SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End-use	Substitute	Decision	Use conditions	Further information
Household refrigerators, freezers, and combination refrigerators and freezers (New equipment only).	Isobutane (R-600a). Propane (R-290). R-441A	Acceptable subject to use conditions.	As of September 7, 2018: ..... These refrigerants may be used only in new equipment designed specifically and clearly identified for the refrigerant (*i.e.,* none of these substitutes may be used as a conversion or ''retrofit'' refrigerant for existing equipment designed for a different refrigerant). These refrigerants may be used only in a refrigerator or freezer, or combination refrigerator and freezer, that meets all requirements listed in the 2nd edition of the Underwriters Laboratories (UL) Standard for Safety: Household and Similar Electrical Appliances—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers, UL 60335–2–24, dated April 28, 2017.	Applicable OSHA requirements at 29 CFR part 1910 must be followed, including those at 29 CFR 1910.106 (flammable and combustible liquids), 1910.110 (storage and handling of liquefied petroleum gases), 1910.157 (portable fire extinguishers), and 1910.1000 (toxic and hazardous substances). Proper ventilation should be maintained at all times during the manufacture and storage of equipment containing hydrocarbon refrigerants through adherence to good manufacturing practices as per 29 CFR 1910.106. If refrigerant levels in the air surrounding the equipment rise above one-fourth of the lower flammability limit, the space should be evacuated and reentry should occur only after the space has been properly ventilated. Technicians and equipment manufacturers should wear appropriate personal protective equipment, including chemical goggles and protective gloves, when handling these refrigerants. Special care should be taken to avoid contact with the skin since these refrigerants, like many refrigerants, can cause freeze burns on the skin. A Class B dry powder type fire extinguisher should be kept nearby. Technicians should only use spark-proof tools when working on refrigerators and freezers with these refrigerants. Any recovery equipment used should be designed for flammable refrigerants. Any refrigerant releases should be in a well-ventilated area, such as outside of a building. Only technicians specifically trained in handling flammable refrigerants should service refrigerators and freezers containing these refrigerants. Technicians should gain an understanding of minimizing the risk of fire and the steps to use flammable refrigerants safely.
*	*	*	*	*	*	*

Note: The use conditions in this appendix contain references to certain standards from Underwriters Laboratories Inc. (UL). The standards are incorporated by reference, and the referenced sections are made part of the regulations in part 82:

1. UL 471. Commercial Refrigerators and Freezers. 10th edition. Supplement SB: Requirements for Refrigerators and Freezers Employing a Flammable Refrigerant in the Refrigerating System. Underwriters Laboratories, Inc. November 24, 2010.
2. UL 484. Room Air Conditioners. 8th edition. Supplement SA: Requirements for Room Air Conditioners Employing a Flammable Refrigerant in the Refrigerating System and Appendices B through F. December 21, 2007, with changes through August 3, 2012.
3. UL 541. Refrigerated Vending Machines. 7th edition. Supplement SA: Requirements for Refrigerated Venders Employing a Flammable Refrigerant in the Refrigerating System. December 30, 2011.
4. UL Standard 60335–2–24. Standard for Safety: Requirements for Household and Similar Electrical Appliances,—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers, Second edition, dated April 28, 2017.

The Director of the Federal Register approves the incorporation by reference of the material under ''Use Conditions'' in the table ''SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS'' (5 U.S.C. 552(a) and 1 CFR part 51). Copies of UL Standards 471, 484, 541, and 60335–2–24, may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: *orders@shopulstandards.com;* Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial 1–415–352–2178); internet address: *http://www.shopulstandards.com/Catalog.aspx.*

You may inspect a copy at U.S. EPA's Air Docket; EPA West Building, Room 3334; 1301 Constitution Ave. NW, Washington, DC or at the National Archives and Records Administration (NARA). For questions regarding access to these standards, the telephone number of EPA'S Air Docket is 202–566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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[FR Doc. 2018–16773 Filed 8–7–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0352; FRL–9978–83]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinetoram 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 August 8, 2018. Objections and requests for hearings must be received on or before October 9, 2018, 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–2017–0352, 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 Printing 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–2017–0352 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 October 9, 2018. 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–2017–0352, 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 October 23, 2017 (82 FR 49020) (FRL–9967–37), 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 7E8554) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268–1054. The petition requested that 40 CFR 180.635 be amended by establishing tolerances for residues of the insecticide spinetoram, 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 AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 spinetoram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spinetoram 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. Spinetoram and spinosad 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 together. The primary toxic effect observed from exposure to spinetoram and spinosad 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 spinetoram or spinosad 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 spinetoram and spinosad in the reproduction toxicity studies. There was no evidence of neurotoxicity, immunotoxicity, or carcinogenicity from spinetoram exposure.

Specific information on the studies received and the nature of the adverse effects caused by spinetoram 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.*

Spinetoram and spinosad should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent. As a result, studies from both toxicological databases were considered for endpoint selection.

A summary of the toxicological endpoints for spinetoram used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPINETORAM/SPINOSAD 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 mg/kg/day.	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 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 (1–6 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). UF_{DB} = to account for the absence of data or other data deficiency. UF_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 spinetoram and spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinetoram tolerances in 40 CFR 180.635 as well as existing spinosad tolerances. With the exception

of tea, 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 active ingredients control the same pest species. For this reason, 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 included 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, with the exception of tea, contain spinosad (because side-by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues); for tea, EPA assumed spinetoram residues were present. EPA assessed dietary exposures from 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 spinetoram or 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 USDA NHANES/WWEIA (2003–2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), average field-trial residues or tolerance-level residues for crop commodities, average residues from the livestock feeding studies, spinosad residue estimates for fish/shellfish (residues of spinetoram in fish/shellfish are expected to be insignificant), and experimental or default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that spinetoram 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 and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment for spinetoram. 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 spinetoram and spinosad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinetoram and spinosad. 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 spinetoram for acute exposures are estimated to be 25.9 parts per billion (ppb) for surface water and below the levels of detection for ground water. For chronic exposures for non-cancer assessments, the spinetoram EDWCs are estimated to be 19.3 ppb for surface water and well below the levels of detection for ground water. EDWCs of spinosad for acute exposures are estimated to be 30.6 ppb for surface water and below the levels of detection for ground water. For chronic exposures for noncancer assessments, the spinetoram EDWCs are estimated to be 22.8 ppb for surface water and below the levels of detection for ground water.

Modeled estimates of drinking water concentration 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).

EPA assessed residential exposure using the following assumptions: The use on tea will not result in residential exposure; however, spinetoram and spinosad are currently registered for 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 spinetoram and spinosad. 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–<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 spinetoram to share a common mechanism of toxicity with any other substances, and 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 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://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 spinetoram is adequate for FQPA SF consideration.

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

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

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in assessing exposures and these assessments will not underestimate the exposure and risks posed by 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, spinetoram 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 spinetoram from food and water will utilize 72% of the cPAD for children 1–2 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 spinetoram is not expected; therefore, the chronic dietary estimate represents the chronic aggregate estimate.

3. *Short- and Intermediate-term risk.* Short- and Intermediate-term aggregate exposures takes into account short-term and intermediated-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Spinetoram is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to 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 780 for adults (handler) and 200 for children (post-application). Because EPA's level of concern for spinetoram is a MOE below 100, these MOEs 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.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spinetoram 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 spinetoram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available for both plant and livestock commodities. Method GRM 05.03 (HPLC/MS/MS) is an acceptable method for the determination of spinetoram residues in a variety of crops. Methods GRM 05.15 and GRM 06.08 (HPLC/MS) are acceptable methods for determination of spinetoram residues in bovine and poultry tissues, milk, cream, and eggs. Both methods are available to enforce the tolerance expression.

The 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; 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.

The Codex has not established a MRL for spinetoram.

V. Conclusion

Therefore, tolerances are established for residues of spinetoram, expressed as the combined residues of XDE–175–J: 1-*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-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,4,5,5a,5b,6,9,10, 11,12,13,14,16a,16b-hexadecahydro 14-methyl-, (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*, 14*R*,16a*S*,16b*R*); XDE–175–L: 1*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-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-(2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*); ND–J: (2*R*,3a*R*,5a*R*,5b*S*,9*S*, 13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13 [[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino)tetrahydro-2*H*-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6, 7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-

d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranoside; and NF–J: (2*R*,3*S*,6*S*)-6-([(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranosyl) oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide, in or on tea, dried at 70 parts per million (ppm) and tea, instant at 70 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: July 24, 2018.

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 § 180.635 add alphabetically the entries for ''Tea, dried''; and ''Tea, instant''; and footnote 1 to the table in paragraph (a) to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Tea, dried [1]	70
Tea, instant [1]	70
* * * * *	

[1] There are no U.S. registrations as of August 8, 2018 for use on tea.

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