[Federal Register Volume 85, Number 118 (Thursday, June 18, 2020)]

[Rules and Regulations]

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[FR Doc No: 2020-11516]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0386; FRL-10009-14]

Fenpyroximate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes and amends tolerances for residues

of fenpyroximate in or on multiple commodities which 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 June 18, 2020. Objections and

requests for hearings must be received on or before August 17, 2020,

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-2019-0386, is available online at

[http://www.regulations.gov](http://www.regulations.gov/) or in-person 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 note that due to the public health emergency, the EPA Docket

Center (EPA/DC) and Reading Room was closed to public visitors on March

31, 2020. Our EPA/DC staff will continue to provide customer service

via email, phone, and webform. For further information on EPA/DC

services, docket contact information and the current status of the EPA/

DC and Reading Room, please visit <https://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](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 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-2019-0386 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

August 17, 2020. 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-2019-0386, online

through the Federal eRulemaking Portal at [http://www.regulations.gov](http://www.regulations.gov/).

Follow the online instructions for submitting comments. Do not submit

electronically any

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information you consider to be CBI or other information whose

disclosure is restricted by statute.

Please note, that due to the public health emergency, the EPA

Docket Center and Reading Room was closed to public visitors on March

31, 2020, and there is a temporary suspension of mail delivery to EPA

(including hand deliveries). Our Docket Center staff will continue to

provide customer service via email, phone, and webform. For further

information on EPA Docket Center services, docket contact information

and the current status of the EPA Docket Center and Reading Room,

please visit <https://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

9E8766) 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 to establish tolerances for

residues of fenpyroximate, including its metabolites and degradates, in

or on the raw agricultural commodities peanut at 0.04 parts per million

(ppm); peanut, hay at 30 ppm; and tropical and subtropical, medium to

large fruit, smooth, inedible peel, subgroup 24B, except banana at 0.6

ppm. Additionally, the petition requested to amend 40 CFR 180.566 by

removing the established tolerances for residues of fenpyroximate in or

on the raw agricultural commodities avocado at 0.15 ppm; canistel at

0.15 ppm; mango at 0.15 ppm; papaya at 0.15 ppm; sapote, black at 0.15

ppm; and star apple at 0.15 ppm. That document referenced a summary of

the petition prepared by Nichino America, the registrant, which is

available in the docket, [http://www.regulations.gov](http://www.regulations.gov/). No comments were

received in response to the notice of filing.

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

establishing tolerances that vary from what was requested. 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 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 fenpyroximate including

exposure resulting from the tolerances established by this action.

EPA's assessment of exposures and risks associated with fenpyroximate

follows.

On December 5, 2019, EPA published in the Federal Register a final

rule establishing tolerances for residues of fenpyroximate in or on

multiple agricultural commodities based on the Agency's conclusion that

aggregate exposure to fenpyroximate is safe for the general population,

including infants and children. See (84 FR 66620) (FRL-10002-00). That

document contains a summary of the toxicological profile and points of

departure, assumptions for exposure assessment, cumulative risk, and

the Agency's determination regarding the children's safety factor,

which have not changed.

EPA's dietary exposure assessments have been updated to include the

additional exposure from the new uses of fenpyroximate on peanuts,

peanut hay, and the tropical and subtropical, medium to large fruit,

smooth, inedible peel subgroup 24B, except banana, including increased

residues in livestock resulting from these uses. The assessment relies

on tolerance-level residues for all crops for the acute and chronic

dietary assessments and assumes 100 percent crop treated (PCT) for the

acute assessment and utilizes percent crop treated estimates for some

commodities for the chronic assessment. EPA's aggregate exposure

assessment incorporated this additional assumed dietary exposure, as

well as exposure in drinking water, although this latter exposure is

not impacted by the new tolerances and thus have not changed since the

last assessment. Further information about EPA's risk assessment and

determination of safety supporting the tolerances established in the

December 5, 2019 Federal Register action as well as these new

fenpyroximate tolerances can be found at [http://www.regulations.gov](http://www.regulations.gov/) in

the document titled ``Fenpyroximate: Human Health Risk Assessment for

Registration Review and a Petition to Establish Tolerances for Residues

in/on the Banana; Leaf Petiole Vegetable Subgroup 22B; Caneberry

Subgroup 13-07A; Bushberry Subgroup 13-07B; Squash/Cucumber Subgroup

9B; and Succulent Shelled Beans; and Crop Group Conversions for Nut,

Tree, Group 14-12; and Cottonseed Subgroup 20C,'' dated September 12,

2019 in docket ID EPA-HQ-OPP-2018-0162 and the document titled

``Fenpyroximate: Human Health Risk Assessment to Support the Petition

for Tolerance for Residues in/on Peanuts and Tropical and Subtropical,

Medium to Large Fruit, Smooth, Inedible Peel, Subgroup 24B, Except

Banana,'' dated March 15, 2020 in docket ID number EPA-HQ-OPP-2019-

0386.

Acute dietary (food and water) risks are below the Agency's level

of concern of 100% of the acute population adjusted dose (aPAD): 8.6%

of the aPAD for children 1 to 2 years old, the population subgroup with

the highest exposure estimate. Chronic dietary risks are below the

Agency's level of concern of 100% of the chronic population adjusted

dose (cPAD): 62% of the cPAD for children 1 to 2 years old, the

population subgroup with the highest exposure estimate. There are no

residential uses for fenpyroximate; therefore, no short- or

intermediate-term assessment was necessary. Aggregate risk is comprised

solely of the dietary exposures, which are all below EPA's levels of

concern.

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 fenpyroximate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method with

nitrogen/phosphorus detection (GC/NPD), Method S19) is available to

enforce the tolerance expression. A data-gathering liquid

chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) method is

also available.

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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](mailto: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.

There are no established Codex MRLs for residues of fenpyroximate

in peanut or peanut hay. A Codex MRL is established for residues of

fenpyroximate (parent compound only) in avocados at a lower level (0.15

ppm) than the new U.S. tolerance on the tropical and subtropical,

medium to large fruit, smooth, inedible peel subgroup 24B, except

banana, of which avocados is a part (0.6 ppm). Harmonization with the

Codex MRL is not possible because the U.S. tolerance expression

includes the parent compound and an additional isomer and because the

U.S. use patterns require higher numerical values for the crop subgroup

in order to avoid potential tolerance exceedances when label directions

are followed.

C. Revisions to Petitioned-For Tolerances

As part of the review of the petition, a revised maximum reasonable

dietary burden (MRDB), including the potential contribution of peanut

hay was evaluated. As indicated in EPA's regulation, 40 CFR 180.6, when

finite pesticide chemical residues will be found in livestock

commodities as a result of the use of a pesticide in or on animal

feedstuffs, EPA will establish tolerances in livestock commodities to

accommodate those residues. The additional uses of fenpyroximate on

peanut (and residues on peanut, hay) result in an increase in the MRDB

for beef and dairy cattle and consequently necessitate increasing

tolerances for fenpyroximate residues in ruminant commodities. New

tolerance levels in ruminant commodities were determined using the

Langmuir model, and based on that analysis, EPA is increasing existing

cattle, goat, horse, and sheep tolerances as follows: Fat 0.03 ppm to

0.1 ppm, liver 0.25 ppm to 0.7 ppm, and kidney 0.25 ppm to 0.5 ppm.

V. Conclusion

Therefore, tolerances are established for residues of

fenpyroximate, including its metabolites and degradates, in or on

peanut, hay at 30 ppm; peanut, at 0.04 ppm; and the tropical and

subtropical, medium to large fruit, smooth, inedible peel subgroup 24B,

except banana at 0.6 ppm.

Additionally, the following existing tolerances are increased as

follows: Cattle, fat from 0.03 ppm to 0.1 ppm; cattle, kidney from 0.25

ppm to 0.5 ppm; cattle, liver from 0.25 ppm to 0.7 ppm; goat, fat from

0.03 ppm to 0.1 ppm; goat, kidney from 0.25 ppm to 0.5 ppm; goat, liver

from 0.25 ppm to 0.7 ppm; horse, fat from 0.03 ppm to 0.1 ppm; horse,

kidney from 0.25 ppm to 0.5 ppm; horse, liver from 0.25 ppm to 0.7 ppm;

sheep, fat from 0.03 ppm to 0.1 ppm; sheep, kidney from 0.25 ppm to 0.5

ppm; and sheep, liver from 0.25 ppm to 0.7 ppm.

Also, the following tolerances are removed as unnecessary due to

the establishment of the above tolerances: Avocado; canistel; mango;

papaya; sapote, black; and star apple.

Lastly, EPA is removing, as a housekeeping measure, an expired

section 18 tolerance on honey since it expired on December 31, 2013 and

is no longer valid.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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), 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 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 (CRA)

Pursuant to the CRA (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

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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: May 11, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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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.

0

2. In Sec. 180.566:

0

a. In paragraph (a)(1):

0

i. Add a heading for the table.

0

ii. Remove the entries for ``Avocado''; ``Canistel''; ``Mango''; and

``Papaya''.

0

iii. Add alphabetically the entries ``Peanut'' and ``Peanut, hay''.

0

iv. Remove the entries for ``Sapote, black'' and ``Star, apple''.

0

v. Add alphabetically the entry for ``Tropical and subtropical, medium

to large fruit, smooth, inedible peel subgroup 24B, except banana''.

0

b. In paragraph (a)(2):

0

i. Add a heading for the table.

0

ii. Revise the entries for ``Cattle, fat''; ``Goat, fat''; ``Horse,

fat''; and ``Sheep, fat''.

0

c. In paragraph (a)(3), revise the table.

0

d. Remove and reserve paragraph (b).

The additions and revisions read as follows:

Sec. 180.566 Fenpyroximate; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 of Paragraph (a)(1)

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Parts per

Commodity million

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\* \* \* \* \*

Peanut...................................................... 0.04

Peanut, hay................................................. 30

\* \* \* \* \*

Tropical and subtropical, medium to large fruit, smooth, 0.6

inedible peel subgroup 24B, except banana..................

\* \* \* \* \*

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\* \* \* \* \*

(2) \* \* \*

Table 2 of Paragraph (a)(2)

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Parts per

Commodity million

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Cattle, fat................................................. 0.1

\* \* \* \* \*

Goat, fat................................................... 0.1

\* \* \* \* \*

Horse, fat.................................................. 0.1

\* \* \* \* \*

Sheep, fat.................................................. 0.1

\* \* \* \* \*

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(3) \* \* \*

Table 3 of Paragraph (a)(3)

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Parts per

Commodity million

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Cattle, kidney.............................................. 0.5

Cattle, liver............................................... 0.7

Goat, kidney................................................ 0.5

Goat, liver................................................. 0.7

Horse, kidney............................................... 0.5

Horse, liver................................................ 0.7

Sheep, kidney............................................... 0.5

Sheep, liver................................................ 0.7

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\* \* \* \* \*

[FR Doc. 2020-11516 Filed 6-17-20; 8:45 am]

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