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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0525; FRL-9995-90]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on tea, dried and tea, instant. Dow AgroSciences, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0525, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket

available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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 Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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-2018-0525 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0525, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 24, 2018 (83 FR 42818) (FRL-9982-37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8674) by Dow Agro Sciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054. The petition requested that 40 CFR 180.495 be amended by establishing import tolerances for residues of the insecticide spinosad, determined by measuring 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 tea, dried at 70 parts per million (ppm) and tea, instant at 70 ppm. That document referenced a summary of the petition prepared by Dow Agro Sciences LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received in response to the notice of filing, and the Agency's response can be found in Unit IV.D.

Based upon review of the data supporting the petition, EPA has established import tolerances for tea, dried and tea, instant each at 2 ppm rather than the requested 70 ppm. The reason for this change 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure 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 and spinetoram are considered by EPA to be toxicologically identical for human health risk assessment based on their very similar chemical structures and similarity of the toxicological databases for currently available studies. Therefore, the Agency has assessed and summarized the toxicological profile for both spinosad and spinetoram together. The primary toxic effect observed from exposure to spinosad and spinetoram was histopathological

changes in multiple organs (specific target organs were not identified). Vacuolization of cells and/or macrophages was the most common histopathological finding noted across the toxicological database with the dog being the most sensitive species. In addition to the numerous organs observed with histopathological changes, anemia was noted in several studies. There was no evidence of increased quantitative or qualitative susceptibility from spinosad or spinetoram exposure. In developmental studies, no maternal or developmental effects were seen in rats or rabbits. In the rat reproduction toxicity studies, offspring toxicity (decreased litter size, survival, and body weights with spinosad; increased incidence of late resorptions and post-implantation loss with spinetoram) was seen in the presence of parental toxicity (increased organ weights, mortality, and histopathological findings) at approximately the same dose for both chemicals. Dystocia and/or other parturition abnormalities were observed with both spinosad and spinetoram in the reproduction toxicity studies. There was no evidence of neurotoxicity, immunotoxicity, or carcinogenicity from spinosad exposure.

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/Spinetoram. Human Health Risk Assessment in Support of Proposed Spinetoram Tolerance for Residues in/on Imported Tea" at page 8 in docket ID number EPA-HQ-OPP-2017-0352 and in document "Spinosad/Spinetoram. Draft Human Health Risk Assessment for Registration Review," at pages 12-17 in docket ID number EPA-HQ-OPP-2011-0666.

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 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 is shown in the Table of this unit.

Table -- Summary of Toxicological Doses and Endpoints for Spinosad/Spinetoram for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	A dose and endpoint of concern attributable to a single dose was not observed.		
Chronic dietary (All populations)	NOAEL= 2.49 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0249 mg/kg/day cPAD = 0.0249	Chronic Toxicity—Dog (Spinetoram). LOAEL = 5.36/5.83 mg/kg/day (males/females) based on arteritis and necrosis of the arterial walls of the

		mg/kg/day	epididymides in males and of the thymus, thyroid, larynx, and urinary bladder in females.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 4.9 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE < 100	Subchronic Oral Toxicity—Dog Study (with spinosad). LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.
Dermal (All durations)	No hazard was identified for dermal exposure; therefore, a quantitative dermal assessment is not needed.		
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL= 4.9 mg/kg/day (inhalation assumed equivalent to oral) UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE < 100	Subchronic Oral Toxicity—Dog Study (with spinosad). LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.
Cancer (Oral, dermal, inhalation)	Classified as "not likely to be carcinogenic to humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UUF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

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

active ingredients control the same pest species, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. The risk assessment includes commodities that have tolerances for both spinosad and spinetoram as well as commodities where only spinosad tolerances are established. EPA aggregated exposure by assuming that all commodities contain spinosad residues as either average field-trial residues; tolerance-level residues for crop commodities; spinosad residue estimates for fish/shellfish (spinetoram residues in fish/shellfish are expected to be insignificant); experimental or default processing factors; and refined milk, egg, and ruminant/hog/poultry tissue spinosad residue estimates. 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 or spinetoram; 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 USDA NHANES/WWEIA (2003-2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) for all commodities; average spinosad field-trial residues or tolerance-level residues for crop commodities (spinosad or spinetoram residues whichever was higher, assumed that crop will not be treated with both spinosad and spinetoram as they control the same pests); spinosad residue estimates for fish/shellfish (spinetoram residues in fish/shellfish are expected to be insignificant); spinetoram tea tolerance (established 70 ppm tea tolerance is higher than the petitioned-for spinosad tea tolerance); experimental or default processing factors; and refined milk, egg, and

ruminant/hog/poultry tissue spinosad residue estimates.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that spinosad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue*. 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.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the surface water concentration calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of spinosad for chronic exposures for non-cancer assessments, the spinosad EDWCs are estimated

to be 22.8 ppb for surface water and below the levels of detection for ground water. EDWCs of spinetoram for chronic exposures for non-cancer assessments are estimated to be 19.3 ppb for surface water and below the levels of detection 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 22.8 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 use on tea will not result in residential exposure; however, spinosad and spinetoram are currently registered for the following uses that could result in residential exposures: including home lawns and pet (cats/kittens) spot-on applications; therefore there is potential for residential handler and post-application exposures to both spinosad and spinetoram 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. EPA assessed residential exposure for both spinosad and spinetoram using the most conservative residential exposure scenarios for either chemical.

EPA assessed the following "worst-case" residential exposure scenarios as: (1) Adult residential handler (inhalation exposure from applications to lawns and turf) and (2) child (1 to <2 years) (hand-to-mouth exposures from post-application exposure to turf). Because EPA's level of concern for spinetoram is a MOE below 100, the MOEs for both of these residential exposure scenarios are not of concern. In addition, the short-term assessment is protective of

intermediate-term exposure as the short- and intermediate-term PODs are identical. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

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 to share a common mechanism of toxicity with any other substances, and spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinosad 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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*. There is no evidence of increased prenatal or postnatal susceptibility.

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 for FQPA SF consideration.

ii. There is no evidence of neurotoxicity from spinosad exposure.

iii. There is no evidence that spinosad results in increased pre- or post-natal susceptibility in rats or rabbits.

iv. There are no residual uncertainties identified in the spinosad and spinetoram exposure databases. The dietary exposure assessment is conservative as it assumes 100 PCT and residue estimates are based on field trial data and fish nature of the residue studies. Moreover, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spinosad and spinetoram in drinking water. EPA used similarly conservative assumptions to assess post-application 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 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*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spinosad from food and water will utilize 72 % of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spinosad is not expected; therefore, the chronic dietary estimate represents the chronic aggregate estimate.

3. *Short- and Intermediate-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 is 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.

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 780 for adults (handler) and 200 for children (post-application). Because EPA's level of concern for spinosad are MOEs below 100, these MOEs are not of concern. The short-term

assessment is protective of intermediate-term exposure as the short- and intermediate-term PODs are identical.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spinosad is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate plant, ruminant, poultry, fish, and shellfish methods (high-performance liquid chromatography (HPLC)/ultraviolet (UV)) are available for enforcement of the established spinosad tolerances. These methods were forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Methods Volume II. Additional details on the analytical methods can be found in the supporting documentation in docket ID (EPA-HQ-OPP-2011-0667-0027).

Methods not found in PAM Vol II may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email 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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

An MRL for spinosad in/on tea has not been established by Codex.

C. Revisions to Petitioned-For Tolerances and Tolerance Definition

The registrant indicated that the proposed 70 ppm tolerances for tea, dried and tea, instant were based on translation of the recently established spinetoram tolerances on import tea to spinosad. However, based on the available residue data and the different application scenarios for spinosad and spinetoram, this translation is not appropriate. Based on the available data, EPA determined that import tolerances for residues of spinosad in or on tea, dried and tea, instant at 2 ppm are appropriate.

Additionally, the tolerance definition has been updated as shown in the part 180 Amendment to be consistent with Chemical Abstracts Service (CAS) Nomenclature.

D. Response to Comments

One comment was submitted opposing sale or use of Dow's product in the United States. This tolerance action does not permit sale or use of spinosad pesticide products in the United States; sale and use of pesticide products are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act. Moreover, the commenter provided no information to support a conclusion that this tolerance is not safe.

V. Conclusion

Therefore, tolerances are established for residues of spinosad, determined by measuring two related active ingredients: Spinosyn A (Factor A: CAS #131929-60-7; (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione); and Spinosyn D (Factor D; CAS #131929-63-0; (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-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-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione), in or on tea, dried at 2 ppm and tea, instant at 2 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action 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); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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: August 28, 2019.

Michael Goodis,

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. In § 180.495, amend paragraph (a) by revising the introductory text and adding alphabetically the entries for "Tea, dried"; and "Tea, instant" to the table to read as follows:

§ 180.495 Spinosad; tolerances for residue.

(a) *General*. Tolerances are established for residues of the insecticide spinosad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spinosyn A (Factor A: CAS #131929-60-7; (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione); and Spinosyn D (Factor D; CAS #131929-63-0) or (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-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-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione), calculated as the stoichiometric equivalent of spinosad.

Commodity	Parts per million
* * * * * * *	
Tea, dried[1]	2
Tea, instant[1]	2
* * * * * * *	

[1] There are no U.S. registrations for use on tea.

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