



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0003; FRL-12872-01-OCSP]

Cyclobutrifluram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance action for residues of cyclobutrifluram in or on the food and feed commodities of cotton, gin byproducts; cotton, undelinted seed; lettuce, leaf; soybean, seed. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Syngenta submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodities.

DATES: This rule is effective on [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.D. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0003, 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, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-2427; email address: 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 might apply 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 proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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. . .”

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2022-0003 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.

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 of which the 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. Petitioned For Tolerance

In the *Federal Register* of May 20, 2022 (87 FR 30855) (FRL-9410–13–OCSPP), 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 1F8954) by Syngenta, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide/nematicide cyclobutrifluram, in or on cotton at 0.010 parts per million (ppm); cotton, by-products at 0.010 ppm; lettuce, romaine at 0.015 ppm; and soybean at 0.010 ppm. That document referenced a summary of the petition that was prepared by the petitioner and included in the docket. There were no comments received in response to the notice of filing.

III. Final Tolerance Action

A. Aggregate Risk Assessment and Determination of Safety

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

B. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Cyclobutrifluram is a novel pyridine-3-carboxamide nematocide/fungicide with a pesticidal mode of action that functions via inhibition of complex II succinate dehydrogenase, but the mammalian mode of action is not known at this time. Following the administration of cyclobutrifluram, the target organs include the liver (mouse) and thyroid (rat). In addition, decreased absolute body weight was observed in rats and dogs following subchronic administration of the test compound. No adverse effects were observed in the chronic/carcinogenicity toxicity study in rats and the carcinogenicity toxicity study in mice up to the highest doses tested (23/34 mg/kg/day (M/F) and 48/54 mg/kg/day (M/F), respectively).

The thyroid is the most sensitive endpoint in the cyclobutrifluram toxicity database. Following subchronic exposure of rats to cyclobutrifluram, follicular cell hypertrophy in males and females was observed after 28- (331 mg/kg/day) and 90-day (187 mg/kg/day) exposures. Increased thyroid weights were observed in males of the F1 generation while follicular cell hypertrophy was observed in both sexes of the P generation and males of the F1 generation of the multigeneration reproductive toxicity study at 43 mg/kg/day. Maternal thyroid hormones levels (T3, T4, and TSH) were measured in the developmental rat toxicity study up to and including the highest dose tested (250 mg/kg/day) and no adverse changes were observed.

Treatment-related effects to the liver and spleen (increased reticulocytes along with increased spleen weights and extramedullary hematopoiesis) were observed in mice following 28-day (338/334 mg/kg/day (M/F)) and 90-day (249/309 mg/kg/day (M/F)) exposures. Liver effects included liver hypertrophy, increased liver weights, increased triglycerides, and increased liver enzymes (alkaline phosphatase (ALP) and alanine transferase (ALT)) as a suite of effects. Cecum effects (increased inflammatory cell infiltration of the lamia propria) were observed in rats at 331/485 mg/kg/day (M/F) following 28-day oral exposure. Lung effects (alveolar duct wall thickening, increased alveolar macrophages, and bronchioles/alveolar wall smooth muscle

cell hypertrophy) were observed following inhalation exposure for 28 days at 0.08 mg/L.

Following chronic oral exposure of rats and mice to cyclobutrifluram, no adverse effects were observed up to the highest doses tested (23/31 mg/kg/day). Also, no dermal toxicity following 28-day exposure was identified up to and including the limit dose in the route specific study.

No quantitative or qualitative lifestage susceptibility was observed in either the developmental or reproductive toxicity studies up to the highest doses tested. Thyroid toxicity to the parental animals in both the P and F1 generations occurred at the same dose level (43/55 mg/kg/day (M/F)) as reproductive toxicity (decreased fertility in both sexes of the F1 generation). In the dose range-finding and definitive development studies for both the rat and rabbit, neither maternal toxicity nor developmental toxicity was detected up to and including the highest doses tested (250 mg/kg/day (rat) and 125 mg/kg/day (rabbit)).

The Agency concluded that the data for the rat and rabbit developmental toxicity studies are considered adequate, and there was no evidence of neurotoxicity.

Cyclobutrifluram is classified as “Not Likely to Be Carcinogenic to Humans.” Cyclobutrifluram exposure did not result in treatment-related tumors in rats or mice, and there were not biologically or statistically significant changes in pre-neoplastic lesions. While both sexes of rats and mice could have tolerated higher doses, the dosing was considered adequate to assess the carcinogenic potential of cyclobutrifluram. There is an extensive database that investigated mutagenicity following exposure to cyclobutrifluram or its metabolites. Within this battery of genotoxicity testing, cyclobutrifluram and its metabolites were negative, demonstrating a low concern for mutagenic potential.

Specific information on the studies received and the nature of the adverse effects caused by cyclobutrifluram as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document Cyclobutrifluram. Human Health Risk Assessment to Support the Registration of a New Active Ingredient for Proposed Uses on Cotton Seed; Soybean

Seed; Romaine Lettuce; Turf; Ornamentals; and Non-bearing (Juvenile) Fruit and Nut Trees, Vines, and Berries (Cyclobutrifluram Human Health Risk Assessment) in docket ID number EPA-HQ-OPP-2022-0003.

C. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints and PODs for Cyclobutrifluram used for human risk assessment can be found in the Cyclobutrifluram Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2022-0003.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyclobutrifluram, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from cyclobutrifluram in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyclobutirfluram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID), Version 4.02, which incorporates 2005-2010 consumption data from United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance equivalent-level residues (cyclobutirfluram and the metabolite SYN510275), 100% crop treated assumptions, and default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyclobutirfluram does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyclobutirfluram. Tolerance level residues and/or 100% PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyclobutirfluram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyclobutirfluram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>.

Based on the Pesticide Root Zone Model (PRZM5 version 5.02), the Variable Volume Water Body Model (VVWM version 1.02), and Pesticide Root Zone Model Ground Water

(PRZM GW version 1.0), the estimated drinking water concentrations (EDWCs) of cyclobutrifluram for acute exposures are estimated to be 14.3 parts per billion (ppb) for surface water and 108.1 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 7.96 ppb for surface water and 94.0 ppb for ground water. For chronic dietary risk assessment, the water concentration value of 94.0 ppb was used to assess the contribution to drinking water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cyclobutrifluram is proposed for registration for the following uses that could result in residential exposures: lawns and turf. EPA assessed the following residential exposure scenarios: Short term residential post-application exposure in children 1 to less than 2 years old (1<2) from incidental oral exposures on treated turf. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyclobutrifluram and any other substances. For the purposes of this action, therefore, EPA has not assumed that cyclobutrifluram has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>.

E. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased qualitative or quantitative susceptibility was seen in the rat and rabbit developmental toxicity studies up to the highest doses tested or in the multigeneration reproduction toxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for cyclobutirfluram is complete.
- ii. There is no indication that cyclobutirfluram is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that cyclobutirfluram results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The Agency used high-end assumptions in the dietary exposure assessment, including the use of tolerance-

level or average field trial residues, 100% crop treated assumptions, and upper-bound (protective) estimates of potential exposure through drinking water. In addition, the residential post-application exposure assessment was conducted using chemical-specific turf transferrable residues (TTR) data and the Agency's 2012 Residential Standard Operating Procedures (SOPs). The exposure estimates for cyclobutrifluram are unlikely to be underestimated.

F. 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 PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyclobutrifluram is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyclobutrifluram from food and water will utilize 1.9% of the cPAD for infants less than 1 year old (<1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyclobutrifluram is not expected.

3. *Short-and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyclobutrifluram is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyclobutrifluram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposure MOEs of 1600 for children 1-2 years old. Because EPA's level of concern for cyclobutrifluram is an MOE below 30, these MOEs are not of concern.

Because no intermediate-term residential exposure is expected, an intermediate-term aggregate assessment was not conducted.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyclobutrifluram is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyclobutrifluram residues. More detailed information on this action can be found in the Cyclobutrifluram Human Health Risk Assessment in docket ID EPA-HQ-OPP-2022-0003.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expressions.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United

States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for cyclobutirfluram.

C. Effective and Expiration Date(s)

In general, a tolerance action is effective on the date of publication of the final rule in the Federal Register. For actions in the final rule that lower or revoke existing tolerances, EPA will set an expiration date for the existing tolerance of six months after the date of publication of the final rule in the Federal Register, in order to allow a reasonable interval for producers in exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

D. Revisions to Petitioned-For Tolerances

The petitioner-requested commodity definitions for cotton (cotton, undelinted seed, and cotton, gin byproducts), lettuce, romaine (lettuce, leaf), and soybean (soybean, seed) were updated to Agency-preferred vocabulary (in parentheses, above) for consistency across chemicals. In addition, the Agency is establishing the tolerances at higher levels than the petitioner requested for cotton, undelinted seed (from 0.010 ppm to 0.02 ppm), cotton, gin byproducts (from 0.010 ppm to 0.02 ppm), lettuce, leaf (from 0.015 ppm to 0.06 ppm), and soybean, seed (from 0.010 ppm to 0.03 ppm) as the recommended residues for tolerance enforcement were parent cyclobutirfluram and metabolite SYN510275 calculated as parent equivalent. The applicant calculated the proposed tolerances using the Organization for Economic Cooperation and Development (OECD) MRL calculation procedures with parent only as the residue for tolerance enforcement.

V. Conclusion

Therefore, tolerances are established for residues of cyclobutrifluram, in or on cotton, gin byproducts at 0.02 ppm, cotton, undelinted seed at 0.02 ppm, lettuce, leaf at 0.06 ppm, and soybean, seed at 0.03 ppm.

VI. 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 or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

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 on the basis of a petition under FFDCA section 408(d), 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 to this action.

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.

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: November 3, 2025.

Edward Messina,

Director, 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. Add § 180.729 to subpart C to read as follows:

§ 180.729 Cyclobutrifluram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nematocide/fungicide cyclobutrifluram, including its metabolites and degradates, in or on the plant commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 is to be determined by measuring the sum of cyclobutrifluram (*rel-N*-[(1*R*,2*R*)-2-(2,4-dichlorophenyl)cyclobutyl]-2-(trifluoromethyl)-3-pyridinecarboxamide) and its metabolite 2-trifluoromethyl-nicotinamide, calculated as the stoichiometric equivalent of cyclobutrifluram in or on plant commodities.

Table 1 to Paragraph (a)

Commodity	Parts per million
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Lettuce, leaf	0.06
Soybean, seed	0.03

(b) [Reserved]