[Federal Register Volume 89, Number 83 (Monday, April 29, 2024)]

[Rules and Regulations]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0280; FRL-11860-01-OCSPP]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation amends the existing tolerance for residues of

flonicamid in or on the raw agricultural commodity berry, low-growing,

subgroup 13-07G by increasing the tolerance from 1.5 parts per million

(ppm) to 2 ppm. ISK Biosciences Corporation requested this amended

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

DATES: This regulation is effective April 29, 2024. Objections and

requests for hearings must be received on or before June 28, 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-2023-0280, is available at

<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: 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-2023-0280, 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

June 28, 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-2023-0280, by one of

the following methods:

Federal eRulemaking Portal: <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/where-send-comments-epa-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 Tolerances

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

3F9050) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A,

Concord, OH 44077-9703. The petition requested that 40 CFR part 180 be

amended by establishing tolerances for residues of flonicamid in or on

the raw agricultural commodities berry, low-growing, subgroup 13-07G,

except strawberry, at 1.5 ppm and strawberry at 2.0 ppm. The petition

also requested removal of the existing tolerance for residues of

flonicamid in or on berry, low-growing, subgroup 13-07G at 1.5 ppm.

That document referenced a summary of the petition, which is

available in the docket at <https://www.regulations.gov>. There were no

comments received on 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 amending the existing tolerance for residues of flonicamid in or on

berry, low-growing, subgroup 13-07G by increasing the tolerance from

1.5 ppm to 2 ppm, rather than establishing different tolerances for

berry, low-growing, subgroup 13-07G, except strawberry, and strawberry

as originally requested. A revised petition was submitted by ISK

Biosciences Corporation to support this change to the petitioned-for

tolerance. For details, see 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

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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 flonicamid including exposure resulting from the

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

and risks associated with flonicamid 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 tolerance rulemakings for flonicamid

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

is a reasonable certainty that no harm would result from aggregate

exposure to flonicamid and established tolerances for residues of the

chemical. EPA is incorporating previously published sections from these

rulemakings as described further in this rulemaking, as they remain

unchanged.

Toxicological profile. For a discussion of the toxicological

profile of flonicamid, see Unit III. of the flonicamid tolerance

rulemaking published in the Federal Register of September 20, 2023 (88

FR 64819) (FRL-11393-01).

Toxicological points of departure/levels of concern. For a summary

of the toxicological points of departure/levels of concern for

flonicamid used for human health risk assessment, see Table 4.0.1. of

the ``Flonicamid. Human Health Risk Assessment for the Petition for

Amendment of Tolerances in/on Low Growing Berry Subgroup 13-07G''

(hereafter the Flonicamid Human Health Risk Assessment) in docket ID

EPA-HQ-OPP-2023-0280 at <https://www.regulations.gov>.

Exposure assessment. EPA's dietary exposure assessments have been

updated to include the additional exposure from the increased tolerance

for residues of flonicamid in or on berry, low-growing, subgroup 13-

07G. The dietary exposure assessments were conducted with Dietary

Exposure Evaluation Model software using the Food Commodity Intake

Database (DEEM-FCID) Version 4.02, which uses the 2005-2010 food

consumption data from the United States Department of Agriculture's

(USDA's) National Health and Nutrition Examination Survey, What We Eat

in America (NHANES/WWEIA). An unrefined chronic dietary exposure

assessment was conducted for all proposed and registered uses of

flonicamid. The analysis assumed 100 percent crop treated (100% CT) and

tolerance level residues for all commodities. Separate tolerances have

been established for potato granules/flakes, tomato paste, and tomato

puree based on processing studies. The processing factors were set to

1.0 for these commodities. The Agency's default processing factors were

used for the other processed commodities for which default processing

factors are available.

Drinking water and non-occupational exposures. The estimated

drinking water concentrations have not changed as a result of the

increased tolerance for residues of flonicamid in or on berry, low-

growing, subgroup 13-07G. For a detailed summary of the drinking water

analysis for flonicamid used for the human health risk assessment, see

Unit III.C.2. of the flonicamid tolerance rulemaking published in the

Federal Register of July 23, 2018 (83 FR 34775) (FRL-9977-82).

There are no proposed residential uses at this time; however, there

are existing registered residential handler uses that were previously

assessed and which resulted in no risks of concern. Registered

residential use patterns are expected to result in only short-term

exposures to flonicamid and, as a dermal endpoint was not selected,

residential risk estimates were calculated for the inhalation route

only.

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.'' 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 mechanism

of toxicity finding as to flonicamid and any other substances, and

flonicamid does not appear to produce a toxic metabolite produced by

other substances. For the purposes of this action, therefore, EPA has

not assumed that flonicamid has a common mechanism of toxicity with

other substances.

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 from 10X to 1X. See Unit

III. of the September 20, 2023, 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 (food and drinking water) exposure estimates to the acute

population-adjusted dose (aPAD) and chronic population-adjusted dose

(cPAD). Short- and intermediate-term risks are evaluated by comparing

the estimated total food, water, and residential exposure to the

appropriate points of departure to ensure that an adequate margin of

exposure (MOE) exists.

No adverse effect resulting from a single oral exposure was

identified and no acute dietary endpoint was selected. Therefore,

flonicamid 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

91% of the cPAD for children 1 to 2 years old, the group with the

highest exposure.

For short-term aggregate risk, adult residential handler exposure

estimates are aggregated with adult dietary exposure estimates, which

are considered background. The estimated aggregate MOE for adult

handlers is 1,100 and is not of concern because it is higher than the

level of concern of 100. Short-term aggregate risk estimates for

children are expected to be equivalent to chronic dietary risks.

A cancer dietary assessment was not conducted as flonicamid has

been determined to be ``suggestive evidence of carcinogenicity, but not

sufficient to assess human carcinogenicity potential.'' The Agency has

determined that quantification of risk using a non-linear approach

(i.e., using a chronic reference dose) adequately accounts for all

chronic toxicity, including

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carcinogenicity that could result from exposure to flonicamid. As

stated above, the chronic risks are not of concern.

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 flonicamid residues. More detailed information on

this action can be found in the Flonicamid Human Health Risk Assessment

in docket ID EPA-HQ-OPP-2023-0280 at <https://www.regulations.gov>.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method,

see Unit IV.A. of the July 23, 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).

The tolerance expression for plant and livestock commodities are

harmonized between the U.S. and Canada, but not Codex and Japan. Codex

and Japanese residues of concern are expressed as flonicamid only,

whereas U.S. residues of concern are flonicamid and its metabolites

TFNA, TFNA-AM, and TFNG. Codex has an MRL for residues of flonicamid in

or on low growing berries at 1.5 ppm, and Canada has MRLs for residues

of flonicamid in or on bearberry; bilberry; blueberry, lowbush;

cloudberry; cranberry; and lingonberry at 1.5 ppm. The existing U.S.

tolerance for residues of flonicamid in or on berry, low-growing,

subgroup 13-07G at 1.5 ppm is harmonized with Codex and Canadian MRLs.

However, the petition requested that EPA increase the existing U.S.

tolerance from 1.5 ppm to 2 ppm in order to harmonize with the Japanese

MRL for residues of flonicamid in or on strawberry, cranberry, and

other berries at 2 ppm and minimize barriers to imports of strawberries

from Japan. Although this action is establishing a higher tolerance for

residues of flonicamid in or on low growing berry, subgroup 13-07G that

is no longer harmonized with Codex or Canadian MRLs, this is not

expected to create a trade barrier to imports of these commodities from

Codex countries and Canada since commodities that comply with the lower

Codex and Canadian MRLs could be imported into the U.S. For these

reasons, EPA has determined it is appropriate to amend the tolerance

for residues of flonicamid in or on low growing berry, subgroup 13-07G

from 1.5 ppm to 2 ppm, as petitioned.

C. Revisions to Petitioned-For Tolerances

EPA is amending the existing tolerance for residues of flonicamid

in or on berry, low-growing, subgroup 13-07G by increasing the

tolerance from 1.5 ppm to 2 ppm, rather than establishing different

tolerances for berry, low-growing, subgroup 13-07G, except strawberry,

and strawberry as originally requested. Because strawberry is the

representative commodity for berry, low-growing, subgroup 13-07G, it

may not be excepted from the crop subgroup under 40 CFR 180.40(h). A

revised petition was submitted by ISK Biosciences Corporation to

support this change to the petitioned-for tolerance.

V. Conclusion

Therefore, the established tolerance for residues of flonicamid in

or on berry, low-growing, subgroup 13-07G is amended from 1.5 ppm to 2

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 to 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.

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Dated: April 23, 2024.

Charles Smith,

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. 180.613, revise the entry in table 1 to paragraph (a)(1)

for ``Berry, low-growing, subgroup 13-07G'' to read as follows:

Sec. 180.613 Flonicamid; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

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Parts per

Commodity million

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Berry, low-growing, subgroup 13-07G.................... 2

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[FR Doc. 2024-09048 Filed 4-26-24; 8:45 am]

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