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[Rules and Regulations]

[Pages 40338-40340]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0334; FRL-8656-01-OCSPP]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes a tolerance for residues of

fludioxonil in or on banana. Syngenta Crop Protection, LLC requested

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

DATES: This regulation is effective July 28, 2021. Objections and

requests for hearings must be received on or before September 27, 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-2020-0334, 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:

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(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-2020-0334 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

September 27, 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-

[[Page 40339]]

2020-0334, 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 April 22, 2021 (86 FR 21317) (FRL-10022-

59), 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

9E8798) by Syngenta Crop Protection, LLC, 410 Swing Road, NC 27419-

8300. The petition requested that 40 CFR 180.516 be amended by

establishing a tolerance for residues of the fungicide fludioxonil, 4-

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

banana at 2.0 parts per million (ppm). That document referenced a

summary of the petition prepared by Syngenta Crop Protection, 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.

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a

tolerance that varies from that sought by the petition. Based upon

review of the data supporting the petition, EPA is modifying the

requested tolerance based on crop field trial data and for consistency

with the Organization for Economic Co-Operation and Development (OECD)

tolerance-rounding class practice. The reason for these changes are

explained in Unit IV.D.

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 tolerance established by this action. EPA's assessment of exposures

and risks associated with fludioxonil follows.

In an effort to streamline Federal Register publications, EPA is

not reprinting here summaries of its analyses that have previously

appeared in the Federal Register in previous tolerance rulemakings for

the same pesticide. To that end, this rulemaking refers the reader to

several sections from the November 6, 2018 tolerance rulemaking for

residues of fludioxonil that remain unchanged for an understanding of

the Agency's rationale in support of this rulemaking. See 83 FR 55491

(FRL-9982-75). Those sections are: Units III.A. (Toxicological

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

III.C. (Exposure Assessment), except as explained in the next

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

Further information about the Agency's risk assessment and

determination of safety supporting the new tolerance for residues of

fludioxonil on bananas can be found in docket ID number EPA-HQ-OPP-

2020-0334 in the document titled ``Fludioxonil. Human Health Risk

Assessment for the Establishment of a Permanent Tolerance on Imported

Bananas.''

Updates to exposure assessments. EPA's dietary (food and drinking

water) exposure assessments have been updated to include the additional

exposure from use of fludioxonil on bananas, and relied on tolerance-

level residues, an assumption of 100 percent crop treated (PCT), and

2018 default processing factors for all processed commodities. EPA's

aggregate exposure assessment incorporated this additional dietary

exposure. Drinking water exposures are not impacted by the new use on

banana, and thus have not changed since the last assessment.

Assessment of aggregate risks. An acute aggregate risk assessment

was not conducted since effects attributable to a single exposure were

not identified. Short-term aggregate risk for adults and children

resulted in margins of exposure >= 280, which is above the level of

concern of 100 and not of concern. An intermediate-term aggregate risk

assessment was not conducted since exposures are not expected based on

the use pattern. The chronic aggregate risk assessment was equivalent

to the chronic dietary risk assessment and was not conducted since

there are no long-term exposures expected based on the use pattern.

Chronic aggregate risks consist of dietary (food and drinking water)

exposure only and are below the Agency's level of concern: 56% of the

chronic population adjusted dose (cPAD) for children 1 to 2 years old,

the group with the highest exposure.

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 fludioxonil residues.

More detailed information on the subject action to establish a

tolerance in or on bananas can be found in the document entitled,

``Fludioxonil. Human Health Risk Assessment for the Establishment of a

Permanent Tolerance on Imported Bananas'' by going to [http://www.regulations.gov](http://www.regulations.gov/). The referenced document is available in the docket

established by this action, EPA-HQ-OPP-2020-0334.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid

chromatography/ultraviolet (HPLC/UV) methods (Methods AG-597 and AG-

597B)) is available for enforcing tolerances for fludioxonil on plant

commodities. An adequate liquid chromatography, tandem mass

spectrometry (LC-MS/MS) method (Analytical Method GRM025.03A) is

available for enforcing tolerances for fludioxonil on livestock

commodities.

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;

[[Page 40340]]

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.

The Codex has not established a MRL for fludioxonil; however,

Canada's Pest Management Regulatory Agency (PMRA) has a default MRL of

0.1 ppm on banana. EPA is establishing a tolerance level for bananas at

3 ppm.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance level of 2.0 ppm in bananas has been

modified to 3 ppm based on crop field trial data and the OECD tolerance

calculation procedure.

V. Conclusion

Therefore, a tolerance is established for residues of fludioxonil,

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

on banana at 3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 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: July 15, 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. 180.516, amend table 1 to paragraph (a)(1) by adding in

alphabetical order the entry ``Banana'' and footnote 1 to read as

follows:

Sec. 180.516 Fludioxonil; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

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Parts per

Commodity million

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\* \* \* \* \*

Banana\1\................................................... 3

\* \* \* \* \*

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\1\ There are no U.S. registrations as of July 28, 2021.

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[FR Doc. 2021-16091 Filed 7-27-21; 8:45 am]

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