



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0013; FRL-9962-15]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flonicamid in or on multiple commodities which are identified and discussed later in this document.

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-2016-0013, 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 review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director, 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 Printing 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-2016-0013 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-2016-0013, 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 May 19, 2016 (81 FR 31581) (FRL-9946-02), 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) 5E8428 submitted by IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requests that 40 CFR 180.613 be amended by establishing tolerances for residues of the fungicide 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 pea and bean, dried shelled, except soybean, subgroup 6C at 3.0 parts per million (ppm); Pea and bean, succulent shelled, subgroup 6B at 6.0 ppm; and Vegetable, legume, edible podded, subgroup 6A at 4.0 ppm. This petition contains an additional request to increase the existing tolerance on Vegetable, fruiting, group 8-10 from 0.4 to 1.50 ppm, but EPA has already taken action on that specific request, in a final tolerance rule published in the **Federal Register** on May 11, 2017 (82 FR 21941) (FRL-9959-91).

A summary of the petition prepared by ISK Biosciences Corporation, the registrant, is available in the docket, <http://www.regulations.gov>, at docket #: EPA-HQ-OPP-2016-0013. One comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing a tolerance for Pea and bean, succulent shelled, subgroup 6B that varies slightly from what the petitioner requested. The reason for this change is explained in Unit IV.D.

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, consistent with FFDCA section 408(b)(2).

In the **Federal Register** of May 11, 2017 (82 FR 21941) (FRL-9959-91), EPA established tolerances for residues of flonicamid in or on several commodities. The risk assessments supporting that action aggregated dietary and non-occupational exposures from existing and proposed uses of flonicamid, including from the exposures associated with the tolerances requested in this action. That assessment, which included the tolerances in today’s action, concluded that the tolerances are safe; therefore, EPA is relying upon that Federal Register document and the risk assessments supporting the findings in that document to support the safety finding for the tolerances that are the subject of this action.

Specific information on the studies received and the nature of the adverse effects

caused by flonicamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document, “Subject: Flonicamid. Human Health Risk Assessment for New Uses on Legume Vegetables, Subgroups 6A, 6B, and 6C; Add Directions for use on Greenhouse Grown Peppers and Increase the Tolerance for Residues on Fruiting Vegetables, Group 8-10; New Use on Citrus Fruits, Group 10-10; and a Tolerance without U.S. Registration for residues in/on Dried Tea” in docket ID number, EPA-HQ-OPP-2016-0013.

Based on the findings of the May 11, 2017 Federal Register document and the supporting documents, 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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (FMC Method No. P-3561M, a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression for flonicamid and its metabolites in or on 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 not established a MRL for flonicamid.

C. Response to Comments

Comment: One anonymous comment on the notice of filing of petition 5E8428 was received. The commenter claims that flonicamid is a “toxic pesticide” and residues at any level in food commodities should not be allowed and requested that EPA deny setting tolerances for the petition-for new uses of flonicamid. The comment stated that the proposed flonicamid use would add to about 25,000 toxic chemicals currently in the environment and combine to create even more toxic chemical residues in food and drinking water further increasing harmful effects to humans and environment.

Agency response: The Agency recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework

provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. In this instance, EPA has examined all the relevant and available data and concluded that the tolerances are safe. The commenter has not provided any information to support a conclusion by the Agency that the tolerances are not safe.

D. Revisions to Petitioned-For Tolerances

EPA is establishing a slightly higher tolerance for Pea and bean, succulent shelled, subgroup 6B at 7.0 ppm compared to the petitioner's request of a tolerance at 6.0 ppm. EPA's decision is based on the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures and available field trial data.

V. Conclusion

Therefore, tolerances are established for residues 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 Pea and bean, succulent shelled, subgroup 6B at 7.0 ppm; Pea and bean, dried shelled, except soybean, subgroup 6C at 3.0 ppm; and Vegetable, legume, edible podded, subgroup 6A at 4.0 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 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: June 2, 2017.

Michael L. 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, add alphabetically the following commodities “Pea and bean, succulent shelled, subgroup 6B”; “Pea and bean, dried shelled, except soybean, subgroup 6C”; and “Vegetable, legume, edible podded, subgroup 6A” to the table in paragraph (a)(1) to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	* *
Pea and bean, succulent shelled, subgroup 6B	7.0
Pea and bean, dried shelled, except soybean, subgroup 6C	3.0
* * * * *	* *
Vegetable, legume, edible podded, subgroup 6A	4.0
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