[Federal Register Volume 88, Number 60 (Wednesday, March 29, 2023)]

[Rules and Regulations]

[Pages 18428-18431]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0744; FRL-10769-01-OCSPP]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation modifies existing tolerances for residues of

fludioxonil in or on mango and papaya. Syngenta Crop Protection, LLC

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

Act (FFDCA).

DATES: This regulation is effective March 29, 2023. Objections and

requests for hearings must be received on or before May 30, 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-2021-0744, 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. Please review the

visitor instructions and additional information about the docket

available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, 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.

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 <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180?toc=1>.

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-2021-0744 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

May 30, 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-2021-0744, 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>.

 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 October 24, 2022 (87 FR 64196) (FRL-

9410-06-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 1E8947) by Syngenta Crop Protection, LLC, 410

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Swing Road, Greensboro, NC 27409. The petition requested that 40 CFR

180.516 be amended by establishing import tolerances for residues of

the fungicide fludioxonil, [4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-

pyrrole-3-carbonitrile], in or on mango at 15 parts per million (ppm)

and papaya at 8 ppm. That document referenced a summary of the petition

prepared by Syngenta Crop Protection, LLC, the registrant, 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.

 Based upon review of the data supporting the petition and in

accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA

is modifying the existing tolerances for residues of fludioxonil in or

on mango and papaya 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 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 fludioxonil, including exposure resulting from

the tolerances modified by this action. EPA's assessment of exposures

and risks associated with fludioxonil follows.

 In an effort to streamline its publications in the Federal

Register, EPA is not reprinting sections of the rule 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 a number of tolerance rulemakings for

fludioxonil in which EPA concluded, based on the available information,

that there is a reasonable certainty that no harm would result from

aggregate exposure to fludioxonil and established tolerances for

residues of that chemical. EPA is incorporating previously published

sections from those rulemakings as described further in this rule, as

they remain unchanged.

A. Toxicological Profile

 EPA has evaluated the available toxicity data and considered its

validity, completeness, and reliability as well as the relationship of

the results of the studies to human risk. EPA has also considered

available information concerning the variability of the sensitivities

of major identifiable subgroups of consumers, including infants and

children.

 Specific information on the studies received and the nature of the

adverse effects caused by fludioxonil as well as the no-observed-

adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-

level (LOAEL) from the toxicity studies are discussed in Unit III.A. of

the final rule published in the Federal Register of November 6, 2018

(83 FR 55491) (FRL-9982-75).

B. Toxicological Points of Departure/Levels of Concern

 A summary of the toxicological endpoints for fludioxonil used for

human health risk assessment is discussed in Unit III.B. of the final

rule published in the Federal Register of August 14, 2015 (80 FR 48743)

(FRL-9931-06).

C. Exposure Assessment

 Much of the exposure assessment remains the same although updates

have occurred to accommodate exposures from the petitioned-for

tolerances. These updates are discussed in this section; for a

description of the rest of the EPA approach to and assumptions for the

exposure assessment, please reference Unit III.C. of the November 6,

2018, rulemaking.

 1. Dietary exposure from food and feed uses. EPA's dietary exposure

assessments have been updated to include the additional exposure from

the petitioned-for tolerances for residues of fludioxonil on mango and

papaya. An acute dietary risk assessment was not performed since no

endpoint attributable to a single exposure (dose) was identified from

the available oral toxicity database. The chronic assessment is based

on tolerance-level residues and assumes 100 percent crop treated (PCT);

the chronic assessment is unrefined. The assessment was conducted using

the Dietary Exposure Evaluation Model software with the Food Commodity

Intake Database (DEEM-FCID), Version 4.02, which incorporates 2005-2010

food consumption information from the United States Department of

Agriculture's (USDA's) National Health and Nutrition Examination

Survey, What We Eat in America, (NHANES/WWEIA). A cancer dietary

exposure and risk assessment was not conducted for fludioxonil as it is

a Group D chemical--not classifiable as to human carcinogenicity.

 2. Dietary exposure from drinking water. The proposed post-harvest

application uses on imported fruit do not result in an increase in the

estimated residue levels in drinking water, so the estimated drinking

water concentrations used in the November 6, 2018, final rule are the

same as those used in this assessment.

 3. From non-dietary exposure. The term ``residential exposure'' is

used in this document to refer to non-occupational, non-dietary

exposure (e.g., for lawn and garden pest control, indoor pest control,

termiticides, and flea and tick control on pets). The assessment used

the same assumptions as the November 6, 2018. The residential exposures

used in the aggregate assessment are inhalation exposures from handlers

applying paints with airless sprayers for adults and incidental oral

exposures (hand-to-mouth) from post-application exposure to outdoor

treated turf for children 1 to <2 years old.

 4. 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, leave in effect, 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

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mechanism of toxicity finding as to fludioxonil and any other

substances, and fludioxonil does not appear to produce a toxic

metabolite produced by other substances. For the purposes of this

tolerance action, therefore, EPA has not assumed that fludioxonil has a

common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

 EPA continues to conclude that there are reliable data to support

the reduction of the Food Quality Protection Act (FQPA) safety factor.

See Unit III.D. of the November 6, 2018, rulemaking for a discussion of

the Agency's rationale for that determination.

E. 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). For linear cancer risks, EPA calculates the lifetime

probability of acquiring cancer given the estimated aggregate exposure.

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.

 An acute dietary exposure assessment was not performed as there

were no indication of an adverse effects attributable to a single dose.

Fludioxonil is not expected to pose an acute risk. Chronic dietary

risks are below the Agency's level of concern of 100% of the cPAD; they

are 14% of the cPAD for the general population and 49% of the cPAD for

children 1-2 years old, the population subgroup receiving the highest

exposure.

 EPA has concluded the combined short-term food, water, and

residential exposures result in aggregate MOEs of 1200 for adults and

290 for children 1-2 years old. Because EPA's level of concern for

fludioxonil is an MOE of 100 or below, short-term aggregate risks are

not of concern. Intermediate- and long-term aggregate risk assessments

were not performed because there are no registered or proposed uses of

fludioxonil that result in intermediate- or long-term residential

exposures. Fludioxonil is not classifiable as to human carcinogenicity;

therefore, EPA does not expect exposures to pose an aggregate cancer

risk.

 Therefore, based on the risk assessments and information described

above, EPA concludes that there is a reasonable certainty that no harm

will result to the general population, or to infants and children, from

aggregate exposure to fludioxonil residues. More detailed information

on this action can be found in the document titled ``Fludioxonil. Human

Health Risk Assessment for the Proposed Tolerances without a U.S.

Registration for Residues of Fludioxonil in/on Mango and Papaya.'' in

docket ID number EPA-HQ-OPP-2021-0744.

IV. Other Considerations

A. Analytical Enforcement Methodology

 For a discussion of the available analytical enforcement method,

see Unit IV.A. of the November 6, 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 is no Codex MRL for fludioxonil in or on papaya. Canada has

established an MRL for fludioxonil in or on papaya at 5 ppm, which is

the same as the U.S. tolerance as modified by this action. Codex and

Canada have established MRLs for fludioxonil in or on mango at 2 ppm.

These MRLs are different than the U.S. tolerance as modified by this

action, which is 8 ppm for fludioxonil residues in or on mango. EPA is

not harmonizing the U.S. tolerance with the Codex and Canadian MRLs

because the proposed post-harvest application use on fruit imported

into the United States results in residues greater than 2 ppm. The

increased tolerance of 8 ppm is needed to cover residues resulting from

post-harvest application to imported fruit and would not affect trade

channels with Canada or the European Union.

C. Revisions to Petitioned-For Tolerances

 The registrant petitioned for import tolerances of 15 ppm for mango

and 8 ppm for papaya. However, EPA has previously established

tolerances for residues of fludioxonil in or on mango and papaya, both

at 5.0 ppm, at 40 CFR 180.516. In this action, EPA is modifying these

established tolerances by increasing the tolerance for mango to 8 ppm

and revising the tolerance for papaya to 5 ppm based on the submitted

field trial data, Organization for Economic Co-operation and

Development (OECD) tolerance calculation procedures, and rounding

rules. These tolerances are inclusive of imported commodities as well

as domestically produced.

V. Conclusion

 Therefore, tolerances are modified for residues of fludioxonil, [4-

(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile], in or

on mango at 8 ppm and papaya at 5 ppm.

VI. Statutory and Executive Order Reviews

 This action modified 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 tolerance 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

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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 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 16, 2023.

Daniel Rosenblatt,

Acting 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. 180.516, revise the commodities ``mango'' and ``papaya'' in

the table in paragraph (a)(1) to read as follows:

Sec. 180.516 Fludioxonil; tolerances for residues.

\* \* \* \* \*

 Table 1 to Paragraph (a)(1)

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 Parts per

 Commodity million

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Mango....................................................... 8

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Papaya...................................................... 5

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[FR Doc. 2023-06457 Filed 3-28-23; 8:45 am]

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