



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0659; FRL-10012-03]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on *Brassica*, leafy greens, subgroup 4-16B, except watercress, at 15 parts per million (ppm); vegetable, *Brassica*, head and stem, group 5-16 at 2 ppm; kohlrabi at 2 ppm; modifies the current watercress tolerance from 7 ppm to 10 ppm; and removes existing tolerances for *Brassica*, head and stem, subgroup 5A and *Brassica*, leafy greens, subgroup 5B. Syngenta Crop Protection, LLC 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-2019-0659, 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 note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://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 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 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-2019-0659 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-2019-0659, 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 February 10, 2020 (85 FR 7500) (FRL-10005-02), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8754) by Syngenta Crop Protection, LLC, 410 Swing Road, Greensboro, NC 27409. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fludioxonil, 4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile, in or on *Brassica* leafy greens subgroup 4-16B at 10.0 parts per million (ppm); Vegetable, Head and Stem *Brassica*, Group 5-16 at 2.0 ppm; and Kohlrabi at 2.0 ppm. The petition also requested that the following established tolerances be removed: *Brassica*, leafy greens, subgroup 5B at 10.0 ppm and *Brassica*, head and stem, subgroup 5A at 2.0 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>.

Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing the requested tolerances, with slight modifications for consistency with the Organisation for Economic Co-

Operation and Development (OECD) tolerance-rounding class practice and EPA's commodity vocabulary and harmonization with the Codex Alimentarius Commission (Codex). In addition, EPA is establishing tolerances for watercress and subgroup 4-16B that vary slightly from what the petitioner requested. The reasons for these changes are discussed in Unit IV.D.

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

In the *Federal Register* on November 6, 2018 (83 FR 55491) (FRL-9982-75), EPA published a final rule establishing a tolerance for residues of the fungicide fludioxonil in or on

beet, sugar, roots. That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, and the Agency's determination concerning the children's safety factor, which have not changed. Those discussions are incorporated by reference into this document. The Agency conducted a revised risk assessment to incorporate exposure to residues of fludioxonil from use on *Brassica*, leafy greens, subgroup 4-16B; Vegetable, *Brassica*, head and stem, group 5-16; and Kohlrabi.

An acute dietary assessment was not performed because there were no adverse effects resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fludioxonil is not expected to pose an acute risk. As to residue levels in food, an unrefined chronic dietary exposure and risk assessment was conducted assuming 100% percent crop treated (PCT) and tolerance-level residues for all food commodities. EPA assessed the exposure in drinking water, additional dietary exposure and the overall aggregate exposure.

Chronic dietary risks are below the Agency's level of concern: 54% of the chronic population-adjusted dose (cPAD) for children 1 to 2 years old, the population group receiving the greatest exposure. Moreover, the short-term aggregate risk for the populations with the highest total exposure margin of exposure (MOEs) of 15,000 for adults and 4,600 for children 1 to 2 years old. Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs above the level of concern (LOC) of 100 for all scenarios assessed and are not of concern.

Intermediate- and long-term aggregate risk assessments were not performed because there are no registered or proposed uses of fludioxonil that result in intermediate- or long-term residential exposures. The chronic aggregate exposure assessment consists of exposure from food and water only.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to fludioxonil residues. More detailed information on the subject action to establish a tolerance in or on *Brassica*, leafy greens, subgroup 4-16B; Vegetable, *Brassica*, head and stem, group 5-16; and Kohlrabi can be found in the document entitled, “Human Health Risk Assessment for Section 3 Registration for Crop Group Conversions/Expansions for *Brassica*, Leafy Greens, Subgroup 4-16B Vegetable and *Brassica*, Head and Stem, Group 5-16 and to Establish an Individual Tolerance on Kohlrabi” by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0659.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology high-performance liquid chromatography/ultraviolet (HPLC/UV) methods (Methods AG-597 and AG-597B) are available for enforcing tolerances for fludioxonil on plant commodities. Additionally, fludioxonil is recoverable by the Quick Easy Cheap Effective Rugged and Safe (QuEChERS) multiresidue method using HPLC with tandem mass spectrometry detection (MS/MS) for analysis. An adequate liquid chromatography, tandem MS (LC-MS/MS) method (Analytical Method GRM025.03A) is available for enforcing tolerances for residues of fludioxonil in or on livestock commodities.

The method 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 tolerance expressions are harmonized for the United States, Canada, and Codex. Codex has adopted MRLs for many commodities contained in subgroup 4-16B: 9 ppm on upland cress; 10 ppm on watercress; 15 ppm on arugula; broccoli raab; cabbage, Chinese, bokchoy; cabbage, Chinese, Napa; collards; cress, garden; kale; mizuna; mustard greens; rape greens; turnip tops; and 20 ppm on radish tops. EPA is establishing a tolerance at 15 ppm for subgroup 4-16B and 10 ppm on watercress, which harmonizes most of the commodities in the group. EPA is not harmonizing the U.S. tolerances for upland cress and radish tops with the Codex MRLs because no data are available to EPA for those commodities that would indicate a tolerance different than the crop group tolerance would be appropriate. Codex has also adopted MRLs for broccoli (0.7 ppm) and cabbage (2 ppm) which are both commodities in the vegetable, *Brassica*, head and stem, group 5-16. The group 5-16 tolerance level of 2 ppm is harmonized with Codex for cabbage, but the Codex MRL of 0.7 ppm for broccoli is too low to harmonize. There are no

Codex MRLs for residues of fludioxonil in or on kohlrabi.

C. Response to Comments

EPA received two anonymous comments in response to the notice of filing for fludioxonil proposed new uses. In summary, one comment states that commodities need to be free from pesticides in order for us to be safe. The other states that the product should not be sold, that it is fluoride on plants, that no one needs to have fluoride ingested from eating plants with pesticides, and that accumulation of pesticides over many years kills people, and should not be authorized.

In response to both comments, the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. In examining whether the pesticide is safe, EPA has evaluated hazard and exposure data and conducted dietary, residential, and aggregate exposure assessments to estimate the risk to human health that will result from all registered and proposed uses of fludioxonil. Based on its assessment of the available information, EPA has concluded that the tolerances for fludioxonil are safe. The commenter has provided no information that would support an Agency determination that these tolerances are not safe. Regarding the comment on fluoride: the benzodioxole group remains intact during fludioxonil metabolism; i.e., all metabolites identified retained both fluorine atoms; therefore, there is no exposure—and thus no risk from exposure—to fluoride.

D. Revisions to Petitioned-for Tolerances

The petitioner requested a conversion of the existing subgroup *brassica*, leafy greens

subgroup 5B at 10 ppm to the new subgroup, *brassica*, leafy greens, subgroup 4-16B at 10 ppm. EPA has decided to establish this new subgroup tolerance at 15 ppm in order to harmonize with a larger number of Codex MRLs for the commodities contained in subgroup 4-16B, with the exception of watercress. Watercress is not a commodity in subgroup 5B; therefore, EPA had previously established a separate tolerance for watercress, which was lower than the subgroup 5B tolerance. At the request of the petitioner, EPA is retaining the separate tolerance for watercress, rather than simply covering residues in or on watercress as part of the subgroup, but is increasing that separate tolerance to 10 ppm, which is in line with the petitioner's request to establish the subgroup 4-16B tolerance at 10 ppm (since watercress is a commodity covered by that subgroup) and harmonized with the Codex MRL for watercress.

V. Conclusion

Therefore, tolerances are established for residues of fludioxonil: [4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile], in or on *brassica*, leafy greens, subgroup 4-16B, except watercress at 15 ppm; vegetable, *brassica*, head and stem, group 5-16 at 2 ppm; and kohlrabi at 2 ppm. In addition, EPA is revising the existing tolerance for watercress from 7.0 ppm to 10 ppm and removing existing tolerances for *brassica* leafy greens subgroup 5B at 10.0 ppm and *brassica*, head and stem, subgroup 5A at 2.0 ppm as they are superseded by the new tolerances established in this rule.

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: July 16, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I 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 § 180.516, paragraph (a)(1):

i. Add a heading to the table;

ii. Remove the entries for “Brassica, head and stem, subgroup 5A” and “Brassica, leafy greens subgroup 5B”;

iii. Add alphabetically the entries “*Brassica*, leafy greens, subgroup 4-16B, except watercress”; “Kohlrabi” and “Vegetable, *brassica*, head and stem, group 5-16”; and

iv. Revise the entry for “Watercress”.

The additions and revision read as follows:

§ 180.516 Fludioxonil; tolerance for residues.

(a) * * *
 (1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * *	*
<i>Brassica</i> , leafy greens, subgroup 4-16B, except watercress	15
* * * * *	*
Kohlrabi	2
* * * * *	*
Vegetable, <i>Brassica</i> , head and stem, group 5-16	2
* * * * *	*
Watercress	10

* * * * *