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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0478; FRL-10020-49]

### Flupyradifurone; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of the insecticide flupyradifurone including its degradates and metabolites in or on sugarcane, cane and sugarcane, molasses. This action is associated with the utilization of a crisis exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarcane. This regulation establishes a maximum permissible level for residues of flupyradifurone in or on these commodities. The time-limited tolerances expire on December 31, 2023.

**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-2020-0478, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto: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 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](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 section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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-2020-0478 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-2020-0478, 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. Background and Statutory Findings**

EPA, on its own initiative, in accordance with FFDCAs sections 408(e) and 408(l)(6) of 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of flupyradifurone in or on sugarcane, cane at 3 parts per million (ppm) and sugarcane, molasses at 90 ppm. These time-limited tolerances expire on December 31, 2023.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### **III. Emergency Exemption for Flupyradifurone on Sugarcane, cane and Sugarcane, molasses and FFDCA Tolerances**

The Louisiana Department of Agriculture and Forestry (LDAF) asserts that an emergency condition exists in accordance with the criteria for approval of an emergency exemption and has

utilized a crisis exemption under FIFRA section 18 to allow the use of flupyradifurone for control of sugarcane aphid infestations in Louisiana sugarcane. According to LDAF, the sugar industry is vital to Louisiana's economy and sugarcane aphids which were once sporadic in the state are now widespread as outbreaks have become more frequent in recent years. After having reviewed the crisis exemption, EPA concurred on the 15-day stand-alone emergency action, which expired on August 5, 2020.

As part of its evaluation of the crisis exemption, EPA assessed the potential risks presented by residues of flupyradifurone in or on sugarcane, cane at 3 ppm and sugarcane, molasses at 90 ppm. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2023, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sugarcane after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether flupyradifurone meets FIFRA's registration requirements for use on sugarcane or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of flupyradifurone by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in

any State other than Louisiana to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for flupyradifurone, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 therein, 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 expected as a result of this emergency exemption request and the time-limited tolerances for residues of flupyradifurone on sugarcane, cane at 3 ppm and sugarcane, molasses at 90 ppm.

On September 23, 2016 (81 FR 65552) (FRL-9951-68) and August 21, 2020 (85 FR 51668-51672) (FRL-10010-98), EPA published final rules that established tolerances for residues of flupyradifurone in or on multiple commodities based on the Agency's determination that aggregate exposure to flupyradifurone resulting from the residues subject to those tolerances is safe for the U.S. general population, including infants and children. The toxicity profile for flupyradifurone has not changed since the September 23, 2016 (81 FR 65552) (FRL-9951-68) rule

was published, therefore EPA is relying upon the discussion of that profile (Unit III.A.) and the identified toxicological endpoints (Unit III.A.) and the identified toxicological endpoints (Unit III B.), as part of this rulemaking.

EPA's most recent exposure assessment for flupyradifurone appears in the comprehensive risk assessment dated June 30, 2020 and 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 Lettuce, Fennel Florence, Kohlrabi; and Coffee," as that assessment included dietary and aggregate exposures to flupyradifurone in or on multiple agricultural and non-agricultural commodities that are complete except for exposures due to the emergency use addressed in this document.

For aggregate risk assessment, risk estimates resulting from food, drinking water, and residential uses are combined. Acute, short-and intermediate-term, and long-term (chronic) aggregate assessments were performed for flupyradifurone. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the August 21, 2020 final rule can be found at <http://www.regulations.gov> 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 Lettuce, Fennel Florence, Kohlrabi; and Coffee,” dated June 30, 2020 (docket ID EPA-HQ-OPP-2019-0460).

EPA conducted unrefined and slightly refined chronic dietary analyses for all current uses of flupyradifurone together with the emergency use in or on sugarcane, cane and sugarcane, molasses. The assessments incorporated tolerance-level residues, average residues (chronic), 2018 default or empirical processing factors, conservative drinking water estimates, and assumed that 100% of the proposed crops were treated. The results of the acute and chronic analyses do not exceed the Agency’s level of concern (LOC). That is, <100% of the acute population adjusted dose (aPAD) or <100% of the chronic population adjusted dose (cPAD) are not of concern for the general U.S. population and all population subgroups. At the 95<sup>th</sup> percentile of exposure, the acute dietary (food and drinking water) risk estimates utilized 24% of the aPAD for the general U.S. general population and utilized 39% the aPAD for children 1 to 2 years old, the most highly exposed population subgroup. The chronic dietary (food and drinking water) risk estimates utilized 29% of the cPAD for the U.S. population and utilized 68% of the cPAD for children 1 to 2 years old, the group with the highest exposed population subgroup.

The aggregate exposure assessment for flupyradifurone is based on food and drinking water as well as residential uses. Neither intermediate- nor long-term (chronic) residential exposures are expected, so only a short-term aggregate assessment was conducted. Aggregate short-term residential exposure to adults and children (residential exposures to handlers and post-application exposures to adults and children) with the chronic (background) dietary exposure yields margins of exposure MOEs of 300 for adults and 220 for children); neither is of concern because EPA considers MOEs of less than 100 to be of concern for aggregate risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children from aggregate exposure to flupyradifurone residues. More detailed information on the subject action to establish time-limited tolerances in or on sugarcane, cane

and sugarcane, molasses can be found at <http://www.regulations.gov> in the document entitled “Flupyradifurone: Human Health Risk Assessment for Section 18 Emergency Exemption Request for Use on Sugarcane in Louisiana.” This document can be found in docket ID number EPA-HQ-OPP-2020-0478.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement methodology (Method RV-001-P10-03) is available to enforce the tolerance expression. This method uses high-performance liquid chromatography with tandem mass spectrometry [HPLC/MS/MS] to quantitate residues of flupyradifurone in various crops is available for enforcement.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto: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.

There are no Codex and Canadian MRLs established on sugarcane.

## **VI. Conclusion**

Therefore, time-limited tolerances are established for residues of flupyradifurone in or on sugarcane, cane at 3 ppm and sugarcane, molasses at 90 ppm. These tolerances expire on December 31, 2023.

## **VII. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCa sections 408(e) and 408(l)(6). 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, 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 in accordance with FFDCa sections 408(e) and 408(l)(6), 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, but does not directly regulate 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).

#### **VIII. 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: April 20, 2021.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.679, amend paragraph (b) by:

a. Revising the introductory text; and

b. Adding in alphabetical order to the table the entries “Sugarcane, cane” and “Sugarcane, molasses”.

The revision and additions read as follows:

**§ 180.679 Flupyradifurone; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide flupyradifurone, including its metabolites and degradates in or on the specified agricultural commodities listed in table 2 to this paragraph (b), resulting from use of the pesticide pursuant to a Federal Insecticide, Fungicide, and Rodenticide Act (FFIFRA) section 18 emergency exemption. Compliance with the tolerance levels specified in table 2 to this paragraph (b) is to be determined by measuring only flupyradifurone, 4-[[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]-2(5H)-furanone. The tolerances expire on the date specified in table 2 to this paragraph (b).

Table 2 to paragraph (b)

Commodity	Parts per million	Expiration date
* * * * *	* * * * *	* * * * *
Sugarcane, cane	3	12/31/2023
Sugarcane, molasses	90	12/31/2023
* * * * *	* * * * *	* * * * *

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