[Federal Register Volume 86, Number 65 (Wednesday, April 7, 2021)]

[Rules and Regulations]

[Pages 17907-17910]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0526; FRL-10020-24]

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 multiple commodities that are identified and

discussed later in this document. Interregional Research Project Number

4 (IR-4) requested these tolerances under the Federal Food, Drug, and

Cosmetic Act (FFDCA).

DATES: This regulation is effective April 7, 2021. Objections and

requests for hearings must be received on or before June 7, 2021 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-2019-0526, is available at [http://www.regulations.gov](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.

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](mailto:RDFRNotices@epa.gov).

SUPPLEMENTARY INFORMATION:

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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-2019-0526 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

June 7, 2021. 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-2019-0526, by one of

the following methods:

Federal eRulemaking Portal: [http://www.regulations.gov](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 February 11, 2020 (85 FR 7708) (FRL-

10005-02), 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

9E8778) by IR-4, IR-4 Project Headquarters, Rutgers, The State

University of New Jersey, 500 College Road East, Suite 201 W,

Princeton, NJ 08540. The petition requested that 40 CFR part 180 be

amended by establishing tolerances for residues of the insecticide

spinetoram, including its metabolites and degradates in or on the raw

agricultural commodities dragon fruit at 1.5 ppm; vegetable, Brassica,

head and stem, group 5-16 at 2.0 ppm; kohlrabi at 2.0 ppm; Brassica,

leafy greens, subgroup 4-16B at 10 ppm; leafy greens subgroup 4-16A at

8.0 ppm; leaf petiole vegetable subgroup 22B at 8.0 ppm; celtuce at 8.0

ppm; fennel, Florence, fresh leaves and stalk at 8.0 ppm; and berry,

low growing, except strawberry, subgroup 13-07H at 0.04 ppm. The

petition also requested to amend 40 CFR 180.635 by removing the

following spinetoram tolerances: Brassica, head and stem, subgroup 5A

at 2.0 ppm; Brassica, leafy greens, subgroup 5B at 10 ppm; vegetable,

leafy, except Brassica, group 4 at 8 ppm; and cranberry at 0.04 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](http://www.regulations.gov/). There were no comments received in response to the

notice of filing.

Based upon review of the data supporting the petition, EPA is

establishing several tolerances at different levels than requested. The

reasons for these changes are 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 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 republishing the same sections is

unnecessary. 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 that

remain unchanged from

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those rulemakings as described further in this rulemaking.

Toxicological Profile. For a discussion of the Toxicological

Profile of spinetoram, see Unit III.A. of the August 8, 2018 rulemaking

(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, see Unit III.B. of the August 8, 2018 rulemaking.

Exposure Assessment. Much of the exposure assessment remains

unchanged from the previous rulemaking, although the new exposure

assessment incorporates the additional dietary exposure from the

petitioned-for tolerances. The residue levels, percent crop treated,

and estimated drinking water concentrations used in the exposure

assessment remain the same and are discussed in Unit III.C. of the

August 8, 2018 rulemaking. Moreover, there have been no changes to

residential exposures, so the Agency's approach for assessing

residential (non-occupational, non-dietary exposures) is also discussed

in that same Unit. Finally, the Agency's conclusions about cumulative

effects remain the same as in that Unit.

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 FQPA SF were reduced from

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

aggregate exposure estimates to the acute population adjusted dose

(aPAD) and chronic PAD (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 analysis 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 780 for adults. These MOEs do not exceed the target level

of concern of 100. 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

[http://www.regulations.gov](http://www.regulations.gov/) in the document titled ``Spinosad/

Spinetoram. Human Health Risk Assessment in Support of Proposed

Spinetoram Tolerance for Residues in/on Imported Tea'' dated January

16, 2018 in docket ID EPA-HQ-OPP-2017-0352 and the document titled

``Spinosad and Spinetoram. Human Health Risk Assessment for Proposed

Use on Dragon Fruit (Pitaya); Crop Group Expansion for Berry, Low

Growing, Except Strawberry, Subgroup 13-07H; and Crop Group Conversions

for Vegetable, Brassica, Head and Stem, Group 5-16; Brassica, Leafy

Greens, Subgroup 4-16B; Leaf Petiole Vegetable Subgroup 22B; Leafy

Greens Subgroup 4-16A; Celtuce; Fennel, Florence, Fresh Leaves and

Stalk; and Kohlrabi.'' dated February 12, 2021 in docket ID number EPA-

HQ-OPP-2019-0526.

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). 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.

There are no Codex MRLs established for dragon fruit; berry, low

growing, except strawberry, subgroup 13-07H; Brassica, leafy greens,

subgroup 4-16B; celtuce; and fennel, Florence, fresh leaves and stalk.

The U.S. tolerances for kohlrabi and leafy greens subgroup 4-16A

are harmonized with the Codex MRLs.

For two crop groups, the Codex MRL is lower than the U.S.

tolerance: Leaf petiole vegetable subgroup 22B at 6 ppm instead of 8

ppm and for vegetable, Brassica, head and stem, group 5-16 at 0.3 ppm

rather than 2 ppm. Harmonization of these tolerances is not possible

because decreasing the U.S. tolerances to harmonize with the Codex MRL

would put U.S. growers at risk of having violative residues despite

legal use of the pesticide according to the label.

C. Revisions to Tolerances

Based upon review of the data supporting the petition, EPA is

establishing tolerance levels consistent with Organization for Economic

Cooperation and Development (OECD) Rounding Class Practice.

The petitioner requested separate subgroup tolerances for the

Brassica, leafy greens, subgroup 4-16B at 10 ppm and leafy greens

subgroup 4-16A at 8.0 ppm. EPA has decided to establish a single group

tolerance for the vegetable, leafy, group 4-16 at 10 ppm to harmonize

with Codex.

V. Conclusion

Therefore, tolerances are established for residues of spinetoram in

or on berry, low growing, except strawberry, subgroup 13-07H at 0.04

ppm; celtuce at 8 ppm; dragon fruit at 1.5 ppm; fennel, Florence, fresh

leaves and stalk at 8 ppm; kohlrabi at 2 ppm; leaf petiole vegetable

subgroup 22B at 8 ppm; vegetable, Brassica, head and stem, group 5-16

at 2 ppm; and vegetable, leafy, group 4-16 at 10 ppm.

Additionally, the following tolerances are removed as unnecessary

due to the establishment of the above tolerances: Brassica, head and

stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; cranberry; and

vegetable, leafy, except Brassica, group 4.

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

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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), nor is

it considered a regulatory action under 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 tolerances and

modifications 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: March 5, 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

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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 in paragraph (a) as follows:

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i. Add a table heading;

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ii. Add alphabetically an entry for ``Berry, low growing, except

strawberry, subgroup 13-07H'';

0

iii. Remove the entries for ``Brassica, head and stem, subgroup 5A'';

and ``Brassica, leafy greens, subgroup 5B'';

0

iv. Add alphabetically an entry for ``Celtuce'';

0

v. Remove the entry for ``Cranberry'';

0

vi. Add alphabetically entries for ``Dragon fruit''; ``Fennel,

Florence, fresh leaves and stalk''; ``Kohlrabi''; ``Leaf petiole

vegetable subgroup 22B''; ``Vegetable, Brassica, head and stem, group

5-16''; and ``Vegetable, leafy, except Brassica, group 4''; and

0

vii. Remove the entry for ``Vegetable, leafy, group 4-16''.

The additions read as follows:

Sec. 180.635 Spinetoram; tolerances for residue.

(a) \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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\* \* \* \* \*

Berry, low growing, except strawberry, subgroup 13-07H...... 0.04

\* \* \* \* \*

Celtuce..................................................... 8

\* \* \* \* \*

Dragon fruit................................................ 1.5

\* \* \* \* \*

Fennel, Florence, fresh leaves and stalk.................... 8

\* \* \* \* \*

Kohlrabi.................................................... 2

Leaf petiole vegetable subgroup 22B......................... 8

\* \* \* \* \*

Vegetable, Brassica, head and stem, group 5-16.............. 2

Vegetable, leafy, group 4-16................................ 10

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[FR Doc. 2021-07186 Filed 4-6-21; 8:45 am]

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