



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0636; FRL-9996-61]

Cyflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide cyflumetofen in or on coffee, green bean. OAT Agrio. Ltd., Tokyo, Japan c/o Landis International, Inc. requested this 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-2018-0636, 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>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, P.E., Director,
Registration Division (750P), 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 Publishing 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 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-2018-0636 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-2018-0636, 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 October 24, 2018 (83 FR 53594) (FRL-9983-46), 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 8E8693) by OAT Agrio. Ltd., Tokyo, Japan, c/o Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, Georgia 31603-5126. The petition requested that 40 CFR 180.677 be amended by establishing a tolerance for residues of the insecticide cyflumetofen, (2-methoxyethyl α -cyano- α -[4-(1,1-dimethylethyl)phenyl]- β -oxo-2-(trifluoromethyl)benzenepropanoate), in or on coffee, green bean at 0.08 parts per million (ppm). That document referenced a summary of the petition prepared by OAT Agrio. Ltd. c/o Landis International, Inc., the registrant, which is available in docket number EPA-HQ-OPP-2018-0636, <http://www.regulations.gov>. These tolerances were requested to cover residues of cyflumetofen in or on coffee, green bean resulting from use of this pesticide on coffee outside the United States. There is no current U.S. registration for use of cyflumetofen on coffee. There were no substantive comments received in response to the notice of filing for this pesticide petition.

Based upon review of the data supporting the referenced petition, EPA is establishing a tolerance for residues of cyflumetofen on coffee, green bean.

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 in or on coffee, green bean.

On May 8, 2019 (82 FR 20037) (FRL-9990-60), EPA published in the **Federal Register** a final rule establishing a tolerance for residues of the insecticide cyflumetofen in or on tea, dried is safe for the general population, including infants and children. *See* 84 FR 20037 (FRL-9990-60). That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, and the safety factor for children, which have not changed. The Agency conducted a revised risk assessment to incorporate exposure to residues of cyflumetofen from use on coffee.

EPA’s exposure assessments have been updated to include the additional exposure from use of cyflumetofen on coffee, *i.e.*, reliance on tolerance-level residues and an assumption of 100 percent crop treated (PCT). Because the use on coffee is not an approved domestic use, there is no expectation of an increased exposure in drinking water or for non-dietary, non-occupational sources, although the additional dietary exposure contributes to overall aggregate exposure. Further information about EPA’s risk assessment and determination of safety supporting the tolerances established in the May 8, 2019 **Federal Register** action, as well as the new cyflumetofen tolerance can be found at <http://www.regulations.gov> in the document entitled “Cyflumetofen. Human Health Risk Assessment to Support New Uses on Imported Tea,” dated

March 4, 2019. The documents can be found in docket ID EPA-HQ-OPP-2017-0532.

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 risks are below the Agency's level of concern: 2.4% of the chronic population adjusted dose (cPAD) for children 1-2 years old, the group with the highest exposure level. Moreover, the short-term aggregate risk for the population with the highest total exposure (adults 50-99 years old) was chosen since this is protective for all other adult sub-populations. There are no residential exposures expected for children; therefore, a short-term aggregate risk assessment for children is equal to the chronic food and drinking water exposure and risk estimates and is not of concern. Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs above the LOC of 100 for all scenarios assessed and 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 cyflumetofen residues. More detailed information on the subject action to establish a tolerance in or on coffee, green bean can be found in the document entitled, "Cyflumetofen. Human Health Risk Assessment to Support New Uses without U.S. Registration in/on Imported Coffee," dated September 16, 2019, 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-2018-0636.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology is available to enforce the HED-recommended tolerances for cyflumetofen in plant commodities. The high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) method 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. The method limit of quantitation (LOQ) for residues of cyflumetofen in coffee is 0.01 ppm. 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.

Codex has not established maximum residue limits (MRLs) for residues of cyflumetofen in coffee commodities; therefore, there are no harmonization issues.

V. Conclusion

Therefore, a tolerance is established for residues of the insecticide cyflumetofen, (2-methoxyethyl α -cyano- α -[4-(1,1-dimethylethyl)phenyl]- β -oxo-2-(trifluoromethyl)benzenepropanoate), in or on coffee, green bean at 0.08 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 Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is 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 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: November 8, 2019.

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, add a footnote and alphabetically the entry for “Coffee, green bean²”

to the table in paragraph (a) to read as follows:

§ 180.677 Cyflumetofen; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* * * *
Coffee, green bean ²	0.08
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²There are no U.S. registrations for these commodities as of [*insert date of publication in the Federal Register*].

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