes and generations. The reproductive toxicity NOAEL was 0.6 mg/kg/day. The reproductive toxicity LOAEL of 1.8 mg/kg/day was based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations.

11. An acute neurotoxicity study was conducted in rats. 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).

12. A subchronic neurotoxicity study was conducted in rats. The neurotoxicity NOAEL was 1.0 mg/kg/day. The neurotoxicity LOAEL was 5.0 mg/kg/day (highest dose tested) based on mild tremors, posture, rearing, excessive salivation, fur appearance, gait, strength, mobility and righting reflex.

13. A dietary neurotoxicity study was conducted with CD–1 mice. The neurotoxicity NOAEL was 2.0 mg/kg/day (highest dose tested). No characteristic neuronal lesions were observed in the brain, spinal cord or sciatic nerve in mice of high dose group (2.0 mg/kg/day).

14. A dietary neurotoxicity study was conducted with CF–1 mice. The neurotoxicity NOAEL was less than 0.1 mg/kg/day. One of the low-dose males had tremors, hunched posture and piloerection on day 14.

15. A dietary neurotoxicity study was conducted with CF–1 mice. The neurotoxicity NOAEL was 0.075 mg/kg/day. The LOAEL was 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.

16. A developmental neurotoxicity study in rats was conducted. The maternal toxicity NOAEL was 3.6/2.5 mg/kg/day (highest dose tested). The developmental neurotoxicity NOAEL was 0.10 mg/kg/day (lowest dose tested). The LOAEL was 0.60 mg/kg/day based on the dose-related decrease in open field motor activity in females at postnatal day 17. This study was the basis of EPA's conclusion that emamectin demonstrated increased susceptibility.

17. All required mutagenicity studies were conducted and found to be negative.

18. A metabolism study in rats was conducted. Radiolabeled MAB_{1a} benzoate was rapidly absorbed, distributed and excreted following oral and intravenus (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.

19. Two bioequivalence studies were conducted with dogs. The first 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. The second study demonstrated that benzoate and HCl salts are bioequivalent after oral administration in male beagle dogs.

20. A repeated-dose dermal toxicity study was conducted in rabbits using the 0.16 EC formulation (Proclaim). The NOAEL was 100 mg/kg/day. The LOAEL was 250 mg/kg/day, based on systemic effects based on axonal degeneration of the sciatic nerve in both sexes (and possibly spinal cord axonal degeneration in one male).

21. A dermal absorption study was conducted. A group of 4 male Rhesus monkeys received a dermal application of 0.8 mCi. H3–MAB1A and 300 µg of MK–244 on a shaved portion of the forearm. Blood and excreta were collected for 26 days following treatment. Dermal absorption was minimal and was approximately 1.79% of the administered dose. The dermal absorption factor is 1.8%

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, an acute Reference Dose (RfD) of 0.00075 mg/kg/day has been selected, based on the NOAEL of 0.075 mg/kg/day from a 15–day neurotoxicity study in mice and an uncertainty factor of 100 (10X for inter-species differences extrapolation and 10X for intra species variability). The endpoint is based on tremors observed beginning on day 3 at the LOAEL of 0.10 mg/kg/day.

2. *Short- and intermediate-term toxicity*. For dermal and inhalation risk assessments, the oral NOAEL of 0.075 mg/kg/day from the 15–day neurotoxicity study in mice was used for the short and intermediate-term exposure scenarios because the neurotoxic clinical signs in mice were seen 3–5 days after dosing, which is appropriate for the short term exposure period of concern, and the toxicological profiles of emamectin benzoate and it metabolites indicated that mice are the most sensitive species. The intermediate-term exposure endpoint was based on tremors on day 3 of dosing, mortality (moribund sacrifices), clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve at the LOAEL of 0.10 mg/kg/day.

Since an oral NOAEL was selected for a dermal and inhalation risk assessment, a rate of 1.8% for dermal absorption and 100% for inhalation absorption was used when converting dermal and

inhalation exposures to oral equivalents. Dermal and inhalation risk assessments are necessary only for short-and intermediate-term exposures. The current use pattern does not indicate the need for a Long-Term dermal or inhalation exposure risk assessment.

3. *Chronic dietary toxicity*. EPA has established the chronic RfD for emamectin benzoate at 0.00025 mg/kg/day. The RfD is based on the NOAEL of 0.075 mg/kg/day, from the 15–day neurotoxicity study in mice and an uncertainty factor of 300 (10X for inter-species differences extrapolation and 10X for intra species variability and 3X for use of a study of short duration). The endpoint is based on mortality (moribund sacrifices), clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve at the LOAEL of 0.10 mg/kg/day.

4. *Carcinogenicity*. Emamectin benzoate was classified as a ''not likely'' human carcinogen. This classification was based on the lack of evidence of carcinogenicity in male and female rats/mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical.

C. Exposures and Risks

1. *From food and feed uses*. There are currently no permanent tolerances for emamectin benzoate in/on raw agricultural commodities. A time-limited temporary tolerance was established for cabbage (head and Napa) at 0.025 ppm under FIFRA section 18 emergency exemptions. The tolerance expired on December 31, 1998.

For the dietary risk assessment, chronic analysis used tolerance level residues and percent crop treated data at 25% for all commodities. Thus this risk assessment should be viewed as highly refined. Further refinement using anticipated residue values would result in a lower estimate of chronic dietary exposure.

As a result of the retention of the FQPA safety factor, EPA will consider the population-adjusted-doses (PAD) for infants, children and females 13 years and older to be 0.00025 mg/kg/day for acute and 0.000083 mg/kg/day for chronic dietary exposure. For other populations (i.e., adult males). exposures will be compared to the acute and chronic RfDs, 0.00075 mg/kg/day and 0.00025 mg/kg/day, respectively.

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 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 PCT information as follows:

A routine chronic dietary exposure analysis for Brassica, head & stem subgroup (5-A), head lettuce and celery was based on 25% PCT. For this action, residues were highly refined: 25% crop treated was assumed, along with residue levels at ½ the limit of quantitation. Since emamectin is a new chemical, it is unlikely that it would be used on 25% of crops. Although dietary risk was not calculated based on the assumption of 100% crop treated, EPA is confident that the estimate of percent of crop treated which was used, 25%, is an over estimate, and does not expect more than 25% of any crop to be treated with emamectin.

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. EPA finds that the PCT information is reliable and has a valid basis. Before the petitioner can increase production of product for treatment of greater than a maximum of 0.09 lb ai/acre/season, permission from the Agency must be obtained. 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 emamectin benzoate in a particular area. Risk assessments were conducted by EPA to assess dietary exposures from emamectin benzoate as follows:

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. An acute dietary risk assessment was performed for emamectin benzoate. EPA used Dietary Exposure Evaluation Model (DEEM) software to conduct an acute dietary analysis and used the acute RfD of 0.00075 mg/kg/day from the 15–day mouse study and the acute PAD of 0.00025 mg/kg/day for subgroups of concern (infants, children and females 13+). The DEEM detailed acute analysis estimates the distribution of single exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–1991 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of emamectin in the commodity supply.

EPA is generally concerned with acute exposures that exceed 100% of the PAD or RfD. For the population subgroups of concern, infants, children and females 13 years and older, the estimated 99.9th percentile of acute dietary exposure occupies 8% of the PAD, 65% of PAD and 27% of PAD, respectively.

ii. *Chronic exposure and risk*. A chronic dietary risk assessment was performed for emamectin benzoate. The analysis used the chronic RfD of 0.00025 mg/kg/day and the chronic PAD of 0.000083 mg/kg/day for subgroups of concern. Tolerance level residues and 25% of crop treated information were

used. EPA is generally concerned with chronic exposures that exceed 100% of the chronic RfD or PAD. For the population subgroups of concern, infants, children and females 13 years and older, the estimated exposure occupies < 1% of PAD, 5% of PAD and 5% of PAD, respectively.

2. *From drinking water.* No Maximum Contaminant Level or health advisory levels have been established for residues of emamectin benzoate in drinking water.

EPA does not have monitoring data available to perform a quantitative drinking water risk assessment for emamectin at this time. However, Environmental Fate data for this compound indicates that emamectin benzoate and its metabolites would be expected to be relatively immobile in the environment due to the high degree of sorption to particles.

EPA used its Screening Concentration in Ground Water (SCI-GROW) screening model and environmental fate data to determine the estimated environmental concentration (EEC) for emamectin benzoate in ground water. The Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model was used to determine the EECs for emamectin benzoate in surface water. The EEC for emamectin benzoate in ground water was 6 ppt (parts per trillion) when applied at the maximum recommended application rate of 0.015 lbs ai/acre with a maximum of six applications. The EECs for surface water range from the peak concentration of 107.22 ppt to the 90 day average of 24.13 ppt when applied at the maximum label rate of 0.015 lb ai/acre and maximum of 0.09 lb ai/acre/season. The computer generated EECs represent conservative estimates and should be used only for screening.

The ground and surface water exposure estimates were calculated from the use of emamectin on cabbage. The drinking water values were calculated for the parent compound, emamectin; however, based on an evaluation of available data, these values can be considered to include both emamectin and its metabolites AB_{1a}, MFB_{1a}, and FAB_{1a}. These estimates were compared to back-calculated Drinking Water Levels of Comparison (DWLOCs) for emamectin for risk assessment purposes.

A 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.

i. *Acute exposure and risk.* The Agency has calculated the DWLOC for acute exposure to emamectin benzoate in drinking water for various population subgroups. The DWLOC's for emamectin benzoate (acute exposure) are summarized in the following table 1.

TABLE 1.— SUMMARY OF ACUTE DWLOC CALCULATIONS

Population Subgroup[1]	Acute Scenario					
	Acute PAD (mg/kg/day)	Acute Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)[2]	SCI-GROW (µg/L)	PRZM/EXAMS (ppb)	DWLOC(µg/L)
U.S. Population	0.00025	0.000078	0.000172	0.006	0.107	6
Children (1–6 years)	0.00025	0.000163	0.000087	0.006	0.107	1
Females 13+ years/nursing	0.00025	0.000067	0.000183	0.006	0.107	5

[1] Population subgroups chosen were U.S. population (70 kg. body weight assumed), and the two children subgroups with the highest food exposure (10 kg. body weight assumed).
[2] Maximum Water Exposure (mg/kg/day) = Acute PAD (mg/kg/day) - ARC from DEEM (mg/kg/day)

ii. *Chronic exposure and risk.* The Agency has calculated DWLOCs for chronic (non-cancer) exposure to emamectin benzoate and its metabolites for the U.S. population and selected subgroups. The DWLOCs for emamectin benzoate are summarized in the following table 2.

TABLE 2.— SUMMARY OF CHRONIC DWLOC CALCULATIONS

Population Subgroup[1]	Chronic Scenario					
	Chronic PAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)[2]	SCI-GROW (µg/L)[3]	PRZM/EXAMS (ppb)	DWLOC(µg/L)
U.S. Population	0.000083	0.000003	0.00008	0.0006	0.0203	3
Children (1–6 years)	0.000083	0.000004	0.00008	0.0006	0.0203	1
Females (13+ years)	0.000083	0.000004	0.00008	0.0006	0.0203	2

[1] Population subgroups chosen were U.S. population (70 kg. body weight assumed), the infant or children subgroup with the highest food exposure (10 kg. body weight assumed), and females 13+ (60 kg body weight assumed).
[2]Maximum Water Exposure (mg/kg/day) = Chronic RfD (mg/kg/day) - ARC from DEEM (mg/kg/day)
[3] The crop producing the highest level was used.

The estimated maximum concentrations of emamectin and its metabolites in surface and ground water are less than the DWLOCs as a contribution to acute and chronic aggregate exposure. The estimated concentrations of emamectin and its metabolites in ground and surface water are conservative estimates. Therefore, the Agency concludes with reasonable certainty that residues of emamectin in food and drinking water would not result in an unacceptable estimate of acute or chronic (non-cancer) aggregate human health risk at this time.

3. *From non-dietary exposure.* There are no registered or proposed residential uses for emamectin benzoate. Therefore, there is no risk associated with non-dietary 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.''

Emamectin benzoate is synthetically derived from avermectin, which is derived from the antibiotic-producing actinomycetes, the source of all of the antibiotic fungicides. *Streptomyces avermitilus* produces the insecticide avermectin, which is a mixture of two homologs, avermectin B_{1a} and B_{1b}, which have equal biological activity. Currently, the only member of this class which is registered for agricultural uses is avermectin. Avermectin and ivermectin are structurally similar to emamectin. EPA does not have at this time available data to determine whether emamectin benzoate 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 upon a common mechanism, emamectin benzoate does not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action therefore, EPA has not assumed that emamectin benzoate has a common mechanism of toxicity with these other substances. An explanation of the current Agency approach to assessment of pesticides with a common mechanism of toxicity may be found in the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Exposure to emamectin benzoate residues in food will occupy no more than 31% of the acute PAD for adult population subgroups and no more than 65% PAD for infant/children subgroups. Residue levels used for food-source dietary risk assessments were highly refined (used ½ level of quantitation (LOQ) residues) and did incorporate 25% of crop treated information. Acute dietary exposure estimates were for the 99.9th percentile. Estimated concentrations of emamectin residues in surface and ground water are lower than EPA's DWLOCs. Therefore, EPA does not expect acute aggregate risk to emamectin benzoate residues from food and water sources to exceed level of concern for acute dietary exposure.

2. *Chronic risk.* The chronic dietary exposure to emamectin residues in food will occupy no more than 4% of the chronic RfD for adult population subgroups and no more than 5% PAD for infant/children subgroups. Residue levels used for food-source dietary risk assessments were highly refined and did incorporate percent of crop treated information, as indicated above. EPA generally has no concern for exposures below 100% of the PAD/RfD because of PAD/RfD represents the level at or below which daily aggregated dietary exposure over a lifetime will not pose appreciable risks to human health. The estimated concentrations of emamectin residues in surface and ground water are lower than the Agency's DWLOCs. Despite the potential for exposure to emamectin benzoate in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the PAD/RfD. Therefore, EPA does not expect chronic aggregate risk to emamectin residues from food and water sources to exceed level of concern for chronic dietary exposure.

3. *Aggregate cancer risk for U.S. population.* There is no evidence of carcinogenicity.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to emamectin benzoate residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of emamectin benzoate, 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 post-natal 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.

For emamectin benzoate, the Agency has determined the tenfold safety factor for the protection of infants and children should be reduced to 3x. The rationale for reducing the FQPA Safety Factor is as follows:

- No increased susceptibility was demonstrated in rats or rabbits following *in utero* and/or postnatal exposure to emamectin. However, increased susceptibility was demonstrated in a developmental neurotoxicity study in rats.
- Although increased susceptibility was demonstrated in a developmental neurotoxicity study in rats, the Committee determined that the 10x factor should be reduced to 3x based on the following weight-of-the-evidence considerations in the developmental neurotoxicity study: (1) The LOAEL was based on a single effect/end point (i.e., decrease in open field motor activity); (2) theeffect at the LOAEL was seen only on postnatal day 17 and was not seen either on earlier (Day 13) or later (Day 21) evaluations whereas at the high dose (3.6/2.5 mg/kg/day), this effect was seen on postnatal days 13 and 17; (3) the effect at the LOAEL was not accompanied with other toxicity whereas at the high dose tremors and

hind limb splay were also seen; (4) the decreased performance was lower only when compared to the concurrent control; and (5) there was limited (only 2 studies) historical control data available for comparison.

Exposure assessments do not indicate a concern for potential risk to infants and children because: (1) The dietary exposure estimates are based on market share data assuming 25% percent crop treated resulting in an overestimate of dietary exposure. This is considered an overestimate because the 25% figure is considered to be a conservative upper-bound estimate, since a new chemical would have a very small market share; (2) modeling data were used for the ground and surface source drinking water exposure assessments; the resulting estimates are considered to be reasonable upper-bound concentrations; (3) there are no registered residential uses.

EPA also determined that the FQPA Safety Factor (3x) is applicable for acute dietary risk assessments for the general population including infants and children because the endpoint for this risk assessment is neurotoxicity (tremors), and to chronic dietary because the endpoint for this risk assessment is based on clinical signs of neurotoxicity histopathological lesions in the sciatic nerve following oral exposure. As a result of the retention of the FQPA Safety Factor, the Agency considered the PAD for infants, children and females 13 years and older to be 0.00025 mg/kg/day for acute and 0.000083 mg/kg/day for chronic dietary exposure. For other populations (i.e., adult males) exposures were compared to the acute and chronic RfDs, 0.00075 mg/kg/day and 0.00025 mg/kg/day, respectively.

ii. *Conclusion*. There is a complete toxicity database for emamectin benzoate and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Taking into account the completeness of the data base, EPA concludes, based on reliable data, the use of the additional safety factor would be safe for infants and children.

2. *Acute risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to emamectin benzoate from food will utilize no more than 65% of the acute PAD/RfD for infants and children. EPA generally has no concern for exposures below 100% of the PAD/RfD because the PAD/RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to emamectin benzoate from food will utilize no more than 5% of the chronic PAD/RfD for infants and children. EPA generally has no concern for exposures below 100% of the PAD/RfD because the PAD/RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The following residues are required in the tolerance expression and dietary risk assessment for the proposed use: emamectin, 8,9-ZMA, and metabolites/photodegradates AB_{1a}, MFB_{1a} and FAB_{1a}. Metabolites/photodegradates 8AOXOMA and 8AOHMA are also of toxicological concern, but based upon their relative levels to the emamectin and the other four emamectin-like residues (8,9-ZMA, AB_{1a}, MFB_{1a} and FAB_{1a}), these are not needed in the tolerance expression or dietary risk assessment.

No animal feed items are associated with the commodities for which permanent tolerances are proposed. Therefore, no animal metabolism or feeding studies are required.

B. Analytical Enforcement Methodology

The proposed enforcement method for residues of emamectin on plant commodities is currently undergoing the Agency's method validation at this time. In the interim, EPA has conducted a preliminary review of the method and has indicated that it appears to be suitable for enforcement purposes pending the outcome of the actual method validation. Given that the registrant has provided concurrent fortification data to demonstrate that the method is adequate for data collection purposes and has provided the Agency with a successful Independent Laboratory Validation, coupled with the EPA laboratory's preliminary review, EPA concludes that the method is suitable as an enforcement method to support tolerances associated with this action.

C. Multiresidue Methods Testing

Data previously submitted by the petitioner show that residues of emamectin are not likely to be recovered by FDA multiresidue methods. The petitioner submitted data pertaining to the multiresidue methods testing of emamectin (B_{1a} and B_{1b} components), AB_{1a}, FAB_{1a}, MFB_{1a} and the 8,9-Z isomer (B_{1a} component). The data have been forwarded to FDA for inclusion in PAM I.

D. Magnitude of Residues

EPA has concluded that there were sufficient residue field trial data using the end use product Proclaim 1.6 EC and Proclaim 5 SG to support a 0.025 ppm tolerance on Brassica, head & stem subgroup (5-A), head lettuce and celery.

E. International Residue Limits

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

F. Rotational Crop Restrictions

The confined rotational crop data base is adequate. No plantback restrictions need to be listed on the label.

G. Residues in Meat, Milk, Poultry and Eggs

No animal metabolism or feeding studies were submitted with this petition. However, tolerances in milk, eggs, and animal tissues are not required at this time since no feed items are associated with the subject commodities for which permanent tolerances are being proposed.

IV. Conclusion

Therefore, the tolerance is established for combined residues of 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 (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) in Brassica, head & stem subgroup (5-A), head lettuce and celery at 0.025 ppm

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of

objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 19, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300856] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by 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).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal

governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 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**. 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: May 11, 1999.

Susan B. Hazen,

Actinig Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.505, by revising paragraph (a) to read as follows:

§ 180.505 Emamectin Benzoate; tolerances for residues.

(a) *General.* Tolerances are established for the 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 (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) in or on the following commodities:

Commodity	Parts per million
Brassica, head & stem subgroup (5-A)	0.025
Celery	0.025
Lettuce, head	0.025

* * * * *

[FR Doc. 99–12593 Filed 5–18–99; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[FCC 99–93]

Amendment of the Commission's Rules of Practice and Procedure

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document we amend the Commission's rules, to extend the deadline for the filing of paper documents such as petitions, pleadings, and tariffs, that are not required to be accompanied by a fee, and that are hand-delivered to the Commission's Office of the Secretary. The filing deadline for all such documents is extended from 5:30 p.m. until 7:00 p.m.

DATES: Effective May 19, 1999.

FOR FURTHER INFORMATION CONTACT: Andra Cunningham, Office of the Secretary, (202) 418–0300.

SUPPLEMENTARY INFORMATION:

1. By this Order, the Commission amends section 1.4(f) of the Commission's rules, 47 CFR 1.4(f), to extend the deadline for the filing of paper documents such as petitions, pleadings, and tariffs, that are not required to be accompanied by a fee, and that are hand-delivered to the Commission's Office of the Secretary.

2. Currently, the filing deadline for all such documents is 5:30 p.m. The amendment adopted here extends the deadline for the filing of paper documents to 7:00 p.m. The document must be tendered for filing in complete form with the Office of the Secretary at the designated filing counter, TW–A325, at the Commission's new offices, located at 445 12th Street, SW, Washington, DC. This amendment is designed to facilitate the filing of paper documents in a timely manner.

3. Because the rule amendment adopted here is a matter of agency practice and procedure, compliance with the notice and comment and effective date provisions of the Administrative Procedure Act is not required. *See* 5 U.S.C. 553(b)(A)–(d).

4. It is ordered that, pursuant to authority found in sections 4(i), 4(j), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154 (i), 154(j), and 303(r).

5. It is further ordered that the rules as amended shall become effective upon publication in the **Federal Register**.

List of Subjects in 47 CFR Part 1

Administrative practice and procedure.