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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0250; FRL-10009-26]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation revises the tolerance for residues of

flonicamid in or on Leafy greens subgroup 4-16A, except spinach.

Interregional Research Project Number 4 (IR-4) requested these

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

DATES: This regulation is effective May 28, 2020. Objections and

requests for hearings must be received on or before July 27, 2020 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-2019-0250, 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.

Please note that due to the public health emergency, the EPA Docket

Center (EPA/DC) and Reading Room was closed to public visitors on March

31, 2020. Our EPA/DC staff will continue to provide customer service

via email, phone, and webform. For further information on EPA/DC

services, docket contact information and the current status of the EPA/

DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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, any person may file an

objection to any aspect of this regulation

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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-2019-0250 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 July 27, 2020. 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-2019-0250, 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 August 2, 2019 (84 FR 37818) (FRL-9996-

78), 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

9E8743) by IR-4, Rutgers, The State University of New Jersey, 500

College Road East, Suite 201 W, Princeton, NJ 08540. The petition

requested that 40 CFR 180.613 be amended by increasing the existing

tolerance for residues of the insecticide flonicamid, including its

metabolites and degradates, to be determined by measuring only the sum

of flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-

pyridinecarboxamide, and its metabolites, TFNA (4-

trifluoromethylnicotinic acid), TFNA-AM (4-

trifluoromethylnicotinamide), and TFNG, N-(4-

trifluoromethylnicotinoyl)glycine, calculated as the stoichiometric

equivalent of flonicamid, in or on Leafy greens subgroup 4-16A, except

spinach, from 4.0 parts per million (ppm) to 8.0 ppm. That document

referenced a summary of the petition prepared by ISK Biosciences

Corporation, the registrant, for IR-4 which is available in the docket,

[http://www.regulations.gov](http://www.regulations.gov/). One comment was received on the notice of

filing. EPA's response to this comment is discussed in Unit IV.C.

EPA is establishing the tolerance at 8 ppm rather than 8.0 ppm to

be consistent with the Organization for Economic Cooperation and

Development (OECD) Rounding Class Practice.

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 flonicamid including exposure

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

assessment of exposures and risks associated with flonicamid follows.

On April 8, 2019, EPA published in the Federal Register a final

rule establishing tolerances for residues of flonicamid on sunflower

subgroup 20B based on the Agency's conclusion that aggregate exposure

to flonicamid is safe for the general population, including infants and

children. See 84 FR 13805 (FRL-9990-52). That document contains a short

discussion of the toxicological profile, assumptions for exposure

assessment, cumulative risk, and Agency's determination regarding the

children's safety factor, which have not changed. In addition, the

April 8, 2019 final rule referred to a summary of the toxicological

profile and the toxicological endpoints and the points of departure for

flonicamid used for human risk assessment in Unit III.B. of the final

rule published in the Federal Register of July 23, 2018 (83 FR 34775)

(FRL-9977-82). Those discussions are also incorporated here, as they

have not changed since those documents were published.

EPA's exposure assessments have been updated to include the

additional exposure from use of flonicamid in greenhouses on

commodities in the Leafy greens subgroup 4-16A, except spinach. EPA

relied on tolerance-level residues and an assumption of 100 percent

crop treated for all commodities. EPA's aggregate exposure assessment

incorporated this additional dietary exposure, as well as exposure in

drinking water, although the drinking water exposures are not impacted

by this new greenhouse use and thus have not changed since the last

assessment. Flonicamid is not registered for any specific use patterns

that would result in residential exposure. Further information about

EPA's risk assessment and determination of safety supporting the

tolerances established in the April 8, 2019 Federal Register action, as

well as the new flonicamid tolerance can be found at [http://www.regulations.gov](http://www.regulations.gov/) in ``Flonicamid. Human Health Risk Assessment for

the Establishment of Permanent Tolerances in or on Sunflower Subgroup

20B,'' dated December 6, 2018 in docket ID number EPA-HQ-OPP-2018-0273

and the document titled, ``Flonicamid. Human Health Risk Assessment for

a Petition to Increase the Tolerance for Leafy Greens, Except Spinach

(Subgroup 4-16A) to Support Use on Greenhouse-Grown Commodities,''

dated April 28, 2020 in docket ID number EPA-HQ-OPP-2019-0250.

No adverse effects resulting from a single oral exposure was

identified and no acute dietary endpoint was selected; therefore, an

acute dietary assessment was not conducted. Chronic dietary risks are

below the Agency's level of concern: 62% of the chronic population-

adjusted dose (cPAD) for children 1 to

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2 years old, the group with the highest exposure. Flonicamid is not

registered for any use patterns that would result in short- or

intermediate-term residential exposures. EPA has concluded that the

cPAD is protective of possible cancer effects from flonicamid. Because

aggregate exposure to flonicamid is below the cPAD, EPA concludes that

there is not an aggregate cancer risk from exposures to flonicamid.

Therefore, based on these 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 flonicamid residues. More detailed

information on the subject action to revise the tolerance in or on the

Leafy greens subgroup 4-16A, except spinach, can be found in the

document entitled, ``Flonicamid. Human Health Risk Assessment for a

Petition to Increase the Tolerance for Leafy Greens, Except Spinach

(Subgroup 4-16A) to Support Use on Greenhouse-Grown Commodities'' by

going to [http://www.regulations.gov](http://www.regulations.gov/). The referenced document is

available in the docket established by this action, which is described

under ADDRESSES. Locate and click on the hyperlink for docket ID number

EPA-HQ-OPP-2019-0250.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the

tolerance expression. FMC Method No. P-3561M, a liquid chromatography-

tandem mass spectrometry (LC/MS/MS) method, is an acceptable

enforcement method for flonicamid and its metabolites in plant

commodities.

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 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 established MRLs for flonicamid in or on leaf lettuce

at 8.0 ppm and head lettuce at 1.5 ppm. No other Codex MRLs are

established for the crops within this subgroup. While the tolerance

expression for U.S. flonicamid tolerances is different than the

expression for the Codex flonicamid MRLs, the level of the new U.S.

tolerance for Leafy greens subgroup 4-16A, except spinach, is

harmonized with the Codex MRL for leaf lettuce. Because the U.S.

tolerance is for a crop subgroup, it not possible to harmonize with the

Codex MRL for head lettuce, which is another commodity in the Leafy

greens subgroup 4-16A.

C. Response to Comments

One commenter opposed approval of this tolerance claiming it could

have detrimental effects on beneficial insects. Whether a pesticide has

detrimental effects on beneficial insects, however, is a question

outside the scope of analysis under the FFDCA because it is not

relevant to whether tolerances are safe. The existing legal framework

provided by section 408 of the FFDCA states that tolerances may be set

when persons seeking such tolerances or exemptions have demonstrated

that the pesticide meets the safety standard imposed by that statute.

This comment provides no information relevant the Agency's safety

determination. Concerns about environmental impacts of a pesticide are

more appropriately raised in actions related to pesticides being

registered under the Federal Insecticide, Fungicide and Rodenticide

Act.

V. Conclusion

Therefore, the existing tolerance for residues of flonicamid,

including its metabolites and degradates, in or on Leafy greens

subgroup 4-16A, except spinach, is modified to be 8 ppm, rather than

4.0 ppm.

VI. Statutory and Executive Order Reviews

This action modifies 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), nor is it considered a

regulatory action under Executive Order 13771, entitled ``Reducing

Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3,

2017). 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

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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 6, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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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 ``Leafy greens subgroup 4-16A,

except spinach'' in the table in paragraph (a)(1) to read as follows:

Sec. 180.613 Flonicamid; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Leafy greens subgroup 4-16A, except spinach................. 8

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[FR Doc. 2020-10565 Filed 5-27-20; 8:45 am]

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