



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0049; FRL-9966-68]

### Oxathiapiprolin; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of the fungicide oxathiapiprolin in or on cacao bean, dried bean. Interregional Research Project Number 4 (IR-4) requested the 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-2016-0049, 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, Director, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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](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-2016-0049 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-2016-0049, 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 Tuesday, December 20, 2016 (81 FR 92758) (FRL-9956-04), 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# 6E8505) by Interregional Research Project Number 4 (IR-4). The petition requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]-ethanone, in or on cacao bean, bean at 0.10

parts per million (ppm); cacao bean, roasted bean at 0.15 ppm; cacao bean, chocolate at 0.15 ppm; and cacao bean, cocoa powder at 0.15 ppm. A summary of the petition prepared by IR-4 is available in the docket, <http://www.regulations.gov>. There were no comments received on the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that differ from what the petitioner requested including; the commodity definition, tolerance level, and for which commodities. 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 oxathiapiprolin including exposure resulting from the tolerance established by this action, consistent with FFDCA section 408(b)(2).

In the **Federal Register** of Monday, December 5, 2016 (81 FR 87463) (FRL-9954-69), EPA established tolerances for residues of oxathiapiprolin in or on several food commodities. The risk assessments supporting that action aggregated dietary and non-occupational exposures from existing and proposed uses of oxathiapiprolin, including from the exposures associated with the tolerances requested in this action. That assessment, which included the tolerances in today's action, concluded that the tolerances are safe; therefore, EPA is incorporating the findings in that Federal Register document and the supporting risk assessments as the basis for the safety finding in this tolerance rulemaking. In brief, the Agency determined that the lack of toxicity of oxathiapiprolin warranted a qualitative risk assessment, without the need for the additional Food Quality Protection Act safety factor to protect infants and children.

Specific information on the studies received and the nature of the adverse effects caused by oxathiapiprolin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document, "Oxathiapiprolin—New Active Ingredient Human Health Risk Assessment of Uses on Turf, Ornamentals, and a Number of Crops" dated June 25, 2015, in docket ID number EPA-HQ-OPP-2016-0049-0018. In addition, an abbreviated human health risk assessment document was developed to support the proposed uses of oxathiapiprolin on multiple crops, including cacao. That

document, “SUBJECT: Oxathiapiprolin. Human Health Risk Assessment to Support the Registration of New Uses of the Fungicide on Various Crops” dated October 31, 2016 is available in docket ID number EPA-HQ-OPP-2016-0049-0017.

In conclusion, based on the findings of the December 5, 2016 Federal Register document and the supporting documents, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to oxathiapiprolin residues.

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

##### *A. Analytical Enforcement Methodology*

Method 30422 (Supplement No. 1) was developed for plant commodities, and Method 31138 was developed for livestock commodities. Residues of oxathiapiprolin and associated metabolites are extracted from crop or livestock commodity samples using a solution of formic acid, water and acetonitrile, and diluted with acetonitrile and water. Both methods use liquid chromatography with tandem mass spectrometry (LC/MS/MS), specifically reverse-phase liquid chromatography (LC), and detection by electrospray tandem mass spectrometry (MS/MS).

The FDA multi-residue methods are not suitable for detection and enforcement of oxathiapiprolin residues or associated metabolites. However, the European Multiresidue Method (DFG Method S19) and the QuEChERS Multiresidue Method have shown success in some matrices.

Adequate enforcement methodology (LC/MS/MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch/BEAD/OPP, Environmental Science Center, 701 Mapes Rd., Ft. George G. 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established maximum residue limits (MRLs) for oxathiapiprolin.

### *C. Revisions to Petitioned-For Tolerances*

A tolerance is established for “Cacao bean, dried bean”, rather than “Cacao bean, bean”, to comply with current Agency crop-naming policy. Also, EPA determined that tolerances for residues of oxathiapiprolin in or on the processed commodities of cacao

bean, roasted bean; cacao bean, chocolate; and cacao bean, cocoa powder are unnecessary because these commodities are covered by cacao bean, dried bean tolerance. Finally, the tolerance for cacao bean, dried bean is being established at 0.15 ppm, rather than at 0.1 ppm as requested, based on the available residue data.

## **V. Conclusion**

Therefore, a tolerance is established for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidiny]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]-ethanone, in or on cacao bean, dried bean at 0.15 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). 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 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 FFDCFA 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 29, 2017.

Michael L. 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 § 180.685, redesignate paragraph (a)(1) as paragraph (a) and add alphabetically the following commodity “Cacao bean, dried bean” to the table in paragraph (a) in alphabetical order to read as follows:

**§ 180.685 Oxathiapiprolin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * *	* * *
Cacao bean, dried bean	0.15
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