



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2016-0286; FRL-9964-40]**

**Prothioconazole; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of prothioconazole in or on Sunflower subgroup 20B at 0.2 parts per million (ppm). Bayer CropScience 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-2016-0286, 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 (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-2016-0286 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-2016-0286, 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 July 20, 2016 (81 FR 47150) (FRL-9948-45), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announced the filing of a pesticide petition (PP 6E8469) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive,

Research Triangle Park, NC 27709. This petition requested that 40 CFR 180.626 be amended by establishing tolerances for residues of prothioconazole in or on imported commodities in the sunflower subgroup 20B at 0.2 ppm. This document referenced a summary of a petition prepared by Bayer CropScience, the registrant, which are available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

### **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 prothiconazole including exposure resulting from the tolerance established by this action.

#### *A. Risk Assessment*

In the **Federal Register** of November 10, 2016 (81 FR 78917) (FRL-9953-71), EPA established tolerances for residues of prothioconazole in or on cotton, gin byproducts at 4.0

ppm and the cottonseed subgroup 20C at 0.4 ppm. Because much of the safety assessment of prothioconazole for the current action remains the same, EPA is relying in part upon the findings made in the November 10, 2016 final rule in support of this action.

A summary of the toxicological profile and endpoints used for human risk assessment is discussed in Units III.A. and III.B of the November 10, 2016 final rule.

In evaluating dietary exposure for this action, EPA considered exposure under the petitioned-for tolerances as well as all existing prothioconazole tolerances in 40 CFR 180.626. The residue data used for the acute and chronic dietary exposure assessments have not changed since the assessment supporting the November 10, 2016 final rule, except to incorporate the recommended tolerance on commodities associated with Sunflower subgroup 20B, for which the Agency assumed tolerance-level residues and 100 percent crop treated. For a summary of how EPA assessed these dietary exposures, see Unit III.C.1 of the November 10, 2016 final rule.

In addition, because the requested sunflower subgroup tolerance is not accompanied by a corresponding request for a U.S. registration for use of prothioconazole on the commodities in the sunflower subgroup, the drinking water and residential exposure assessments remain the same. A summary of EPA's assessment of drinking water exposure and residential exposure is discussed in Units III.C.2. and III.C.3.

A summary of EPA's conclusions about the cumulative effects of prothioconazole can be found in Unit III.C.4. of the November 10, 2016 final rule; however, since the November 10, 2016 final rule was published, the Agency has updated its dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP). The update was completed in association with registration requests for several triazole fungicides and includes, inter alia, the potential exposure to the common triazole metabolites resulting from the use of prothioconazole on commodities in the

sunflower subgroup 20B. That analysis concluded that risk estimates were below the Agency's level of concern for all population groups. This assessment may be found

on <http://www.regulations.gov> by searching for the following title and docket number:

*"Common Triazole Metabolites: Updated Dietary (Food+Water) Exposure and Risk Assessment to Address the New Section 3 Registrations For Use of Difenoconazole on Rice and Cotton."* (located in docket ID number EPA-HQ-OPP-2016-0254).

Because there have been no changes to the potential for prenatal and postnatal toxicity or in the completeness of data with respect to toxicity and exposure, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the additional tenfold (10X) margin of safety required under section 408(b)(2)(C) ("FQPA safety factor") were reduced to 1X. A summary of EPA's rationale for this determination is discussed in Unit III.D. of the November 10, 2016 final rule.

#### *B. Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists.

Using the exposure assumptions discussed above and in the November 10, 2016 final rule, EPA assessed acute and chronic dietary exposure from food and drinking water and concluded that the new tolerances on sunflower subgroup 20B do not change the risk estimates from the November 10, 2016 final rule. The acute dietary exposure utilized 40% of the aPAD for females 13-49 years old at the 95<sup>th</sup> percentile. The chronic dietary exposure utilized 32% of the

cPAD for the U.S. population, and 77% for all infants (<1 year), the most highly exposed population subgroup.

Because there are no existing or proposed residential uses for prothioconazole, there are no exposures expected via the residential exposure pathway. Therefore, all aggregate risk estimates are expected to be equivalent to dietary (food and drinking water) risk estimates mentioned above.

Therefore, 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 prothioconazole residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer both to the November 10, 2016 final rule and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2015-0722, and to the risk assessment for this current action "*Prothioconazole: Human Health Risk Assessment for the Petition for a Tolerance Without U.S. Registration for Residues in/on sunflower subgroup 20B.*" in docket ID number EPA-HQ-OPP-2016-0286.

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

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

Adequate liquid chromatography with tandem mass spectrometry (LC/MS/MS) methods are available for enforcing prothioconazole tolerances in crop and livestock commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-350; 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.

There is currently a Codex MRL for sunflower/safflower established at 0.05 ppm. The U.S. EPA is establishing a tolerance on sunflower at 0.2 ppm to harmonize with a major trading partner, Canada, in order to have a harmonized North America MRL for the Sunflower subgroup 20B. A tolerance cannot be established at the lower Codex MRL because it would present a trade irritant for sunflower commodities coming into the United States.

## **V. Conclusion**

Therefore, a tolerance is established for residues of prothioconazole, in or on sunflower subgroup 20B at 0.2 parts 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: July 26, 2017.

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 § 180.626, add alphabetically the entry “Sunflower subgroup 20B” to the table in paragraph (a)(1), and add footnote 1 to the table to read as follows:

**§ 180.626 Prothioconazole; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * *	* * *
Sunflower subgroup 20B <sup>1</sup>	0.2
* * *	* * *

<sup>1</sup> There are no U.S. registrations allowing use of prothioconazole on the commodities in the Sunflower subgroup 20B as of [*insert date of publication in the Federal Register*].

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