[Federal Register Volume 88, Number 165 (Monday, August 28, 2023)]

[Rules and Regulations]

[Pages 58506-58509]

From the Federal Register Online via the Government Publishing Office [[www.gpo.gov](http://www.gpo.gov/)]

[FR Doc No: 2023-18410]

-----------------------------------------------------------------------

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0139; FRL-11276-01-OCSPP]

Methoxyfenozide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

-----------------------------------------------------------------------

SUMMARY: This regulation establishes tolerances for residues of

methoxyfenozide in or on coffee bean, sugar cane, and sugar cane

molasses. There are no U.S. registrations associated with these

tolerances. Corteva Agrisciences, LLC requested these tolerances under

the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 28, 2023. Objections and

requests for hearings must be received on or before October 27, 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-2022-0139, 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-2022-0139 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

October 27, 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 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-2022-0139, 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/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 July 5, 2023 (88 FR 42935) (FRL-10579-

05), 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

1E8910) by Corteva Agriscience LLC, 9330 Zionsville Rd., Indianapolis,

IN 46268. The petition requested that 40 CFR 180.544 be amended by

establishing tolerances for residues of the insecticide

methoxyfenozide, including its metabolites and degradates, in or on

coffee at 0.15 parts per million (ppm) and sugarcane at 0.03 ppm and in

the processed commodity sugarcane molasses at 0.1 ppm. Compliance with

the tolerance levels is to be determined by measuring only

methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-

dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide). That document

referenced a summary of the petition prepared by Corteva Agrisciences,

LLC, which is available in the docket, [https://www.regulations.gov](https://www.regulations.gov/).

There were no comments received in response to the notice of filing.

[[Page 58507]]

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

recommended revisions in commodity definitions. 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 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 methoxyfenozide including exposure resulting

from the tolerances established by this action. EPA's assessment of

exposures and risks associated with methoxyfenozide follows.

In an effort to streamline its publications in the Federal

Register, EPA is not reprinting sections that repeat what has been

previously published in tolerance rulemakings for 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

methoxyfenozide in which EPA concluded, based on the available

information, that there is a reasonable certainty that no harm would

result from aggregate exposure to methoxyfenozide and established

tolerances for residues of that chemical. EPA is incorporating

previously published sections from those rulemakings as described

further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological

Profile of methoxyfenozide, see Unit III.A. of the methoxyfenozide

tolerance rulemaking published in the Federal Register of March 12,

2019 (84 FR 8820) (FRL-9985-06).

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

of the Toxicological Points of Departure/Levels of Concern for

methoxyfenozide used for human health risk assessment, see Unit III.B.

of the March 12, 2019, rulemaking.

Exposure assessment. Much of the exposure assessment for

methoxyfenozide remains unchanged from the discussions in Unit III.C.

of the March 12, 2019, rulemaking and Unit III.C. of the

methoxyfenozide tolerance rulemaking published in the Federal Register

of October 11, 2022 (87 FR 61259) (FRL-9525-01), except as described

below.

Dietary exposure from food and feed uses. The exposure assessment

has been updated to include the additional dietary exposure from the

new tolerances for residues of methoxyfenozide on coffee bean and sugar

cane commodities using the same previous assumptions of tolerance level

residues and 100 percent crop treated (PCT) described in Unit III.C.1.

of the March 12, 2019, rulemaking.

Dietary exposure from drinking water. Because the requested

tolerances for residues of methoxyfenozide in or on coffee bean and

sugar cane commodities do not include registrations for use on coffee

bean and sugar cane commodities in the United States, the estimated

drinking water concentrations have not changed. For a detailed summary

of the drinking water analysis for methoxyfenozide used for the human

health risk assessment, see Unit III.C.2. of the March 12, 2019,

rulemaking and Unit III.C. of the October 11, 2022, rulemaking.

Non-occupational exposure. As described in Unit III.C. of the

October 11, 2022, rulemaking, the Agency assumes that when labels

require specific clothing and/or personal protective equipment (PPE)

such products are not for residential use. The methoxyfenozide label

requires specific clothing and/or PPE; therefore, the Agency has made

the assumption that the registered methoxyfenozide labels are not

intended for use by residential handlers and a quantitative residential

handler assessment has not been conducted. The approach to assessing

post-application exposure is the same as described in Unit III.C.3 of

the March 12, 2019, rulemaking.

Cumulative effects from substances with a common mechanism of

toxicity. 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.'' In 2016, EPA's Office of

Pesticide Programs released a guidance document entitled Pesticide

Cumulative Risk Assessment: ``Framework for Screening Analysis''

(<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>). This document provides

guidance on how to screen groups of pesticides for cumulative

evaluation using a two-step approach beginning with the evaluation of

available toxicological information and, if necessary, followed by a

risk-based screening approach. This framework supplements the existing

guidance documents for establishing common mechanism groups (CMGs) and

conducting cumulative risk assessments (CRA).

The Agency has utilized this framework for methoxyfenozide and

determined that the diacylhydrazine class of insecticides

(methoxyfenozide, halofenozide and tebufenozide) form a candidate CMG.

This group of pesticides is considered a candidate CMG because they

share characteristics to support a testable hypothesis for a common

mechanism of action.

Following this determination, the Agency conducted a screening-

level cumulative risk assessment consistent with the 2016 guidance

document. This assessment included only methoxyfenozide and

tebufenozide since there are no registered uses for halofenozide. The

current screening assessments for methoxyfenozide and tebufenozide are

below the Agency's levels of concern. No further cumulative evaluation

is necessary for methoxyfenozide.

For more information, see Appendix E of the document titled

``Methoxyfenozide. Human Health Risk Assessment for the Petition to

Establish Permanent Tolerances without a U.S. Registration on Coffee

Beans and Sugar Cane,'' available at docket ID number EPA-HQ-OPP-2022-

0139.

Safety factor for infants and children. EPA continues to conclude

that there are reliable data to support the reduction of the Food

Quality Protection

[[Page 58508]]

Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the March

12, 2019, rulemaking for a discussion of the Agency's rationale for

that determination.

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 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 risk assessment was not needed for methoxyfenozide

since no toxic effects attributable to a single dose were identified in

the toxicity database. Chronic dietary risks are below the Agency's

level of concern of 100% of the cPAD; they are 78% of the cPAD for

children 1 to 2 years old, the group with the highest exposure. There

are currently no residential handler uses for methoxyfenozide, and none

are pending before the Agency. Therefore short- and intermediate-term

exposure to methoxyfenozide is not expected, and the short- and

intermediate-term risk is equivalent to the chronic dietary risk, which

is not of concern. Methoxyfenozide is classified as ``Not Likely to Be

Carcinogenic to Humans''; therefore, EPA does not expect

methoxyfenozide exposures to pose an aggregate cancer risk.

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 methoxyfenozide

residues. More detailed information on this action can be found in the

document titled ``Methoxyfenozide. Human Health Risk Assessment for the

Petition to Establish Permanent Tolerances without a U.S. Registration

on Coffee Beans and Sugar Cane,'' available at docket ID number EPA-HQ-

OPP-2022-0139.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method,

see Unit IV.A. of the March 12, 2019, 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.

The Codex has not established a MRL for methoxyfenozide in/on

coffee bean or sugar cane commodities.

C. Revisions to Petitioned-For Tolerances

EPA is changing the commodity definitions from coffee to coffee

bean, sugarcane to sugar cane, and sugarcane, molasses to sugar cane,

molasses to be consistent with Agency nomenclature.

V. Conclusion

Therefore, tolerances are established for residues of

methoxyfenozide, in or on coffee bean at 0.15 ppm, sugar cane at 0.03

ppm, and sugar cane, molasses at 0.1 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

[[Page 58509]]

and pests, Reporting and recordkeeping requirements.

Dated: August 18, 2023.

Charles Smith,

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

0

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. 180.544, in paragraph (a)(1) amend the table by:

0

a. Adding in alphabetical order the entries ``Coffee bean''; ``Sugar

cane''; and ``Sugar cane, molasses''; and

0

b. Adding footnote 2 at the end of the table.

The additions read as follows:

Sec. 180.544 Methoxyfenozide; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

------------------------------------------------------------------------

Parts per

Commodity million

------------------------------------------------------------------------

\* \* \* \* \*

Coffee bean \2\............................................. 0.15

\* \* \* \* \*

Sugar cane \2\.............................................. 0.03

Sugar cane, molasses \2\.................................... 0.1

\* \* \* \* \*

------------------------------------------------------------------------

\* \* \* \* \*

\2\ There are no U.S. registrations as of August 28, 2023.

[FR Doc. 2023-18410 Filed 8-25-23; 8:45 am]

BILLING CODE 6560-50-P