requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998); 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 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 FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: December 21, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 [AMENDED]

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

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

2. In § 180.384, by revising the section heading, paragraph (a) introductory text and by alphabetically adding entries for grapes and raisins to the table in paragraph (a) to read as follows:

§ 180.384 Mepiquat chloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator mepiquat chloride, *N,N*-dimethylpiperidinium chloride in or on the following commodities:

Commodity	Parts per million
* * * * *	
Grapes	1.0
* * * * *	
Raisins	5.0
* * * * *	

* * * * *

[FR Doc. 00–362 Filed 1–11–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300958; FRL–6398–5]

RIN 2070–AB78

Emamectin Benzoate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of emamectin benzoate and its metabolites and photodegradates 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-aminoavermectin 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 cottonseed, cottonseed oil, cotton meal, hulls, and gin trash; and the milk, meat, fat, kidney, and liver of cattle, goats, sheep, and swine. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cotton. This regulation establishes maximum permissible levels for residues of emamectin benzoate in these food and feed commodities. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective January 12, 2000. Objections and requests

for hearings, identified by docket control number OPP–300958, must be received by EPA on or before March 13, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''*SUPPLEMENTARY INFORMATION.*'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300958 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9356; and e-mail address: beard.andrea@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

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

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300958. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the insecticide emamectin benzoate, in or on cottonseed at 0.002 part per million (ppm), cottonseed oil at 0.006 ppm, cotton meal at 0.002 ppm, cotton hulls at 0.004 ppm, and cotton gin trash at 0.025 ppm; and the milk, meat, fat, kidney, and liver of cattle, goats, sheep, and swine at 0.002 ppm. These tolerances will expire and are revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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. . . .''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Emamectin Benzoate on Cotton and FFDCA Tolerances

Beet armyworm has infested cotton fields to a high degree in recent growing seasons. This pest had not previously been a significant pest in cotton, and had been controlled with available alternatives. However, in recent years, beet armyworm populations have reached devastating levels in southeastern cotton-growing areas, and registered alternatives have proven to provide inadequate control to prevent significant economic losses from occurring. The resistant tobacco budworm is also negatively affecting yields in these states. EPA has reviewed the submissions and has concluded that these pest situations represent urgent and non-routine problems. EPA has authorized under FIFRA section 18 the use of emamectin benzoate on cotton for control of beet armyworm and resistant tobacco budworm in Alabama, Arkansas, Louisiana, Mississippi, Oklahoma, and Texas. After having

reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of emamectin benzoate in or on cotton commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on cotton commodities after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by the tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether emamectin benzoate meets EPA's registration requirements for use on cotton or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of emamectin benzoate by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Alabama, Arkansas, Louisiana, Mississippi, Oklahoma, and Texas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for emamectin benzoate, contact the Agency's Registration Division at the address provided under '' *FOR FURTHER INFORMATION CONTACT.*''

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 time-limited tolerances for combined residues of emamectin benzoate and its metabolites and photodegradates on cottonseed at 0.002 ppm, cottonseed oil at 0.0006 ppm, cotton meal at 0.002 ppm, cotton hulls at 0.004 ppm, and cotton gin trash at 0.025 ppm; and the milk, meat, fat, kidney, and liver of cattle, goats, sheep, and swine at 0.002 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by emamectin benzoate are discussed in Unit II.A. of the final rule on Emamectin Benzoate Pesticide Tolerances published in the **Federal Register** on May 19, 1999 (64 FR 27192) (FRL–6079–7).

B. Toxicological Endpoint

The toxicological endpoints for emamectin benzoate are discussed in Unit II.B. of the final rule on Emamectin Benzoate Pesticide Tolerances published in the **Federal Register** on May 19, 1999.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.505) for the combined residues of emamectin benzoate and its metabolites and photodegradates, in or on Brassica, head and stem (subgroup 5-A under 40 CFR 180.41), celery, and head lettuce. Risk assessments were conducted by EPA to assess dietary exposures and risks 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. For conducting the acute dietary risk assessment, the population subgroups of concern are infants, children, and females 13 years and older. An acute dietary risk assessment was performed using the Dietary Exposure Evaluation Model (DEEM) system, Tier 3 (Monte Carlo) approach. This methodology incorporates distributions of residues and refined percent of crop treated (PCT) estimates for some crops and thus results in refined risk estimates. This exposure analysis was conducted using the Acute Population-Adjusted Dose (PAD) of 0.00025 milligrams/kilograms/day (mg/kg/day). The analysis evaluated individual food consumption as reported in the USDA Continuing Surveys of Food Intake by Individuals (CSFII) conducted in 1989–92. The model accumulated exposure to emamectin for each commodity and expresses risk as a function of dietary exposure. For the most highly exposed population subgroup, children 1–6 years old, the resulting high-end exposure (at the 99.9th percentile) occupies 65% of the acute PAD. For the overall U.S. population, the high-end exposure (99.9th percentile) occupies 29% of the acute PAD. All risk estimates are within acceptable limits, thus there is reasonable certainty of no harm due to acute dietary exposure to emamectin.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment used the chronic PAD of 0.000083 mg/kg/day, and consumption reported in the USDA-CSFII of 1989–92, and accumulates exposure to emamectin for each commodity. This analysis used tolerance-level residues and 25% crop treated figures for broccoli, Brussels sprouts, cabbage, cauliflower, lettuce, and celery. For the most highly exposed population subgroup, children 1–6 years old, the resulting exposure occupies 21% of the chronic PAD. For the overall U.S. population, the exposure occupies 15% of the chronic PAD. All risk estimates are within acceptable limits, thus there is reasonable certainty of no harm due to chronic dietary exposure to emamectin.

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

The Agency used PCT figures of: 25% for broccoli, Brussels sprouts, cabbage, cauliflower, lettuce, and celery.

The Agency believes that the three conditions in section 408(b)(2)(F), discussed in this unit, concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. 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 regional consumption of food to which emamectin benzoate may be applied in a particular area.

2. *From drinking water*. There are no established Maximum Contaminant Levels (MCLs) of health advisory levels for residues of emamectin in drinking water. The Agency currently lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for emamectin. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. None of the drinking water models used by the Agency include consideration of the impact that processing 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.

In the environment, emamectin and its primary degradates are expected to be relatively immobile due to the high degree of sorption to soil particles. Estimated concentrations for surface water exceeded those for ground water; therefore, surface water values were used for risk calculations. The estimated environmental concentration (EEC) for acute drinking water exposure is 0.107 part per billion (ppb), derived from the PRZM/EXAMS model which estimates pesticide concentrations in a farm pond. The highest EEC for chronic drinking water exposure is 0.0203 ppb from the PRZM/EXAMS model. These drinking water estimates are considered to include both emamectin and its metabolites of concern.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and compared to the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits for a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. The estimates for drinking water levels, derived from the models mentioned in the preceding paragraph, are all well below the DWLOCs calculated for all population subgroups. Since DWLOCs address total aggregate exposure to emamectin they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure*. Emamectin benzoate is currently not registered for use on any residential non-food sites. The proposed and existing uses of emamectin are not expected to result in residential exposure. Therefore, a non-dietary risk assessment was not conducted.

4. *Cumulative exposure to substances with a 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 on a common mechanism of toxicity, emamectin benzoate 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 benzoate has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. There are currently no registered residential uses of emamectin or uses which may result in residential exposure. Therefore, acute aggregate risk consists of exposure from food and drinking water sources only. As discussed earlier, exposure to emamectin residues in food will occupy no more than 29% of the acute PAD for adult population subgroups, and no more than 65% of the acute PAD for infant/children subgroups. Estimated concentrations of emamectin residues in surface and ground water are lower than the DWLOCs calculated by the Agency. The drinking water estimates were calculated using drinking water models,

and are considered conservative. Therefore, EPA does not expect chronic aggregate risk to emamectin residues from food and water sources to exceed levels of concern for acute aggregate risk, and thus finds reasonable certainty that no harm will result from aggregate acute exposure to emamectin.

2. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to emamectin benzoate from food will utilize 15% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years old, at 21% of the chronic PAD. This is discussed below. EPA generally has no concern for exposures below 100% of the PAD because the PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. As stated above, the estimated drinking water levels, calculated using EPA models, and thus considered conservative, were lower than all DWLOCs. Thus, despite the potential for exposure to emamectin benzoate in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the chronic PAD, and thus concludes that there is reasonable certainty that no harm will result from chronic aggregate exposure to emamectin.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Since there are no registered residential uses or other uses that would be expected to result in residential exposure, there is no exposure expected in these scenarios, and thus this risk assessment is not necessary.

4. *Aggregate cancer risk for U.S. population*. Based on the available data available for emamectin, there is no evidence of carcinogenicity, and thus this risk assessment is not necessary.

5. *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*. The determination of the 3X safety factor to account for the potential for increased sensitivity of infants and children to residues of imidacloprid is discussed in Unit II.E.1.i. of the final rule on Emamectin Benzoate Pesticide Tolerances published in the **Federal Register** on May 19, 1999.

ii. *Developmental toxicity studies*. Developmental toxicity is discussed in Units II.A.8. and II.A.16. and II.E.1. of the **Federal Register** document published on May 19, 1999.

iii. *Reproductive toxicity study*. Reproductive toxicity is discussed in Units II.A.10. and II.E.1. of the **Federal Register** document published on May 19, 1999.

iv. *Prenatal and postnatal sensitivity*. Prenatal and postnatal sensitivity is discussed in Unit II.E.1. of the **Federal Register** document published on May 19, 1999.

v. *Conclusion*. There is a complete toxicity data base for emamectin benzoate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

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 for infants and children. EPA generally has no concern for exposures below 100% of the PAD because the PAD represents the level at or below which daily aggregate dietary exposure 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 21% of the PAD for the most highly exposed infant and children subgroup, children 1 to 6 years old. EPA generally has no concern for exposures below 100% of the PAD because the PAD represents the level at or below which daily aggregate dietary exposure will not pose appreciable risks to human health. Despite the potential for exposure to emamectin benzoate in drinking water and from non-dietary, nonoccupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the PAD.

4. *Short- or intermediate-term risk*. Since there are no registered residential uses or other uses that would be expected to result in residential exposure, there is no exposure expected in these scenarios, and thus this risk assessment is not necessary.

5. *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.

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residues of emamectin benzoate in plants is adequately understood. The tolerance expression for emamectin benzoate must contain the following: 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 metabolism data in livestock and poultry have been provided. For the purposes of this section 18 request, the residue of concern in livestock is emamectin, and 8,9 isomer of B_{1a} and B_{1b}.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available for both plant and livestock commodities; it is a HPLC method using fluorescence as the means of detection. The methods described in MRID 44795001 are adequate to enforce the tolerance expression.

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of the Residues

Residues of emamectin and its metabolites and photodegradates are not expected to exceed 0.002 ppm in/on cottonseed, 0.006 ppm in cottonseed oil, 0.002 ppm cotton meal, 0.004 ppm in cotton hulls, and 0.025 ppm in gin trash; and 0.002 ppm in the meat, milk, fat, liver, and kidney of cattle, goats, sheep, and swine as a result of this section 18 use. Secondary residues are expected in animal commodities as gin trash containing measurable residues is among the feed items associated with this section 18 use. Secondary residues in milk, meat, fat, kidney and liver of cattle, goats, sheep, and swine are not expected to exceed 0.002 ppm. Residues are not expected in poultry commodities, since cotton gin trash is not a significant feed item of poultry, and exposure would be negligible.

D. Rotational Crop Restrictions

Based on available information, the confined rotational crop data base is adequate and no plantback restrictions are needed on labels.

E. International Residue Limits

There are no Codex, Canadian, or Mexican MRLs for emamectin.

VI. Conclusion

Therefore, tolerances are 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-aminoavermectin 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 cottonseed at 0.002 ppm, cottonseed oil at 0.0006 ppm, cotton meal at 0.002 ppm, cotton hulls at 0.004 ppm, and cotton gin trash at 0.025 ppm; and in the milk, meat, fat, liver, and kidney of cattle, goats, sheep, and swine at 0.002 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300958 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 March 13, 2000.

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 willnot be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission 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, 401 M St., SW., Washington, DC 20460.

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.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.2. Mail your copies, identified by the docket control number OPP–300958, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled

Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998); 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 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 FIFRA section 18 petition under FFDCA section 408, 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 FFDCA section 408(n)(4).

IX. Submission to Congress and the General Accounting Office

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).

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

Dated: December 22, 1999.

James Jones,

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. In §180.505, by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§180.505 Emamectin Benzoate; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation date
* *	*	*
Cattle, fat	0.002	12/31/01
Cattle, meat	0.002	12/31/01
Cattle, meat by-product	0.002	12/31/01
Cotton gin by-product	0.025	12/31/01
Cotton hulls	0.004	12/31/01
Cotton, meal	0.002	12/31/01
Cottonseed	0.002	12/31/01
Cottonseed oil	0.006	12/31/01
Goats, fat	0.002	12/31/01
Goats, meat	0.002	12/31/01
Goats, meat by-product	0.002	12/31/01
Hogs, fat	0.002	12/31/01
Hogs, meat	0.002	12/31/01
Hogs, meat by-product	0.002	12/31/01
Sheep, fat	0.002	12/31/01
Sheep, meat	0.002	12/31/01
Sheep, meat by-product	0.002	12/31/01

* * * * *

[FR Doc. 00–735 Filed 1–11–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300960; FRL–6399–7]

RIN 2070–AB78

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for the insecticide spinosad (Factor A and Factor D). Factor A is 2-[(6-deoxy-2,3, 4-tri-*O*-methyl-alpha-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,6b-tetradecahydro-14-methyl-1 *H*-as-Indaceno [3,2-d]oxacyclododecin-7,15-dione. Factor D is 2-[(6-deoxy-2,3,4-tri-*O*- methyl-alpha-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydri-6-methyl-2*H*-pyran -2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl- 1*H*-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. This regulation establishes tolerances for residues of spinosad in or on the raw agricultural commodities (RACs), in or on barley, buckwheat, oats, and rye (grains) at 0.02 parts per million (ppm); pearl millet, proso millet, and amaranth (grains) at 1 ppm; teosinte and popcorn (grains) at 0.02 ppm; grass, forage, fodder and hay group; nongrass animal feed group at 0.02 ppm; turnip greens at 10 ppm; cilantro, and watercress at 8 ppm; tropical fruits (sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, lychee, longan, spanish lime, rambutan, pulasan, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, avocado, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, acerola, and white sapote) at 0.3 ppm; ti leaves at 10 ppm. Additionally, this rule establishes a tolerance for spinosad on pistachio at 0.02 ppm under conditional registration.