ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0013; FRL-9738-01-OCSPP]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide flonicamid, including its metabolites and degradates, in or on small fruit vine climbing (except fuzzy kiwifruit), subgroup 13–07F at 3 parts per million (ppm). In addition, this regulation amends the existing tolerance for residues of flonicamid, including its metabolites and degradates, in or on alfalfa, hay, by increasing the current tolerance from 1.0 ppm to 7 ppm. ISK Biosciences Corporation requested tolerances for these commodities 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 *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. 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; 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. section 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-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*: *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.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html*.

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 Tolerance

In the *Federal Register* of June 28, 2021 (86 FR 33926) (FRL-10025-08), 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 0F8884) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, OH 44077. The petition requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide flonicamid, including its metabolites and degradates, determined by measuring 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 small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F at 3.0 parts per million (ppm). In addition, this regulation amends the existing tolerance for residues of the insecticide flonicamid in or on alfalfa, hay, by increasing the current tolerance from 1.0 ppm to 7.0 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in docket ID number EPA-HQ-OPP-2016-0013, *https://www.regulations.gov*. No public comments were received in response to 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 establishing tolerances that vary from what the petitioners sought. The reasons for these changes are explained in full detail in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 the insecticide flonicamid in or on small fruit vine climbing (except fuzzy kiwifruit), subgroup 13–07F and the increased tolerance on alfalfa, hay.

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 of 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 republishing the same sections is unnecessary. 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 several 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 that chemical. In December 2020, EPA also finalized the "Flonicamid Interim Registration Decision" (go to *https://www.regulations.gov/* and search for docket ID number EPA-HQ-OPP-2014-0777). EPA is incorporating previously published sections from those rulemakings and any updates to the toxicological data base for flonicamid provided as part of the Flonicamid Interim Registration Decision in this tolerance rulemaking.

Toxicological profile. For a discussion of the Toxicological Profile for flonicamid used for human risk assessment, see the Flonicamid Interim Registration Decision by going to docket ID number EPA–HQ–OPP–2014-0777 at *https://www.regulations.gov*.

Toxicological points of departure/Levels of concern. EPA has reevaluated the toxicological database for the Flonicamid Interim Registration Decision. The table of the Toxicological points of departure/Levels of concern for flonicamid in the risk assessment included an endpoint for incidental oral exposures. However, the Agency has made the assumption in the current risk assessment that the new use of flonicamid and the increased tolerance on alfalfa, hay were not likely to result in incidental oral exposures, as young children are not expected in the areas where applications occur. An additional difference in the current risk assessment is that the inhalation point of departure was based on an oral study. Since no inhalation data are available, toxicity by the inhalation route of exposure is considered to be equivalent to the estimated toxicity by the oral route of exposure. For a full summary of the Toxicological points of departure/Levels of concern for flonicamid used for human risk assessment, see "Flonicamid: Human Health Draft Risk Assessment for Registration Review" by going to docket ID number EPA-HQ-OPP-2014-0777 at *https://www.regulations.gov*.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of flonicamid and the increased

tolerance on alfalfa, hay. The assessment used the same assumptions as the July 23, 2018 rulemaking final rule concerning tolerance-level residues, default processing factors for all processed commodities, and 100 percent crop treated, see Unit III.C. of the July 23, 2018 rulemaking (83 FR 34775) (FRL-9977-82). For a more detailed description related to these updates, see "Flonicamid: Establishment of Permanent Tolerances in/on Small Vine-Climbing Fruit, except Fuzzy Kiwifruit (Subgroup 13-07F) and an Increased Tolerance on Alfalfa. Summary of Analytical Chemistry and Residue Data" by going to docket ID number EPA-HQ-OPP-2016-0013 at *https://www.regulations.gov*.

Drinking water exposure. The new use of flonicamid in or on small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F and increased residue levels for alfalfa, hay do not result in an increase in the estimated residue levels in drinking water, so EPA used the same estimated drinking water concentrations (EDWCs) in the chronic dietary assessment as identified in the July 23, 2018, rulemaking and in the Flonicamid Interim Registration Decision.

Non-Occupational exposure. Residential handler and post-application exposures are not expected from the new use of flonicamid and the increased tolerance on alfalfa, hay. However, there are pending uses on roses, flowers, shrubs, and small (non-fruit bearing) trees that would result in residential handler as well as post-application exposures that were recently assessed. All registered flonicamid product labels with residential use sites require that handlers wear specific clothing (*e.g.,* long-sleeved shirt/long pants) and/or use personal protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment. A quantitative residential post-application assessment was also not conducted as incidental oral exposures are not anticipated and there is no dermal exposure endpoint. Therefore, no residential exposures are applicable for the aggregate risk assessment.

Cumulative exposures. 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." EPA's assessment of cumulative exposures has not changed since the July 23, 2018, rulemaking (83 FR 34775) (FRL-9977-82).

Safety factor for infants and children. The scientific information underpinning EPA's prior safety factor determination remains unchanged from the July 23, 2018, rulemaking (83 FR 34775) (FRL-9977-82). Therefore, EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor for flonicamid. See Unit III.D. of the July 23, 2018, rulemaking (83 FR 34775) (FRL-9977-82) for a discussion of the Agency's rationale for that determination.

C. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the cPAD. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute risk. An acute aggregate dietary risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral dose was identified and no acute dietary endpoint was selected. Therefore, flonicamid is not expected to pose an acute risk.

Short-term and Intermediate-term risk. Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus

chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for any use patterns that would result in short- and intermediate-term residential exposures. The estimated aggregate MOE for adult handlers is 1,100 (LOC = 100) and is not of concern. Risk estimates for children are expected to be equivalent to the dietary exposure and risk assessment.

Chronic risk. Chronic dietary (food + water) risk to flonicamid was below the EPA's LOC (<100% cPAD) for the general U.S. population. The chronic dietary (food + drinking water) exposure were estimated at 29% of the cPAD for the general U.S. population and 91% cPAD for children 1 to 2 years old (the most highly exposed population subgroup) and are below EPA's LOC (<100% cPAD).

Aggregate cancer risk for U.S. population. Flonicamid has been determined to have suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic 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. Therefore, the chronic reference dose is considered protective for carcinogenic effects. As a result, a separate cancer risk assessment was not conducted, and the chronic dietary exposure is considered protective of any cancer dietary risks.

Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general U.S. population, or to infants and children, from aggregate exposure to flonicamid residues. More detailed information on the subject action to establish tolerances in or on small fruit, vine climbing (except fuzzy kiwifruit), subgroup 13-07F and to increase the existing tolerance in or on alfalfa, hay can be seen in the documents "Flonicamid: Petition for the Establishment of Permanent Tolerances in/on Small Vine-Climbing Fruit, except Fuzzy Kiwifruit (Subgroup 13-07F) and a Tolerance Increase on Alfalfa. Summary of

Analytical Chemistry and Residue Data and Flonicamid (128016); Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Petition for the Establishment of Permanent Tolerances in/on Small Vine-climbing Fruit, except Fuzzy Kiwifruit (Subgroup 13-07F) and a Tolerance Increase on Alfalfa" by going to docket ID number EPA-HQ-OPP-2016-0013 at *https://www.regulations.gov*.

IV. Other Considerations

A. Analytical Enforcement Methodology

Analytical methodology has been developed to determine the residues of flonicamid and its three major plant metabolites, TFNA, TFNG, and TFNA–AM in various crops. The residue analytical method for the majority of crops includes an initial extraction with acetonitrile (ACN)/deionized (DI) water, followed by a liquid-liquid partition with ethyl acetate. The residue method for wheat straw is similar, except that a C18 solid phase extraction (SPE) is added prior to the liquid-liquid partition. The final sample solution is quantitated using a liquid chromatograph (LC) equipped with a reverse phase column and a triple quadruple mass spectrometer (MS/MS).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, 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 tolerance expression for plant and livestock commodities are harmonized between the U.S. and Canada, but not Codex. There are no Codex MRLs established on

small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F or alfalfa. Thus, harmonization is not an issue with Codex. There are no Canada MRLs established on small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F. Canada has a default MRL of 0.1 ppm established in/on alfalfa. Therefore, tolerances/MRLs are not harmonized between the U.S. and Canada for alfalfa.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerances for small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F are different from those being established by EPA. These differences are attributable to the petitioned-for levels not being consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice.

V. Conclusion

A tolerance is therefore established for residues of the insecticide flonicamid, including its metabolites and degradates, in or on small fruit vine climbing (except fuzzy kiwifruit), subgroup 13-07F at 3 ppm. In addition, this tolerance rulemaking amends the existing tolerance for residues of the insecticide flonicamid in or on alfalfa, hay at 7 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. section 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. section 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. section 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. section 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. section 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. section 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 16, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I 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. Section 180.613(a)(1) is amended in the table by:

a. Adding a table heading;

b. Revising the entry for "Alfalfa, hay"; and

c. Adding the commodity "Small fruit vine climbing (except fuzzy kiwifruit), subgroup 13–07F" in alphabetical order.

The additions and revision read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * *	* * * *
Alfalfa, hay	7
* * *	* * * *
Small fruit vine climbing (except fuzzy kiwifruit), subgroup 13–07F	3
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[FR Doc. 2022-10785 Filed: 5/18/2022 8:45 am; Publication Date: 5/19/2022]