*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.

These tolerances were requested by the Interregional Research Project (IR-4), Rutgers, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. Spinosad is manufactured by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The IR-4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective January 12, 2000. Objections and requests for hearings, identified by docket control number OPP–300960, 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 VI. of the ''*SUPPLEMENTARY INFORMATION.*'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300960 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–7610; and e-mail address: jackson.sidney@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this Action Apply to Me?*

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

| Categories | NAICS codes | Examples of potentially affected entities |
|---|---|---|
| Industry | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>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–300960. 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

In the **Federal Register** of October 14, 1999 (64 FR 55714) (FRL–6382–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for these tolerances by the IR-4. This notice included a summary of the petition prepared by Dow AgroScience, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide, in or on the RACs considered in this rule.

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).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of spinosad in or on the RACs considered in this rule. 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 spinosad are discussed in this unit.

1. *Acute toxicity*. Spinosad has low acute toxicity. The rat oral lethal dose $(LD)_{50}$ is 3,738 milligrams/kilograms (mg/kg) for males and >5,000 mg/kg for females, whereas the mouse oral $LD_{50}$ is >5,000 mg/kg. The rabbit dermal $LD_{50}$ is >5,000 mg/kg and the rat inhalation lethal concentration $(LC)_{50}$ is >5.18 milligrams/liter (mg/L) air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water-based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicity*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with spinosad. These studies show that spinosad does not elicit a genotoxic response.

3. *Reproductive and developmental toxicity*. Spinosad caused decreased body weight (bwt) in maternal rats given 200 milligrams/kilograms/day (mg/kg/day) by gavage, the highest dose tested (HDT). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The no observed adverse effect levels (NOAELs) for maternal toxicity and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased bwt gain and a few abortions in maternal rabbits given 50 mg/kg/day, the HDT. Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOAELs for maternal and fetal toxicity in rabbits were 10 and 50 mg/kg/day, respectively. In a 2–generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day, the HDT. Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were attributed to maternal toxicity. The NOAEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity*. Spinosad was evaluated in 13–week dietary studies and showed NOAELs of 4.89 and 5.38 mg/kg/day, respectively in male and female dogs; 6 and 8 mg/kg/day, respectively in male and female mice; and 33.9 and 38.8 mg/kg/day, respectively in male and female rats. No dermal irritation or systemic toxicity occurred in a 21–day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity*. Based on chronic testing with spinosad in the dog and the rat, EPA has set a reference dose (RfD) of 0.027 mg/kg/day for spinosad. The RfD has incorporated a 100-fold uncertainty factor (UF) to the NOAELs found in the chronic dog study to account for interspecies and intraspecies variation. The NOAELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOAELs (systemic) shown in the rat chronic/carcinogenicity/neurotoxicity studies were 9.5 and 12.0 mg/kg/day, respectively for male and female rats. Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18–month mouse feeding study and a 24–month rat feeding study at all dosages tested. The NOAELs shown in the mouse carcinogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality.

6. *Animal metabolism*. There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. Urine and fecal excretions were almost completed in 48–hours post dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material spinosyn A and spinosyn D. Thus, there is no need to address metabolite toxicity.

8. *Endocrine disruption*. There is no evidence to suggest that spinosad has an effect on any endocrine system.

*B. Toxicological Endpoints*

1. *Acute toxicity*. EPA did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects attributable to a single exposure (dose) in studies available in the data base including oral developmental toxicity studies in rats and rabbits. In the acute neurotoxicity study, the NOAEL was not shown at 2,000 mg/kg/day, HDT. A risk assessment is not necessary as no appropriate endpoint is available.

2. *Short- and intermediate- term toxicity*. Short- (1 day to 7 days), intermediate- (1 week to several months), and chronic-term occupational and residential dermal and inhalation toxicity. EPA did not select a dose or endpoint for short-, intermediate-, and long-term dermal risk assessments because:

i. Lack of appropriate endpoints.

ii. The combination of molecular structure and size as well as the lack of dermal or systemic toxicity at 2,000 mg/kg/day in a 21–day dermal toxicity study in rats which indicates the lack of dermal absorption.

iii. The lack of long-term exposure based on the current use pattern. EPA also determined that based on the current use pattern and exposure scenario, an inhalation risk assessment is not appropriate.

3. *Chronic toxicity*. EPA has established the RfD for spinosad at 0.027 mg/kg/day. This RfD is based on a NOAEL of 2.68 mg/kg/day established in a chronic toxicity study in dogs. The lowest observed adverse effect level (LOAEL) was 8.46 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis and increases in serum enzymes such as alanine aminotransferase, and aspartate aminotransferase, and triglyceride levels in dogs fed spinosad in the diet at dose levels of 1.44, 2.68, or 8.46 mg/kg/day for 52 weeks. A 100-fold UF was applied to the NOAEL of 2.68 mg/kg/day to account for interspecies and intraspecies variation. The resulting RfD was calculated to be 0.027 mg/kg/day.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in studies in either the mouse or rat. Therefore, a carcinogenic risk assessment is not appropriate.

*C. Exposures and Risks*

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of plant and livestock commodities ranging from 0.02 ppm in almonds to 10 ppm in the Brassica leafy vegetable and greens subgroup. Tolerances are pending or were recently issued for use on cucurbit vegetables, stone fruits, legume vegetables, corn, sorghum, and wheat. The Agency used the Dietary Exposure Evaluation Model (DEEM) to estimate dietary (food only) exposure to spinosad. This analysis assumes that 100% of crops with spinosad tolerances (requested, published, and pending) are treated and that those crops contain tolerance-level residues of spinosad (Tier 1). A number of the exotic fruits

do not appear in the DEEM™ consumption data base. The Agency assumes that exposure via these foods is negligible.

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The Agency did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects attributable to a single exposure (dose) in available studies including oral developmental toxicity studies in rats and rabbits. In the acute neurotoxicity study, the NOAEL was ≥ 2,000 mg/kg/day. The Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of the crops and ruminant commodities having spinosad tolerances will contain spinosad residues and those residues will be at the level of the established tolerance. Additionally, residues of 0.02 ppm were assumed for all other food forms to support a pending section 18 action(s) on spinosad for use in controlling Mediterranean Fruit Fly in Florida and California.

The Agency used the DEEM™ anaylsis to estimate dietary (food only) exposure to spinosad. Exposure estimates for all population subgroups except those specific to infants and children were similar to that of the general U.S. population (0.009 mg/kg/day, 34% chronic population adjusted dose (cPAD)). The cPAD is equivalent to the RfD divided by the FQPA safety factor (SF). For spinosad, EPA has determined that the additional 10x SF for the protection of infants and children be reduced to 1x, i.e., removed. Thus, the cPAD of 0.027 mg/kg/day is equivalent to the chronic RfD.

Exposure to children ages 1–6 years (the subgroup with the highest overall estimated exposure) is estimated to be 0.020 mg/kg/day, which occupies 74% of the chronic cPAD. The primary contributor to chronic dietary exposure is milk, which alone occupies 30% of the cPAD for children 1–6 years. Dietary exposure estimates based on the requested uses of spinosad along with currently registered and pending uses, are below the Agency's level of concern for all population subgroups, including those of infants and children.

2. *From drinking water*. Monitoring data depicting residue levels of spinosad in drinking water are not available. Therefore, EPA cannot perform a quantitative risk assessment for drinking water exposure. Instead, EPA had used modeled estimated environmental concentrations (EECs) and back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern.

EPA concludes that the available data on spinosad show that the compound is not mobile or persistent, and therefore has little potential to leach to ground water. Spinosad may however contaminate surface water upon the release of water from flooded fields to the environment. Additionally, EPA determined that the spinosyn Factors A and D are not expected to reach ground water. In order to assess drinking water exposures, EPA used the screening models Pesticide Root Zone Model (PRZM) and Exposure Analysis Modeling Systems (EXAMS) to generate surface water EECs associated with application of spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90$^{th}$ percentile for surface water vulnerability, given the chemical's geographic use range. The Tier 2 chronic surface water EEC for spinosad is 0.092 µg/L and is based on application of the insecticide to commodities in this ruling at rates ranging from 0.023 to 0.094 lb (active ingredient/acre (ai/acre), with total seasonal application not to exceed 0.045 lb ai/acre. The EEC value is over 1,000 times less than the lowest DWLOC.

i. *Acute exposure and risk*. No acute toxicity endpoints were determined from testing and the Agency concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

ii. *Chronic exposure and risk*. For the most highly exposed population subgroup, children (1–6 years old), chronic dietary (food only) exposure occupies 74% of the cPAD. This is a conservative risk estimate for reasons described above. The lowest chronic DWLOC for the infants and children subgroup is 170 parts per billion (ppb). The chronic modeling estimates (EECs) for spinosad residues in surface water are as high as 0.092 ppb from use on Brassica leafy vegetables. The maximum estimated concentrations of spinosad in surface water are less than EPA's levels of concern for spinosad in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this risk assessment, EPA concludes with reasonable certainty that residues of spinosad in drinking water (when considered along with other sources of exposure for which the Agency has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure*. Spinosad is currently registered for use on the following residential non-food sites: Spinosad is registered on turf grass, creating a potential for non-dietary oral exposure to children who ingest grass. To calculate a quantitative dietary risk from a potential ingestion of grass (in the absence of acute-, short-, or intermediate-term oral endpoints), EPA would need to default to the chronic dietary endpoint. This scenario would represent a child eating grass for > 6 months continuously. Based on the low application rate for spinosad on turf (0.41 lbs. ai./acre), its non-systemic nature, its short half-life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, EPA believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. EPA believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating turf grass. Qualitatively, the risk from children eating turf grass does not exceed the Agency's level of concern.

Another registered product contains spinosad for use on structural lumber may have residential exposure potential, however, the product is injected into drilled holes and then sealed after treatment. The product can only be applied by commercial applicators with very minimal potential risk to the public. Due to the lack of toxicity endpoints (hazard) and minimal contact with the active ingredient during and after application, exposure to residential occupants is not expected. The Agency concludes that there is a reasonable certainty of no harm from non-dietary exposure.

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.''

EPA does not have, at this time, available data to determine whether spinosad 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, spinosad 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 spinosad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. Because no acute dietary endpoint was determined from toxicity testing, the Agency concludes that there is a reasonable certainty of no harm from acute aggregate risk.

2. *Chronic risk*. Using the Theoretical Maximum Residue Contribution (TMRC) taking into account existing spinosad tolerances (published, pending, and including the necessary section 18 tolerances) exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 34% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to spinosad in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to spinosad residues.

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.

No dermal or inhalation endpoints were identified. Due to the nature of the non-dietary use, the Agency believes that the use of spinosad in treating timbers will not result in any exposure through the oral route. Therefore, the short-and intermediate-term risk is equal to the chronic dietary (food and water) risk.

4. *Aggregate cancer risk for U.S. population*. There is no evidence of carcinogenicity in studies in either the mouse or rat.

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 spinosad 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 spinosad, 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 prenatal and postnatal toxicity and the completeness of the data base 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 interspecies and intraspecies 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.

ii. *Prenatal and postnatal sensitivity*. There was no increased susceptibility to rats or rabbits following *in utero* and/or postnatal exposure to spinosad.

iii. *Conclusion*. EPA determined that the 10x should be removed. The FQPA factor is removed because:

a. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity.

b. No neurotoxic signs have been observed in any of the standard required studies conducted.

c. The toxicology data base is complete and there are no data gaps.

d. Exposure data are complete or are estimated based on data that reasonably account for potential exposure.

2. *Acute risk*. No acute toxicological endpoints were identified for spinosad. The Agency concludes that there is a reasonable certainty of no harm to infants and children from aggregate exposure.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 74% of the cPAD for children (1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to spinosad in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% ot the cPAD.

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 residues.

**IV. Other Considerations**

*A. Metabolism in Plants and Animals*

EPA has reviewed the results of plant metabolism studies (apples, cabbage, cotton, tomatoes, turnips) and livestock metabolism studies (goat and hen). The metabolism of spinosad in plants and animals is adequately understood for the purposes of these tolerances. Based on structure/activity relationships, EPA concluded that the spinosad metabolites/fermentation impurities (spinosyns Factor B, Factor B or D, Factor K, and other related Factors) were of no more toxicological concern than the two parent compounds (spinosyns Factor A and Factor D).

EPA focused on the following data/information: the overall low toxicity of spinosad; the low levels of metabolites/fermentation impurities present; and that spinosad appears to photodegrade rapidly and become incorporated into the general carbon pool. EPA concluded that only two parent compounds (spinosyns Factor A and Factor D) need to be included in the tolerance expression and used for dietary risk assessment purposes.

*B. Analytical Enforcement Methodology*

The gas chromotography method is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, 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 Residues*

Because of limited field studies available for crops considered in this ruling, the Agency relied on previously submitted field trial data on similar crops to set tolerances on certain commodities in this ruling. Specifically, tolerances for oats, barley, buckwheat, and rye are translated from wheat (0.020 ppm); grass forage, fodder and hay crop group (Crop Group 17) and nongrass animal feeds crop group (Crop Group 18) tolerances of 0.02 ppm are based on the low toxicological properties of spinosad and the proposed use pattern (mound treatment of fire ants); watercress and cilantro leaves are based on the leafy vegetable tolerance (Crop Group 4, at 8 ppm); turnip greens and ti leaves are translated from the Brassica leafy vegetables tolerance (Crop Subgroup 5B, at 10 ppm); and 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 are translated from the citrus fruit group (0.3 ppm).

*D. International Residue Limits*

No Codex, Canadian, or Mexican MRLs have been established for residues of spinosad on any crops.

**V. Conclusion**

Therefore, the tolerances are established for residues of spinosad 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 and a tolerance for spinosad on pistachio at 0.02 ppm under conditional registration.

**VI. Objections and Hearing Requests**

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300960 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 will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in 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 judgment 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 VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300960, 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).

## 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 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).

## 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 28, 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. Section 180.495, is amended by alphabetically adding commodities to the table in paragraph (a), and by revising the entry for ''apple'' to the table in paragraph (a) to read as follows:

### §180.495 Spinosad; tolerances for residues.

(a) * * *

| Commodity | Parts per million | Expiration/ Revocation Date |
|---|---|---|
| * * * | | * * |
| Acerola | 0.3 | None |
| * * * | * | * |
| Amaranth, grain | 1.0 | None |
| Animal feed, nongrass, group | 0.3 | None |
| * * * | * | * |
| Apple | 0.3 | None |
| * * * | * | * |
| Atemoya | 0.3 | None |
| * * * | * | * |
| Avocado | 0.3 | None |
| * * * | * | * |
| Barley | 0.3 | None |
| Biriba | 0.3 | None |
| * * * | * | * |
| Buckwheat, grain | 0.02 | None |
| * * * | * | * |
| Canistel | 0.3 | None |
| * * * | * | * |
| Cherimoya | 0.3 | None |
| * * * | * | * |
| Cilantro, leaves | 8.0 | None |
| Corn, pop, grain | 0.02 | None |
| * * * | * | * |
| Custard apple | 0.3 | None |
| * * * | * | * |
| Feijoa | 0.3 | None |
| * * * | * | * |
| Grass, forage, fodder and hay, group | 0.02 | None |
| Guava | 0.3 | None |
| * * * | * | * |
| Ilama | 0.3 | None |
| Jaboticaba | 0.3 | None |
| Longan | 0.3 | None |
| Lychee | 0.3 | None |

| Commodity | Parts per million | Expiration/ Revocation Date |
|---|---|---|
| * * * | * | * |
| Mango | 0.3 | None |
| Millet, pearl, grain | 1.0 | None |
| * * * | * | * |
| Millet, proso, grain | 1.0 | None |
| Oat, grain | 0.02 | None |
| Papaya | 0.3 | None |
| Passionfruit | 0.3 | None |
| Pistachio | 0.02 | None |
| * * * | * | * |
| Pulasan | 0.3 | None |
| * * * | * | * |
| Rambutan | 0.3 | None |
| Rye, grain | 0.02 | None |
| Sapodilla | 0.3 | None |
| Sapote, black | 0.3 | None |
| Sapote, mamey | 0.3 | None |
| Sapote, white | 0.3 | None |
| * * * | * | * |
| Soursop | 0.3 | None |
| Spanish lime | 0.3 | None |
| * * * | * | * |
| Star apple | 0.3 | None |
| Starfruit | 0.3 | None |
| * * * | * | * |
| Sugar apple | 0.3 | None |
| * * * | * | * |
| Teosinte, grain | 0.3 | None |
| Ti, leaves | 10.0 | None |
| * * * | * | * |
| Turnip greens | 10.0 | None |
| * * * | * | * |
| Watercress | 8.0 | None |
| Wax jambu | 0.3 | None |
| * * * | * | * |

* * * * *

[FR Doc. 00–736 Filed 1–11–00; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–300964; FRL–6486–2]**

**RIN 2070–AB78**

### N,N-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for the plant growth regulator *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride (PT807-HCl), in or on oranges. GMJA Specialties 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 January 12, 2000. Objections and requests for hearings, identified by docket control number OPP–300964, 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 VI. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300964 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this Action Apply to Me?*

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed 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–300964. 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

In the **Federal Register** of November 10, 1999 (64 FR 61336) (FRL–6388–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for a tolerance by GMJA Specialties. This notice included a summary of the petition prepared by GMJA Specialties, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for the plant growth regulator *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride, in or on oranges at 0.01 (ppm).