



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0228; FRL-8663-01-OCSP]

### Fluxapyroxad; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluxapyroxad in or on the cottonseed subgroup 20C, the fruiting vegetable group 8-10, the pome fruit group 11-10, and pomegranate. 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-2020-0228, 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-2020-0228 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-2020-0228, 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 September 30, 2020 (85 FR 61681) (FRL-10014-74), 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 0E8825) by IR-4, IR-4 Project Headquarters Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The

petition requested that EPA establish tolerances in 40 CFR part 180 for residues of fluxapyroxad, (BAS 700 F); 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, its metabolites, and degradates in or on the raw agricultural commodities: pomegranate at 0.2 ppm; vegetable, fruiting, group 8-10 at 0.7 ppm; fruit, pome, group 11-10 at 0.8 ppm; and cottonseed subgroup 20C at 0.3 ppm. The petition also requested to remove the established tolerances for fluxapyroxad in or on fruit, pome, group 11; vegetables, fruiting, group 8; and cotton, undelinted seed. 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 one tolerance at a different level than requested. The reason for this change is explained in 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 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 fluxapyroxad including exposure resulting from

the tolerances established by this action. EPA's assessment of exposures and risks associated with fluxapyroxad 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 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 a number of tolerance rulemakings for fluxapyroxad, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluxapyroxad and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

*Toxicological Profile.* For a discussion of the Toxicological Profile of fluxapyroxad, see Unit III.A. of the May 5, 2016 rulemaking (81 FR 27019) (FRL-9945-48).

*Toxicological Points of Departure/Levels of Concern.* For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the May 5, 2016 rulemaking.

*Exposure Assessment.* Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; the remaining discussion of EPA's assumptions for exposure remain unchanged since the 2016 rulemaking. For a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the May 5, 2016 rulemaking.

EPA's dietary exposure assessments have been updated to include the additional

exposure from the new use of fluxapyroxad on pomegranate, and the crop group expansions to the cottonseed subgroup 20C, the fruiting vegetable group 8-10, and the pome fruit group 11-10. A partially refined acute dietary exposure analysis was performed for the general population and all population subgroups. Tolerance-level residues adjusted to account for the metabolite of concern (M700F008) and 100 percent crop treated (PCT) assumptions were used for all plant commodities. For livestock commodities, anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. A moderately refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Average field trial residues for parent plus maximum metabolite residue were used for all plant commodities. For livestock commodities anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. An assumption of 100 PCT was also used for the chronic dietary analysis.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Drinking water exposures are not impacted by the new uses, and thus have not changed since the last assessment in the May 5, 2016 rulemaking.

*Safety Factor for Infants and Children.* EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the May 5, 2016 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 aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (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 (PODs) 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 dietary risks are below the Agency's level of concern of 100% of the aPAD: they are 14% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: they are 75% of the cPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate. The short-term MOE is greater than the Agency's level of concern of 100: it is 1100 for adults and 400 for children. Intermediate-term or long-term residential exposures are not expected.

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 fluxapyroxad residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Fluxapyroxad. Human Health Risk Assessment for a Proposed Use of Fluxapyroxad on Pomegranate, Crop Group Expansion for Cottonseed Subgroup 20C and Crop Group Conversions for Vegetable, Fruiting, Group 8-10 and Fruit, Pome, and Group 11-10" in docket ID number EPA-HQ-OPP-2020-0228.

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

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

An adequate residue analytical method is available for the purpose of tolerance enforcement. Liquid chromatography–mass spectrometry LC/MS/MS BASF Method L0137/01,

previously deemed acceptable as an enforcement method for plant matrices, is applicable for the analysis of fluxapyroxad residues.

#### *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 FFDCFA section 408(b)(4).

Codex does not have an MRL for fluxapyroxad in/on pomegranate. For the cottonseed crop subgroup 20C, the 0.5 ppm tolerance is harmonized with the Codex MRL. The Agency is not harmonizing with the Codex pome fruit (group 11-10) MRL of 0.9 ppm because the petitioner requested that the tolerance remain at 0.8 ppm in order to harmonize with Canada and other key exporting countries. EPA also concludes that harmonization with the Codex fruiting vegetable (group 8-10) MRL of 0.6 ppm is not appropriate as it could result in violative residues despite application consistent with approved label rates. The Codex fruiting vegetable MRL is based on a 7-day pre-harvest interval (PHI), not a 0-day PHI as currently registered in the United States.

#### *C. Revisions to petitioned-for tolerances*

The tolerance for the cottonseed subgroup 20C is being established at 0.5 ppm rather than 0.3 ppm as requested in order to harmonize with Codex.

### **V. Conclusion**

Therefore, tolerances are established for residues of fluxapyroxad in or on the Cottonseed subgroup 20C at 0.5 ppm; Fruit, pome, group 11-10 at 0.8 ppm; Pomegranate at 0.2 ppm; and Vegetable, fruiting, group 8-10 at 0.7 ppm. Additionally, the existing tolerances for Cotton, undelinted seed; Fruit, pome, group 11; and Vegetables, fruiting, group 8 are removed since they are superseded by the new tolerances established in today's action.



## 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 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: July 6, 2021.

**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 § 180.666, paragraph (a):

- i. Add a heading to the table;
- ii. Remove the entry for “Cotton, undelinted seed”;
- iii. Add an entry for “Cottonseed, subgroup 20C” in alphabetical order;
- iv. Remove the entry for “Fruit, pome, group 11”;
- v. Add entries for “Fruit, pome, group 11-10” and “Pomegranate” in alphabetical order;
- v. Remove the entry for “Vegetables, fruiting group 8”; and
- vi. Add an entry for “Vegetable, fruiting, group 8-10” in alphabetical order.

The additions read as follows:

**§ 180.666 Fluxapyroxad; tolerances for residues.**

(a) \* \* \*

**Table 1 to Paragraph (a)**

<b>Commodity</b>	<b>Parts per million</b>
* * * * *	
Cottonseed, subgroup 20C	0.5
* * * * *	
Fruit, pome, group 11-10	0.8
* * * * *	
Pomegranate	0.2
* * * * *	
Vegetable, fruiting, group 8-10	0.7
* * * * *	

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