ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0022; FRL-9123-01-OCSPP]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinetoram in or on multiple commodities which are identified and discussed later in this document. Clarke Mosquito Control Products, Inc., 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-2020-0022, is available at *https://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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff

continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2020-0022 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-2020-0022, by one of the following methods:

• *Federal eRulemaking Portal*: *https://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 *https://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of March 3, 2020 (85 FR 12454) (FRL-10005-58), 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 9F8804) by Clarke Mosquito Control Products, Inc., 675 Sidwell Court, St. Charles, IL 60174. The petition requested that 40 CFR 180.635 be amended by establishing tolerances for residues of the insecticide spinetoram, expressed as a combination 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-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-[(6deoxy-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*,6R)-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 fish at 4.0 parts per million (ppm); fish-shellfish, crustacean at 4.0 ppm; fish-shellfish, mollusc at 4.0 ppm; grass, forage, fodder and hay, group 17, forage at 10.0 ppm; grass, forage, fodder and hay, group 17, hay at 5.0 ppm; animal feed, nongrass, group 18, forage at 35.0 ppm; and animal feed, nongrass, group 18, hay at 30.0 ppm to account for incidental residues from the proposed use of

spinetoram as a mosquito larvicide in aquatic areas and standing water within agricultural sites. That document referenced a summary of the petition prepared by Clarke Mosquito Control Products, Inc., the petitioner, which is available in the docket, *https://www.regulations.gov*. Two non-substantive comments were received on the notice of filing and the notice of receipt and did not result in changes to EPA's decision.

Based upon review of the data supporting the petition, EPA has removed the trailing zeros on the requested tolerance values and revised certain commodity terms. 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 FFDCA section 408(b)(2)(D), and the factors specified therein, 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.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for spinetoram, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to spinetoram and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged as described further in this rulemaking. While these tolerances are being established for spinetoram use as a larvicide, the previous spinetoram tolerance rulemaking was based on the databases for both spinetoram and spinosad.

Toxicological profile. 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. For a discussion of the Toxicological Profile of spinetoram and spinosad, see Unit III.A. of the previous spinetoram tolerance rulemaking published in the *Federal Register* of August 8, 2018 (83 FR 38976) (FRL-9978-83).

Toxicological points of departure/Levels of concern. 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. For a summary of the

Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the August 8, 2018 rulemaking.

Exposure assessment. In evaluating dietary exposure to spinetoram and spinosad, EPA considered exposure under the petitioned-for spinetoram tolerances as well as all existing spinetoram and spinosad tolerances. Spinosad is currently registered for use as a mosquito larvicide in aquatic areas and standing water within agricultural sites, and there are existing tolerances for incidental residues of spinosad in or on the same commodities identified in this action. Because application rates for the proposed mosquito larvicide use of spinetoram are lower than spinosad, incidental residues of spinetoram in or on these commodities will not exceed the existing spinosad tolerances. Moreover, because spinetoram and spinosad are used to control similar pests and are not likely to be used in combination with each other, EPA has concluded it would overstate exposure to assume that residues of both spinetoram and spinosad would appear on the same commodities. Therefore, much of the dietary exposure assessment remains unchanged from the August 8, 2018 rulemaking, which included the existing spinosad tolerances.

The currently registered maximum application rate for spinosad was used to assess residential exposure, as this rate is higher than the proposed application rate for spinetoram. The residential assessment for spinosad is protective for spinetoram for the reasons described above.

For a description of the rest of the EPA approach to and assumptions for the exposure assessment, including with respect to dietary exposure, residential exposure, and cumulative effects, see Unit III.C. of the August 8, 2018 rulemaking.

Safety factor for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children is adequately protected if the Food Quality Protection Act safety factor is reduced from 10X to 1X. The reasons for that determination are articulated in Unit III.D. of the August 8, 2018 rulemaking.

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 population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not conducted as toxicological effects attributable to a single dose were not identified. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: children 1 to 2 years old are the population subgroup with the highest exposure estimate at 72% of the cPAD. The short-term aggregate MOE (food, water, and residential) is 200 for children 1 to less than 2 years old and 840 for adults. These MOEs do not exceed the level of concern, which are MOEs of 100 or below. The short-term aggregate risk assessment is protective of intermediate-term exposure as the short-term and intermediate-term PODs are identical. EPA has also concluded that spinetoram is not expected to pose a cancer risk to humans based on the lack of evidence of carcinogenicity in the database.

Determination of safety. Based on the risk assessments and information described above, EPA concludes 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. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the document titled “Spinetoram: Human Health Risk Assessment in Support of Proposed New Granular Sand Formulation for Use as a Mosquito/Larvicide and Proposed Tolerance for Residues of Spinetoram on Fish; Fish-shellfish, Crustacean; Fish-Shellfish, Mollusc; Grass, Forage, Fodder and Hay, Group 17,

Forage; Grass, Forage, Fodder and Hay, Group 17, Hay; Animal Feed, Nongrass, Group 18, Forage; and Animal Feed, Nongrass, Group 18, Hay" in docket ID number EPA-HQ-OPP-2020-0022.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the August 8, 2018 rulemaking.

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). 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 MRLs for spinetoram on the commodities identified in this action.

C. Revisions to Petitioned-For Tolerances

EPA has removed the trailing zeros on the requested tolerance values to be consistent with Organization for Economic Co-operation and Development (OECD) Rounding Class Practice. EPA has also revised the commodity terms for fish, freshwater, finfish; fish, shellfish, crustacean; and fish, shellfish, mollusc to be consistent with the Agency's preferred vocabulary terms for these commodities; see the document titled "Preferred Vocabulary for Establishing Pesticide Tolerances" dated September 27, 2017 in docket ID number EPA-HQ-OPP-2020-0022 at *https://www.regulations.gov*.

V. Conclusion

Therefore, tolerances are established for residues of spinetoram, in or on fish, freshwater, finfish at 4 ppm; fish, shellfish, crustacean at 4 ppm; fish, shellfish, mollusc at 4 ppm; grass, forage, fodder and hay, group 17, forage at 10 ppm; grass, forage, fodder and hay, group 17, hay at 5 ppm; animal feed, nongrass, group 18, forage at 35 ppm; and animal feed, nongrass, group 18, hay at 30 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). 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 tolerances 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: December 10, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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, amend table 1 to paragraph (a) by adding in alphabetical order the entries "Animal feed, nongrass, group 18, forage"; "Animal feed, nongrass, group 18, hay"; "Fish, freshwater, finfish"; "Fish, shellfish, crustacean"; "Fish, shellfish, mollusc"; "Grass, forage, fodder and hay, group 17, forage" and "Grass, forage, fodder and hay, group 17, hay" to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * *	* * * *
Animal feed, nongrass, group 18, forage	35
Animal feed, nongrass, group 18, hay	30
* * *	* * * *
Fish, freshwater, finfish	4
Fish, shellfish, crustacean	4
Fish, shellfish, mollusk	4
* * *	* * * *

Grass, forage, fodder and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	5
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