[Federal Register Volume 87, Number 108 (Monday, June 6, 2022)]

[Rules and Regulations]

[Pages 34206-34209]

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[FR Doc No: 2022-11558]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0434; FRL-9636-01-OCSPP]

Teflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of the

insecticide teflubenzuron in or on grape and grape, raisin. There is no

U.S. registration associated with these tolerances. BASF Corporation

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

Act (FFDCA).

DATES: This regulation is effective June 6, 2022. Objections and

requests for hearings must be received on or before August 5, 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).

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ADDRESSES: The docket for this action, identified by docket

identification (ID) number EPA-HQ-OPP-2021-0434, 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: Marietta Echeverria, Acting 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-2021-0434 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 5, 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-2021-0434, 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 August 24, 2021 (86 FR 47275) (FRL-8792-

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

0E8874) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC

27709. The petition requested that 40 CFR 180.687 be amended by

establishing tolerances for residues of the insecticide teflubenzuron,

(N-[[(3,5-dichloro-2,4-difluorophenyl)amino]carbonyl]-2,6-

difluorobenzamide), in or on grape at 0.7 parts per million (ppm) and

grape, raisin at 0.9 ppm. That document referenced a summary of the

petition prepared by BASF Corporation, which is available in docket ID

number EPA-HQ-OPP-2021-0434 in [https://www.regulations.gov](https://www.regulations.gov/). No

substantive public comments were received in response to the notice of

filing.

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 teflubenzuron including exposure resulting from

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

exposures and risks associated with teflubenzuron follows.

In an effort to streamline its publications in the Federal

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

previously published for tolerance rulemakings of 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

teflubenzuron in which EPA concluded, based on the available

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

result from aggregate exposure to teflubenzuron and established

tolerances for residues of that chemical.

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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 teflubenzuron, see Unit III.A of the teflubenzuron tolerance

rulemaking published in the Federal Register of October 30, 2015 (80 FR

66805) (FRL-9933-25).

Toxicological Points of Departure/Levels of Concern. For a

discussion of the Toxicological Points of Departure/Levels of Concern

used for the safety assessment of teflubenzuron, see Unit III.B of the

October 30, 2015, rulemaking.

Exposure Assessment. Much of the exposure assessment for

teflubenzuron remains unchanged from the discussion in Unit III.C of

the October 30, 2015, rulemaking, except as described below.

The current exposure assessment incorporates the additional dietary

exposure from this petitioned-for tolerances. Because this action

establishes tolerances for residues of teflubenzuron in or on imported

commodities for which there are no associated U.S. registrations,

dietary exposure (food only) is the only anticipated exposure pathway.

There are no domestic agricultural or residential uses registered or

proposed for teflubenzuron that would result in drinking water or

residential exposures. This tolerance petition does not warrant an

occupational handler exposure assessment because the petition is for

import tolerances without a U.S. registration. There are no short- or

intermediate-term exposures from the use of teflubenzuron. An acute

risk assessment was not performed because there were no toxicological

effects attributable to a single dose identified.

The unrefined chronic dietary (food only) exposure estimates

represent the aggregate exposure assessment and assumed that

teflubenzuron residues are present in all commodities at tolerance

levels and that 100% of all crops are treated. Empirical processing

factors of 0.08 for apple juice and 0.04 for orange juice were

incorporated into the dietary exposure model and the Agency's 2018

default processing factors were used to estimate residues in other

processed commodities. The Agency's approach for assessing these

factors is discussed in detail in the document titled ``Chronic Dietary

(Food Only) Exposure and Risk Assessment for the Proposed Tolerances

Without a U.S. Registration for Residues in/on Grapes.'' in docket ID

number EPA-HQ-OPP-2021-0434.

Safety Factor for Infants and Children. EPA continues to conclude

that there is reliable data showing that the safety of infants and

children would be adequately protected if the Food Quality Protection

Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for

that decision are articulated in Unit III.D of the October 30, 2015,

rulemaking.

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 PAD (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 (PODs) to ensure that an adequate

margin of exposure (MOE) exists.

An endpoint of concern attributable to a single dose was not

identified; therefore, an acute dietary assessment was not performed.

Chronic dietary risks are below the Agency's level of concern of 100%

of the cPAD for the U.S. general population and all population

subgroups. The most highly exposed population subgroup is children 1-2

years old with an estimated risk of 48% of the cPAD.

In accordance with the EPA's ``Final Guidelines for Carcinogen Risk

Assessment'' (March 2005), the Cancer Assessment Review Committee

(CARC) classified teflubenzuron as ``Suggestive Evidence of

Carcinogenic Potential'' based on the presence of rare liver tumors in

male mice only. The Agency has determined that quantification of risk

using a non-linear approach (i.e., reference dose [RfD]) will

adequately account for all chronic toxicity, including carcinogenicity,

that could result from exposure to teflubenzuron. Therefore, the

chronic dietary risks, which are not of concern, are considered

protective of both non-cancer and cancer effects.

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 teflubenzuron

residues. More detailed information about the Agency's analysis can be

found at [https://www.regulations.gov](https://www.regulations.gov/) in the document titled ``Chronic

Dietary (Food Only) Exposure and Risk Assessment for the Proposed

Tolerances Without a U.S. Registration for Residues in/on Grapes.''

This document can be found in docket ID number EPA-HQ-OPP-2021-0434.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available to enforce the

petitioned-for tolerances for residues of teflubenzuron in/on crop

commodities. Samples were analyzed for residues of teflubenzuron using

a high-performance liquid chromatography method with tandem mass

spectrometry detection (LC/MS/MS), SOP-PA.0250. Acceptable concurrent

recoveries were reported for samples of grape fortified with

teflubenzuron at 0.01-1.0 ppm, thus validating the method. The limit of

quantitation (LOQ; determined as the lowest level of method validation,

LLMV) was 0.01 ppm. The estimated LOD (limit of detection) was 20% of

the LOQ or 0.002 ppm.

These methods may be requested from: Chief, Analytical Chemistry

Branch, Environmental Science Center, 701 Mapes Road, Fort 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.

The U.S. tolerance level for grape residues established in this

action is harmonized with Codex. There are no established Canadian or

Mexican MRLs for residues of teflubenzuron on grape. Additionally,

there are no established Codex, Canadian, or Mexican MRLs for residues

of teflubenzuron on grape, raisin.

C. Revisions to Petitioned-For Tolerances

Based upon the submitted data, no revisions to the petitioned-for

tolerances proposed for residues in/on grape and grape, raisin are

needed.

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V. Conclusion

Therefore, tolerances are established for residues of the

insecticide teflubenzuron, (N-[[(3,5-dichloro-2,4-

difluorophenyl)amino]carbonyl]-2,6-difluorobenzamide), in or on grape

at 0.7 ppm; and grape, raisin, at 0.9 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 and pests, Reporting and

recordkeeping requirements.

Dated: May 24, 2022.

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

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. 180.687:

0

a. Amend paragraph (a)(1) by:

0

i. Adding a table heading;

0

ii. Adding the commodities ``Grape'' and ``Grape, raisin'' to the table

in alphabetical order; and

0

iii. Revising footnote 1.

0

b. Add a reserved paragraph (a)(2).

0

c. Remove and reserve paragraphs (b), (c), and (d).

The additions and revision read as follows:

Sec. 180.687 Teflubenzuron; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

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Parts per

Commodity million

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\* \* \* \* \*

Grape \1\............................................... 0.7

Grape, raisin \1\....................................... 0.9

\* \* \* \* \*

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\1\ Tolerance without U.S. registration.

\* \* \* \* \*

[FR Doc. 2022-11558 Filed 6-3-22; 8:45 am]

BILLING CODE 6560-50-P