IV. Will this Notification be Subject to the Congressional Review Act?

No. This action is not a rule for purposes of the Congressional Review Act (CRA), 5 U.S.C. 804(3), and will not be submitted to Congress and the Comptroller General. EPA will submit the final rule to Congress and the Comptroller General as required by the CRA.

List of Subjects in 40 CFR Part 158

Environmental protection, Confidential business information, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 30, 2007.

James Jones,

Director, Office of Pesticide Programs.

[FR Doc. E7–5162 Filed 3–20–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0579; FRL–8114–4]

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and amends tolerances for residues of spinosad in or on certain commodities. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 21, 2007. Objections and requests for hearings must be received on or before May 21, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0579. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0579 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 May 21, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0579, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of July 14, 2006 (71 FR 40105) (FRL–8077–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7068 and 3E6802) by the IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.495 be amended by establishing a tolerance for residues of the insecticide spinosad, in or on hops at 22 parts per million (ppm) (under PP 6E7068) and amaranth, grain, stover at 10 ppm; cattle, meat at 2 ppm; sheep, meat at 2 ppm; goat, meat at 2 ppm; horse, meat at 2 ppm; poultry, meat at 0.1 ppm; cattle, fat at 50 ppm; sheep, fat at 50 ppm; goat, fat at 50 ppm; horse, fat at 50 ppm; poultry, fat at 1.3 ppm; milk at 7.0 ppm; milk, fat at 85 ppm; and egg at 0.3 ppm (under PP 3E6802).

Additionally, existing tolerances for meat byproducts which are currently based on residues in liver will be amended to establish separate liver tolerances and lower the meat byproducts tolerances which will now be based on residues in the kidney as follows: Cattle, meat byproducts, except liver at 5 ppm; sheep, meat byproducts, except liver at 5 ppm; goat, meat byproducts, except liver at 5 ppm; horse, meat byproducts, except liver at 5 ppm; poultry meat byproducts tolerance raised from 0.03 ppm and set at 0.1 ppm; cattle, liver at 10 ppm; sheep, liver at 10 ppm; goat, liver at 10 ppm; and horse, liver at 10 ppm (under PP 3E6802). That notice referenced a summary of the petition prepared by Dow AgroScience, the registrant, that is available in the docket for this rulemaking. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of 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 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 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....''

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 FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm* and *http://www.epa.gov/fedrgstr/EPA-PEST/2003/July/Day-30/p19357.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of spinosad in or on hop, dried cones at 22 ppm; amaranth, grain, stover at 10 ppm; cattle, meat at 2.0 ppm; sheep, meat at 2.0 ppm; goat, meat at 2.0 ppm; horse, meat at 2.0 ppm; poultry, meat at 0.10 ppm; cattle, fat at 50 ppm; sheep, fat at 50 ppm; goat, fat at 50 ppm; horse, fat at 50 ppm; poultry, fat at 1.30 ppm; milk at 7.0 ppm; milk, fat at 85 ppm; and egg at 0.30 ppm. Additionally, existing tolerances for meat byproducts which are based on residues in liver will be amended to establish separate liver tolerances and lower the meat byproducts tolerances which will now be based on residues in the kidney as follows: Cattle, meat byproducts, except liver at 5.0 ppm; sheep, meat byproducts, except liver at 5.0 ppm; goat, meat byproducts, except liver at 5.0 ppm; horse, meat byproducts, except liver at 5.0 ppm; poultry meat byproducts tolerance raised from 0.03 ppm and set at 0.10 ppm; cattle, liver at 10 ppm; sheep, liver at 10 ppm; goat, liver at 10 ppm; and horse, liver at 10 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the toxic effects caused by spinosad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which 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 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for spinosad used for human risk assessment can be found at *http://www.regulations.gov* in the following indices:

1. Docket ID number EPA–HQ–OPP–2006–0579, entitled *Application of Spinosad to Hops and as a Mosquito Larvicide*. Human Health Risk Assessment, dated August 2, 2006.

2. Docket ID number EPA–HQ–OPP–2005–0510, entitled *PPs 3E6699, 3E6780, and 4E6811. Application of Spinosad to Mint; Banana; Plantain; Peanut; Bulb Vegetables; Legume Vegetables; Forage, Fodder, and Straw of Cereal Grains (crop group 16); Grass Forage, Fodder, and Hay (crop group 17); and Nongrass Animal Feeds (crop group 18) and Application of Spinosad for Control of Fruit Flies*. HED Risk Assessment, dated September 15, 2005.

C. 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. Risk assessments were conducted by EPA to assess dietary exposures from spinosad in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

The Agency did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects of concern attributable to a single exposure (dose) in studies available in the database including oral developmental toxicity studies in rats and rabbits. In the acute neurotoxicity study, the NOAEL was 2,000 milligrams/kilograms/day (mg/kg/day), highest dose tested. An acute dietary exposure assessment is not required.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) version 2.03 (acute and cancer endpoints were not identified), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The chronic dietary analyses assumed average/projected percent crop treated (PPCT) estimates; projected percent head treated resulting from the dermal and premise treatments to ruminants, average field trial residues, and experimentally determined processing factors; and anticipated livestock residues. The chronic analysis assumed tolerance level residues for all crop, poultry, and egg commodities and anticipated residues for ruminant and milk commodities.

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 quantitative cancer exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of 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 pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of 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 FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Almond 5%; apple 30%; apricot 10%; avocado 5%; broccoli 40%; brussel sprout 15%; cabbage 30%; cantaloupes 10%; cauliflower 45%; celery 50%; cherry 25%; citrus 5%, excluding lemon, tangerine, and orange; collards 25%; corn, sweet 1%; cotton 5%; cucumber 20%; eggplant 15%; green, mustard 15%; green, turnip 5%; kale 30%; lemon 10%; lettuce 50%; nectarine 30%; orange 10%; peach 5%; pear 10%; pepper 35%; potato 5%; prune and plum 10%; spinach 30%; squash 10%; strawberry 35%; tangerine 10%; tomato 20%; and watermelon 5%.

Exposure analysis also incorporated projected percent ruminant head treated resulting from the registered dermal and premise use (dairy cattle 23% and beef cattle 31%, actual data are not available despite this being a registered use) and projected PCT for alfalfa of 1%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases assumed not less than 1%, is used as the average and 2.5% is used the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, State, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA estimates PPCT for a new pesticide Use for use in chronic dietary risk assessment by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the dominant pesticide (i.e., the market leader pesticide with the greatest PCT) on that site over the three most recent pesticide usage surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with the new insecticide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses data from the USDA/NASS as the source for the PCT data because they are publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other data which may include proprietary data.

The estimated PPCT, equivalent to the average PCT of the market leader is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use.

The predominant factors that bear on whether the estimated PPCT could be exceeded are whether the new pesticide use is more efficacious or controls a broader spectrum of pests than the dominant pesticides, whether there are

concerns with pest pressure as indicated in emergency exemption requests or other readily available information, and/or other factors based on analysis of additional information. All information readily available has been considered for spinosad on dairy cattle, beef cattle and alfalfa, and it is the opinion of the Agency that it is unlikely that actual PCTs for spinosad on these sites will exceed the corresponding estimated PPCTs during the next 5 years. For cattle, the estimated PPCTs likely would not be exceeded because spinosad generally is more expensive than the leading alternative insecticides although it has efficacy on the same order for the targeted pests. For alfalfa, its estimated PPCT likely also would not be exceeded because it is considerably more expensive than the leading alternative, and treatments for the targeted pest, armyworms, have been relatively small on average over the past 8 years.

The Agency believes that the three conditions listed in Unit III.C.1.iv. 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. 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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Typically, EPA evaluates the potential for human exposure to pesticides in drinking water through an assessment of available surface water and ground water monitoring data and modeling. For spinosad, no monitoring data were available for use in this drinking water assessment. Therefore, potential human exposures to spinosad were evaluated through modeling. Estimated exposure concentrations (EECs) in surface water were calculated using Pesticide Root Zone Model/Exposure Analyses Modeling System (PRZM/EXAMS). Ground water concentrations were modeled using Screening Concentration in Ground Water (SCI-GROW) (version 2.3). Drinking water residues were then incorporated into the DEEM-FCID™ into the food categories ''water, direct, all sources'' and ''water, indirect, all sources.''

Available environmental fate data indicate that the spinosad transformation products maintain the basic ring structure of spinosad and that combined spinosad and its transformation products are stable. Therefore, the Agency concluded that a total residue method should be used when estimating spinsad residues in water, and that spinosad and its transformation products are stable under the aqueous photolysis, aerobic soil metabolism, and anaerobic aquatic metabolism conditions.

Based on modeling results from surface water FQPA Index Reservoir Screening Tool (FIRST) and ground water SCI-GROW drinking water concentrations from application of spinosad to turf (4 x 0.4 pound active ingredient/acre (lb ai/acre); re-entry interval (RTI) = 7 days; highest registered/proposed rate excluding the mosquito larvicide use): The EECs of spinosad for acute exposures are 34.5 parts per billion (ppb), 10.5 ppb for chronic exposures, and 1.1 ppb for ground water. The dietary exposure assessment assumed a water concentration of 10.5 ppb for all water sources (direct and indirect). Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™).

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 numerous crops with tolerances for combined residues of spinosad ranging from 0.01 to 200 ppm, as well as residential, non-dietary sites including turf and ornamentals to control a variety of worms, moths, flies, beetles, midges, thrips, leafminers, and fire ants. Granular (homeowner) and EC (commercial applicators) formulations are registered. No dermal endpoints were identified and based on the granular formulation and low-vapor pressure for spinosad, residential handler/applicator and post-application dermal/inhalation exposure assessments were not conducted. The Agency concluded that there is a potential for toddler short-term, non-dietary, oral exposures (hand-to-mouth, object-to-mouth, ingestion of granulars, and soil ingestion). Since EPA did not identify an acute dietary endpoint, episodic ingestion of granulars was not assessed.

The Agency notes that the registered fruit fly bait application scenario permits application to non-crop vegetation and this use may result in residential exposures. Based on the application rates (fruit fly bait—0.0003 lb ai/acre and turf/ornamental—0.41 lbs ai/acre), EPA concludes that residential exposure resulting from the fruit fly application will be insignificant when compared to the exposure resulting from the turf/ornamental application. Therefore, quantitative analysis of the residential exposure resulting from the fruit fly bait application was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spinosad and any other substances and 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 policy statements released by

EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 database on toxicity and exposure unless EPA determines based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

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

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicological database for spinosad is complete for FQPA assessment.

ii. 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.

iii. There are no residual uncertainties identified in the exposure databases; 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.

iv. EPA has indicated that the dietary drinking water exposure is based on conservative modeling estimates.

v. EPA Residential Standard Operational Procedures (SOPs) 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.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk*. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified for the general population or to the subpopulation females 13–50 years old. No acute risk is expected from 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 and water will utilize 37% of the cPAD for the U.S. population, 32% of the cPAD for all infants less than a year old, and 86% of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of spinosad is not expected. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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 uses (turf and ornamental application) that could result in short-term residential exposures (incidental oral exposures to toddlers). This incidental oral exposure is combined with chronic dietary (food and water) exposure for determination of aggregate short-term exposure. The Agency uses chronic dietary exposure when conducting short-term aggregate assessments as it has been determined this will more accurately reflect exposure from food than will acute exposure.

Upon analyses of all available data, resulting aggregate MOEs are greater than or equal to 160. Therefore, the Agency concludes that short-term aggregate exposure to spinosad from food and residential uses is below the LOC.

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

There is a practical method; liquid chromatography mass spectroscopy-accelerated climate prediction initiative (LCMS-ACPI) for detecting and measuring levels of spinosad in or on food with a limit of detection (0.002 ppm) that allows monitoring of food with residues at or above the level set for these tolerances. The method has undergone successful EPA laboratory validation.

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 the Food and Drug Administration (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: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for residues of spinosad on the raw agricultural commodities associated with this action.

V. Conclusion

Therefore, tolerances are established for residues of spinosad. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consist of two selected 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-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-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-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione, in or on hop, dried cones at 22 ppm and amaranth, grain, stover at 10 ppm; cattle, meat at 2.0 ppm; sheep, meat at 2.0 ppm; goat, meat at 2.0 ppm; horse, meat at 2.0 ppm; poultry, meat at 0.10 ppm; cattle, fat at 50 ppm; sheep, fat at 50 ppm; goat, fat at 50 ppm; horse, fat at 50 ppm; poultry, fat at 1.3 ppm; milk at 7.0 ppm; milk, fat at 85 ppm; egg at 0.30 ppm; cattle, meat byproducts, except liver at 5.0 ppm; sheep, meat byproducts, except liver at 5.0 ppm; goat, meat byproducts, except liver at 5.0 ppm; horse, meat byproducts, except liver at 5.0 ppm; poultry meat byproducts tolerance raised from 0.03 ppm and set at 0.10 ppm; cattle, liver at 10 ppm; sheep, liver at 10 ppm; goat, liver at 10 ppm; and horse, liver at 10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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 final rule has been exempted from review under Executive Order 12866 due to its lack of significance, this final 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 petition under section 408(d) of 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 FFDCA. For these same reasons, the Agency has determined that this final 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 final 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 final rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: March 5, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. The table in paragraph (a) of § 180.495 is amended by:

■ i. Alphabetically adding amaranth, grain, stover; cattle, liver; goat, liver; hop, dried cones; horse, liver; and sheep, liver.

■ ii. Revising the remainder of the entries listed.

The additions and revisions to the table in paragraph (a) read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Amaranth, grain, stover	10	None
* * * * *		
Cattle, fat	50	None
Cattle, liver	10	None
Cattle, meat	2.0	None
Cattle, meat byproducts, except liver	5.0	None
* * * * *		
Egg	0.30	None
* * * * *		
Goat, fat	50	None
Goat, liver	10	None
Goat, meat	2.0	None
Goat, meat byproducts, except liver	5.0	None
* * * * *		
Hop, dried cones	22	None
Horse, fat	50	None
Horse, liver	10	None
Horse, meat	2.0	None
Horse, meat byproducts, except liver	5.0	None
* * * * *		
Milk	7.0	None
Milk, fat	85	None
* * * * *		
Poultry, fat	1.3	None
Poultry, meat	0.10	None
Poultry, meat byproducts	0.10	None
* * * * *		
Sheep, fat	50	None
Sheep, liver	10	None
Sheep, meat	2.0	None
Sheep, meat byproducts, except liver	5.0	None
* * * * *		

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0325; FRL–8117–9]

6-Benzyladenine; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide, 6-benzyladenine (6–BA), in or on pear when applied/used as a plant regulator. Valent BioSciences Corporation (Valent) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 6-benzyladenine.

DATES: This regulation is effective March 21, 2007. Objections and requests for hearings must be received on or before May 21, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0325. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The 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.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION: