

instructions for submitting comments. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

2. *By Mail.* Written comments should be sent to the name and address listed in the ADDRESSES section of this document.

#### Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, 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 by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885,

April 23, 1997), because it is not economically significant.

In reviewing state operating permits programs submitted pursuant to Title V of the CAA, EPA will approve state programs provided that they meet the requirements of the CAA and EPA's regulations codified at 40 CFR part 70. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state operating permits program for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews an operating permit program submission, to use VCS in place of a state program that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 6, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

#### List of Subjects 40 CFR Part 70

Environmental Protection, Administrative practice and procedure, Air pollution control, Intergovernmental

relations, Operating permits, Reporting and recordkeeping requirements.

Dated: July 28, 2003.

**William Rice,**

*Acting Regional Administrator, Region 7.*

■ 40 CFR part 70 is amended as follows:

#### PART 70—[AMENDED]

■ 1. The authority citation for part 70 continues to read as follows:

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

■ 2. Appendix A to part 70 is amended by adding paragraph (b) under Kansas to read as follows:

#### Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

\* \* \* \* \*

#### Kansas

\* \* \* \* \*

(b) The Kansas Department of Health and the Environment approved revisions to the Kansas Administrative Record (K.A.R.), 28-19-202 and 28-19-517, which became effective on March 23, 2001, and February 28, 1998, respectively. These revisions were submitted on June 25, 2001. We are approving these program revisions effective October 6, 2003.

\* \* \* \* \*

[FR Doc. 03-20019 Filed 8-5-03; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2003-0207; FRL-7317-3]

#### Spinosad; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of spinosad in or on onion, dry bulb. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on onion, dry bulb. This regulation establishes a maximum permissible level for residues of spinosad in this food commodity. The tolerance will expire and is revoked on December 31, 2006.

**DATES:** This regulation is effective August 6, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0207, must be received on or before October 6, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; e-mail address: *Sec-18-Mailbox@epamail.epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are a Federal or State Government Agency involved in Administration of Environmental quality programs (i.e., Departments of Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

- Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

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

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

1. *Docket.* EPA has established an official public docket for this action under docket identification ID number OPP-2003-0207. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

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

**II. Background and Statutory Findings**

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide spinosad, in or on onion, dry bulb at 0.10 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2006. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance the

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

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State Agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA) of 1996. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

**III. Emergency Exemption for Spinosad on Onion, Dry Bulb and FFDCA Tolerances**

The State of New Mexico requested the use of spinosad to control thrips on onion, dry bulb due to documented resistance of thrips to pyrethroid insecticides. EPA has authorized under FIFRA section 18 the use of spinosad on onion for control of thrips in New Mexico. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of spinosad in or on onions. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31,

2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on onions after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

#### IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the

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

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of spinosad and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of spinosad in or on onions at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

##### A. Toxicological Endpoints

The dose at which no observed adverse effect level are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which observed 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 (aRfD or cRfD) 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 SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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  $1 \times 10^{-6}$  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 ( $MOE_{cancer} = \text{point of departure/exposures}$ ) 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 USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary females (13–50 years of age)	N/A	N/A	This risk assessment is not required. No endpoint of concern attributable to a single exposure was identified.
Acute dietary general population including infants and children	N/A	N/A	This risk assessment is not required. No endpoint attributable to a single exposure of concern was identified for the general population, including infants and children.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary all populations	NOAEL = 2.68 milligrams/kilogram/day (mg/kg/day) UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.027 mg/kg/day	Chronic toxicity - dog LOAEL = 8.22 mg/kg/day based on 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.
Incidental oral Short-term (1–30 days) Residential only	NOAEL = 4.9 mg/kg/day MOE = 100	FQPA SF = 1x	Subchronic feeding study in dogs LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in mean body weights and food consumption and biochemical evidence of anemia and possible liver damage.
Incidental oral Intermediate-term (1–6 months) Residential only	NOAEL = 2.7 mg/kg/day MOE = 100	FQPA SF = 1x	Chronic toxicity study in dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglyceride levels.
Dermal (any time period) (Residential)	N/A	N/A	Dermal risk assessment is not required. Short-term, intermediate-term, and long-term dermal risk assessments are not required because: (1) Lack of concern for prenatal and/or postnatal toxicity; (2) the combination of molecular structure and size as well as the lack of dermal or systemic toxicity at 1,000 mg/kg/day in a 21-day dermal toxicity study in rats which indicates poor dermal absorption; and (3) the lack of long-term exposure based on the current use pattern.
Short-term inhalation (1–30 days) (Residential)	Oral NOAEL = 4.9 mg/kg/day UF = 100	FQPA SF = 1x MOE = 100	Subchronic feeding study in dogs LOAEL = 9.73 mg/kg/day based on microscopic changes in a multiple organs, clinical signs of toxicity, decreases in mean body weights and food consumption and biochemical evidence of anemia and possible liver damage.
Intermediate-term inhalation (1–6 months) (Residential)	Oral NOAEL = 2.7 mg/kg/day UF = 100	FQPA SF = 1x MOE = 100	Chronic toxicity study in dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglycerides levels
Long-term inhalation (>6 months) (Residential)	Oral NOAEL = 2.7 mg/kg/day UF = 100	FQPA SF = 1x MOE = 100	Chronic toxicity study in dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglycerides levels

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	N/A	N/A	Classification: Not likely to be carcinogenic to humans Q1* = N/A Risk Assessment not required.

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

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. Tolerances range from 0.02 ppm (many commodities; limit of quantitation) to 20 ppm (aspirated grain fractions). 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 one day or single exposure. An acute dietary exposure risk assessment is not required because the Agency did not identify an acute dietary endpoint that was applicable to females (13+ years) or to the general population, including infants and children.

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 U. S. Department of Agriculture (USDA) 1989–1992 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 (food only) analysis represents a moderately refined estimate of dietary exposure to spinosad due to the use of default processing factors, percent crop treated (PCT) estimates for agricultural crops having previously registered uses, and anticipated residues for meat and milk. This Tier 3 DEEM™ analysis shows that dietary (food only) exposure estimates are below the Agency's LOC for all population subgroups. The highest chronic dietary exposure was for children 1–6 years old at 0.018540 mg/kg/day, representing 69% of the cPAD. Exposure for the U.S. population was 0.008127 mg/kg/day, representing 30% of the cPAD.

iii. *Cancer.* Spinosad has been classified by the Agency as a not likely human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

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

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

The Agency used PCT information as follows: Almond 5%; apple 28%; apricot 5%; avocado 5%, bean, snap 9%; broccoli 62%; cabbage 32%; cauliflower 54%; celery 78%; collards

24%; cherry 5%; eggplant 14%; grapefruit 1%; grape, wine 1%; kale 32%; lemon 11%; lettuce, head 59%; Lettuce, other 42%; mustard greens 17%; orange 6%; peach 4%; pepper 45%; pistachio 1%; prune/plum 5%; spinach 32%; pumpkin 1%; squash 1%; sweet corn 1%; tangerine 6%; turnip, greens 6%; tomato, fresh 30%; tomato, processed 2%; watermelon 1%; cotton 3%; dry bean/pea 1%; peanut 1%; potato 1%; wheat, and winter 1%.

The Agency believes that the 3 conditions listed above have been met. With respect to condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant

subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which spinosad may be applied in a particular area.

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison

against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to spinosad they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of spinosad for acute exposures are estimated to be 25 parts per billion (ppb) for surface water and 0.037 ppb for ground water. The EECs for chronic exposures are estimated to be 2.3 ppb for surface water and 0.037 ppb for ground water.

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). Spinosad is currently registered for use on residential turf and ornamentals to control a variety of insect pests. The registered residential products for spinosad are Conserve SC Turf and Ornamental (EPA Reg No. 62719-291) and Conserve Fire Ant Bait (EPA Reg No. 62719-304). Conserve Fire Ant Bait is a ready-to-use granular formulation that may be applied by homeowners. For adults, residential exposures may result from dermal and inhalation exposure while applying Conserve Fire Ant Bait and/or from dermal contact with treated turf. However, dermal, post-application exposure is not of concern since no toxicological endpoint was established for dermal exposure. Inhalation exposure is not expected due to the low vapor pressure of spinosad and because the homeowner product is formulated as a granular. Post-application exposure to toddlers was not assessed for the Conserve Fire Ant Bait product since children are not likely to "habit" lawn areas where fire ant mounds are present. Conserve SC is labeled for use on turfgrass and ornamentals by commercial applicators. Since this product will be applied by commercial applicators, homeowner applicator exposure was not assessed. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. Since dermal post-application exposure is not of concern, only hand-to-mouth, object-to-mouth and incidental ingestion of soil exposures for the turf and ornamental uses were performed. The average aerobic soil metabolism half-life of spinosad (containing factors A and D) is

13-14 days. For the intermediate-term duration, typical lawn maintenance practices, such as mowing and watering, are expected to expedite the dissipation of spinosad on turfgrass. Since residue on turf that is available for transfer after day 30 is expected to be negligible, intermediate-term post-application incidental oral exposures were not assessed. The Agency developed exposure formulas and estimated doses to theoretically assess residential post-application incidental oral exposure scenarios including: (1) Hand-to-mouth, (2) object-to-mouth (turfgrass), and (3) incidental ingestion of soil. The resulting incidental oral ingestion MOEs from residential use of spinosad on turf are as follow:

- MOE for oral hand-to-mouth activities on treated lawns is 800 for short-term (1-30 days).
- MOE for oral object-to-mouth (turfgrass) from treated lawns is 3,300 for short-term.
- MOE for incidental ingestion of soil from treated lawns is 240,000 for short-term.
- Combined incidental oral MOE (hand-to-mouth, object-to-mouth, and soil ingestion) is 640. All MOEs are below EPA's LOC.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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).

### C. 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 risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no indication of increased susceptibility of rat and 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:

i. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with spinosad, and there is no evidence of increased susceptibility of young rats in the reproduction study with spinosad.

ii. There are no residual uncertainties identified in the exposure data bases; the dietary food exposure assessment (chronic only; no acute endpoint was identified) is refined using Anticipated Residues calculated from field trial data and available PCT information (100% crop treated is assumed for proposed new uses).

iii. The dietary drinking water exposure is based on conservative modeling estimates.

iv. EPA's Health Effect Division Residential Standard Operating

Procedures were used to assess post-application exposure to children as well as incidental oral exposure of toddlers, so these assessments do not underestimate the exposure and risks posed by spinosad.

v. A developmental toxicity study is not required.

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to spinosad in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of spinosad on 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 unit C for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 30% of the cPAD for the U.S. population, 41% of the cPAD for infant <1 year old and 69% of the cPAD for children 1–6 years old (subpopulation at greatest exposure). Based on the use pattern, 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 and ground 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)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.027	30	2.3	0.037	660
All infants (<1 year old)	0.027	41	2.3	0.037	160
Children (1–6 years old)	0.027	69	2.3	0.037	85
Children (7–12 years old)	0.027	45	2.3	0.037	150
Females (13–50)	0.027	24	2.3	0.037	620

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

Spinosad is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for spinosad.

Using the exposure assumptions described in Unit IV. B. for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 600 for the U.S. population, 260 for all infants less than 1-year old, 190 for children 1–6 years old (greatest risk subpopulation) and 250 for children 7–12 years old. These aggregate MOEs do not exceed the Agency’s LOC for aggregate exposure to

food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of spinosad in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency’s LOC, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO SPINOSAD

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	600	100	2.3	0.037	1,400
All infants (<1 year old)	260	100	2.3	0.037	300
Children (1–6 years old)	190	100	2.3	0.037	230
Children (7–12 years old)	250	100	2.3	0.037	290
Female (13–50)	760	100	2.3	0.037	1,300

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational 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, the average aerobic soil metabolism half-life of spinosad (containing factors A and D) is 13–14 days. For the intermediate-term duration, typical lawn maintenance practices, such as mowing and watering, are expected to expedite the dissipation of spinosad on turfgrass. Since residue on turf that is available for transfer after day 30 is expected to be negligible, intermediate-term post-application incidental oral exposures were not assessed.

5. *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.

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

**V. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) is available to enforce the tolerances in plants. Adequate livestock methods are available for tolerance enforcement. Method RES 94094 (GRM 95.03) is an HPLC/UV method suitable for determination of spinosad residues in ruminant commodities. Method GRM 95.03 has undergone successful independent laboratory validation (ILV) and EPA laboratory validation, and has been forwarded to FDA for inclusion in PAM Volume II. Method GRM 95.15 is another HPLC/UV method suitable for determination of spinosad residues in poultry commodities. This method has been forwarded to FDA for inclusion in PAM Volume II. Method RES 95114, an immunoassay method for determination of spinosad residues in ruminant commodities, underwent a successful ILV and EPA laboratory validation. It has been submitted to FDA for inclusion in PAM Volume II. The methods may be requested from: Paul Golden, U.S. EPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2960; FAX (410) 305–3091; e-mail address: RAM Mailbox.

*B. International Residue Limits*

There are no Codex, Canadian or Mexican maximum residue limits

established for spinosad in/on root and tuber vegetables. Therefore, no compatibility problems exist for the proposed tolerances.

**VI. Conclusion**

Therefore, the tolerance is established for residues of spinosad in or on onion, dry bulb at 0.10 ppm.

**VII. Objections and Hearing Requests**

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

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

You must file your objection or request a hearing on this regulation in

accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0207 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 October 6, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

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

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP-2003-0207, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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).

#### **VIII. Statutory and Executive Order Reviews**

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR

51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This

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

**IX. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: July 28, 2003.

**Debra Edwards,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.495 is amended by alphabetically adding the following commodity to the table in paragraph (b) to read as follows:

**§ 180.495 Spinosad; tolerances for residues.**

*	*	*	*	*
(b)	*	*	*	*

Commodity	Parts per million	Expiration/Revocation date
Onion, dry bulb .....	0.10	12/31/06

\* \* \* \* \*

[FR Doc. 03-20017 Filed 8-5-03; 8:45 am]

**BILLING CODE 6560-50-S**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 69**

[CC Docket No. 01-174; FCC 03-151]

**2000 Biennial Review—Requirement Governing the NECA Board of Directors**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Commission modifies the requirements governing how the National Exchange Carrier Association (NECA) conducts elections for its board of directors (Board). The Commission eliminates the requirement that NECA hold annual elections and that Board members serve one-year terms. The Commission also liberalizes its rules regarding contested elections for NECA’s non-

telecommunications industry directors (Outside Directors).

**DATES:** Effective September 5, 2003.

**FOR FURTHER INFORMATION CONTACT:** Cara Voth, Attorney, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418-7400.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order in CC Docket No. 01-174, FCC 03-151 released on July 3, 2003. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street SW., Washington, DC, 20554.

**I. Introduction**

1. In this Report and Order, as part of our biennial regulatory review under section 11 of the Communications Act of 1934, as amended (the Act), we modify the requirements governing how the National Exchange Carrier Association (NECA) conducts elections for its board of directors (Board). We eliminate the requirement that NECA hold annual elections and that Board

members serve one-year terms. We also liberalize our rules regarding contested elections for NECA’s non-telecommunications industry directors (Outside Directors). Under the liberalized rules, no Outside Director may serve for more than six consecutive calendar years without standing for an election in which that director is opposed by at least one other qualified candidate. By modifying our election requirements for the Board, we reduce the regulatory burdens that the current election requirements impose on NECA, while furthering our goal of ensuring that NECA fulfills certain Commission-specified functions.

**II. Discussion**

2. We find that the current election process imposes several unnecessary administrative burdens on NECA and therefore we eliminate certain election requirements for NECA’s Board. We also find, however, that because NECA continues to perform certain functions pursuant to Commission rules, we have a continuing interest in ensuring that NECA fulfills its obligations. In retaining certain requirements, we seek