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[Pages 71155-71158]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0538; FRL-9194-01-OSCPP]

Mefentrifluconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

mefentrifluconazole in or on banana and coffee, green bean. BASF

Corporation requested these tolerances under the Federal Food, Drug,

and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 15, 2021. Objections and

requests for hearings must be received on or before February 14, 2022

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-2020-0538, 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 is (202) 566-1744, and the telephone number for the OPP

Docket is (703) 305-5805.

Due to the public health concerns relating to COVID-19, the EPA

Docket Center (EPA/DC) and Reading Room is closed to visitors with

limited exceptions. The staff continues to provide customer service via

email, phone, and webform. For the latest status information on EPA/DC

services, 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:

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-2020-0538 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

February 14, 2022. 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-2020-0538, by one of

the following methods:

Federal eRulemaking Portal: [https://www.regulations.gov](https://www.regulations.gov/).

Follow the online instructions for submitting

[[Page 71156]]

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 December 21, 2020 (85 FR 82998) (FRL-

10016-93), 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

0E8849) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research

Triangle Park, NC 22709-3528. The petition requested that 40 CFR part

180 be amended by establishing tolerances for residues of

mefentrifluconazole in or on banana at 1.5 parts per million (ppm) and

coffee at 0.4 ppm. That document referenced a summary of the petition

prepared by BASF Corporation, the petitioner, which is available in the

docket for this action, docket ID number EPA-HQ-OPP-2020-0538 at,

[https://www.regulations.gov](https://www.regulations.gov/). One comment from an anonymous citizen was

received in response to the notice of filing (NOF). The Agency response

is listed in Unit IV.C.

With respect to the subject action, the proposed tolerance levels

were not altered, but the commodity definition for coffee was revised.

The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

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 mefentrifluconazole, including exposure

resulting from the tolerances established by this action. EPA's

assessment of exposures and risks associated with mefentrifluconazole

follows.

B. Aggregate Risk Assessment

In an effort to streamline Federal Register publications, EPA is

directing readers to certain sections of Federal Register notices for

previous tolerance rulemakings for the same pesticide that contain

information that has not changed in the current risk assessment. To

that end, on June 28, 2019, EPA published in the Federal Register a

final rule establishing a tolerance for residues of mefentrifluconazole

in or on many livestock, corn, fruit, grain, nut and vegetable

commodities based on the Agency's conclusion that aggregate exposure to

mefentrifluconazole is safe for the general population, including

infants and children. See 84 FR 30939 (FRL-9994-51). Please refer to

the following sections of the aforementioned tolerance rulemaking that

contain information that has remained the same under the current risk

assessment for this rulemaking: Units III.A (Toxicological Profile);

III.B (Toxicological Points of Departure/Levels of Concern); III.C

(Exposure Assessment), except as explained in the next paragraph; and

III.D (Safety Factor for Infants and Children).

Updates to exposure assessment. The Agency conducted an updated

risk assessment to evaluate exposure to residues of mefentrifluconazole

on banana and coffee. EPA's acute and chronic dietary (food and

drinking water) exposure assessments have been updated to include the

additional exposure from use of mefentrifluconazole on banana and

coffee. As to residue levels in food, a partially refined chronic

dietary exposure and risk assessment was conducted assuming 100 percent

crop treated (PCT) and using average field-trial residues for some

commodities and tolerance-level residues for other commodities (banana

and coffee). There will be no U.S. registrations for use of

mefentrifluconazole on banana and coffee, and there is no proposed new

residential use. Therefore, EPA's assessments of dietary exposure from

drinking water and non-dietary (i.e., residential) exposure, as well as

cancer classification and cumulative effects from substances with a

common mechanism of toxicity, have not changed and are described in the

June 2019 tolerance rulemaking.

Assessment of aggregate risks. Acute aggregate risk estimates are

equal to acute dietary (food and drinking water) risk estimates, which

are below the Agency's level of concern of 100% of the acute population

adjusted dose (aPAD): The exposure estimate is 5.6% of the aPAD at the

95th percentile of exposure for females 13 to 49 years old, which is

the population subgroup with the highest exposure estimate. Chronic

aggregate risk estimates are equal to chronic dietary (food and

drinking water) risk estimates, which are below the Agency's level of

concern of 100% of the chronic population adjusted does (cPAD): The

exposure estimate is 82% of the cPAD for children 1 to 2 years old,

which is the population subgroup with the highest exposure estimate.

Short-term aggregate risk estimates are equal to the total short-term

residential post-application dermal exposure estimates plus average

dietary exposure estimates. For adults, the most conservative

residential exposure estimate is from post-application dermal exposure

from golfing activities after applications to golf courses, with a

margin of exposure (MOE) above the Agency's level of concern of 100

(MOE = 2600). For children 6 to less than 11 years old, the most highly

exposed child subgroup for residential exposure, the most conservative

residential exposure estimate is from post-application dermal exposure

from golfing activities after applications to golf courses. The dietary

exposure for children 6 to 12 years old was used to calculate aggregate

exposure as this subgroup is similar to the subgroup children 6 to less

than 11 years old. The MOE is above the Agency's level of concern of

100 (MOE = 1900). Children 1 to <2 years old were the highest exposed

child subgroup for dietary exposures, which does not match the most

highly exposed child subgroup for residential exposure (children 6 to

<11 years old). However, the selected residential exposure scenarios

for aggregation, adults and children (6 to <11 years old), represent

[[Page 71157]]

the worst-case risk estimates and are protective of all other life

stages and exposure scenarios. Considering both the total short-term

residential post-application dermal exposures and average dietary

exposures for both adults and children, EPA has concluded the short-

term aggregate MOEs are 790 and 620 for adults and children 6 to less

than 11 years old, respectively, which are above the level of concern

of 100 and therefore are not of concern. Intermediate-term residential

exposures are not expected from the residential use of

mefentrifluconazole; therefore, intermediate-term aggregate risk is not

a concern and quantitative estimates were not calculated.

Mefentrifluconazole is classified as ``not likely to be carcinogenic to

humans''; therefore, a quantitative cancer assessment was not

conducted.

C. Determination of Safety

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 mefentrifluconazole residues. More detailed

information on the subject action to establish a tolerance in or on

banana and coffee can be found in the document entitled,

``Mefentrifluconazole. Human Health Risk Assessment for Petition for

the Establishment of Permanent Tolerances for Use on Banana and Coffee

without U.S. Registration.'' dated 10/20/2021 at [https://www.regulations.gov](https://www.regulations.gov/), under docket ID number EPA-HQ-OPP-2020-0538.

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical enforcement methodologies found in Unit IV.A. of the

final rule published in the Federal Register on June 28, 2019,

establishing tolerances for residues of mefentrifluconazole in or on

multiple commodities are adequate for banana and coffee. See 84 FR

30939 (FRL-9994-51). 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). Codex 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 currently no Codex or Canadian MRLs established for

residues of mefentrifluconazole in banana or coffee; therefore, there

are no issues with harmonization.

C. Response to Comments

One anonymous comment to the NOF was submitted insisting that no

residues of fluoride, which is a different chemical, should be

permitted for bananas and coffee. Even so, no additional information

was provided that would support a conclusion that the tolerances

requested for mefentrifluconazole are not safe. Although some

individuals do not want pesticides to be used on food, the FFDCA

authorizes EPA to establish tolerances that permit certain levels of

pesticide residues in or on food when the Agency can determine that

such residues are safe. EPA has made that determination for the

tolerances subject to this action, and the commenter provided no

information to support a determination that the tolerance is not safe.

D. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance on ``coffee, green bean'' rather

than the requested tolerance on ``coffee'' to be consistent with the

terminology the Agency uses for that commodity.

V. Conclusion

Therefore, tolerances are established for residues of

mefentrifluconazole in or on banana at 1.5 ppm and coffee, green bean,

at 0.4 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

[[Page 71158]]

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 9, 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. 180.705, amend table 1 to paragraph (a) by adding in

alphabetical order the entries ``Banana'' and ``Coffee, green bean'' to

read as follows:

Sec. 180.705 Mefentrifluconazole; tolerances for residues.

(a) \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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\* \* \* \* \*

Banana \1\.................................................. 1.5

\* \* \* \* \*

Coffee, green bean \1\...................................... 0.4

\* \* \* \* \*

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\1\ There are no U.S. registrations as of December 15, 2021.

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[FR Doc. 2021-27093 Filed 12-14-21; 8:45 am]

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