

when applied as an insecticide or miticide and used in accordance with good agricultural practices.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0849; FRL-8889-1]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and increases tolerances for residues of fluazifop-P-butyl in or on cotton, gin byproducts; cotton, refined oil; and cotton, undelinted seed. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 28, 2011. Objections and requests for hearings must be received on or before November 28, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0849. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone

number: (703) 305-1243; e-mail address: montague.kathryn@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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-2010-0849 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 November 28, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0849, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of December 15, 2010 (75 FR 78240) (FRL-8853-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7768) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on cotton, undelinted seed at 0.9 ppm; and cotton, gin byproducts at 0.8 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, 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 has made changes to the requested tolerances. First, EPA is raising the proposed cotton, gin byproducts tolerance from 0.8 ppm to 1.5 ppm; second, raising the established cotton, refined oil tolerance from 0.2 ppm to 1.3 ppm; and finally,

raising the proposed cotton, undelinted seed tolerance from 0.9 ppm to 1.0 ppm. EPA also retains the current tolerance expression for fluzifop-P-butyl that was established in 40 CFR 180.411 paragraph (a) in the **Federal Register** of February 2, 2011 (76 FR 5696) (FRL-8861-1). The reason for these changes are explained 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. * * *

In the **Federal Register** of February 2, 2011 EPA issued a final rule establishing a tolerance for residues of fluzifop-P-butyl in or on banana; beet, sugar; citrus, fruit, group 10; grape and potato. EPA has determined that establishing revised tolerances for cotton commodities will not significantly change the risk assessments the Agency relied on to support the February 2, 2011, tolerance action, as explained in this unit.

Cotton commodities (undelinted seed, gin byproducts, meal, and hulls) may be used as roughage or protein concentrate feedstuffs in the diets of livestock. When the Agency conducted the risk assessment in support of the February 2, 2011 tolerance action, it considered secondary residues of fluzifop-P-butyl in livestock commodities from consumption of fluzifop-P-butyl treated feed. In calculating livestock dietary burdens for fluzifop-P-butyl, EPA assumed that 100% of feed items consumed by livestock are treated with fluzifop-P-butyl. EPA also assumed residues were present in the roughage and protein concentrate components of livestock diets at the tolerance level for soybean feedstuffs of 2.5 parts per million (ppm) which is greater than the

tolerances being established for cotton feedstuffs. Therefore, the Agency has determined that the establishment of a tolerance on the feed commodity cotton, gin byproducts at 1.5 ppm and raising the cotton, undelinted seed tolerance from 0.1 ppm to 1.0 ppm will not increase residues of fluzifop-P-butyl in livestock feed commodities above those calculated in the previous risk assessment conducted for the February 2, 2011 tolerance action.

The only human food item affected by this action is cotton, refined oil. This commodity was included in the most recent acute and chronic dietary exposure assessment for the February 2, 2011 tolerance action at the level of 0.2 ppm using the food consumption data from the USDA 1994-1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). EPA conducted additional calculations using the increased level of 1.3 ppm for cotton, refined oil to determine if any increase in dietary exposure results. For both acute and chronic analyses, identical results were obtained to three significant figures. EPA typically reports dietary exposures as a percentage of the population adjusted dose (PAD) to just two significant figures. Therefore, EPA concludes that no significant increase in human dietary exposure resulting from the establishment of the revised cotton tolerances.

Based on these considerations, EPA has determined that establishing the tolerance for fluzifop-P-butyl in cotton, gin byproducts at 1.5 ppm, raising the established cotton, refined oil from 0.2 ppm to 1.3 ppm and raising the cotton, undelinted seed tolerance from 0.1 ppm to 1.0 ppm will not affect the estimated livestock dietary burden and will not change the estimated aggregate risks resulting from use of fluzifop-P-butyl, as discussed in the February 2, 2011 **Federal Register**. Refer to the **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessment and determination of safety.

Therefore, based on this information and the findings in the final rule published in the **Federal Register** of February 2, 2011, 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 fluzifop-P-butyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultra-Violet

Spectrometry (HPLC/UV)) is available to enforce the tolerance expression. The method is available in *Pesticide Analytical Methods* (PAM), Volume II or may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail 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 U.N. 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 fluzifop-P-butyl.

C. Revisions to Petitioned-for Tolerances

EPA has revised the proposed tolerances levels. Based on the submitted cotton undelinted seed and gin byproducts data, EPA calculated that the cotton, gin byproducts tolerance should be 1.5 ppm; cotton, refined oil tolerance should be 1.3 ppm, and cotton, undelinted seed tolerance should be 1.0 ppm.

Also, EPA is retaining the current tolerance expression for fluzifop-P-butyl. The current tolerance expression makes clear that the tolerances cover residues of the herbicide fluzifop-P-butyl, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only the sum of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluzifop, in or on the commodity.

V. Conclusion

Therefore, tolerances are established for residues of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluzifop, in or on cotton, gin byproducts; cotton, refined oil; and cotton, undelinted seed at 1.5 ppm, 1.3 ppm and 1.0 ppm, respectively.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). 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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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 15, 2011.

Daniel J. 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. Section 180.411, paragraph (a), the table is amended by:

- i. Revising the entries for “cotton, refined oil” and “cotton, undelinted seed”; and
- ii. Adding the entry for “cotton, gin byproducts” to the table in paragraph (a)

■ iii. The amendments read as follows:

§ 180.411 Fluzifop-P-butyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	1.5
Cotton, refined oil	1.3
Cotton, undelinted seed	1.0
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0888; FRL-8888-3]

Chlorantraniliprole; Pesticide Tolerances; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction amendment.

SUMMARY: EPA issued a final rule in the **Federal Register** of July 27, 2011, concerning the regulation to establish pesticide tolerances for residues of chlorantraniliprole in or on multiple commodities. This document is being issued to correct an omission of the tolerance for Bushberry, subgroup 13-07B.

DATES: This final rule is effective September 28, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0888. All documents in the docket are listed in the docket index available in <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m.