



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0066; FRL-9962-60]

### Pyroxsulam; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyroxsulam in or on teff, grain; teff, forage; teff, hay; and teff, straw. 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-2016-0066, 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 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](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 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-2016-0066 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-2016-0066, 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 March 16, 2016 (81 FR 14030) (FRL-9942-86), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8439) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.638 be amended by establishing tolerances for residues of the herbicide pyroxsulam, N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide, in or on teff, grain at 0.01 parts per million (ppm); teff, forage 0.06 ppm; teff, hay 0.01 ppm; and teff, straw 0.03 ppm. The published notice of filing (NOF)

mistakenly listed the following incorrect tolerances for residues of pyroxsulam in or on the cereal crops: teff at 0.06 parts per million (ppm); teff, forage at 0.01 ppm; teff, grain at 0.03 ppm; teff, hay at 0.01 ppm; and teff, straw at 0.01 ppm. That document referenced a summary of the petition containing the correct tolerance amounts prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed 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, consistent with FFDC section 408(b)(2).

In the **Federal Register** of February 27, 2008 (73 FR 10402) (FRL-8349-9), EPA established tolerances for residues of pyroxsulam in or on wheat, forage; wheat, grain; wheat, hay; and wheat, straw at the same levels as those requested for residues in or on corresponding teff commodities. Since these wheat tolerances were established in 2008, the toxicological profile and the endpoints for assessment have not changed. Moreover, as explained below, EPA has concluded that the new tolerances for teff commodities does not alter the previous conclusions about the potential aggregate exposure to pyroxsulam residues.

Although teff residue data were not submitted with this petition, EPA concluded that the level of pyroxsulam residues on teff commodities would be the same or similar to the level of pyroxsulam residues on wheat commodities, based on the similarity in application rates. Furthermore, EPA concluded that because teff is a likely substitute for wheat products, there would be no additional exposure to pyroxsulam residues beyond what was previously assessed to support the wheat tolerances. Finally, because there is no corresponding request for a U.S. registration allowing use of pyroxsulam on teff, there are no additional drinking water or residential exposures beyond previous assessments.

Based on this assessment of potential exposure from use of pyroxsulam on teff and the findings supporting the February 27, 2008 tolerances established for wheat commodities, 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 pyroxsulam residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for the proposed tolerances, please refer to the February 27, 2008 Federal Register document and its supporting documents as well as Human Health Risk Assessments D431295, D. Dotson, 3/25/2016 and D439358, D. Dotson, 4/21/2017 available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2006-0785.

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

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

An adequate enforcement methodology, Method GRM 04.17, an Liquid chromatography with tandem mass spectrometry (LC/MS/MS) method, is available to enforce the tolerance expression.

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](mailto: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 pyroxsulam.

*C. Response to Comments*

EPA received two comments to the published Notice of Filing. Both comments stated, in part and without any supporting information, that EPA should deny this petition because it is a harmful and toxic chemical with no benefits. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. The existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. These comments provide no information to support an alternative conclusion.

*D. Revisions to Petitioned-For Tolerances*

EPA is revising the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyroxsulam not specifically mentioned; and (2) that compliance with the specified tolerance levels is to

be determined by measuring only the specific compounds mentioned in the tolerance expression.

## **V. Conclusion**

Therefore, tolerances are established for residues of pyroxsulam, N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide, in or on teff, forage 0.06 ppm; teff, grain at 0.01 ppm; teff, hay 0.01 ppm; and teff, straw at 0.03 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 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: May 19, 2017.

Daniel Rosenblatt,

*Acting 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 § 180.638:

- a. Revise paragraph (a) introductory text; and
- b. Add alphabetically the commodities “teff, forage”; “teff, grain”; “teff, hay”; and “teff, straw”; and footnote 1 to the table in paragraph (a).

The revision and additions read as follows:

**§ 180.638 Pyroxsulam; tolerances for residues.**

(a) *General.* Tolerances are established for residues of pyroxsulam, including its metabolites and degradates, in or on the commodities listed in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only pyroxsulam, N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide, in or on the commodity.

Commodity	Parts per million
Teff, forage <sup>1</sup>	0.06
Teff, grain <sup>1</sup>	0.01
Teff, hay <sup>1</sup>	0.01
Teff, straw <sup>1</sup>	0.03
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<sup>1</sup> There are no U.S. registrations on teff as of May 8, 2017.

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