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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0099; FRL-9962-13]

Flubendiamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of flubendiamide in or on tea at 50 parts per million (ppm). Nichino America, Inc. 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-2007-0099, 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*.

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-2007-0099 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-2007-0099, 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 August 12, 2016 (81 FR 53379) (FRL-9949-53), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announced the filing of a pesticide petition (PP 6E8463) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501,

Wilmington, DE 19808–2951. This petition requested that 40 CFR 180.639 be amended by establishing an import tolerance for residues of flubendiamide, N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on the processed commodity of dried tea at 60 parts per million (ppm). This document referenced a summary of a petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. This tolerance was requested to cover residues of flubendiamide in or on tea resulting from uses of this pesticide on tea outside the United States; there is no current U.S. registration for use of flubendiamide on tea. In order to harmonize with Codex, EPA is establishing a tolerance for residues of flubendiamide in or on tea at 50 ppm. The available residue data supports this tolerance level. A revised Section F was submitted by Nichino America, Inc. to support this change to the petitioned-for tolerance. There were no comments 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 flubendiamide including exposure resulting from the tolerance established by this action.

In the **Federal Register** of December 12, 2012 (77 FR 73940) (FRL–9373-3), EPA amended tolerances for residues of flubendiamide in or on apple, wet pomace and fruit, pome, group 11. EPA is relying upon significant portions of those risk assessments and the corresponding findings made in the December 12, 2012 **Federal Register** document in support of this action for the following reasons. The toxicity profile of flubendiamide has not changed. Much of the exposure profiled remains the same as well because there is no U.S. registration associated with the tea use (i.e., the estimated drinking water exposures reported in 2012 are not expected to change nor is there any need to conduct a residential exposure assessment due to the lack of proposed or existing residential uses for flubendiamide). The Agency did take into consideration the potential additional dietary exposure to flubendiamide as a result of residues in or on imported tea. Aggregating that exposure with the dietary exposure estimated in the December 2012 tolerance assessment resulted in no change to the acute dietary exposure (3.1% of the aPAD for the general U.S. population and 5.5% of the aPAD for children 1-2 years old, the most highly exposed population subgroup) and only a 1% change in the chronic dietary risk (21% of the cPAD) for the general U.S. population and an increase of 9% in the chronic dietary risk (67% of the cPAD) for children 1-2 years old, the most highly exposed population subgroup. The Agency's findings concerning cumulative effects and the children's safety factor as reflected in the December 2012 tolerance rulemaking are also relied upon in this action.

Based upon the risk assessments supporting the December 12, 2012 **Federal Register** document, the findings therein, and the updated risk assessment accounting for the residues of flubendiamide on imported tea, 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 flubendiamide residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer to the December 12, 2012, **Federal Register** document and its supporting documents, available at *http://www.regulations.gov* in docket ID number EPA-HQ-OPP-2007-0099. Further information about EPA's determination that an updated risk assessment was not necessary may be found in the document, ''Flubendiamide: Human Health Risk Assessment for the Petition for a Tolerance Without U.S. Registration for Residues in/on Tea.'' in docket ID number EPA-HQ-OPP-2007-0099.

IV. Other Considerations

A. Analytical Enforcement Methodology.

An independently validated liquid chromatography/tandem mass spectrometry (LC/MS/MS) method, Method 00816/M002, was previously submitted for the determination of residues of in/on samples of plant commodities. The validated limit of quantitation (LOQ) is 0.01 ppm for each analyte in each matrix.

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 tea established at 50 ppm; therefore, the U.S. EPA is establishing a tolerance on tea at the same level to harmonize with Codex.

C. Revisions to Petitioned-for Tolerance

If only dried tea data are submitted for imported tea (data in/on the RAC are not required for imported tea) and the tolerance level based on these data is also meant to cover for detectable residues in instant tea (may be demonstrated by data depicting detectable residues in brewed tea), then the correct commodity definition for tolerance setting should be "tea" to cover incurred residues in or on all tea commodities and eliminate any regulatory ambiguity. In order to harmonize with Codex, EPA is establishing a tolerance for residues of flubendiamide in or on tea at 50 ppm. The available residue data supports this tolerance level. A revised Section F was submitted by Nichino America, Inc. to support this change to the petitioned-for tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of flubendiamide, N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on tea at 50 ppm. At this time, there is no U.S. registration for use of flubendiamide on tea.

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 23, 2017.

Donna S. Davis,
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 § 180.639, add alphabetically the entry “Tea” to the table in paragraph (a) to read as follows:

§ 180.639 Flubendiamide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * * * *	
Tea[1]	50
* * * * * * *	

[1] There are no U.S. registrations as of [*insert date of publication in the* **Federal Register**], for use of flubendiamide on tea.

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[FR Doc. 2017-14108 Filed: 7/3/2017 8:45 am; Publication Date: 7/5/2017]