



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2025-1973; FRL- 13080-01-OCSPP]

### Flupyradifurone; Pesticide Tolerance for Emergency Exemption

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of flupyradifurone, including its metabolites and degradates, in or on sugarcane, cane and sugarcane, molasses. This action is in response to EPA's concurrence 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, 2028.

**DATES:** This rule 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-2025-1973, is available at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What is EPA's authority for taking this action?*

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(l)(6), EPA is establishing time-limited tolerances for residues of flupyradifurone, including its metabolites and degradates, 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, 2028.

#### *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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2025-1973 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*]**.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/oa/eab/eab-alj\\_upload.nsf](https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf).

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 at <https://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. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

## **II. Background and Statutory Findings**

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 related to FIFRA section 18 time-limited tolerances to set binding precedents for the application of FFDCCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCCA 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).

FFDCCA Section 408(b)(2)(A)(i) 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 FFDCCA 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 FFDCCA 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 and FFDCCA Tolerances**

The Louisiana Department of Agriculture and Forestry (LDAF) utilized a crisis exemption under FIFRA for the use of flupyradifurone to control West Indian canefly, sugarcane aphid, and yellow sugarcane aphid. The applicant asserts that an emergency pest situation exists

due to simultaneous widespread infestations of hemipteran insects such as cane flies and aphids. According to LDAF, there is a lack of available insecticides to control these pests that can fit with integrated pest management in sugarcane. Without an effective control, Louisiana sugarcane growers affected by uncontrolled cane flies and aphids face significant economic yield losses.

After having reviewed the crisis exemption, EPA concurred on the crisis exemption and determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of flupyradifurone in or on sugarcane, cane and sugarcane, molasses. In doing so, EPA considered the safety standard in FFDC section 408(b)(2), and EPA decided that the necessary tolerances under FFDC 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 these tolerances without notice and opportunity for public comment as provided in FFDC section 408(l)(6). Although these time-limited tolerances expire on December 31, 2028, under FFDC section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerances remaining in or on sugarcane, cane and sugarcane, molasses 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 the time-limited tolerances earlier if any experience with, scientific data on, or other relevant information about this pesticide indicates 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 these time-limited tolerance decisions serve as a basis for registration of flupyradifurone by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Louisiana to use this pesticide on sugarcane 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 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 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 the use proposed by 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. EPA's assessment of exposures and risks associated with establishing these time-limited tolerances follows. 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) and the identified toxicological endpoints (Unit III) as part of this rulemaking.

EPA's most recent exposure assessment for flupyradifurone appears in the comprehensive risk assessment dated April 6, 2023, titled: "*Flupyradifurone. Human Health Risk Assessment for the Proposed Use on Indoor and Outdoor Non-Food Uses*," as that assessment included dietary and aggregate exposures to flupyradifurone in or on multiple agricultural and non-agricultural commodities, including for flupyradifurone on sugarcane in Louisiana submitted in 2021 (sugarcane, cane at 3 ppm and sugarcane, molasses at 90 ppm).

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, and no risk estimates of concern were identified. Further information about EPA's risk assessment and determination of safety supporting these tolerances can be found at <http://www.regulations.gov> in the document titled "*Flupyradifurone. Human Health Risk Assessment for the Proposed Use on Indoor and Outdoor Non-Food Uses*," dated April 6, 2023, and identified by docket ID EPA-HQ-OPP-2022-0444.

In the 2023 assessment, EPA conducted unrefined acute and partially 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 for some commodities (chronic), Health Effects Division default and empirical processing factors, and 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. That is, less than 100% of the acute population adjusted dose (aPAD) or less than 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 (i.e., food and drinking water) risk estimates utilized 27% of the aPAD for the general U.S. population and 55% of the aPAD for children 1-2 years old, the most highly exposed population subgroup. The chronic dietary (i.e., food and drinking water) risk estimates utilized 30% of the cPAD for the general U.S. population and 70% of the cPAD for children 1-2 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. No acute or long-term (chronic) residential exposures are expected, therefore acute and chronic aggregate risks are equivalent to acute and chronic dietary exposure estimates, respectively. Since the dermal and incidental oral point of departures are the same for both short- and intermediate-term durations, the short-term aggregate risk estimates are considered protective of any potential intermediate-term exposures and risks. Aggregate short-term residential exposure to adults (residential handlers) and children (residential post-application exposures) plus background (chronic) dietary exposure yields margins of exposure (MOEs) of 270 for adults, 180 for children (1 to <2 years old), and 210 for children (6 to <11 years old); no aggregate risk estimates are 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 general U.S. 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 titled "*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-2025-1973.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement methodology (Method RV-001-P10-03) is available to enforce the tolerance expression for flupyradifurone. This method uses high-performance liquid chromatography with tandem mass spectrometry to quantitate residues of flupyradifurone in various crops. This method may be requested from the 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*.

### *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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. There are no Codex 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, 2028.

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

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes a time-limited tolerance or an exemption from the requirement of 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. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

*B. Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCa section 408 are exempted from review under Executive Order 12866.

*C. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

*D. Regulatory Flexibility Act (RFA)*

Since tolerance actions that are established in accordance with FFDCa sections 408(e) and 408(1)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the RFA, 5 U.S.C. 601 *et seq.*, do not apply.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit IV.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

*J. National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 4, 2025.

**Charles Smith,**

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

For the reasons set forth in the preamble, 40 CFR chapter I is amended 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, add paragraph (b) to read as follows:

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

\* \* \* \* \*

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

**Table 2 to Paragraph (b)**

<b>Commodity</b>	<b>Parts per million</b>	<b>Expiration date</b>
Sugarcane, cane	3	12/31/2028
Sugarcane, molasses	90	12/31/2028

\* \* \* \* \*

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