



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0560; FRL-9963-66]

### Florpyrauxifen-benzyl; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of florpyrauxifen-benzyl in or on rice grain, freshwater fish, shellfish crustacean, and mollusc. Dow AgroSciences LLC 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-2016-0560, 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: [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 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-2016-0560 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-2016-0560, 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 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 5F8403) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide florpyrauxifen-benzyl (2-Pyridinecarboxylic acid, 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-, phenylmethyl ester) and florpyrauxifen (metabolite; 2-

Pyridinecarboxylic acid, 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-, in or on the raw agricultural commodities rice, grain (dehulled) at 0.01 parts per million (ppm); rice, grain at 0.2 ppm; fish, freshwater at 2 ppm; shellfish, crustacean at 0.5 ppm; and shellfish, mollusk at 9 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, 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 tolerance levels that vary from the petitioned-for levels for certain crops and is correcting commodity definitions, as needed, to be consistent with current EPA policy. These changes are explained further 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 florpyrauxifen-benzyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with florpyrauxifen-benzyl follows.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Florpyrauxifen-benzyl is not genotoxic and there were no treatment-related findings up to the limit dose (1,000 milligrams/kilogram (mg/kg)/day) or highest doses tested in the acute, short-term, sub-chronic, or chronic oral toxicity studies, two-generation reproduction or developmental toxicity studies or in the neurotoxicity study. Chronic administration of florpyrauxifen-benzyl did not show any carcinogenicity potential and did not cause any adverse effects in mice, rats or dogs even up to the highest doses tested.

Specific information on the studies received and the nature of the adverse effects caused by florpyrauxifen-benzyl 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 document “Florpyrauxifen-benzyl: New Active Ingredient, First Food Use. Human Health Risk Assessment for the Establishment of Permanent Tolerances on Rice, Fish, and Shellfish and Registration for Uses on Rice and Freshwater Aquatic Weed Control” dated December 1, 2016 in docket ID number EPA-HQ-OPP-2016-0560.

Because no single or repeated dose study performed by any route of exposure produced an adverse effect following florpyrauxifen-benzyl exposure, toxicity endpoints and points of departure were not selected for florpyrauxifen-benzyl exposure scenarios and a quantitative risk assessment was not conducted. Instead, a qualitative human health risk assessment has been conducted to support the proposed uses of florpyrauxifen-benzyl.

Florpyrauxifen-benzyl is proposed for use on rice and aquatic sites. Humans could potentially be exposed to florpyrauxifen-benzyl residues in food (including fish and shellfish) because florpyrauxifen-benzyl may be applied directly to growing rice and aquatic sites. These applications can also result in florpyrauxifen-benzyl reaching surface and ground water, both of which can serve as sources of drinking water. There are no proposed uses in residential settings and there are no anticipated residential exposures.

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to

account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. EPA considers the toxicity database to be complete and there are no residual uncertainties in the florpyrauxifen-benzyl exposure database. Because there are no threshold effects in the florpyrauxifen-benzyl database, the requirement to retain this safety factor is inapplicable to the current tolerance action.

Based on the lack of toxicity from exposure to residues of florpyrauxifen-benzyl, 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 florpyrauxifen-benzyl.

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

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

Adequate analytical enforcement methodology which uses high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS-MS) to quantitate residues of florpyrauxifen-benzyl and florpyrauxifen is available for enforcement.

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.

The Codex has not established a MRL for flupyrauxifen-benzyl.

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

Although a tolerance for rice, grain (dehulled) was requested, EPA determined that no such tolerance is required. Rice, grain (dehulled) is covered by the rice grain tolerance. Based on the Organization of Economic Cooperation and Development (OECD) statistical calculation applied to the field trial (U.S.) residue data, EPA determined that the appropriate tolerance level for rice, grain is 0.30 ppm. The OECD calculation procedures are globally recognized for calculating MRLs to facilitate the harmonization of regulatory limits.

For fish-shellfish, mollusc the tolerance level is established at 20 ppm, rather than the requested 9 ppm, based on the residue data. Also, to be consistent with current EPA policy, the commodity definitions were revised as fish-freshwater finfish; fish-shellfish, crustacean; and fish-shellfish, mollusc, and the Agency added a significant figure to the tolerances for rice, grain; fish-freshwater finfish; and fish-shellfish, crustacean.

## **V. Conclusion**

Despite the lack of toxicity, the EPA is establishing tolerances as requested by the petitioner for international trade purposes. Therefore, tolerances are established for residues of florpyrauxifen-benzyl, including its metabolites and degradates, in or on rice, grain at 0.30 ppm; fish-freshwater finfish at 2.0 ppm; fish-shellfish, crustacean at 0.50 ppm; and fish-shellfish, mollusc at 20 ppm.

## **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 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: September 8, 2017.

Richard P. Keigwin, Jr.,

*Director, 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. Add § 180.695 to subpart C to read as follows:

**§ 180.695 Florpyrauxifen-benzyl; Pesticide Tolerances**

(a) *General.* Tolerances are established for residues of florpyrauxifen-benzyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of florpyrauxifen-benzyl (phenylmethyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-2-pyridinecarboxylate) and its acid metabolite (4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid) calculated as the stoichiometric equivalent of florpyrauxifen-benzyl, in or on the commodity.

Commodity	Parts per million
Fish – freshwater finfish	2.0
Fish – shellfish, crustacean	0.50
Fish – shellfish, mollusc	20

Rice, grain	0.30
-------------	------

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2017-21614 Filed: 10/5/2017 8:45 am; Publication Date: 10/6/2017]