



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2019-0388; FRL-10013-77]

### Saflufenacil; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of saflufenacil in or on the caneberry subgroup 13-07A, fig, chia seed and chia straw. 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-2019-0388, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, 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](mailto: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](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-2019-0388 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-2019-0388, 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 9E8763) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested the establishment of tolerances in 40 CFR 180.613(a) for residues of the herbicide saflufenacil, including its metabolites and degradates, in or on the following raw agricultural commodities: Caneberry subgroup 13-07A at 0.03 parts per million (ppm), Chia, seed at 1 ppm, Chia, straw at 15 ppm, Fig at 0.03 ppm, and Fig, dried at 0.05 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what was requested. The reasons for these changes are explained in Unit IV.C.

## **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 FFDCFA 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 FFDCFA 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 FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA 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 saflufenacil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with saflufenacil follows.

On November 25, 2015, EPA published in the *Federal Register* a final rule establishing tolerances for residues of saflufenacil in or on pomegranate based on the Agency's conclusion that aggregate exposure to saflufenacil is safe for the general population, including infants and children. *See* (80 FR 73663) (FRL-9936-71). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency's current assessment of saflufenacil tolerances: the toxicological profile and points of departure, the conclusions about cumulative risk, and the Agency's determination regarding the children's safety factor.

EPA's dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from the new uses of saflufenacil on the caneberry subgroup, fig, and chia. The assessment used the same assumptions concerning percent crop treated and tolerance-level residues and the same estimated drinking water concentrations as the November

25, 2015 final rule.

Acute dietary risks are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): they are less than 1% of the aPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): they are 20% of the cPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate. There is no short- or intermediate-term exposure expected since there are no residential uses. Therefore, the acute and chronic aggregate risks consist only of the dietary risks from food and water and, as stated above, are below the Agency's level 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 saflufenacil residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Saflufenacil. Human Health Risk Assessment in Support of Tolerances for Residues in/on Pomegranate" dated November 5, 2015 in docket ID EPA-HQ-OPP-2014-0640 and the document titled "Saflufenacil. Human Health Draft Risk Assessment for a Petition to Establish Tolerances for Residues in/on Caneberry Subgroup 13-07A, Fig, and Chia" dated August 7, 2020 in docket ID number EPA-HQ-OPP-2019-0388.

#### **IV. Other Considerations**

##### *A. Analytical enforcement methodology*

Adequate enforcement methodology (liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) Method D0603/02 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 FFDCIA 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, FFDCIA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Codex MRLs have been established for saflufenacil on fig, chia and caneberry.

*C. Revisions to petitioned-for tolerances*

The tolerance levels being established by EPA for the caneberry subgroup 13-07A and fig differ from those proposed by the petitioner due to differences in calculating the combined limits of quantitation (LOQs) for residues of saflufenacil and its metabolites. The combined LOQs of 0.035 ppm were rounded to 0.04 ppm by EPA versus 0.03 ppm by the petitioner. For chia, EPA is translating from the currently established tolerances for residues on wheat commodities rather than barley commodities, resulting in tolerance levels of 0.6 ppm for Chia, seed and 6 ppm for Chia, straw. Quantifiable residues were found in dried figs; however, when residues are adjusted for the degree of exaggeration, the residue value is below the recommended

fresh fig tolerance level (0.04 ppm). A separate tolerance for residues on dried fig is therefore not required.

## **V. Conclusion**

Therefore, tolerances are established for residues of saflufenacil in or on the caneberry subgroup 13-07A at 0.04 ppm; chia, seed at 0.6 ppm; chia, straw at 6 ppm; and fig at 0.04 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes 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 FFDCFA section 408(d), such as the tolerances and modifications 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: August 25, 2020.

**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. In § 180.649 amend paragraph (a)(1) by designating the table and adding, alphabetical order, in newly designated Table 1 to paragraph (a)(1) the entries “Caneberry subgroup 13-07A”; “Chia, seed”; “Chia, straw”; and “Fig” to read as follows:

**§ 180.649 Saflufenacil; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Table 1 to paragraph (a)(1)

| Commodity                 | Parts per million |
|---------------------------|-------------------|
| * * *                     | * * *             |
| Caneberry subgroup 13-07A | 0.04              |
| Chia, seed                | 0.6               |
| Chia, straw               | 6                 |
| * * *                     | * * *             |
| Fig                       | 0.04              |
| * * *                     | * * *             |

\* \* \* \* \*