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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.

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 **[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-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*.

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 **[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-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 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

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.

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

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 in table 1 to paragraph (a)(1) for "Berry, low-growing, subgroup 13-07G" to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Berry, low-growing, subgroup 13-07G	2
* * * * * * *	

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[FR Doc. 2024-09048 Filed: 4/26/2024 8:45 am; Publication Date: 4/29/2024]