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[Rules and Regulations]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0384; FRL-11035-01-OCSPP]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

spinetoram in or on Spice group 26, and Stalk and stem vegetable

subgroup 22A. Interregional Research Project Number 4 (IR-4) requested

these tolerances under the Federal Food, Drug, and Cosmetic Act

(FFDCA).

DATES: This regulation is effective September 5, 2023. Objections and

requests for hearings must be received on or before November 6, 2023,

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-2022-0384, is available at

[https://www.regulations.gov](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 and the OPP Docket is (202) 566-1744. For the latest

status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration

Division (7505T), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-

0001; main telephone number: (202) 566-1030; email address:

[RDFRNotices@epa.gov](mailto: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-2022-0384 in the subject line on the first

page of your submission. All objections and requests for a hearing must

be in writing and must be received by the Hearing Clerk on or before

November 6, 2023. 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

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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-2022-0384, by one of the following methods:

Federal eRulemaking Portal: [https://www.regulations.gov](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/where-send-comments-epa-dockets>.

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 January 3, 2023 (88 FR 38) (FRL-9410-08-

OCSPP), 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

2E8994) by IR-4, North Carolina State University, 1730 Varsity Drive,

Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to

amend 40 CFR part 180 by establishing tolerances for residues of

spinetoram in or on the raw agricultural commodities Stalk and stem

vegetable subgroup 22A at 0.4 parts per million (ppm), and Spice group

26 at 1.7 ppm.

The petition also requested to remove established tolerances for

residues of spinetoram in or on the following: Asparagus, and Spice

subgroup 19B, except black pepper.

That document referenced a summary of the petition, which is

available in the docket, [https://www.regulations.gov](https://www.regulations.gov/). There were no

comments received in response to the notice.

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 rulemaking of the same pesticide

chemical. Where scientific information concerning a particular chemical

remains unchanged, the content of those sections would not vary between

tolerance rulemaking, 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 several 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. Specific information on the risk assessment

conducted in support of this action, including on the studies received

and the nature of the adverse effects caused by spinetoram, can be

found in the document titled ``Spinosad and Spinetoram: Human Health

Risk Assessment in Support of Proposed Uses on Stalk and Stem

Vegetables (22A) and Greenhouse-Grown Cucumbers, Lettuce, Pepper, and

Tomato; and Crop Group Conversion for Spice Group 26'' (hereinafter

``Spinosad and Spinetoram Human Health Risk Assessment'') which is

available in the docket for this action at [https://www.regulations.gov](https://www.regulations.gov/).

Toxicological profile. For a discussion of the Toxicological

Profile of spinetoram, see Unit III.A. of the rulemaking published in

the Federal Register of August 8, 2018 (83 FR 38976) (FRL-9978-83).

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

of the Toxicological Points of Departure/Levels of Concern used for the

safety assessment of spinetoram, see Unit III.B. of the August 8, 2018,

rulemaking.

Exposure assessment. Much of the exposure assessment remains

unchanged from the August 8, 2018, rulemaking, although the new

exposure assessment incorporates the additional dietary exposure from

the petitioned-for tolerances. Other changes are described below.

A chronic dietary exposure assessment was conducted using DEEM-FCID

Version 4.02. This software uses 2005-2010 food consumption data from

the U.S. Department of Agriculture's (USDA's) National Health and

Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

Acute and cancer analyses were not conducted as toxicological effects

attributable to a single dose were not identified, and spinetoram is

classified as not likely to be carcinogenic. The chronic dietary

analysis assumed 100 percent crop treated (PCT), average field-trial

residues or tolerance-level residues for crop commodities, average

residues from the livestock feeding studies, experimental processing

factors when available, and modeled drinking water estimates.

Anticipated residue information. Section 408(b)(2)(E) of FFDCA

authorizes EPA to use available data and information on the anticipated

residue levels of pesticide residues in food and the actual levels of

pesticide residues that have been measured in food. If EPA relies on

such information, EPA must require pursuant to FFDCA section 408(f)(1)

that data be provided 5 years after the tolerance is established,

modified, or left in effect, demonstrating that the levels in food are

not above the levels anticipated. For the present action, EPA will

issue such data call-ins as are required by FFDCA section 408(b)(2)(E)

and authorized under FFDCA section 408(f)(1). Data will be required to

be submitted no later than 5 years from the date of issuance of these

tolerances.

Drinking water and non-occupational exposures. The estimated

drinking water concentrations (EDWCs) of spinetoram have been updated

since the

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last assessment. Based on the Tier I Rice Model and Pesticide Root Zone

Model Ground Water (PRZM GW), the EDWCs of spinetoram for chronic

exposures are estimated to be 38 parts per billion (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 the chronic dietary risk

assessment, the water concentration value of 38 ppb was used to assess

the contribution to drinking water.

There have been no changes to residential exposures since the

August 8, 2018, rulemaking. For calculation of aggregate short-term

exposure, residential exposure to adults (residential handler exposure

from applying spinetoram to turf/ornamentals/home garden), children 3

to less than 6 years old (combined post-application inhalation and

ingestion of water exposure during recreational swimming), and children

1 to less than 2 years old (post-application exposure resulting from

the application of spinetoram to turf/ornamentals/home gardens) yield

the highest residential short-term exposure and were therefore used in

calculation of aggregate exposure.

Cumulative exposure. 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.'' Unlike other

pesticides for which EPA has followed a cumulative risk approach based

on a common mechanism of toxicity, EPA has not made a common mechanism

of toxicity finding as to spinetoram and any other substances and

spinetoram does not appear to produce a toxic metabolite produced by

other substances. For the purposes of this action, therefore, EPA has

not assumed that spinetoram has a common mechanism of toxicity with

other substances.

Safety factor for infants and children. EPA continues to conclude

that there is reliable data showing that the safety of infants and

children would be adequately protected if the Food Quality Protection

Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for

that decision 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

dietary exposure estimates to the acute population-adjusted dose (aPAD)

and chronic population-adjusted dose (cPAD). Short-, intermediate-, and

chronic-term aggregate risks are evaluated by comparing the estimated

total food, water, and residential exposure to the appropriate points

of departure to ensure that an adequate margin of exposure (MOE)

exists.

An acute assessment was not conducted because toxicological effects

attributable to a single dose were not identified. Chronic dietary

(food and drinking water) risks are below the Agency's level of concern

of 100% of the cPAD: they are 73% of the cPAD for children 1 to 2 years

old, which is the population subgroup with the highest exposure

estimate.

The short-term aggregate risks combine chronic dietary (food and

drinking water) and residential exposures. The short-term aggregate

risk for adults is an aggregate MOE of 740; for children aged 3 to less

than 6, the aggregate MOE is 330; and for children 1 to less than 2

years old, the aggregate MOE is 200. MOEs below 100 are of concern;

these MOEs are above 100 and therefore are not of concern. Short-term

aggregate risk calculations are protective of the intermediate-term

duration of exposure.

Because spinetoram is classified as ``not likely to be carcinogenic

to humans'', EPA has concluded that aggregate exposure to spinetoram is

not likely to pose a cancer risk.

Therefore, 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](https://www.regulations.gov/)

in the Spinosad and Spinetoram Human Health Risk Assessment in docket

ID EPA-HQ-OPP-2022-0384.

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).

There are currently no established Codex MRLs for residues of

spinetoram in or on Stalk and stem vegetable subgroup 22A or Spice

Group 26.

V. Conclusion

Therefore, tolerances are established for residues of spinetoram in

or on Spice group 26 at 1.7 ppm, and the Stalk and stem vegetable

subgroup 22A at 0.4 ppm.

Additionally, the established tolerances on Asparagus, and Spice,

subgroup 19B, except black pepper, are removed as unnecessary.

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 to 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

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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 24, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending

40 CFR chapter 1 as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

IN FOOD

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1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

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2. In Sec. 180.635, amend the table 1 to paragraph (a) by:

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a. Removing the commodity ``Asparagus'';

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b. Adding in alphabetical order the commodity ``Spice group 26''

0

c. Removing the commodity ``Spice, subgroup 19B, except black pepper'';

and

0

d. Adding in alphabetical order the commodity ``Stalk and stem

vegetable subgroup 22A''.

The additions read as follows:

Sec. 180.635 Spinetoram; tolerances for residues.

\* \* \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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\* \* \* \* \*

Spice group 26.............................................. 1.7

Stalk and stem vegetable subgroup 22A....................... 0.4

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[FR Doc. 2023-19012 Filed 9-1-23; 8:45 am]

BILLING CODE 6560-50-P