



BILLING CODE 6560-50-P

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.

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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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> 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.

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 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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>. 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 FFDCFA 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>. 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 FFDCFA 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> 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 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>. 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*.

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 to 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 FFDCFA 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 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]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.613, revise the entry “Leafy greens subgroup 4-16A, except spinach” in the table in paragraph (a)(1) to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1)* * *

Commodity	Parts per million
* * * * *	
Leafy greens subgroup 4-16A, except spinach	8
* * * * *	

* * * * *