[Federal Register Volume 89, Number 23 (Friday, February 2, 2024)]

[Rules and Regulations]

[Pages 7291-7294]

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[FR Doc No: 2024-02092]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0868; FRL-11673-01-OCSPP]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

saflufenacil in or on corn, field, forage; corn, field, stover; and

corn, field, milled byproducts; and amends the existing commodity

definition for Crop Group 16 to Crop Group 16-22. BASF Corporation

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

Act (FFDCA).

DATES: This regulation is effective February 2, 2024. Objections and

requests for hearings must be received on or before April 2, 2024, 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-2022-0868, 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-2022-0868 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

April 2, 2024. 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-2022-0868, 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,

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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-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

2F9019) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research

Triangle Park, NC 27709. The petition requested that 40 CFR

180.649(a)(1) be amended by establishing tolerances for residues of the

herbicide saflufenacil, including its metabolites and degradates, in or

on Corn, field, forage at 0.3 parts per million (ppm), Corn, field,

milled byproducts at 0.125 ppm, and Corn, field, stover at 5.0 ppm. The

petition also requested to amend the existing commodity definition in

40 CFR 180.649(a)(1) for residues of the herbicide saflufenacil,

including its metabolites and degradates, in or on ``Grain, cereal,

forage, fodder and straw group 16 (except barley and wheat straw)'' to

``Grain, cereal, forage, hay, stover, and straw group 16-22 (except

field corn forage, field corn stover, barley straw, wheat straw, and

chia straw)'' unchanged at 0.1 ppm. That document referenced a summary

of the petition prepared by BASF Corporation, 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

has made modifications to the proposed tolerance values and 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 in FFDCA section 408(b)(2)(D), 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 saflufenacil including exposure

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

assessment of exposures and risks associated with saflufenacil 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 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 tolerance rulemaking in 2015 for

saflufenacil in which EPA concluded, based on the available

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

result from aggregate exposure to saflufenacil and established

tolerances for residues of that chemical. EPA is incorporating

previously published sections from that rulemaking as described further

in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological

profile for saflufenacil, see Unit III.A. of the saflufenacil tolerance

rulemaking published in the Federal Register of November 25, 2015 (80

FR 73663) (FRL-9936-71).

Toxicological points of departure/Levels of concern. A summary of

the toxicological points of departure and levels of concern for

saflufenacil used for human health risk assessment is discussed in Unit

III.B. of the November 25, 2015, rulemaking.

Exposure assessment. Much of the exposure assessment remains

unchanged from the November 2015 rulemaking, although updates have

occurred to accommodate the 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, see Unit III.C of the November 25, 2015,

rulemaking.

EPA's dietary exposure assessments have been updated to include the

additional exposure from the petitioned-for tolerances for

saflufenacil. Acute and chronic dietary exposure assessments were

performed for saflufenacil that incorporated tolerance-level residues,

100% crop treated (CT) assumptions, and default processing factors.

These assessments were revised to reflect the updated Dietary Exposure

Evaluation Model software with the Food Commodity Intake Database

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

data from the United States Department of Agriculture (USDA) National

Health and Nutrition Examination Survey, What We Eat in America

(NHANES/WWEIA). The acute and chronic estimated drinking water

concentrations (EDWCs) of 133 parts per billion (ppb) and 120 ppb,

respectively, are unchanged from the November 25, 2015, rulemaking and

were directly incorporated into the dietary assessments. A cancer

dietary assessment was not conducted as saflufenacil is classified as

``not likely'' to be a human carcinogen. Saflufenacil is not registered

for any specific use patterns that would result in residential

exposure. Therefore, a quantitative residential exposure assessment was

not conducted.

Cumulative exposure. 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.'' EPA has not

found saflufenacil to share a common mechanism of toxicity with any

other substances, and saflufenacil does not appear to produce a toxic

metabolite produced by other substances. For the purposes of this

tolerance action, therefore, EPA has assumed that saflufenacil does not

have a common mechanism of toxicity with other substances. For

information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of

such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

Safety factor for infants and children. EPA continues to conclude

that there are reliable data to support the

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

10X to 1X. See Unit III.D. of the November 25, 2015, 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

dietary exposure estimates to the acute population adjusted dose (aPAD)

and the chronic population adjusted dose (cPAD). Short-, intermediate-,

and chronic-term aggregate risks are evaluated by comparing the

estimated total food, water, and residential exposure to the

appropriate points of departure (PODs) to ensure that an adequate

margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the

Agency's level of concern of 100% of the acute population adjusted dose

(aPAD); they are <1% of the aPAD for all infants less than 1 year old,

the population group receiving the greatest exposure. Chronic dietary

(food and drinking water) risks are below the Agency's level of concern

of 100% of the chronic population adjusted dose (cPAD); they are 26% of

the cPAD for all infants less than 1 year old, the population group

receiving the greatest exposure. There is no short- or intermediate-

term residential exposure expected since there are no proposed or

previously registered residential uses of saflufenacil. Therefore, the

acute and chronic aggregate risks consist only of the dietary risks

from food and water only, and as stated above, are below the Agency's

level of concern. Based on the lack of evidence of carcinogenicity in

two adequate rodent carcinogenicity studies, saflufenacil is not

expected to pose a cancer risk to humans.

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 saflufenacil residues, including its metabolites

and degradates. More detailed information about the Agency's analysis

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

``Saflufenacil. Human Health Risk Assessment for Proposed New and

Amended Uses on Field Corn Commodities, Post-Harvest and Fallow'' in

docket ID number EPA-HQ-OPP-2022-0868.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid

chromatography with tandem mass spectroscopy detection (HPLC-MS/MS)

Method D0603/04) is available to enforce the tolerance expression. The

method 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). The Codex has not established MRLs for saflufenacil

for feed items of raw agricultural commodities. Therefore,

harmonization of MRLs and U.S. tolerances is not an issue at this time.

C. Revisions to Petitioned-For Tolerances

EPA is revising the tolerance level proposed for corn, field,

forage from 0.3 ppm to 0.4 ppm based on field trial residues values and

the combined residue calculation. The tolerance level proposed for

corn, field, stover is also being revised from 5.0 ppm to 5 ppm based

on the Organization for Economic Co-operation and Development (OECD)

rounding class practice. EPA is also revising the tolerance level

proposed for corn, field, milled byproducts from 0.125 ppm to 0.2 ppm

to adjust for degree of exaggeration and the OECD rounding class. Also,

EPA is revising the proposed commodity definition ``Grain, cereal,

forage, hay, stover, and straw group 16-22 (except field corn forage,

field corn stover, barley straw, wheat straw, and chia straw)'' to the

following definitions to align better with the Agency's current

preferred commodity vocabulary: ``Grain, cereal, forage, hay, stover,

and straw, group 16-22, forage, except corn, field, forage''; ``Grain,

cereal, forage, hay, stover, and straw, group 16-22, hay''; ``Grain,

cereal, forage, hay, stover, and straw, group 16-22, stover, except

corn, field, stover''; and ``Grain, cereal, forage, hay, stover, and

straw, group 16-22, straw, except barley, chia, and wheat, straw.''

V. Conclusion

Therefore, tolerances are established for residues of saflufenacil,

including its metabolites and degradates, in or on Corn, field, forage

at 0.4 ppm; Corn, field, milled byproducts at 0.2 ppm; Corn, field,

stover at 5 ppm; Grain, cereal, forage, hay, stover, and straw, group

16-22, forage, except corn, field, forage at 0.1 ppm; Grain, cereal,

forage, hay, stover, and straw, group 16-22, hay at 0.1 ppm; Grain,

cereal, forage, hay, stover, and straw, group 16-22, stover, except

corn, field, stover at 0.1 ppm; and Grain, cereal, forage, hay, stover,

and straw, group 16-22, straw, except barley, chia, and wheat, straw at

0.1 ppm. In addition, EPA is removing the established tolerance in or

on Grain, cereal, forage, fodder and straw group 16 (except barley and

wheat straw) 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 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

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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: January 30, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 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. 180.649, amend the table in paragraph (a)(1) by:

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a. Adding in alphabetical order the entries ``Corn, field, forage'';

``Corn, field, milled byproducts''; and ``Corn, field, stover''.

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b. Removing the entry for ``Grain, cereal, forage, fodder and straw

group 16 (except barley and wheat straw)''.

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c. Adding in alphabetical order the entries ``Grain, cereal, forage,

hay, stover, and straw, group 16-22, forage, except corn, field,

forage''; ``Grain, cereal, forage, hay, stover, and straw, group 16-22,

hay''; ``Grain, cereal, forage, hay, stover, and straw, group 16-22,

stover, except corn, field, stover''; and ``Grain, cereal, forage, hay,

stover, and straw, group 16-22, straw, except barley, chia, and wheat,

straw''.

The additions read as follows:

Sec. 180.649 Saflufenacil; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \* \* \*

Corn, field, forage......................................... 0.4

Corn, field, milled byproducts.............................. 0.2

Corn, field, stover......................................... 5

\* \* \* \* \* \* \*

Grain, cereal, forage, hay, stover, and straw, group 16-22, 0.1

forage, except corn, field, forage.........................

Grain, cereal, forage, hay, stover, and straw, group 16-22, 0.1

hay........................................................

Grain, cereal, forage, hay, stover, and straw, group 16-22, 0.1

stover, except corn, field, stover.........................

Grain, cereal, forage, hay, stover, and straw, group 16-22, 0.1

straw, except barley, chia, and wheat, straw...............

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[FR Doc. 2024-02092 Filed 2-1-24; 8:45 am]

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