

(d) *Effective/applicability date.* This section is applicable beginning November 6, 2006.

■ **Par. 8.** Section 300.6 is amended by adding paragraph (d) to read as follows:

**§ 300.6 Renewal of enrollment of enrolled agent fee.**

\* \* \* \* \*

(d) *Effective/applicability date.* This section is applicable beginning November 6, 2006.

■ **Par. 9.** Section 300.7 is amended by adding paragraph (d) to read as follows:

**§ 300.7 Enrollment of enrolled actuary fee.**

\* \* \* \* \*

(d) *Effective/applicability date.* This section is applicable beginning January 22, 2008.

■ **Par. 10.** Section 300.8 is amended by adding paragraph (d) to read as follows:

**§ 300.8 Renewal of enrollment of enrolled actuary fee.**

\* \* \* \* \*

(d) *Effective/applicability date.* This section is applicable beginning January 22, 2008.

■ **Par. 11.** Section 300.9 is added to read as follows:

**§ 300.9 Fee for obtaining a preparer tax identification number.**

(a) *Applicability.* This section applies to the application for and renewal of a preparer tax identification number pursuant to 26 CFR 1.6109-2(d).

(b) *Fee.* The fee to apply for or renew a preparer tax identification number is \$50 per year, which is the cost to the government for processing the application for a preparer tax identification number and does not include any fees charged by the vendor.

(c) *Person liable for the fee.* The individual liable for the application or renewal fee is the individual applying for and renewing a preparer tax identification number from the IRS.

(d) *Effective/applicability date.* This section is applicable beginning September 30, 2010.

**Steven T. Miller,**

*Deputy Commissioner for Services and Enforcement.*

Approved: August 24, 2010.

**Michael Mundaca,**

*Assistant Secretary of the Treasury (Tax Policy).*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0616; FRL-8844-1]

**Spinosad; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation revises tolerances for residues of spinosad in or on hog, fat; hog, meat; hog, meat byproducts; poultry meat byproducts. Elanco Animal Health (A Division of Eli Lilly & Company) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 30, 2010. Objections and requests for hearings must be received on or before November 29, 2010, 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-2009-0616. All documents in the docket are listed in the docket index available at <http://www.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:**

Samantha Hulkower, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0683; e-mail address: [hulkower.samantha@epa.gov](mailto:hulkower.samantha@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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-2009-0616 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 29, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2

may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0616, 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 Facility'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 Facility telephone number is (703) 305-5805.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 26, 2009 (74 FR 55003) (FRL-8794-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7543) by Elanco Animal Health (A Division of Eli Lilly & Company), 2001 West Main Street, Greenfield, IN 46140. The petition requested that 40 CFR 180.495 be amended by reducing established tolerances for residues of the insecticide spinosad, a fermentation product of *Saccharopolyspora spinosa*, which consists of two related active ingredients: Spinosyn A (Factor A; CAS No. 131929-60-7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl- $\alpha$ -*L*-mannopyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-as-Indaceno[3,2-*d*]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS No. 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl- $\alpha$ -*L*-mannopyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1*H*-as-Indaceno[3,2-*d*]oxacyclododecin-7,15-dione, in or on milk from 7 parts per million (ppm) to 5 ppm; milk, fat from 80 ppm to 40 ppm; cattle, goat, and sheep, fat from 50 ppm to 30 ppm; hog, meat from 1.5 ppm to 0.2 ppm; hog, meat byproducts from 8 ppm to 0.6

ppm; and hog, fat from 33 ppm to 2.0 ppm. The petition additionally requested increases in the existing tolerances for residues of spinosad in or on poultry meat byproducts from 0.1 ppm to 0.2 ppm and poultry, fat from 1.3 ppm to 1.5 ppm. That notice referenced a summary of the petition prepared by Elanco Animal Health, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has concluded that revision of the proposed tolerances in or on hog, fat from 2.0 ppm to 5.0 ppm; hog, meat from 0.2 ppm to 0.50 ppm; hog, meat byproducts from 0.6 ppm to 2.0 ppm; poultry, meat byproducts from 0.10 ppm to 0.20 ppm is necessary and revision of the currently-established ruminant fat (i.e., cattle, goat, and sheep) and poultry, fat tolerances, as proposed by Elanco Animal Health in the petition, is unnecessary. The reason for these changes are explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCFA 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 FFDCFA 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 FFDCFA 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..."

Consistent with section 408(b)(2)(D) of FFDCFA, and the factors specified in section 408(b)(2)(D) of FFDCFA, 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 for spinosad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spinosad follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Spinosad has low acute toxicity via the oral and dermal routes of exposure. It is not a dermal sensitizer, nor inhalation, primary eye, or primary skin irritant. In subchronic toxicity studies conducted in mice treatment-related findings included vacuolation of cells of the lymphoid organs, liver, kidney, stomach, female reproductive tract, and epididymis, and less severely in the heart, lung, pancreas, adrenal cortex, bone marrow, tongue, pituitary gland, and anemia. In rats, thyroid follicle epithelial cell vacuolation, anemia, multifocal hepatocellular granuloma, cardiomyopathy, and splenic histiocytosis were observed following subchronic exposure, in dogs microscopic changes in a variety of tissues, anemia, and possible liver damage were seen with short-term repeated dosing. In a chronic feeding study in dogs, increases in serum alanine aminotransferase, aspartate aminotransferase, and triglycerides levels, and the presence of tissue abnormalities, including vacuolated cell aggregations, arteritis, and glandular cell vacuolation (parathyroid) were seen. Vacuolation of thyroid follicular cells, increased absolute and relative thyroid weights were observed in a chronic oral toxicity study in rats. Spinosad is classified as "not likely to be carcinogenic to humans" based on lack of evidence for carcinogenicity of spinosad in mice and rats. No neurotoxic effects were seen in the acute or subchronic neurotoxicity study in rats. In developmental toxicity studies, there is no evidence of increased susceptibility following *in utero* exposures in rats and rabbits. In the 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity.

Specific information on the studies received and the nature of the adverse 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 can be found at <http://www.regulations.gov> in document "Spinosad and Spineteram. Human-Health Risk Assessment for Direct-Spray

Use on Poultry and Discontinuation by Voluntary Cancellation of the Cattle Pour-On and Direct Cattle Spray Registrations,” p. 12 in docket ID number EPA–HQ–OPP–2009–0616.

#### *B. Toxicological Points of Departure/ Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (U/SF) are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for spinosad used for human risk assessment can be found at <http://www.regulations.gov> in document “Spinosad and Spinetoram. Human-Health Risk Assessment for Direct-Spray Use on Poultry and Discontinuation by Voluntary Cancellation of the Cattle Pour-On and Direct Cattle Spray Registrations,” p. 5 in docket ID number EPA–HQ–OPP–2009–0616.

The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion is based on the following: Spinetoram and spinosad are large molecules with nearly identical structures; and the toxicological profiles for each are similar (generalized systemic toxicity) with similar doses and endpoints chosen for human-health risk assessment. Spinosad and spinetoram should be considered toxicologically identical in the same manner that metabolites are generally considered

toxicologically identical to the parent. Although, as just stated, the doses and endpoints for spinosad and spinetoram are similar, they are not identical due to variations in dosing levels used in the spinetoram and spinosad toxicological studies. EPA compared the spinosad and spinetoram doses and endpoints for each exposure scenario and selected the lower of the two doses for use in human risk assessment.

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinosad/spinetoram, EPA considered exposure under the petitioned-for tolerances as well as all existing spinosad/spinetoram tolerances in 40 CFR 180.495 and 180.635. EPA assessed 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.

No such effects were identified in the toxicological studies for spinosad; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, the chronic analysis assumed 100 percent crop treated (PCT) for all food crop commodities excluding those listed below where PCT estimates were incorporated to refine the livestock dietary burden estimates; used average field-trial residues for apple, *Brassica* leafy vegetables, citrus, fruiting vegetables, herbs, banana, grape, several cereal grains, and strawberry; used tolerance-level residues for the remaining food crop commodities; and used Dietary Exposure Evaluation Model DEEM<sup>(TM)</sup> (ver. 7.81) default processing factors for all commodities excluding orange juice, field corn (meal, starch, flour, and oil), grape juice, and wheat (flour and germ) where the results from processing factors were assumed; and modeled drinking water estimates. Tolerance level hog and poultry residues were assumed while the ruminant residue estimates were refined through the incorporation of average residues from the feeding/dermal magnitude of the residue studies and incorporation of the following projected combined spinosad/spinetoram PCT estimates to refine the ruminant dietary

burden: Leaves of root and tuber vegetables – 50%; grain sorghum grain – 5%; soybean seed – 5%; and sweet corn forage – 39%.

Spinosad is registered for application to all of the same crops as spinetoram, with similar pre-harvest and retreatment intervals, and application rates greater than or equal to spinetoram. Further, both products control the same pest species. For this reason, EPA concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. Rather, EPA aggregated exposure by either assuming that all commodities contain spinosad residues (because side-by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues) or summing the percentage of a crop that would be treated with spinosad and the percentage that would be treated with spinetoram.

iii. *Cancer.* Based on the lack of evidence of carcinogenicity in rats and mice, EPA has classified spinosad as “not likely to be carcinogenic to humans;” therefore a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and 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 residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 FFDC section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

Tolerance level hog and poultry residues were assumed while the ruminant residue estimates were refined through the incorporation of average residues from the feeding/dermal magnitude of the residue studies and incorporation of the following projected combined spinosad/spinetoram PCT estimates to refine the ruminant dietary burden uses as follows: 39% sweet corn forage; 50% leaves of root and tuber vegetables; 5% sorghum grain; and 5% soybean seed meal.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, 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 b and c, 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 reliable 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 used screening level water exposure models in the dietary exposure analysis and risk assessment for spinosad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spinosad/spinetoram for acute exposures are estimated to be 14.419 parts per billion (ppb) for surface water and 0.072 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 6.171 ppb for surface water and 0.072 ppb for ground water. EDWCs for spinosad for acute exposures are estimated to be 34.5 parts per billion (ppb) for surface water and 1.1 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 10.5 ppb for surface water and 1.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 10.5 ppb was used to assess the contribution to drinking 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 the following uses that could result in residential exposures: Application to turfgrass and ornamentals. EPA assessed residential exposure using the following assumptions: The Agency has concluded that spinosad and spinetoram are toxicologically equivalent; therefore, residential exposure to both spinosad and spinetoram was evaluated. Spinosad is currently registered for homeowner

application to turf grass and ornamentals. Spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used for the same uses in combination with each other and thus combining spinosad and spinetoram residential exposures would overstate exposure.

There is potential for residential handler and post-application exposures to both spinosad and spinetoram. However, since no dermal endpoints for either spinetoram or spinosad were identified, only short-term incidental oral exposures to toddlers are anticipated from the registered turf and ornamental application scenarios for spinosad and spinetoram and short-term inhalation exposure to handler/applicators is anticipated for the registered home garden, turf, and ornamental application scenarios.

Based on the low application rates, granular formulation, and/or low vapor pressure, quantitative residential inhalation post-application exposure assessments were not performed for spinosad or spinetoram. The Agency notes that the spinetoram residential-handler inhalation MOEs were  $\geq 4,300,000$  for house garden, home lawns and ornamental use; based on this and the low vapor pressure for spinosad, the Agency anticipates the post-application residential inhalation risks to be negligible.

EPA notes that for spinosad 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 pounds active ingredients/acre (lb ai/acre); 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 homeowner uses on the turf/ornamentals. Therefore, quantitative analysis of the residential exposure resulting from the fruit fly bait application was not performed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDC 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 has not found spinosad/spinetoram to share a common mechanism of toxicity with any other substances, and spinosad/spinetoram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinosad/spinetoram does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat and rabbit fetuses to *in-utero* exposure to spinosad or spinetoram. In the spinosad and spinetoram rat and rabbit developmental toxicity studies, no developmental toxicity was observed at dose levels that did not induce maternal toxicity. In the spinosad 2-generation reproduction studies, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre-natal and/or post-natal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spinetoram is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Harmonized Test Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for valuation of the requirements under the FQPA.

There was some evidence of adverse effects on the organs of the immune system at the LOAEL in three short-term studies with spinosad or spinetoram. In these studies, anemia was observed in multiple species (rats, mice and dogs) with the presence of histiocytic aggregates of macrophages in various organs and tissues (lymph nodes, spleen, thymus, and bone marrow). Aggregation of macrophages was indicative of immune stimulation in response to insults of the chemical exposure and was considered secondary effects of the toxic effect to the hematopoietic system. Therefore, these effects are not considered to be indicative of frank immunotoxicity. In the chronic study with dogs, arteritis and necrosis of the arterial walls of the thymus was seen in one female dog at the highest dose tested (HDT). This finding is attributed to the exacerbation of the spontaneous arteritis present in genetically predisposed Beagle dogs ("Beagle Pain Syndrome"), not immunotoxicity. Further, a clear NOAEL was attained in each of these studies, and the observed histopathologies were generally observed in the presence of other organ toxicity. In addition, spinosad and spinetoram do not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic.

Based on the considerations in this Unit, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a POD less than the NOAEL of 2.49 mg/kg/day already set for spinosad and spinetoram. Consequently, an additional database UF does not need to be applied.

ii. There is no indication that spinosad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spinosad results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments utilized 100 PCT and tolerance-level residues, and DEEM™ default processing factors for all registered and proposed crop commodities and all food commodities from livestock except commodities from ruminants. EPA used PCT information when calculating livestock dietary burdens for ruminants from sweet corn forage, leaves of root and tuber vegetables, sorghum grain, and soybean seed meal. EPA believes that the PCT estimates used are conservative estimates. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to spinosad/spinetoram in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spinosad/spinetoram.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, spinosad is not expected to pose an acute risk.

2. *Chronic risk.* Since there are no registered/proposed uses which result in chronic residential exposures, the chronic aggregate exposure assessment consists of exposure from food and water. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spinosad and spinetoram from food and water will utilize 94% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water

(considered to be a background exposure level).

Spinosad and spinetoram are currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to spinosad and spinetoram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of  $\geq 160$  for all population subgroups. As the aggregate MOEs are greater than 100 for all population subgroups, including infants and children, short-term aggregate exposure to spinosad and spinetoram is not of concern to EPA.

#### 4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Spinosad and spinetoram are not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from the exposure to spinosad and spinetoram through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in rats and mice at doses that were judged to be adequate to assess the carcinogenic potential, spinosad and spinetoram were classified as “not likely to be carcinogenic to humans,” and are 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, or to infants and children from aggregate exposure to spinosad and spinetoram residues.

## IV. Other Considerations

### A. Analytical Enforcement Methodology

Adequate methods are available for enforcement of the ruminant and hog tolerances. Method RES 94094 (GRM 95.03; ruminant and hog); Method RES 95114 (ruminant and hog); GRM 95.15 (poultry). Data pertaining to Multiresidue Methods (MRMs) testing of spinosyns A, D, B, and K and N-demethyl spinosyn D were forwarded to

the Food and Drug Administration (FDA) for review.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex does have a MRLs for combined residues of spinosyn A and D in/on fat from mammals other than marine at 2 ppm and edible offal at 0.5 ppm and Canada does have MRLs for residues of spinosyn A and D in/on hog fat at 5.0 ppm, hog meat byproducts at 1.0 ppm, and hog meat at 0.2 ppm. For the most part, these international tolerances are lower than the level of the hog tolerances being established today. The Codex values were set in 2004. At that time only the diets of cattle (beef and dairy) were considered in establishing the MRLs, which were then considered adequate for all mammals, including hogs. However, the United States calculates hog exposure based on specific diets for finishing and breeder hogs. These diets are high in grains and grain byproducts and would not have included forages and other commodities present in the cattle diet. The diets considered were different, leading to different calculated exposures, leading to different MRL/tolerance estimates for the hog commodities. Accordingly, given the manner in which the Codex values were chosen, EPA does not believe it is appropriate to harmonize with the Codex levels.

### C. Revisions to Petitioned-For Tolerances

Elanco Animal Health requested registration for direct spray of Elector PSP (EPA Reg. No. 72642-2) to poultry

and discontinuation by voluntary cancellation of the cattle pour-on and direct cattle spray registrations for Elector Insect Control Product (EPA Reg. No. 72642-1). The petitioner also requested an increase in the currently-established poultry fat (1.3 ppm to 1.5 ppm), poultry meat (0.10 ppm to 0.2 ppm), and poultry meat byproducts (0.10 ppm to 0.2 ppm) tolerances and a decrease in the currently-established milk (7.0 ppm to 5 ppm), milk fat (85 ppm to 40 ppm), hog fat (33 ppm to 2.0 ppm), hog meat (1.5 ppm to 0.2 ppm), hog meat byproducts (8.0 ppm to 0.6 ppm), and ruminant fat (cattle, goat, and sheep – 50 ppm to 30 ppm) tolerances (tolerances for combined residues of spinosyns A and D).

With the elimination of cattle pour-on and direct cattle spray uses, ruminants may be exposed to spinosad via consumption of treated feed, premise application, and through the feed-through (cattle only) and ear tag uses (cattle only). Based on the elimination of the cattle dermal application scenario and a recalculation of spinosad residues in ruminant commodities from the consumption of treated feed, the petitioner requested a reduction in the milk, milk fat, and ruminant (cattle, goat, and sheep) fat tolerances. Based on a comparison of the estimated total residue without the dermal/premise application and the currently-established tolerances, the EPA concludes that revision of the currently-established ruminant tolerances is unnecessary. Since elimination of the dermal uses does not necessitate a change in the current ruminant tolerances, the EPA concludes that residues resulting from premise treated are insignificant when compared to the residue estimates from the other routes of exposure.

The petitioner requested a reduction in the hog fat, meat, and meat byproducts tolerances. The current hog tolerances were established as part of the registration for application of spinosad to stored grains where a hog dietary burden of 41.2 ppm was calculated. As a conservative surrogate for residues following premise treatment, the results from the cattle dermal magnitude of the residue study were used (residue data following only premise treatment are not available). EPA notes that hogs have a significantly lower maximum reasonably balanced dietary burden (MRDB) than ruminants and the residues resulting from the premise treatment were therefore considered when establishing a tolerance (this is on contrast to ruminants where residues resulting from premise treatment were not

considered). Based on these calculations, the EPA concludes that hog tolerance should be lowered as follows: Hog, meat – 0.50 ppm; hog, fat – 5.0 ppm; and hog, meat byproducts – 2.0 ppm.

As part of the current request, the petitioner submitted a poultry magnitude of the residue study monitoring spinosad residues following both the proposed dermal application scenario (0.9x) and the currently-registered premise treatment (1x). Based on these data and the current poultry MRDB, the EPA concludes that the poultry meat byproducts tolerance should be increased to 0.20 ppm (tolerance for the combined residues of spinosyns A and D). All other poultry tolerances remain adequate.

**V. Conclusion**

Therefore, tolerances are established for residues of spinosad in or on poultry at 0.20 ppm poultry, meat byproducts; and tolerances are increased as indicated for the following established commodities: Hog, fat 5.0 ppm; hog, meat 0.50 ppm; hog, meat byproducts 2.0 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**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: September 24, 2010.

**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. Section 180.495 is amended by revising the following entries in the table in paragraph (a) to read as follows:

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

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Hog, fat .....	5.0
Hog, meat byproducts ....	2.0
Hog, meat .....	0.50
* * *	* *
Poultry, meat byproducts	0.20
* * *	* *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2007–0677; FRL–8845–7]

**Fluoxastrobin; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluoxastrobin in or on multiple commodities which are identified and discussed later in this document. Arysta LifeScience North America, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 30, 2010. Objections and requests for hearings must be received on or before November 29, 2010, 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–2007–0677. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some