



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0160; FRL-9960-50]

Fluazinam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fluazinam in or on tea, dried. ISK Biosciences Corporation requested this tolerance 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-2016-0160, 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 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 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-2016-0160 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-2016-0160, 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 31583) (FRL-9946-02), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8449) by ISK Biosciences Corporation, 7470 Auburn RD, Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.574 be amended by establishing tolerances for residues of the fungicide fluazinam, in or on dried tea at 5.0 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance from 5.0 ppm to 6.0 ppm. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDC 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." Section 408(b)(2)(A)(ii) of FFDC 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. Section 408(b)(2)(C) of FFDC 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 FFDC section 408(b)(2)(D), and the factors specified in FFDC 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 fluazinam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazinam follows.

In the **Federal Register** of April 8, 2016 (81 FR 20545) (FRL 9942-99), EPA established tolerances for residues of fluazinam in or on cabbage at 3.0 parts per million (ppm), mayhaw at 2.0 ppm, the cucurbit vegetable crop group 9 at 0.07 ppm, and the tuberous and corm vegetable subgroup 1C at 0.02 ppm, and amended the commodity definition for the existing tolerance in vegetable, *Brassica* leafy, group 5 to vegetable, *Brassica* leafy, group 5, except cabbage.

Fluazinam is also registered for use in other plant commodities at levels ranging from 0.01 ppm to 7.0 ppm. A tolerance (without US registration) has been established for residues of fluazinam and its metabolite AMGT in/on wine grapes at 3.0 ppm, and tolerances of 0.05 ppm have been established for residues of fluazinam and its metabolites AMPA and DAPA and their sulfamate conjugates in/on the fat and meat byproducts of cattle, goats, horses, and sheep.

ISK Biosciences submitted 5 field trials for fluazinam on dried tea. The Agency finds these data are acceptable and sufficient to support the requested tolerance. The Agency also determined that establishing this tolerance would not result in any change in the exposure estimates from the previous risk assessment for fluazinam. Since the publication of the April 8, 2016 final rule, the toxicity profile of fluazinam has not changed, and the risk assessments that supported the establishment of those tolerances published in the **Federal Register** remain valid. The dietary risks for fluazinam are based on the parent compound for bulb vegetables and in root and tuber vegetables. For all other plant commodities, the residues of concern in plants for risk assessment are fluazinam and its metabolite AMGT. In drinking water, the degradates of concern are parent fluazinam and its transformation products. In livestock commodities, the

residues of concern are fluazinam, the metabolites AMPA, DAPA, and their sulfamate conjugates.

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 fluazinam residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for the proposed tolerances, please refer to the April 8, 2016 **Federal Register** document and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2015-0197.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a gas chromatographic method with electron capture detection (GC/ECD)) is available to enforce the tolerance expression.

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 an MRL for fluazinam in any commodities.

C. Response to Comments

EPA received one comment to the published Notice of Filing. This comment stated, in part and without any supporting information, that EPA should deny this petition because it is a harmful and toxic chemical with no benefits. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. The existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, 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. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. This comment provides no information to support an alternative conclusion.

D. Revisions to Petitioned-For Tolerances

The petitioner proposed tolerances for fluazinam in or on dried tea at 5.0 ppm. When mean residues from each of the tea field trials were entered into the Organization for Economic Cooperation and Development (OECD) MRL/Tolerance Calculation Procedure, the resulting tolerance was 6.0 ppm. Therefore, EPA is establishing a tolerance of 6.0 ppm rather than the requested tolerance of 5.0 ppm.

V. Conclusion

Therefore, a tolerance is established for residues of fluazinam, 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine, in or on tea, dried at 6.0 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: March 28, 2017.

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 § 180.574, add alphabetically the entry “Tea, dried¹” and footnote 1 to the table in paragraph (a)(1) to read as follows:

§ 180.574 Fluazinam; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * *	* * *
Tea, dried ¹	6.0
* * *	* * *

¹There is no U.S. registration as of January 19, 2017.

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