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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0810; FRL–8434–2]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on date and pomegranate, and additionally increases established tolerances in or on almond hulls; tree nut, group 14; and pistachio. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, 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–2008–0810. 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0810 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 as required by 40 CFR part 178 on or before November 23, 2009.

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 this copy, identified by docket ID number EPA–HQ–OPP–2008–0810, 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. Petition for Tolerance

In the **Federal Register** of December 3, 2008 (73 FR 73648) (FRL–8391–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7445) by IR-4, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide, spinosad, a fermentation product of *Saccharopolyspora spinosa*, consisting of two related active ingredients: Spinosyn A (Factor A; CAS#131929-60-7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-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 pomegranate at 0.3 parts per million (ppm) and date at 0.1 ppm. The petition additionally requested an increase in the existing tolerances for residues of spinosad in or on tree nut, group 14 and pistachio from 0.02 to 0.08 ppm; and almond, hulls from 2.0 to 9.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, LLC, the registrant, which is available to the public 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 revised the proposed tolerance levels for almond hulls; tree nut, group 14; and pistachio. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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.''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for residues of spinosad on almond, hulls at 19 ppm; tree nut, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; and pomegranate at 0.30 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The existing spinosad data indicate that it possesses low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a dermal irritant, dermal sensitizer or eye irritant. No dermal toxicity was seen at the limit dose in a 21–day dermal toxicity study in rabbits.

In mice, rats, and dogs, the target organs appeared to be the liver, kidney, spleen, heart, thyroid, and bone marrow (anemia). In the mouse subchronic toxicity study, increased vacuolation of cells was noted in the lymphoid organs, liver, kidney, stomach, female reproductive tract and epididymis. A similar effect was seen in the heart, lung, pancreas, adrenal cortex, bone marrow, tongue, pituitary gland, and anemia but to a less severe degree. The rat subchronic toxicity study showed evidence of thyroid follicle epithelial cell vacuolation, anemia, multifocal hepatocellular granuloma, cardiomyopathy, and splenic histiocytosis. Microscopic changes in a variety of tissues, anemia and possible liver damage were seen in the dog subchronic toxicity study. Additionally, long-term dietary administration of spinosad resulted in increases in serum alanine aminotransferase, aspartate aminotransferase and triglyceride levels.

Spinosad is classified as ''not likely to be carcinogenic to humans'' based on the lack of evidence for carcinogenicity in mice and rats. No evidence of neurotoxicity was seen in any of the submitted studies, including the acute and subchronic neurotoxicity studies in rats. Spinosad is negative for mutagenicity in various mutagenicity assays.

No developmental effects were seen in the rat and rabbit developmental toxicity studies. In a 2–generation reproduction study in rats, decreased litter size, survival and body weights were observed in the presence of maternal toxicity (deaths) at the highest dose tested (HDT). In addition, male rats exhibited chronic active inflammation of the prostate gland.

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 the document ''Spinosad and Spinetoram. Human-Health Risk Assessment for Application of Spinosad to Date and Pomegranate and Spinetoram to Pineapple, Date, Pomegranate, Hops, and Spices (Crop Subgroup 19B, except black pepper)'' at pages 44-48 in docket ID number EPA–HQ–OPP–2008–0810.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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*.

The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion

is based on the following: (1) Spinetoram and spinosad are large molecules with nearly identical structures; and (2) 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 stated above, 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.

A summary of the toxicological endpoints for spinosad and spinetoram used for human risk assessment can be found at *http://www.regulations.gov* in the document ''Spinosad and Spinetoram. Human-Health Risk Assessment for Application of Spinosad to Date and Pomegranate and Spinetoram to Pineapple, Date, Pomegranate, Hops, and Spices (Crop Subgroup 19B, except black pepper)'' at pages 8 and 21 in docket ID number EPA–HQ–OPP–2008–0810.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spinosad and spinetoram, EPA considered exposure under the petitioned-for tolerances as well as all existing spinosad and spinetoram tolerances in 40 CFR 180.495 and 180.635, respectively. EPA assessed dietary exposures from spinosad and spinetoram 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 and spinetoram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. Spinosad and spinetoram are considered to be toxicologically equivalent. However, as both products control the same pest species, EPA concluded that it would overstate exposure to assume that residues of both chemicals would appear on the same crop. Therefore, the Agency aggregated exposure from residues of spinosad and spinetoram by assuming that spinosad residues would be present in all commodities, because side-by-side spinosad and spinetoram residue data indicated that spinetoram residues were less than or equal to spinosad residues.

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) for all food crop commodities; used average field trial residues for apple, *Brassica* leafy vegetables, citrus, fruiting vegetables, herbs, banana, and strawberry; used tolerance-level residues for the remaining food crop commodities; and used Dietary Exposure Evaluation Model (DEEM) 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 studies were used. Residues in livestock were refined through the incorporation of a refined dietary burden (average feed crop residues and combined spinosad and spinetoram PCT estimates) and through the incorporation of average residues from the feeding and dermal magnitude of the residue studies.

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

EPA assumed 100 PCT for all food crop commodities. For certain feed crop commodities, the Agency used combined spinosad and spinetoram projected PCT (PPCT) information to calculate beef and dairy cattle burdens as follows:

Sweet corn forage (39%); leaves of root and tuber vegetables (50%); sorghum grain (5%); and soybean seed meal (5%).

Spinetoram is a recently registered pesticide. EPA estimates an upper bound of PPCT for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the recent PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA calls this the market leader PPCT estimate. In this specific case, the new use to be estimated is the combined use of spinosad together with that of spinetoram, since most new uses of spinetoram will likely replace a previous use of spinosad. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment. The average market leader PCT may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCT may be based on a cross-section of state PCTs. Comparisons are only made among pesticides of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide), or, for refined estimates, among pesticides targeting the same pests. The market leader PCTs are used to determine the average for the same pesticide or for different pesticides for any year since the same or different pesticides may dominate for each year. Typically, EPA uses U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) as the

source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the combined use of spinetoram and spinosad on each of these several crops. It is the Agency's opinion that it is unlikely that actual combined PCTs for spinetoram and spinosad will exceed the corresponding estimated PPCTs during the next 5 years.

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 and spinetoram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinosad and spinetoram. 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 for surface water are estimated to be 34.5 parts per billion (ppb) for acute exposures, and 10.5 ppb for chronic exposures. For ground water, the estimated drinking water concentration is 1.1 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As explained above, an acute dietary risk assessment was not conducted for spinosad and spinetoram. 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).

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 and spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass.

There is potential for residential handler and postapplication exposures to both spinosad and spinetoram. Since spinosad and spinetoram control the same pests, EPA concluded that these products will not be used in combination with each other and combining the residential exposures is unnecessary. Short-term residential inhalation risks were estimated for adult residential handlers, as well as short-term postapplication incidental oral risks (hand-to-mouth, object-to-mouth and soil ingestion) for toddlers, based on applications to home lawns, home gardens and ornamentals. Dermal exposures were not assessed, since no dermal endpoints of concern were identified in the toxicology studies for spinosad and spinetoram.

In addition, a registered fruit fly bait application scenario permits application to non-crop vegetation, which may result in residential exposures to spinosad. Based on the application rates, EPA concluded that residential exposure resulting from this scenario would be insignificant when compared to the residential exposure resulting from the turf/ornamental application scenarios; therefore, a quantitative analysis of residential exposure resulting from the fruit fly bait application scenario is unnecessary and 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.''

EPA has not found spinosad and spinetoram to share a common mechanism of toxicity with any other substances, and spinosad and spinetoram do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinosad and spinetoram do 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 FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The following acceptable studies are available for both spinosad and spinoteram: Developmental toxicity studies in rats and rabbits and a 2–generation reproduction study in rats. There is no evidence of increased susceptibility of rat or 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 induced maternal toxicity. In the spinosad 2–generation rat reproduction study, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2-generation rat reproduction study, no adverse effects were observed in 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 prenatal and/or postnatal 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 spinosad is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation 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 hematopoetic system. Therefore, these effects are not considered to be indicative of frank immunotoxicity. In the spinetoram chronic toxicity study in dogs, areteritis and necrosis of the areterial walls of the thymus was seen in one female dog at the 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 above considerations, EPA does not believe that conducting a special series OPPTS Guideline 870.7800 immunotoxicity study will result in a POD less than the NOAEL of 2.49 miligrams/kilograms/day (mg/kg/day) already set for spinosad and spinetoram. Consequently, an additional database uncertainty factor does not need to be applied.

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

iii. There is no evidence that spinosad and spinetoram result 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 were performed based on tolerance-level residues or reliable data from field trial studies and 100 PCT for all registered and proposed commodities except certain feed crop commodities. The PPCT estimates used to refine certain feed crop estimates provide conservative, high-end estimates developed using the market leader approach that are unlikely to be exceeded. Conservative ground and surface water modeling estimates were used to assess exposure to spinosad and 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 and spinetoram.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 and spinetoram are not expected to pose an acute risk.

2. *Chronic risk*. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spinosad and spinetoram are not expected; therefore, the chronic aggregate exposure assessment consists of exposures from food and water only. 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 95% of the cPAD for children 1 to 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 aggregated result in aggregate MOEs of greater than or equal to 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 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 mice and rats 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

Method RES 94025, GRM 94.02 (a high performance liquid chromatography method with ultraviolet absorption detection (HPLC/UV)) has been adequately validated and determined to be acceptable to enforce the tolerance expression in plant commodities. In addition, the following additional methods (which are essentially similar to GRM 94.02) have been submitted for other crop matrices: GRM 95.17 for leafy vegetables; GRM 96.09 for citrus; GRM 96.14 for tree nuts; GRM 95.04 for fruiting vegetables; and GRM 94.02.S1 for cotton gin byproducts. These methods have been forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Methods Volume II (PAM II). These methods 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

There are currently no Canadian maximum residue limits (MRLs) established for residues of spinosad in or on the crops associated with this review. Codex MRLs exist for spinosad on almond hull (2 ppm) and almond nutmeat (0.01 ppm). These MRLs are based on field trial data which employed a 14–day pre-harvest interval (PHI), while the U.S. almond hull (19 ppm) and tree nut (0.10 ppm) tolerances are based on a 1–day PHI. Since the U.S. and Codex tolerances are based on different application scenarios and since the U.S. tolerances are significantly greater (10x) than those currently established by Codex, harmonization is not possible.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised tolerances for certain proposed commodities as follows: almond, hulls from 9.0 ppm to 19 ppm; nut, tree, group 14 from 0.08 ppm to 0.10 ppm; and pistachio from 0.08 ppm to 0.10 ppm. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

V. Conclusion

Therefore, tolerances are established for residues of spinosad, consisting of two related active ingredients: Spinosyn A (Factor A; CAS#131929-60-7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-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 almond, hulls at 19 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; and pomegranate at 0.30 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 8, 2009.

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 in paragraph (a) by revising the entries in the table for ''Almond, hulls''; ''Nut, tree, group 14'' and ''Pistachio''; and by alphabetically adding entries for ''Date'' and ''Pomegranate'' to the table to read as follows:

180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Almond, hulls	19
* * * * *	
Date	0.10
* * * * *	
Nut, tree, group 14	0.10
* * * * *	
Pistachio	0.10
Pomegranate	0.30
* * * * *	

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[FR Doc. E9–22534 Filed 9–22–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0239; FRL–8438–9]

Metolachlor, S-Metolachlor, Bifenazate, Buprofezin, and 2,4-D; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is modifying, establishing and revoking certain tolerances for the herbicides metolachlor and S-metolachlor and correcting the tolerance for guava (from guave) on bifenazate and buprofezin and 2,4-D on cranberry. The regulatory actions finalized in this document are in follow-up to the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance reassessment program under the Federal Food, Drug, and Cosmetic Act (FFDCA), section 408(q).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, 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–2009–0239. 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 either 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 hours of operation of this Docket Facility are 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: Jane Smith, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0048; e-mail address: *smith.jane-scott@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).
- 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 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 electronically available documents 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 e-CFR site at *http://www.gpoaccess.gov/ecfr*.