ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0460; FRL-10010-98]

Flupyradifurone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flupyradifurone in or on multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) and the registrant, Bayer CropScience, 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-2019-0460, 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)
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 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-2019-0460 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-2019-0460, 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),
II. Summary of Petitioned-For Tolerance

In the Federal Register of February 11, 2020 (85 FR 7708) (FRL-10005-02), 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 9E8771) by Interregional Project Number 4 (IR-4), Rutgers, the State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.679 be amended by establishing tolerances for residues of the insecticide flupyradifurone, 4-[[6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]-2(5H)-furanone, in or on Brassica, leafy greens, subgroup 4-16B at 40 parts per million (ppm); Celtuce at 9 ppm; Coffee, green bean at 1.5 ppm; Fennel, Florence, fresh leaves and stalk at 9 ppm; Kohlrabi at 6 ppm; Leaf petiole vegetable subgroup 22B at 9 ppm; Leafy greens subgroup 4-16A at 30 ppm; Pineapple at 0.3 ppm; Sesame, seed at 3 ppm; Stalk and stem vegetable subgroup 22A, except prickly pear, pads, and prickly pear, Texas, pads at 0.01 ppm; Sunflower subgroup 20B at 0.7 ppm; Tropical and subtropical, inedible peel, cactus, subgroup 24D at 0.3 ppm; Tropical and subtropical, palm fruit, edible peel, subgroup 23C at 8 ppm; and Vegetable, Brassica, head and stem, group 5-16 at 6 ppm.

In addition, the IR-4 petition requested that 40 CFR 180.679(c) be amended by establishing tolerances with regional restrictions for residues of the insecticide flupyradifurone,
4-[[[6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone, in or on Grass, forage, fodder and hay, group 17 at 15 ppm.

Upon establishment of the above tolerances, IR-4 requested the removal of the existing tolerances in 40 CFR part 180.679 for residues of the insecticide flupyradifurone, 4-[[[6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone, in or on Brassica, head and stem subgroup 5A at 6.0 ppm; Brassica, leafy greens subgroup 5B at 40 ppm; Cactus, fruit at 0.30 ppm; Cilantro, fresh leaves at 30 ppm; Coffee, green been (import tolerance) at 1.5 ppm; Leaf petioles, subgroup 4B at 9.0 ppm; Leafy greens, subgroup 4A at 30 ppm; Pitaya at 0.30 ppm; and Turnip greens at 40 ppm.

IR-4 also requested removal of the section 18 emergency exemption tolerances on sorghum, syrup at 90.0 ppm and sorghum, forage at 30 ppm. Through inadvertent error however, EPA failed to provide notice of this petitioned-for request in its February 11, 2020 document.

In the Federal Register of October 28, 2019 (84 FR 57417) (FRL-10001-12), 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 9F8775) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, that requested to establish a tolerance in in 40 CFR part 180.679 for residues of the insecticide flupyradifurone 4-[[[6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone, in or on Rapeseed subgroup (Crop Subgroup 20A) at 0.03 ppm. This document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, http://www.regulations.gov.

One comment was submitted on each 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 revised the commodity definitions for two commodities to be consistent with EPA’s preferred terminology, changing Fennel, Florence, fresh leaves and stalk to Fennel, florence, fresh leaves and stalk; and Vegetable, Brassica, head and stem, group 5-16 to Vegetable, brassica, head and stem, group 5-16. Finally, due to the failure to provide timely notice of the request to remove the section 18 emergency exemption tolerances for sorghum commodities, EPA is not removing those tolerances at this time.

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

On September 23, 2016, EPA published in the Federal Register a final rule establishing tolerances for residues of flupyradifurone in or on several commodities based on the Agency’s conclusion that aggregate exposure to flupyradifurone is safe for the general population, including infants and children. See (81 FR 65552) (FRL-9951-68). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency’s current assessment of flupyradifurone tolerances—the toxicological profile and points of departure, the conclusions about cumulative risk, and the Agency’s rationale for reducing the children’s safety factor.

EPA’s exposure assessments have been updated to include the additional exposure from use of flupyradifurone on the Brassica, leafy greens, subgroup 4-16B; Celtuce; Coffee, green bean; Fennel, florence, fresh leaves and stalk; Kohlrabi; Leaf petiole vegetable subgroup 22B; Leafy greens subgroup 4-16A; Pineapple; Rapeseed subgroup 20A; Sesame, seed; Stalk and stem vegetable subgroup 22A, except prickly pear, pads, and prickly pear, Texas, pads; Sunflower subgroup 20B; Tropical and subtropical, inedible peel, cactus, subgroup 24D; Tropical and subtropical, palm fruit, edible peel, subgroup 23C; and Vegetable, brassica, head and stem, group 5-16. EPA has assumed tolerance-level residues and 100 percent crop treated (PCT) for the acute dietary assessment. For the chronic dietary assessment, EPA assumed average residues, rather than tolerance-level residues, for some commodities and 100 PCT. EPA’s aggregate exposure assessment incorporated this dietary exposure, as well as exposure in drinking water and from residential sources, although drinking water and residential exposures are not impacted by the new uses and thus have not changed since the last assessment and as reflected in the preamble to the September 23, 2016 rule.
Acute dietary risks are below the Agency’s level of concern of 100% of the acute population adjusted dose (aPAD); they are 38% of the aPAD for children 1 to 2 years old, the most highly exposed population group. Chronic dietary risks are below the Agency’s level of concern of 100% of the chronic population adjusted dose (cPAD); they are 64% of the cPAD for children 1 to 2 years old, the group with the highest exposure. As required by the FFDCA, EPA considered aggregate exposures to flupyradifurone, i.e., exposures from food, drinking water, and residential uses, in its risk assessment. There are no residential uses expected to result in acute, intermediate-term, or chronic exposures; therefore, aggregate risks for those exposure durations are equal to the dietary risks for those exposure durations and not of concern. Aggregating short-term exposures to adults and children with the chronic (background) dietary exposures yields margins of exposure (MOEs) of 300 (adults) and 220 (children). Both of these exceed the Agency’s level of concern, which is an MOE of 100 or lower; therefore, short-term exposures are not of concern.

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, or to infants and children from aggregate exposure to flupyradifurone residues. More detailed information about the Agency’s analysis can be found in the document entitled, “Flupyradifurone; Human Health Risk Assessment for Uses on Grass Forage Fodder and Hay Group 17, Pineapple, Rapeseed Subgroup 20A, Sesame Seed, Stalk and Stem Vegetable Subgroup 22A (except Prickly Pear Pads and Prickly Pear Texas Pads), Sunflower Subgroup 20B, Sweet Sorghum, Tropical and Subtropical Palm Fruit Edible Peel Subgroup 23C, Crop Group Expansions/Conversions of Tolerances to Brassica Leafy Greens Subgroup 4-16B, Leafy Greens Subgroup 4-16A, Leaf Petiole Vegetable Subgroup 22B, Tropical and Subtropical
Inedible Peel Cactus Subgroup 24D, Vegetable *Brassica* Head and Stem Group 5-16 and
Establish Individual Tolerances on Celtuce, Fennel Florence, Kohlrabi; and Coffee,” which is described under ADDRESSES. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0460.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology Method RV-001-P10-03, which uses high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS/MS) to quantitate residues of flupyradifurone and its metabolite difluoroacetic acid (DFA) in various crops is available for enforcement. An HPLC/MS/MS method, Method RV-004-A11-05 is adequate as the enforcement method for determination of residues of flupyradifurone and its metabolite DFA in 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.

Codex MRLs have been established for head cabbage at 1.5 ppm, cauliflower at 6 ppm, and lettuce (head and leaf) at 4 ppm. For leafy greens subgroup 4-16A, harmonization with Codex is not possible because the U.S. tolerance of 30 ppm is much higher than the Codex MRLs for head lettuce and leaf lettuce. Harmonizing with the Codex MRLs would put U.S. growers at risk of having violative residues despite legal use of the pesticide. The U.S. tolerance on *Brassica* head and stem group 5-16 is harmonized with the Codex cauliflower MRL (6 ppm). It is not possible to also harmonize with head cabbage, which is another commodity in crop group 5-16.

**C. Response to Comments**

One comment was received stating that residues of pesticide chemicals on various commodities are a serious health hazard that needs to be regulated. Another comment received stated that this chemical should not be used on any food products that Americans eat. The existing legal framework provided by section 408 of the FFDCA 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. These comments appear to be directed at the underlying statute and not EPA’s implementation of it; the comments provide no information relevant to the Agency’s safety determination.

**V. Conclusion**

Therefore, tolerances are established for residues of flupyradifurone, 4-[[((6-chloro-3-pyridinyl)methyl)(2,2-difluoroethyl)amino]- 2(5H)-furanone, in or on *Brassica*, leafy greens,
subgroup 4-16B at 40 ppm; Celtuce at 9 ppm; Fennel, florence, fresh leaves and stalk at 9 ppm; Kohlrabi at 6 ppm; Leaf petiole vegetable subgroup 22B at 9 ppm; Leafy greens subgroup 4-16A at 30 ppm; Pineapple at 0.3 ppm; Rapeseed subgroup 20A at 0.03 ppm; Sesame, seed at 3 ppm; Stalk and stem vegetable subgroup 22A, except prickly pear, pads, and prickly pear, Texas, pads at 0.01 ppm; Sunflower subgroup 20B at 0.7 ppm; Tropical and subtropical, inedible peel, cactus, subgroup 24D at 0.3 ppm; Tropical and subtropical, palm fruit, edible peel, subgroup 23C at 8 ppm; and Vegetable, brassica, head and stem, group 5-16 at 6 ppm. A tolerance with regional restrictions is established for residues of the insecticide flupyradifurone, 4-[[6-chloro-3-pyridinyl)methyl][2,2-difluoroethyl]amino]-2(5H)-furanone, in or on Grass, forage, fodder and hay, group 17 at 15 ppm. Additionally, the existing tolerance for Coffee, green bean is revised to remove the footnote.

In addition, the existing tolerances in 40 CFR part 180.679 for residues of the insecticide flupyradifurone, 4-[[6-chloro-3-pyridinyl)methyl][2,2-difluoroethyl]amino]-2(5H)-furanone, in or on the following commodities are removed: Brassica, head and stem subgroup 5A at 6.0 ppm; Brassica, leafy greens subgroup 5B at 40 ppm; Cactus, fruit at 0.30 ppm; Cilantro, fresh leaves at 30 ppm; Leaf petioles, subgroup 4B at 9.0 ppm; Leafy greens, subgroup 4A at 30 ppm; Pitaya at 0.30 ppm; and Turnip greens at 40 ppm.

VI. Statutory and Executive Order Reviews

This action establishes 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

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.


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:


2. In § 180.679:

   a. In paragraph (a):

      i. Add a heading for the table.

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

      iii. Add alphabetically the entry “Brassica, leafy greens, subgroup 4-16B”.

      iv. Remove the entry for “Cactus, fruit”.

      v. Add alphabetically the entry “Celtuce”.

      vi. Remove the entry for “Cilantro, fresh leaves”.

      vii. Revise the entry for “Coffee, green bean”.

      viii. Add alphabetically the entries “Fennel, florence, fresh leaves and stalk”; “Kohlrabi” and “Leaf petiole vegetable subgroup 22B”.

      ix. Remove the entries for “Leaf petioles, subgroup 4B” and “Leafy greens, subgroup 4A”.

      x. Add alphabetically the entries “Leafy greens subgroup 4-16A” and “Pineapple”.

      xi. Remove the entry for “Pitaya”.

      xii. Add alphabetically the entries “Rapeseed subgroup 20A”; “Sesame, seed”; “Stalk and stem vegetable subgroup 22A, except prickly pear, pads, and prickly pear, Texas, pads”; “Sunflower subgroup 20B”; “Tropical and subtropical, inedible peel, cactus, subgroup 24D” and
“Tropical and subtropical, palm fruit, edible peel, subgroup 23C”.

xiii. Remove the entry for “Turnip greens”.

xiv. Add alphabetically the entry “Vegetable, brassica, head and stem, group 5-16”.

b. In paragraph (c):

i. Add a heading for the table.

ii. Add alphabetically the entry “Grass, forage, fodder and hay, group 17”.

The additions and revisions read as follows:

§ 180.679 Flupyradifurone; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

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[FR Doc. 2020-17153 Filed: 8/20/2020 8:45 am; Publication Date: 8/21/2020]