is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2). This rule will be effective November 26, 2001 unless EPA receives adverse written comments by October 25, 2001.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the Act.)

List of Subjects in 40 CFR Part 52

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

Dated: September 10, 2001.

William J. Muszynski,

Acting Regional Administrator, Region 2.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart HH—New York

2. Section 52.1670 is amended by adding new paragraph (c)(101) to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(c) * * *

(101) Revisions to the State Implementation Plan submitted on July 8, 1994 by the New York State Department of Environmental Conservation that establishes VOC and NO_X Reasonably Available Control Technology requirements statewide for general process emission sources.

(i) Incorporation by reference:

(A) Regulation Part 212 of Title 6 of the New York Code of Rules and Regulations, entitled ''General Process Emission Sources'' filed on August 23, 1994 and effective on September 22, 1994.

(ii) Additional information.

(A) Letter from the New York State Department of Environmental Conservation dated July 8, 1994, submitting the Part 212 Regulation and amendments as revisions to the New York State Implementation Plan for ozone.

(B) Letter from the New York State Department of Environmental Department Conservation dated August 31, 2001 submitting an analysis of mass NO_X emissions from generic sources throughout the State.

(C) Letter from the New York State Department of Environmental Conservation dated July 11, 2001 affirming that there are no sources regulated by Parts 214, ''Byproduct Coke Oven Batteries,'' 216, ''Iron and/or Steel Processes,'' and 220, ''Portland Cement Plants'' in, or considered in the attainment demonstration for, the New York portion of the New York-Northern New Jersey-Long Island severe 1-hour ozone nonattainment area.

3. In section 52.1679, the table is amended by revising the entry for Part 212 to read as follows:

§ 52.1679 EPA—approved New York State regulations

New York State regulation	State effective date	Latest EPA approval date	Comments
* * * * * * *			
Part 212, General Process Emission Sources	9/22/94	September 25, 2001, 66 FR 48961.	
* * * * * * *			

[FR Doc. 01–23762 Filed 9–24–01; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301177; FRL–6802–9]

[RIN 2070–AB78]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on asparagus at 0.020 part per million (ppm), bushberry subgroup (crop subgroup 13B) at 0.250 ppm, cranberry at 0.01 ppm, foliage of legume vegetable group (crop group 7) at 8.0 ppm, garden beet roots at 0.10 ppm, globe artichoke at 0.30 ppm, juneberry at 0.250 ppm, leaves of root and tuber vegetable group (crop group 2) at 10.0 ppm, lingonberry at 0.250 ppm, okra at 0.40 ppm, pistachio at 0.020 ppm, pome fruit group (crop group 11) at 0.20 ppm, salal at 0.250 ppm, strawberry at 1.0 ppm, sugar beet roots at 0.10 ppm, and the tree nut group (crop group 14) at 0.020 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This final rule establishes permanent tolerances for spinosad and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for spinosad were established after August 2, 1996. Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective September 25, 2001. Objections and requests for hearings, identified by docket control number OPP–301177, must be received by EPA on or before November 26, 2001.

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–301177 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9368; and e-mail address: jamerson.hoyt@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	111 112 311 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,'' ''Regulations and Proposed Rules,'' 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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301177. 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 June 6, 2001 (66 FR 30463) (FRL–6785–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) for tolerances by IR-4, 681 U.S. Highway #1, South, North Brunswick, NJ 08902–3390. This notice included a summary of the petitions prepared by Dow Agrosciences, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide spinosad, in or on food commodities, as follows:

1. PP 0E6173 proposed the establishment of tolerances for the pome fruit group at 0.2 ppm and foliage of legume vegetable group at 8.0 ppm.

2. PP 0E6217 proposed the establishment of a tolerance for asparagus at 0.02 ppm.

3. PP 1E6230 proposed the establishment of tolerances for the tree nut group, and pistachio at 0.02 ppm.

4. PP 1E6236 proposed the establishment of a tolerance for okra at 0.4 ppm.

5. 1E6245 proposed the establishment of tolerances for garden beet roots and sugar beet roots at 0.1 ppm, cranberry at 0.01 ppm, and the leaves of root and tuber vegetable group at 10 ppm.

6. PP 1E6255 proposed the establishment of tolerances for the bushberry subgroup, juneberry, lingonberry, and salal at 0.25 ppm.

7. PP 1E6256 proposed the establishment of a tolerance for globe artichoke at 0.3 ppm.

8. PP 1E6260 proposed the establishment of a tolerance for strawberry at 0.75 ppm. The petition was subsequently amended to propose a tolerance for strawberry at 1.0 ppm.

Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: Spinosyn A (Factor A; CAS #131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*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,16b-tetradecahydro-14-methyl-1*H*-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS #131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-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-methyl-1*H*-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Typically, the two factors are present at an 85:15 (A:D) ratio.

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 on asparagus at 0.020 part per million (ppm), bushberry subgroup (crop subgroup 13B) at 0.250 ppm, cranberry at 0.01 ppm, foliage of legume vegetable group (crop group 7) at 8.0 ppm, garden beet roots at 0.10 ppm, globe artichoke at 0.30 ppm, juneberry at 0.250 ppm, leaves of root and tuber vegetable group (crop group 2) at 10.0 ppm, lingonberry at 0.250 ppm, okra at 0.40 ppm, pistachio at 0.020 ppm, pome fruit group (crop group 11) at 0.20 ppm, salal at 0.250 ppm, strawberry at 1.0 ppm, sugar beet roots at 0.10 ppm, and the tree nut group (crop group 14) at 0.020 ppm. EPA's assessment of 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 Unit III.A. of the **Federal Register** of September 23, 1999 (64 FR 51451) (FRL–6381–9),

B. Toxicological Endpoints

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

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for spinosad used for human risk assessment is shown in the following Table 1:

TABLE 1.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPINOSAD FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary	Not applicable	Not applicable	No appropriate endpoint available. There were no effects observed in oral toxicity studies including oral developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, a dose and endpoint were not selected for this risk assessment.
Chronic dietary (all populations)	NOAEL= 2.68 mg/kg/day UF = 100 Chronic RfD = 0.027 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.027 mg/kg/day	Chronic feeding study in dogs LOAEL = 8.46 mg/kg/day based on the occurrence of vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes such as alanine aminotranferase, and aspartate aminotransferase, and triglyceride levels in dogs fed spinosad in the diet at dose levels of 1.44, 2.7, 8.46 mg/kg/day for 52 weeks.
Dermal (short-and intermediate-term) (residential)	Not applicable	Not applicable	No appropriate endpoint available. No toxicity at 2,000 mg/kg/day in a 21-day dermal toxicity study in rats. No dermal absorption expected based on molecular structure and size.

TABLE 1.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPINOSAD FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term dermal (several months to lifetime) (residential)	Not applicable	Not applicable	No appropriate endpoint available. Long-term exposure is not expected from registered use patterns.
Inhalation (any time period) (residential)	Not applicable	Not applicable	Low toxicity, use pattern and application rate does not indicate a need for risk assessment via inhalation.
Cancer (oral, dermal, inhalation)	Not applicable	Not applicable	Spinosad is classified as a ''Not Likely'' carcinogen.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.495) for residues of spinosad, in or on a variety of raw agricultural commodities. Spinosad is registered for use on a large number of agricultural commodities. Due to a section 18 use for control of Mediterranean fruit fly, tolerances for residues of spinosad have been established for all agricultural commodities not covered by other registrations. Risk assessments were conducted by EPA to assess dietary exposures from spinosad in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1999 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

The chronic dietary analysis used residue values at the established and recommended tolerance levels for all commodities having spinosad tolerances with the exception of meat (all non-poultry sources) and milk. Anticipated residues were used for meat and milk from beef and dairy cattle as follows: Muscle at 0.09 ppm, fat at 2.54 ppm, kidney at 0.19 ppm, liver at 0.48, whole milk at 0.19 ppm, cream at 0.74 ppm, skim milk at 0.037 ppm. The chronic dietary analysis also assumed that 100 percent crop treatment for registered uses and the proposed uses.

iii. *Cancer.* Spinosad has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, a cancer risk assessment was not performed.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* 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.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use EECs from these models to quantify drinking water exposure and risk as a percent of the reference dose (%RfD) or percent of the population

adjusted dose (%PAD). Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to spinosad, they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS model, the EECs of spinosad for chronic exposures are estimated to be 0.092 parts per billion (ppb) for surface water. The chronic surface water EEC value for spinosad is based on application of the insecticide to cole crops at 0.13 lb active ingredient per acre per application with a maximum of 0.45 lb active ingredient/acre/season.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Registered residential uses for spinosad currently include Conserve SC Turf and Ornamental (EPA Reg. No. 62719–291) and Conserve Fire Ant Bait (EPA Reg. No. 62719–291). Both products are registered for outdoor use only. The risk assessment was conducted using the following residential exposure assumptions: The turf/ornamental and fire ant bait uses may result in non-dietary ingestion of spinosad-treated plant material or soil by children. Half-life estimates for spinosyn A on various plant foliage ranges from 1.6 to 16 days and generally is dependent on the amount of sunlight received on the plant surfaces. To calculate a quantitative 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 lb/a.i./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/ornamentals and soil 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 ingesting spinosad-treated plants or soil. Qualitatively, the risk from children's ingestion of plant or soil as a result of turf/ornamental and fire ant bait uses does not exceed EPA's level of concern.

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. Safety Factor for Infants and Children

1. *In general*. 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for spinosad and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. This recommendation is based on (1) the completeness of the toxicological data base, (2) no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure, and (3) no requirement for a developmental neurotoxicity study.

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Acute aggregate risk consists of the combined dietary exposures from food and drinking water sources. The total exposure is compared to the acute RfD. An acute RfD was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute aggregate exposure to spinosad.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 29% of the cPAD for the U.S. population, 26% of the cPAD for infants, and 57% of the cPAD for children 1 to 6 years old, the subpopulation at greatest risk. Based on the use pattern, spinosad's short half-life and non-systemic nature, and the rapid incorporation of spinosad metabolites into the general carbon pool, chronic residential exposure to residues of spinosad is not expected. In addition, there is potential for chronic dietary exposure to spinosad in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPINOSAD

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.027	29	0.092	670
All infants	0.027	26	0.092	200
Children (1 to 6 years)	0.027	57	0.092	120
Children (7 to 12 years)	0.027	40	0.092	160

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

Though residential exposure could occur with the use of spinosad, no toxicological effects have been identified for short- or intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Spinosad has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, spinosad is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC/UV is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

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

V. Conclusion

Therefore, the tolerances are established for residues of spinosad in or on asparagus at 0.020 ppm, bushberry subgroup (crop subgroup 13B) at 0.250 ppm, cranberry at 0.01 ppm, foliage of legume vegetable group (crop group 7) at 8.0 ppm, garden beet roots at 0.10 ppm, globe artichoke at 0.30 ppm, juneberry at 0.250 ppm, leaves of root and tuber vegetable group (crop group 2) at 10.0 ppm, lingonberry at 0.250 ppm, okra 0.40 ppm, pistachio at 0.020 ppm, pome fruit group (crop group 11) at 0.20 ppm, salal at 0.250 ppm, strawberry at 1.0 ppm, sugar beet roots at 0.10 ppm, and tree nut group (crop group 14) at 0.020 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301177 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 26, 2001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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–301177, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. 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 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 a tolerance 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other 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). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and

responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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: September 10, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.495 is amended by deleting the entries for almonds, apple, and turnip greens; revising the entry for pistachio; and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a)* * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Artichoke, globe	0.30	None
Asparagus	0.020	None
* *	*	* *
Beet, garden, roots	0.10	None
Beet, sugar, roots	0.10	None
* *	*	* *
Bushberry subgroup	0.250	None
* *	*	* *
Cranberry	0.01	None
* *	*	* *
Fruit, pome, group	0.20	None
* *	*	* *
Juneberry	0.250	None
* *	*	* *
Lingonberry	0.250	None
* *	*	* *
Nut, tree, group	0.020	None
* *	*	* *
Okra	0.40	None
* *	*	* *
Pistachio	0.020	None
* *	*	* *
Salal	0.250	None
* *	*	* *
Strawberry	1.0	None
* *	*	* *
Vegetable, foliage of legume, group	8.0	None
Vegetable, leaves of root and tuber, group	10.0	None
* *	*	* *

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[FR Doc. 01–23609 Filed 9–24–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7062–9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Final deletion of the Shenandoah Stables Superfund site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Shenandoah Stables site in Lincoln County, Missouri, from the NPL. The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. The EPA and the State of Missouri have determined that the site poses no significant threat to public health or the environment and, therefore, no further remedial measures pursuant to CERCLA are appropriate.

EFFECTIVE DATE: September 25, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Feild, Remedial Project Manager, U.S. Environmental Protection Agency, Region 7, 901 N. 5th Street, Kansas City, Kansas 66101.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Shenandoah Stables site, Lincoln County, Missouri.

A Notice of Intent to Delete for this site was published in the **Federal Register** on August 7, 2001 (66 FR 41177). The closing date for comments on the Notice of Intent to Delete was September 6, 2001. No comments were received; therefore, EPA has not prepared a Responsiveness Summary.

The EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.