



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0046; FRL-10009-25]

Cyflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyflumetofen in or on multiple commodities which are identified and discussed later in this document. 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 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-2019-0046, 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>.

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://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 FFDCFA 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-2019-0046 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-2019-0046, 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 April 19, 2019 (84 FR 16430) (FRL-9991-14), 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 8E8724) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cyflumetofen, 2-methoxyethyl a-cyano-a-[4-(1,1-dimethylethyl)phenyl]-b-oxo-2-(trifluoromethyl)benzenepropanoate, including its metabolites and degradates, to be determined by measuring only cyflumetofen, in or on the agricultural commodities: Cucumber at 0.15 parts per million (ppm); fruit, stone, group 12-12 at 2.0 ppm; plum, prune, dried at 0.41 ppm; strawberry at 0.80 ppm; and vegetable, fruiting, group 8-10 at 2.0 ppm. The petition also requested that upon approval of the above tolerances that 40 CFR 180.677 be amended by revising or removing the existing tolerances for residues of the insecticide cyflumetofen, in or on the agricultural commodities strawberry at 0.60 ppm and tomato at 0.40 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than requested and in some cases is establishing tolerances for different commodities than requested. The reason for these changes 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 cyflumetofen including exposure resulting from the tolerances established by this action.

On May 8, 2019, EPA published in the *Federal Register* a final rule establishing a tolerance for residues of the insecticide cyflumetofen in or on tea, dried. See 84 FR 20037 (FRL-9990-60). That document contains a summary of the toxicological profile, assumptions for dietary exposure assessment, cumulative risk, and the safety factor for children, which have not

changed. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the May 8, 2019 *Federal Register* action can be found at <http://www.regulations.gov> in the document titled, "Cyflumetofen. Human Health Risk Assessment to Support New Uses on Imported Tea" dated March 4, 2019. The document can be found in docket ID EPA-HQ-OPP-2017-0532.

The Agency conducted a revised risk assessment to incorporate exposure to residues of cyflumetofen from use on the cucumber, the stone fruit group 12-12, strawberries, and the fruiting vegetable group 8-10. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water, although drinking water exposures are not impacted by the new uses. In addition, the aggregate exposure assessment no longer includes residential handler exposures; no post-application exposures were assessed due to a lack of residential post-application exposures and lack of dermal hazard.

As indicated in the supporting documents, no acute dietary exposure and risk analysis was performed for cyflumetofen since there were no appropriate studies identified in the toxicology database that demonstrated evidence of toxicity attributable to a single dose. Chronic dietary (food and water) risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD); they are 3% of the cPAD for children 1–2 years old, the group with the highest exposure level. Because EPA has determined there are no residential exposures, the chronic dietary risk is the same as the overall aggregate risk for cyflumetofen.

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 cyflumetofen residues.

More detailed information on the subject action to establish a tolerance in or on

cucumber, the stone fruit group 12-12, prunes, strawberries, and the fruiting vegetable group 8-10 can be found in the document titled, “Cyflumetofen. Human Health Risk Assessment for the Section 3 Registration Action for New Uses on Fruiting Vegetable (Crop Group 8-10), Stone Fruits (Crop Group 12-12), and Greenhouse Uses on Fruiting Vegetable, Cucumber, and Strawberry”, dated April 29, 2020, by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0046.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available to enforce the Agency-recommended tolerances for cyflumetofen in plant commodities. The high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) method, BASF D1003, has been adequately validated, has undergone a successful ILV (independent laboratory validation), is considered adequately radio-validated and has been reviewed by the Agency for appropriateness as an enforcement method. Cyflumetofen has also been subjected to analysis by the Food and Drug Administration (FDA) multi-residue method (MRM) protocols. Cyflumetofen is not adequately recovered through any of the FDA multi-residue protocols.

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.

There are Codex MRLs established for cyflumetofen residues in/on strawberry (0.6 ppm) and tomato (0.3 ppm). The strawberry tolerance is harmonized with Codex. The tolerance for tomato is not harmonized with Codex; harmonization is not possible at this time since lowering the newly established U.S. tolerance may result in over-tolerance residues in the United States.

C. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance for cucumber at 0.3 ppm rather than the petitioned-for tolerance level of 0.15 ppm to fully account for residue loss from the field trial samples during freezer storage from the time of harvest to the time of analysis.

EPA is establishing tolerances for the subgroups in the stone fruit crop group 12-12 rather than the whole crop group based on the highest maximum residue limit (MRL) calculated for each of the representative crops: Cherry (1.5 ppm), peaches (0.4 ppm), and plums (0.3 ppm) to harmonize with Canada's MRLs.

A tolerance is not required for dried plums (prune) because this commodity is covered under the plum subgroup 12-12C tolerance.

For strawberry, the Agency is maintaining the existing tolerance to remain harmonized with Codex. Although the Organization for Economic Cooperation and Development (OECD) MRL calculator produces a tolerance of 0.8 ppm for (greenhouse) strawberry, the currently established tolerance level for strawberry (0.60 ppm) is adequate for foliar and greenhouse uses. EPA is revising the strawberry tolerance to 0.6 ppm based on OECD rounding classes.

EPA is establishing tolerances for the tomato subgroup 8-10A at 0.7 ppm and pepper/eggplant subgroup 8-10B at 2 ppm rather than the full crop group vegetable, fruiting, group 8-10 in order to harmonize with the Canadian tolerances on tomato and pepper.

V. Conclusion

Therefore, tolerances are established for residues of cyflumetofen, (2-methoxyethyl α -cyano- α -[4-(1,1-dimethylethyl)phenyl]- β -oxo-2-(trifluoromethyl)benzenepropanoate), in or on cherry subgroup 12-12A at 1.5 ppm; cucumber at 0.3 ppm; peach subgroup 12-12B at 0.4 ppm; pepper/eggplant subgroup 8-10B at 2 ppm; plum subgroup 12-12C at 0.3 ppm; and tomato subgroup 8-10A at 0.7 ppm.

Additionally, the existing tolerance on tomato is removed as unnecessary due to the establishment of the above tolerances. Also, the existing tolerance for strawberry is modified to 0.6 ppm.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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), 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 FFDCA section 408(d), such as the tolerances 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: June 8, 2020.

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 § 180.677 amend the table in paragraph (a) by:

- i. Adding alphabetically the commodities “Cherry subgroup 12-12A”; “Cucumber”; “Peach subgroup 12-12B”; “Pepper/eggplant subgroup 8-10B”; “Plum subgroup 12-12C”; and “Tomato subgroup 8-10A”;
- ii. Revise the tolerance entry for “Strawberry”; and
- iii. Remove the commodity “Tomato” from the table in paragraph (a).

The additions and revisions read as follows:

§ 180.677 Cyflumetofen; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Cherry subgroup 12-12A	1.5
****	***
Cucumber	0.3
****	***
Peach subgroup 12-12B	0.4
Pepper/eggplant subgroup 8-10B	2
Plum subgroup 12-12C	0.3
Strawberry	0.6
****	***
Tomato subgroup 8-10A	0.7

* * * * *