



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0337; FRL-9459-01-OCSP]

Fluridone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide fluridone including its degradates and metabolites in or on peanut and peanut, hay. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on peanut. This regulation establishes a maximum permissible level for residues of fluridone in or on these commodities. The time-limited tolerances expire on December 31, 2024.

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-2021-0337, is available at <https://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 and OPP

docket is (202) 566-1744.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and 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 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 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

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-2021-0337 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-2021-0337, by one of the following methods:

- *Federal eRulemaking Portal:* <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.

- *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 <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets, is available at <https://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(l)(6), is establishing time-limited tolerances for residues of fluridone, in or on peanut at 0.1 parts per million (ppm) and peanut, hay at 0.1 ppm. These time-limited tolerances expire on December 31, 2024.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or 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. 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 Fluridone on Peanut and Peanut, hay and FFDCA Tolerances

The Arkansas and Missouri Departments of Agriculture submitted specific emergency exemptions for the use of fluridone on peanut to control Palmer amaranth, *Amaranthus palmeri*, populations in peanut fields where glyphosate-resistant Palmer amaranth biotypes are present. According to the States, peanut growers in Arkansas and Missouri are experiencing widespread multiple herbicide-resistant populations of Palmer amaranth. These States reported that an urgent and non-routine situation exists because a registered effective soil residual herbicide is currently unavailable to reduce the impact and prevent the expansion of this destructive weed species. Significant economic losses are expected for peanut growers due to yield and quality decreases without a suitable pesticide control.

After having reviewed the submission, EPA determined that an emergency condition exists for these States, and that the criteria for approval of these emergency exemptions have been met.

As part of its evaluation of these emergency exemption applications, EPA assessed the potential risks presented by residues of fluridone in or on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances 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 these emergency exemptions in order to address an urgent non-routine situation in these States 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 FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2024, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peanut 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 fluridone meets FIFRA's registration requirements for use on peanut 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 fluridone 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 States other than Arkansas and Missouri 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 exemptions for fluridone, 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 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 expected as a result of these emergency exemption requests and the time-limited tolerances for residues of fluridone on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing these time-limited tolerances follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considers in making its safety determination for the new rulemaking.

In the *Federal Register* of May 18, 2020 (85 FR 29633) (FRL-10007-09), EPA published a final rule that established tolerances for residues of fluridone in or on multiple commodities based on the Agency's determination that aggregate exposure to fluridone resulting from the residues subject to those tolerances is safe for the U.S. general population, including infants and children. EPA is incorporating sections from

that final rule as described further in this rulemaking, as they remain unchanged.

Toxicological profile. The toxicological profile for fluridone has not changed since the May 18, 2020, final rule was published; therefore, EPA is relying upon the discussion of that profile in Unit III. A. as part of this rulemaking.

Toxicological points of departure/Levels of concern. The toxicological points of departure and levels of concern for fluridone have not changed since the May 18, 2020, final rule was published; therefore, EPA is relying upon the discussion in Unit III. B. as part of this rulemaking.

Exposure assessment. Much of the exposure assessment for fluridone remains unchanged from the discussion in Unit III. C. of the May 18, 2020, final rule, except that EPA considered the additional dietary exposure from the time-limited tolerances established by this action. Specifically, EPA conducted acute and chronic dietary exposure assessments to determine if the emergency use on peanut increases the dietary exposure to fluridone. Updated acute and chronic Dietary Exposure Evaluation Model (DEEM) runs were conducted with peanut included at a 0.1 ppm residue level. These results compared to the most recent dietary assessment supporting the May 18, 2020, final rule showed no exposure changes to two significant figures. Therefore, the previous assessment is protective of dietary exposure potential from the emergency use of fluridone on peanut.

Safety factor for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that determination are articulated in Unit III. D. of the May 18, 2020, final rule.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates

to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

The results of the acute and chronic analyses for fluridone do not exceed the Agency's level of concern (LOC). That is, all risk estimates were <100% of the aPAD or <100 of the cPAD and are not of concern for the general U.S. population and all population subgroups. The acute dietary exposure from food and water will occupy 2.3% of the aPAD for all infants (1-year old), the population with the highest estimated risk. Chronic exposure to fluridone from food and water will utilize 7% of the cPAD for children aged 1 to 2, the population with the highest estimated risk.

The short-term aggregate exposure assessment for fluridone is based on food and drinking water as well as residential uses. For short-term aggregate risk assessment, potential residential exposures (dermal, inhalation, and incidental ingestion from swimming in treated waters for children; dermal and inhalation from applications via pouring into recreational ponds for adults) were combined with background dietary exposures. The combined short-term food, water, and residential exposures result in aggregate MOEs for of 1,300 for adults and 1,600 for children, which are greater than the LOC of 100. Because EPA's level of concern for fluridone is an MOE of 100 or below, these MOEs are not of concern. Fluridone is not registered for any use patterns that would result in intermediate-term residential exposure.

Further, since there is no evidence of carcinogenicity in the toxicological database for fluridone, EPA concluded that fluridone is not carcinogenic and is classified as "not likely" to be a human carcinogen.

Therefore, based on the risk assessments and information described above, EPA concludes that there is reasonable certainty that no harm will result to the U.S. general

population, or to infants and children from aggregate exposure to fluridone residues. More detailed information on the subject action to establish time-limited tolerances in or on peanut and peanut, hay can be found at <https://www.regulations.gov> in the document entitled, “Fluridone: ID# 21AR03 Section 18 Specific Exemption for Use on Peanut in Arkansas.” This document can be found in docket ID number EPA-HQ-OPP-2021-0337.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (high performance liquid chromatography (HPLC) method (originally submitted as method AM-AA-CA-RO52-AA-755)) is available to enforce the tolerance expression.

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 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 Codex has not established a MRL for fluridone.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of fluridone, in or on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. These tolerances expire on December 31, 2024.

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). 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 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 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, or 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: February 17, 2022.

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. Amend §180.420, by adding paragraph (b) to read as follows:

§ 180.420 Fluridone; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the specified agricultural commodities in the table, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the following table is to be determined by measuring only fluridone, (1-methyl-3-phenyl-5-[3-trifluoromethyl] phenyl)-4(1H)-pyridinone). The tolerances expire on the date specified in table 3.

Table 3 to paragraph (b)

Commodity	Parts per million	Expiration date
Peanut	0.1	12/31/2024
Peanut, hay	0.1	12/31/2024

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