[Federal Register Volume 88, Number 16 (Wednesday, January 25, 2023)]

[Rules and Regulations]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0447; FRL-10478-01-OCSPP]

Rimsulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

rimsulfuron in or on pomegranate and tropical and subtropical, small

fruit, edible peel, subgroup 23A. The Interregional Research Project

No. 4 (IR-4) requested these tolerances under the Federal Food, Drug,

and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 25, 2023. Objections and

requests for hearings must be received on or before March 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-2021-0447, 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: Daniel Rosenblatt, 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, 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-2021-0447 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

March 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

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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-2021-0447, 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 September 22, 2021 (86 FR 52624) (FRL-

8792-03-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 1E8926) by IR-4, North Carolina State University, 1730

Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition

requested that 40 CFR 180.478 be amended by establishing tolerances for

residues of the herbicide rimsulfuron (N-[[(4,6-dimethoxy-2-

pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide),

in or on pomegranate at 0.01 parts per million (ppm) and tropical and

subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm. There

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

III. Aggregate Risk Assessment and Determination of Safety

FFDCA section 408(b)(2)(A)(i) 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.'' FFDCA section

408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C)

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 rimsulfuron including exposure

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

assessment of exposures and risks associated with rimsulfuron 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 rulemaking of the same pesticide

chemical. Where scientific information concerning a particular chemical

remains unchanged, the content of those sections would not vary between

tolerance rulemaking and republishing the same sections is unnecessary.

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 for rimsulfuron

in which EPA concluded, based on the available information, that there

is a reasonable certainty that no harm would result from aggregate

exposure to rimsulfuron and established tolerances for residues of that

chemical. EPA is incorporating previously published sections from this

rulemaking as described further in this rulemaking, as they remain

unchanged.

Toxicological profile. For a discussion of the Toxicological

Profile of rimsulfuron, see Unit III.A of the February 12, 2018, final

rulemaking (83 FR 5942) (FRL-9972-36).

Points of departure/Levels of concern. A summary of the

toxicological endpoints for rimsulfuron used for human risk assessment

is discussed in Unit III.B of the February 12, 2018, final rulemaking.

Exposure assessment. Much of the exposure assessment remains the

same 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, please reference Unit III.C of

the February 12, 2018, final rulemaking.

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

additional exposures from the new uses of rimsulfuron on pomegranate

and tropical and subtropical, small fruit, edible peel, subgroup 23A.

An unrefined chronic dietary (food and drinking water) exposure and

risk assessment was conducted using the Dietary Exposure Evaluation

Model software with the Food Commodity Intake Database (DEEM-FCID)

Version 4.02. This software incorporates 2005-2010 consumption data

from the U.S. Department of Agriculture's (USDA's) National Health and

Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA).

The chronic assessment used tolerance level residues for all crops and

assumed that 100% of the crops were treated with rimsulfuron. The

Agency's default processing factors were used where available. An acute

dietary exposure assessment was not conducted since there was no

adverse effect observed for a single dose of rimsulfuron.

Dietary exposure from drinking water. The new uses do not result in

an increase in the estimated residue levels in drinking water, so EPA

used the same estimated drinking water concentrations in the chronic

dietary assessment as identified in Unit III.C of the February 12,

2018, rulemaking.

From non-dietary exposure. There are no proposed residential uses

at this time; however, there are existing residential uses on turf that

have been previously assessed using current data and assumptions. For

the residential assessment of the turf uses, EPA did not conduct a

quantitative residential handler risk assessment. The end use label

requires handlers to wear specific clothing (long-sleeve shirt and long

pants) and chemical-resistant gloves, so EPA assumed the product is not

for homeowner use. There is the potential for post-application dermal

exposures; however, a residential post-application dermal exposure

assessment was not conducted because no dermal hazard was identified in

the rimsulfuron database. The quantifiable post-application residential

risk estimates reflect incidental oral exposure to children 1 to less

than 2 years old from hand-to-mouth exposure to turf treated with

rimsulfuron. The margin of exposure (MOE) is 26,000, which is greater

than the level of concern of 100 and is not of concern.

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Cumulative effects from substances with 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>. The agency has utilized this framework for rimsulfuron and

determined that although rimsulfuron shares some chemical and/or

toxicological characteristics (e.g., chemical structure or apical

endpoint) with other pesticides, the toxicological database does not

support a testable hypothesis for a common mechanism of action. No

further data are required to determine that no common mechanism of

toxicity exists for rimsulfuron and other pesticides and no further

cumulative evaluation is necessary for rimsulfuron.

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 (SF) from 10X to 1X for all

risk scenarios. See Unit III.D. of the February 12, 2018, final

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 the 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 MOE exists.

For linear cancer risks, EPA calculates the lifetime probability of

acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not conducted since there

was no adverse effect observed for a single dose of rimsulfuron.

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

of the cPAD; they are 1.8% of the cPAD for all infants (<1 year old),

the population group receiving the greatest exposure.

The short-term aggregate exposure assessment for children 1 to less

than 2 years old includes dietary (food and drinking water) and

incidental oral exposure from hand-to-mouth activities from post-

application exposure to turf. The short-term aggregate risk estimate

for children 1 to less than 2 years old is an MOE of 3,700, which is

greater than the level of concern of 100 and is not of concern. Acute

risks are not expected due to no adverse effect observed for a single

dose of rimsulfuron; and chronic aggregate risks to adults and children

are equivalent to the dietary (food and drinking water) risks for those

respective assessments and are not of concern. Because there is no

intermediate-term residential exposure and chronic dietary exposure has

already been assessed under the appropriately protective cPAD, no

further assessment of intermediate-term risk is necessary. Based on the

lack of evidence of carcinogenicity in two adequate rodent

carcinogenicity studies, rimsulfuron is not expected to pose a cancer

risk to humans.

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 rimsulfuron residues. More detailed information

on this action can be found in the document ``Rimsulfuron. Human Health

Risk Assessment in Support of a Petition for the Establishment of

Permanent Tolerances on Pomegranate and Tropical and Subtropical, Small

Fruit, Edible Peel, Subgroup 23A'' in docket ID No. EPA-HQ-OPP-2021-

0447.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method for

various crops, see Unit IV.A of the February 12, 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). Codex has not established MRLs for residues of

rimsulfuron in or on any commodity associated with this action.

V. Conclusion

Therefore, tolerances are established for residues of rimsulfuron

(N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-

pyridinesulfonamide), in or on pomegranate at 0.01 ppm and tropical and

subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm.

In addition, as a housekeeping measure, EPA is removing the

tolerance for potato at 0.1 ppm, which expired on August 12, 2018, and

has no effect at this time.

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

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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: January 13, 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 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. 180.478, in paragraph (a) amend table 1 by:

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a. Adding in alphabetical order the entry ``Pomegranate'';

0

b. Removing the entry for ``Potato'' and the footnote; and

0

c. Adding in alphabetical order the entry ``Tropical and subtropical,

small fruit, edible peel, subgroup 23A''.

The additions read as follows:

Sec. 180.478 Rimsulfuron; tolerances for residues

(a) \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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

Pomegranate............................................. 0.01

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Tropical and subtropical, small fruit, edible peel, 0.01

subgroup 23A...........................................

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[FR Doc. 2023-01131 Filed 1-24-23; 8:45 am]

BILLING CODE 6560-50-P