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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0817; FRL-9974-32]

Flutianil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flutianil in or on multiple commodities that are identified and discussed later in this document and an exemption for indirect or inadvertent residues of flutianil on other crops rotated into fields previously treated with flutianil. OAT AGRIO Company, Ltd. 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-2015-0817, 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, 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*.

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*.

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-2015-0817 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-2015-0817, 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 April 25, 2016 (81 FR 24044) (FRL-9944-86), 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 5F8408) by OAT AGRIO Company, Ltd, 1-3-1 Kanda Ogawa-machi, Chiyoda-ku, Tokyo 101-0052, Japan. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide flutianil, (2Z)-2-[2-fluoro-5-(trifluoromethyl)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene]acetonitrile, in or on apple, fruit at 0.2 parts per million (ppm); apple, juice at 0.03 ppm; apple, wet pomace at 2 ppm; cantaloupe at 0.07 ppm; cherry, fruit at 0.4 ppm; cucumber at 0.02 ppm; grape, fruit at 0.7 ppm; grape, juice at 0.2 ppm; grape, raisins at 0.3 ppm; squash at 0.03 ppm; and strawberry, fruit at 0.3 ppm. That document referenced a summary of the petition prepared by OAT AGRIO Company Ltd., the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comments is discussed in Unit IV.C.

Following the publication of this notice, the petitioner revised its petition by revising commodity terms to be consistent with the terminology EPA uses for commodities, removing certain processed commodities for which specific tolerances are not needed, amending tolerance levels, and requesting an exemption to cover inadvertent residues. EPA published a notice in the **Federal Register** of October 12, 2017 (82 FR 47422) (FRL-9967-09), pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing OAT AGRIO Company's amended pesticide petition (PP 5F8408). Superseding the original petition, the revised petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide flutianil in or on apple at 0.15 parts per million (ppm); apple, wet pomace at 0.30 ppm; cantaloupe at 0.07 ppm; cherry at 0.40 ppm; cucumber at 0.20; ppm; grape at 0.70 ppm; squash at 0.05 ppm; and strawberry at 0.50 ppm. Additionally, OAT AGRIO Company requested that an

exemption from the requirement of a tolerance be established in 40 CFR 180 for indirect or inadvertent residues of fungicide, flutianil in or on all food commodities for which tolerances are not separately established. 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...."

Similarly, FFDCA section 408(c)(2) authorizes EPA to establish an exemption from the requirement of a tolerance only if EPA determines the exemption is "safe", which has the same definition for exemptions as for tolerances and requires consideration of the same exposures and factors as for tolerances. 21 USC 346a(c)(2)(B).

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 flutianil including exposure resulting from the

tolerances established by this action. EPA's assessment of exposures and risks associated with flutianil 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.

No single or repeated dose study performed by any route of exposure produced an adverse effect following flutianil exposure below, at, or above the limit dose (1,000 mg/kg/day). The only toxic effect of flutianil exposure in the rat 28-day, 90-day, or 104-day oral toxicity studies was associated with hyaline droplet formation in the renal proximal tubular cells of males. No toxicity was observed in the female rats dosed up to the limit dose for comparable time periods. An immunohistochemical staining demonstrated that the hyaline droplets in the proximal tubular cells were related to the presence of alpha-2μ-globulin, which is not relevant for human toxicity. Based on the link to alpha-2μ-globulin and the lack of any degenerative or other associated effects, the hyaline droplet was not considered biologically relevant to humans.

No toxicity was seen in the developmental, reproductive, neurotoxic, or immunotoxic studies for flutianil. No dermal or systemic toxicity was observed at the limit dose in the rat 28-day dermal toxicity study. Nevertheless, in the rat 28-day inhalation toxicity study, increased lung weights in females and histopathological findings of minimal nasal mucous cell hypertrophy/hyperplasia and minimal lung centriacinar inflammation in males and females were observed at the highest dose tested. These observations were consistent with response to aerosol exposure to an airway irritant. The nasal mucous cell hypertrophy/hyperplasia is considered the physiological response of these cells to irritant; however, the increased lung weights and cellular inflammation reflect some degree of edema in air spaces, and inflammation

in the lung could affect airway responsiveness and pulmonary function. Therefore, the increased lung weights in females and lung lesions in both sexes were considered adverse effects. Flutianil is classified as "Not Likely to be Carcinogenic to Humans" based on lack of evidence of carcinogenicity in rats and mice and no evidence of mutagenicity. Flutianil produced no genotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by flutianil 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 "Flutianil. Draft Human Risk Assessment to Support New Uses for a New Active Ingredient, Flutianil on Apple, Cantaloupe, Cherry, Cucumber, Grape, Summer Squash, and Strawberry" dated November 1, 2017 in docket ID number EPA-HQ-OPP-2015-0817.

Based on the analysis of the available flutianil toxicological studies, there is no adverse toxicity from oral exposures seen in any of the required submitted toxicology studies. No toxicity endpoint and point of departure for regulating dietary exposure is established for the human health risk assessment. There are no registered or proposed residential uses at this time for flutianil; therefore, residential handler and post-application exposure and risk were not assessed.

Flutianil is proposed for use on a variety of crops. Humans could potentially be exposed to flutianil residues in food because flutianil may be applied directly to growing crops. These applications can also result in flutianil reaching surface and ground water, both of which can serve as sources of drinking water. There are no proposed uses in residential settings; therefore, there are no anticipated residential exposures.

Based on the toxicological profile of flutianil, EPA has concluded that the FFDCA requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) of the FFDCA (21 USC 346a) requires an additional tenfold margin of safety in the case of threshold risks, which are not present in this case. Section 408(b)(2)(D)(v) of the FFDCA requires consideration of information concerning cumulative effects of substances that have a common mechanism of toxicity, which flutianil does not have.

Based on the available data indicating a lack of adverse effects from exposure to flutianil, 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 flutianil.

IV. Other Considerations

A. Analytical Enforcement Methodology

The gas chromatography-mass spectrometry detector (GC/MSD) is used to measure and evaluate the chemical flutianil on apples, cantaloupe, cherry, cucumber, squash, and strawberry. The high performance liquid chromatography with tandem mass spectral detection (LCMS/MS) is used to measure and evaluate the chemical flutianil and the metabolite OC-56635 in grapes.

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression.

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 flutianil.

C. Response to Comments

Several comments were received, although many simply expressed concern about the use of pesticides on food generally. While EPA recognizes that some individuals oppose the use of pesticides in or on food, the FFDCA authorizes EPA to establish tolerances or exemptions where it determines that doing so is safe. As required by the FFDCA, EPA conducted a comprehensive assessment of flutianil, including its potential for carcinogenicity. Based on its assessment of the available data, the Agency believes that given the observed lack of toxicity of this chemical, no risks of concern are expected. Therefore, EPA concludes that the tolerances and exemption are safe and can be supported. The commenters did not provide any information to indicate otherwise.

Some comments (i.e., comments from the Center for Biological Diversity (CBD)) were not relevant to this action because they raised issues concerning compliance with the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is not relevant to the determination needed to support tolerance actions under the FFDCA.

Comments were received on the potential of flutianil to harm humans based on the human health and environmental toxicity findings of the European Food Safety Authority (EFSA). Although concerns were raised in the EFSA report about the potential for carcinogenicity and

reproductive toxicity of flutianil, EPA has received additional data on flutianil supporting the Agency's conclusions of a lack of carcinogenicity or reproductive toxicity. Therefore, EPA concludes that it has sufficient data to address the concerns raised by the EFSA assessment and support its safety finding for flutianil. For further information concerning these studies, see the "Final Registration Decision for the New Active Ingredient Flutianil: A Fungicide for Use on Apples, Cantaloupes, Cherries, Cucumbers, Grapes, Squash, and Strawberries" [Docket ID Number EPA-HQ-OPP-2015-0817].

V. Conclusion

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops. EPA is establishing numerical tolerances for residues resulting from direct applications to certain commodities because the petitioner requested them for international trade purposes. Therefore, tolerances are established for residues of flutianil, (2Z)-2-[2-fluoro-5-(trifluoromethy)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene]acetonitrile, in or on apple at 0.15 ppm; apple, wet pomace at 0.30 ppm; cantaloupe at 0.07 ppm; cherry at 0.40 ppm; cucumber at 0.20 ppm; grape at 0.70 ppm; squash at 0.05 ppm; and strawberry at 0.50 ppm.

Additionally, an exemption from the requirement of a tolerance is established for indirect or inadvertent residues of flutianil, (2Z)-2-[2-fluoro-5-(trifluoromethy)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene]acetonitrile, in or on all food commodities, except for those commodities with tolerances established.

VI. Statutory and Executive Order Reviews

This action establishes tolerances and an exemption from the requirement of 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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 tolerances and exemption 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: March 8, 2018.

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 § 180.697 to subpart C to read as follows:

§ 180.697 Flutianil; tolerances for residues.

(a) *General*. Tolerances are established for the combined residues of the fungicide flutianil, including its metabolites and degradates in or on food commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flutianil, (2*Z*)-2-[2-fluoro-5-(trifluoromethyl)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene]acetonitrile in or on the following commodities:

Commodity	Parts per million
Apple	0.15
Apple, wet pomace	0.30
Cantaloupe	0.07
Cherry	0.40
Cucumber	0.20
Grape	0.70
Squash	0.05
Strawberry	0.50

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

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

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

3. Add § 180.1354 to subpart D to read as follows:

§ 180.1354 Flutianil; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for indirect and inadvertent residues of the fungicide flutianil, including its metabolites and degradates, in or on

all food commodities not listed in §180.697 (a), when residues are present therein as a result of uptake by crops rotated into fields containing the crops in §180.697 (a) that were previously treated with flutianil.

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