



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0509; FRL-13127-01-OCSP]

Afidopyropen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the current tolerance for residues of the insecticide afidopyropen in or on the food and feed commodities of raw agricultural commodity of strawberry by increasing it from 0.15 parts per million (ppm) to 0.3 ppm and removes the established time-limited tolerance in or on strawberry at 0.3 ppm. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), BASF Corporation submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodity.

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-2024-0509, is available online 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 Avenue, NW., Washington, DC 20460-0001; telephone number: (202) 566-1030;

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 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 FFDCFA 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 the docket ID number EPA-HQ-OPP-2024-0509 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 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. Petitioned for Tolerance

In the *Federal Register* of December 9, 2024 (89 FR 97577) (FRL-11682-10-OCSP), 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 4F9153) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528. The pesticide petition requested that 40 CFR § 180.700 be amended by increasing the current tolerance for residues of the insecticide afidopyropen in or on the raw agricultural commodity of strawberry at 0.15 ppm to 0.3 ppm. That document referenced a summary of the petition that was prepared by the petitioner and has been 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 afidopyropen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with afidopyropen is summarized in this unit.

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 for 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 considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for afidopyropen in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to afidopyropen and established tolerances for residues of the chemical. Most recently, in the *Federal Register* of July 23, 2025 (90 FR 34602) (FRL-12842-01-OCSPP). As a result, EPA is not incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

B. Toxicological Profile

For a detailed discussion of the toxicological profile of afidopyropen, see Section A.2. of the document entitled “Afidopyropen. Human Health Risk Assessment for the Petition for Amendment of Tolerances in/on Field Grown Strawberries.”, dated January 29, 2026, in docket ID EPA-HQ-OPP-2024-0509 at <https://www.regulations.gov>.

C. Toxicological Points of Departure/Levels of Concern

All points of departure (POD), toxicity endpoints, and levels of concern (LOC) for afidopyropen remain unchanged from the previous human health risk assessment in support of the use of afidopyropen on leaf lettuce grown in greenhouses, dated June 24, 2025. In addition, the hazard characterization also remains unchanged. For a summary of the toxicological points of departure/levels of concern for afidopyropen used for human health risk assessment, see Tables 4.5.4.1 and 4.5.4.2. of the document entitled “Afidopyropen. Human Health Risk Assessment for the Petition for Amendment of Tolerances in/on Field Grown Strawberries.”, dated January 29, 2026, in docket ID EPA-HQ-OPP-2024-0509 at <https://www.regulations.gov>.

D. Exposure Assessment

An aggregate dietary (food + drinking water) exposure and risk assessment was

previously conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America. An unrefined acute dietary assessment was conducted in support of the use of afidopyropen on leaf lettuce grown in greenhouses and included the current proposed tolerance of 0.3 ppm for strawberry. The assessment was based on tolerance-level residues and the recommended tolerance for leaf lettuce, 100% crop treated (PCT) assumptions, and default and empirical processing factors. At the 95th percentile of exposure, the estimated risk is 4.2% of the acute population-adjusted dose (aPAD) for females 13-49 years old. Since an acute toxicological endpoint was only identified for the population subgroup females 13-49, an acute dietary exposure assessment was not conducted for any of the other population subgroups. In addition, an unrefined chronic dietary assessment was conducted in support of use of afidopyropen on leaf lettuce grown in greenhouses and included the current proposed tolerance of 0.3 ppm for strawberry. The assessment was based on tolerance-level residues and the recommended tolerance for leaf lettuce, 100 PCT assumptions, and default and empirical processing factors. The estimated risk is 2.7% of the chronic population-adjusted dose (cPAD) for the general U.S. population and the population subgroup with the highest estimated risk is children 1-2 years old at 6.3% of the cPAD.

Drinking water and non-occupational exposures. Strawberry is not a significant feed commodity, and the most recent EDWCs remain unchanged from the most recent risk assessment conducted in support of the use of afidopyropen on leaf lettuce grown in greenhouses, which accounted for afidopyropen residue levels in/on strawberry at 0.3 ppm. As such, these EDWCs remain current and protective of the proposed amended use on field-grown strawberries.

The proposed amended tolerance is not expected to result in residential exposure; therefore, a residential assessment was not conducted. There are existing residential ornamental

uses that were assessed previously and were not found to be of concern. The residential risk estimates for use in the aggregate assessment for afidopyropen remain unchanged from the most recent risk assessment conducted in support of the use of afidopyropen on leaf lettuce grown in greenhouses, which can be found in docket ID EPA-HQ-OPP-2024-0020 at <https://www.regulations.gov>.

Cumulative exposure. 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 afidopyropen and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that afidopyropen has a common mechanism of toxicity with other substances. Afidopyropen and another pesticide, aminocyclopyrachlor, both produce the common toxic metabolite cyclopropanecarboxylic acid (CPCA). Drinking water is the only expected exposure pathway for CPCA for either pesticide. The likelihood of having ground water residues of both afidopyropen and aminocyclopyrachlor at the EDWC predicted in the screening ground water modeling in the same location is miniscule for the following reasons: ground water modeling assumes application of a chemical at the maximum rate, and the maximum number of applications, every year for up to 100 years, and because lateral flow of chemicals away from the application site is relatively slow, both chemicals would have to be applied in approximately the same location every year at the maximum application rates and maximum numbers of applications for each, for the exposures to be additive. This is not a feasible scenario.

E. Safety Factor for Infants and Children

FFDCA section 408(b)(2)(C) 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 Food Quality Protection Act (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.

EPA has determined that reliable data support the reduction of the Food Quality Protection Act (FQPA) safety factor for afidopyropen from 10X to 1X for all exposure scenarios since the toxicology database is complete and exposure analyses are unlikely to underestimate risk of exposure from afidopyropen. Although there is evidence of increased fetal and offspring susceptibility, the effects are well-characterized with clearly established no-observed-adverse-effect level (NOAEL) values and selected endpoints that are protective for the observed effects.

F. Aggregate risks and determination of safety

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (*e.g.*, a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. The acute and chronic aggregate risk assessments include food and drinking water only. There are no acute or chronic aggregate risk estimates of concern for afidopyropen or CPCA. The short-term aggregate risk assessment applies only to residues of afidopyropen and combines residential exposures (contacting previously treated ornamentals) and average dietary (food and drinking water) exposures. The short-term aggregate assessment results in MOEs of 1,900 for adults and 2,100 for children (LOC = 100). There are no short-term aggregate risk estimates of concern for afidopyropen. CPCA is not a residue of concern for residential exposures.

Afidopyropen is classified as “*Suggestive Evidence of Carcinogenic Potential.*”

Quantification of risk using a non-linear approach (*i.e.*, a cPAD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to afidopyropen. As a result, a quantitative cancer dietary assessment was not performed.

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 afidopyropen residues. More detailed information on this action can be found in the document entitled “Afidopyropen. Human Health Risk Assessment for the Petition for Amendment of Tolerances in/on Field Grown Strawberries”, dated January 29, 2026, in docket ID EPA-HQ-OPP-2024-0509 at <https://www.regulations.gov>.

IV. Other Considerations

A. Analytical Enforcement Methodology

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

Residues of afidopyropen can be measured in samples of strawberry using liquid chromatography-tandem mass spectrometry (LC/MS/MS), BASF Method No. D1103/01. This quick, easy, cheap, effective, rugged, and safe (QuEChERS)-based method was previously deemed acceptable for tolerance enforcement. The limit of quantitation (LOQ; determined as the lowest level of method validation) for afidopyropen is 0.01 ppm. Acceptable method validation and concurrent recoveries within the range of 70-120% were obtained from samples of strawberry fruit fortified with afidopyropen at 0.010-1 ppm, thus the method.

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 recommended tolerance for afidopyropen residues in/on strawberry were obtained using the Organization for Economic Co-operation and Development (OECD) maximum residue limit (MRL) calculation procedures. The recommended strawberry tolerance would change the harmonization status with Codex since Codex currently has an MRL for strawberry at the U.S. existing tolerance level of 0.15 ppm.

There are no Canadian MRLs established for residues of afidopyropen in/on strawberry.

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.

V. Conclusion

Therefore, the existing strawberry tolerance established under 40 CFR §180.700 will be increased from 0.15 ppm to 0.3 ppm. EPA will also remove the existing time-limited tolerance established for residues of afidopyropen in or on strawberry at 0.3 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. 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 III.E.I.

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: February 10, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth 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 § 180.700 amend paragraph (a) in table 1 by revising the entry for “Strawberry” to read as follows:

§ 180.700 Afidopyropen; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * *	*
Strawberry	0.3
* * * * *	*

* * * * *

§ 180.700 [Amended]

3. Amend § 180.700 by removing and reserving paragraph (b).