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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0205; FRL-10002-71]

Flutianil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flutianil in or on the following commodities: berry, low growing, subgroup 13-07G; cherry subgroup 12-12A; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; hop, dried cones; and vegetable, cucurbit, group 9. Interregional Research Project Number 4 (IR-4) 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-2019-0205, 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*.

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 Publishing 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-2019-0205 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-2019-0205, 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 June 7, 2019 (84 FR 26630) (FRL-9993-93), 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 8E8730) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested to amend 40 CFR 180.697 by removing the established tolerances for residues of flutianil, (2Z)-2-[2-fluoro-5-(trifluoromethyl)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene] acetonitrile, including its metabolites and degradates, in or on the raw agricultural commodities 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.

In the **Federal Register** of October 3, 2019 (84 FR 52850) (FRL-9999-89), 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 8E8730) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested to amend 40 CFR 180.697 by establishing tolerances for residues of flutianil, (2Z)-2-[2-fluoro-5-(trifluoromethyl)phenyl]sulfanyl-2-[3-(2-methoxyphenyl)thiazolidin-2-ylidene] acetonitrile, including its metabolites and degradates in or on berry, low growing, subgroup 13-07G at 0.50 ppm; cherry subgroup 12-12A at 0.40 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.70 ppm; hop, dried cones at 2.0 ppm; and vegetable, cucurbit, group 9 at 0.20 ppm.

The documents referenced a summary of the petition prepared by OAT Agrio Co., Ltd., c/o Landis International, Inc., the registrant, which is available in the docket,

http://www.regulations.gov. A comment was received on the notices of filing. EPA's response to this comment is discussed in Unit IV.C.

For reasons discussed in Unit IV.D., EPA is establishing tolerances that vary slightly from what was requested, consistent with its authority in FFDCA section 408(d)(4)(A)(i).

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 flutianil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flutianil follows.

A. Toxicological Profile

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 an 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* on pages 24-28 of the document titled “Flutianil. Human Risk Assessment to Support New Uses for a New Active Ingredient, Flutianil on Apple, Cantaloupe, Cherry, Cucumber, Grape, Summer Squash, and Strawberry” in docket ID number EPA-HQ-OPP-2019-0205.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA

uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide*.

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 are 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.

C. Exposure Analysis

Flutianil is used 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.

D. Additional FFDCA Factors

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 U.S.C. 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.

E. Safety Determination

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

Adequate enforcement methodology - gas chromatography-mass spectrometry detector (GC/MSD) and high-performance liquid chromatography with tandem mass spectral detection (LC/MS/MS) for grapes only - is available to enforce the tolerance expression.

The methods 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 any MRLs for these crops for flutianil.

C. Response to Comments

One comment generally asserting that flutianil is toxic and should not be allowed on vegetables was received in response to the notice of filing. Although 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) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these flutianil tolerances are safe. The commenter has provided no information to indicate that flutianil is not safe.

D. Revisions to Petitioned-for Tolerances

The petitioner seeks a vegetable, cucurbit, group 9 tolerance of 0.20 ppm. Previously, separate tolerances were established for cucumber, cantaloupe, and squash for harmonization purposes with Japan. The available data support establishing subgroup tolerances, so EPA is establishing two subgroup tolerances as follows: melon subgroup 9A at 0.07 ppm and squash/cucumber subgroup 9B at 0.2 ppm. There are no Codex MRLs.

EPA is establishing the remaining tolerances as requested, except for modifications to be consistent with the rounding class practices of the Organisation for Economic Co-operation and Development (OECD).

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 commodities 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 berry, low growing, subgroup 13-07G at 0.5 ppm; cherry subgroup 12-12A at 0.4 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.7 ppm; hop, dried cones at 2 ppm; melon subgroup 9A at 0.07 ppm; and squash/cucumber subgroup 9B at 0.2 ppm.

Additionally, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: cantaloupe; cherry; cucumber; grape; squash; and strawberry.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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), nor is it considered a regulatory action under 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 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: December 5, 2019.

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 § 180.697(a):

a. In the introductory text, remove "the table below" and "below" and add in their places "Table 1 to this paragraph (a)" and "in Table 1," respectively; and

b. Revise the table.

The revision reads as follows:

§ 180.697 Flutianil; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
Apple	0.15
Apple, wet pomace	0.30
Berry, low growing, subgroup 13-07G	0.5
Cherry subgroup 12-12A	0.4
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.7
Hop, dried cones	2
Melon subgroup 9A	0.07
Squash/cucumber subgroup 9B	0.2

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