environment. This rule involves a safety zone lasting only one and a half (1.5) hours that will prohibit entry within a 450-yard radius of the barge at position 47.6399305556, −122.6943722222 being used by the fireworks display company. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T13–0649 to read as follows:

§ 165.T13–0649 Safety Zone, Dyes Inlet, Washington.

(a) *Location.* The following area is a safety zone: All waters within a 450-yard radius of 47.6399305556, −122.6943722222 in Dyes Inlet, Washington.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, no person or vessel may enter or remain in the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF Ch 13 or Ch 16, or Coast Guard Sector Puget Sound Joint Harbor Operations Center (JHOC) via telephone at (206) 217–6002. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from 9:30 p.m. through 11 p.m. on July 25, 2025.

Dated: July 17, 2025.

Michael J. Hunt,

Captain, U.S. Coast Guard, Captain of the Port Sector Puget Sound.

[FR Doc. 2025–13816 Filed 7–22–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2024–0077; FRL–12348–03–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (24–2.5e); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA is making a correction to a final rule that appeared in the **Federal Register** of June 23, 2025 (FR Doc. 2025–11489). The final rule established significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and Orders issued by EPA pursuant to TSCA.

DATES: The final rule correction is effective on August 22, 2025.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPPT–2024–0077, is available online at *https://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC). Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: *wysong.william@epa.gov.*

SUPPLEMENTARY INFORMATION: This action corrects a regulatory amendment established in the final rule that appears in the **Federal Register** of June 23, 2025 (90 FR 26437 (FRL–12348–02–OCSPP)). The amendment to the table in 40 CFR part 9 is removed because EPA subsequently issued a separate amendment to 40 CFR part 9 that makes this change obsolete and unnecessary. See FR Doc. 2025–11573 (90 FR 27785, June 30, 2025 (FRL–12001–01–OCSPP)).

The Agency is not providing a public comment opportunity prior to promulgation of this technical correction, because such public comment is unnecessary under 5 U.S.C. 553(b)(B) of the Administrative Procedure Act (APA). The correction established in this action is very minor and non-substantive and would not alter the regulations established in the final rule. Therefore, pursuant to the APA section 553(b)(B), EPA finds good cause to promulgate this technical correction without notice and comment.

Corrections

In FR Doc. 2025–11489 appearing at 90 FR 26437 in the **Federal Register** of Monday, June 23, 2025 (FRL–12348–02–OCSPP), the following correction is made to the regulatory text:

PART 9—[Corrected]

■ 1. On page 26440, in the third column, amendatory instructions 1 and 2 for 40 CFR part 9 and their accompanying regulatory text are removed.

Dated: July 21, 2025.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2025–13834 Filed 7–22–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0200; FRL–12842–01–OCSPP]

Afidopyropen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide afidopyropen in or on lettuce, leaf. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Interregional Research Project #4 (IR–4) 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 July 23, 2025. Objections and requests for hearings must be received on or before

September 22, 2025 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0200, 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 (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 305–7090; 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 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–2024–0200 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 September 22, 2025.

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 August 27, 2024 (89 FR 68571 (FRL–11682–07–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 4E9104) by the Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.700 be amended by establishing tolerances for the residues of the insecticide afidopyropen, including its metabolites and degradates, in or on lettuce, leaf at 7 parts per million (ppm) and leafy greens subgroup 4–16A, except lettuce, leaf at 2 ppm. Compliance with the tolerance levels specified is to be determined by measuring only afidopyropen, [(3*S*,4*R*,4a*R*,6*S*,6a*S*,12*R*,12a*S*,12b*S*)-3-[(cyclopropylcarbonyl)oxy]-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(3-pyridinyl)-2*H*,11*H*-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl cyclopropanecarboxylate. The petition also requested, upon the approval of the requested tolerances, the removal of the established tolerance for residues of afidopyropen, including its metabolites and degradates, in or on leafy greens subgroup 4–16A at 2.0 ppm.

The notice of filing document referenced a summary of the petition that was prepared by the petitioner and included in the docket. One comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Final Tolerance Action

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(1)(A)(i), EPA is establishing tolerances that vary from what the petitioner proposed. The reason for this change is explained in Unit IV.D.

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.

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.

The toxicity database for afidopyropen is complete. The liver is a main target organ in both subchronic and chronic oral toxicity studies in all three species tested (mouse, rat, and dog). Other target organs identified following exposure to afidopyropen are the heart, brain, spleen, and reproductive organs of both sexes. No evidence of neurotoxicity was seen in the subchronic neurotoxicity (SCN) study in rats. Afidopyropen caused potential neurotoxic effects in the acute neurotoxicity (ACN) study; however, effects only occurred at the limit dose (2000 mg/kg/day), which is not relevant for quantitative risk assessment. There is evidence of increased susceptibility following pre- and/or post-natal exposure to afidopyropen. In a prenatal developmental study in rats, adverse effects in fetuses occurred at a lower dose than maternal toxicity. In a developmental study in rabbits, fetal developmental and maternal effects occurred at the same dose level. Quantitative susceptibility was also observed in two 2-generation reproduction toxicity rat studies. In the first study, no reproductive or parental effects were observed up to the highest dose tested (HDT), while adverse offspring effects occurred at the HDT. In the second study, the parental and reproductive effects occurred at the HDT while offspring effects occurred at a lower dose level. Afidopyropen did not display adverse effects in the 28-day dermal study or in the immunotoxicity study.

Afidopyropen is classified as ''*Suggestive Evidence of Carcinogenic Potential*'' based on benign hepatocellular adenomas in male rats and uterine adenocarcinomas and combined adenocarcinomas and/or adenomas in female rats. There is no mutagenic concern for afidopyropen. Quantification of risk using a non-linear approach (*i.e.,* a chronic reference dose) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to afidopyropen. Specific information on the studies received and the nature of the adverse effects caused by afidopyropen 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 in the document entitled ''Afidopyropen. Human Health Risk Assessment for the Section 3 Request for New Use on Greenhouse Grown Lettuce'' available in docket for this rulemaking.

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/pesticides/factsheets/riskassess.html*.

An acute dietary endpoint for the general population was not identified because effects of concern for this population group were not observed in the database. For females 13–49 years old, an acute reference dose (aRfD) of 0.16 mg/kg/day was derived from the rabbit prenatal developmental toxicity based on increased early resorptions per litter (the statistical unit for early resorptions in developmental toxicity) at the maternal and developmental LOAEL of 32 mg/kg/day (maternal and developmental NOAEL = 16 mg/kg/day). Because of the unknown etiology of this effect, the effect is allocated to both the maternal and developmental life stages. This study was considered appropriate for acute dietary endpoint selection for females of reproductive age. An uncertainty factor of 100X (10X to account for interspecies extrapolation and 10X for intraspecies variation) was applied to derive the aRfD. The Food Quality Protection Act Safety Factor (FQPA SF) was reduced to 1X, therefore the aRfD is equal to the acute Population Adjusted Dose (aPAD).

For the general population, including females 13–49 years old, a chronic reference dose (cRfD) of 0.08 mg/kg/day (NOAEL = 8 mg/kg/day) was selected from two studies considered to be co-critical: (1) the chronic dog study (LOAEL = 20 mg/kg/day) based on hyaline droplet deposition in hepatocytes and vacuolation of the white matter and neuropil of the cerebrum of male dogs; and (2) the 2-generation reproduction study in rats (offspring LOAEL = 41 mg/kg/day) based on decreased absolute body weight and decreased spleen and thymus weights in the offspring. An uncertainty factor of 100X (10X to account for interspecies extrapolation and 10X for intraspecies variation) was applied to derive the cRfD. The FQPA SF was reduced to 1X, therefore, the cRfD is equal to the chronic Population Adjusted Dose (cPAD). This is the lowest NOAEL in the database and is protective of all other observed chronic effects in the mouse carcinogenicity, the chronic carcinogenicity study in rats, and the 1-year rat study.

A chronic dietary endpoint was also established for the afidopyropen metabolite cyclopropanecarboxylic acid (CPCA), which is a residue of concern for dietary risk assessment (food and water are the only pathways of exposure for this metabolite). The POD was selected from a CPCA-specific subchronic toxicity study in rats in which adverse effects included clinical chemistry changes and microscopic findings in the liver, thymus, heart, and pancreas. An uncertainty factor of 1000X (10X to account for interspecies extrapolation, 10X for intraspecies variation, and a 10X FQPA SF) is applied to the chronic dietary POD. The 10X FQPA SF was retained to account

for a subchronic-to-chronic duration extrapolation and the lack of data to assess developmental and reproductive CPCA toxicity.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to afidopyropen, EPA considered exposure under the petitioned-for tolerances as well as all existing afidopyropen tolerances in 40 CFR 180.700. An updated dietary assessment was conducted for afidopyropen to account for the proposed new use on greenhouse-grown lettuce. CPCA is only a residue of concern in livestock and drinking water. Since lettuce is not a contributor to livestock dietary burdens and a greenhouse use will not change the estimated drinking water concentrations (EDWCs), the previously conducted dietary assessment of CPCA, discussed in Unit III of the final rule published in the **Federal Register** of October 8, 2020 (85 FR 63453 (FRL–10003–93–OCSPP), remains current and has not been updated. EPA assessed dietary exposures from afidopyropen 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. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The acute dietary assessment for afidopyropen was conducted using recommended tolerance-level residues and 100% crop treated (PCT) assumptions. Empirical and default processing factors were also used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used DEEM–FCID™, Version 4.02, which incorporates 2005–2010 consumption data from the USDA's NHANES/WWEIA. The chronic dietary assessment for afidopyropen was conducted using recommended tolerance-level residues and 100 PCT assumptions. Empirical and default processing factors were also used.

iii. *Cancer.* 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; the chronic aggregate assessment did not result in estimates of concern. Therefore, a separate cancer assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for afidopyropen. Tolerance level residues and/or 100% CT 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 afidopyropen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of afidopyropen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/oppefed1/models/water/index.htm.*

Previous EDWCs were used in the dietary risk assessment as greenhouse uses are not expected to affect drinking water exposures. Concentrations for both afidopyropen and its degradate CPCA were estimated in the 2017 Drinking Water Assessment, which was discussed in Unit III. of the final rule published in the **Federal Register** of October 8, 2020 (85 FR 63453 (FRL–10003–93–OCSPP)).

For acute dietary risk assessment for afidopyropen, the EDWC value of 7.0 ppb was used to assess the contribution to drinking water. For chronic and cancer dietary risk assessment for afidopyropen, the EDWC value of 3.9 ppb was used to assess the contribution to drinking water. These EDWCs are based on an annual application rate of 0.33 lb a.i./A and a Percent Cropped Area (PCA) of 100%. An acute dietary risk assessment was not conducted for CPCA since an acute dietary endpoint was not identified. For the chronic dietary assessment for CPCA, an EDWC value of 35 ppb was used to assess the contribution to drinking water.

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). Afidopyropen is registered for use on residential ornamentals. EPA has assumed that there will not be residential handler exposure based on a presumption that label language requiring the use of specific clothing or personal protective equipment indicates that the pesticide will be marketed for commercial use and not applied by residential handlers. There is a potential for the registered uses to result in post-application dermal exposure to afidopyropen, due to activities in treated gardens. EPA aggregated the worst-case risk estimates from post-application exposures (*i.e.,* dermal exposures to adults and children (6 to <11 years old) from activities in treated gardens) in its aggregate assessment. CPCA is not a residue of concern for residential exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* FFDCA section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''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.

E. Safety Factor for Infants and Children

1. *In general.* 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 FQPA 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. *Conclusion for afidopyropen.* 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 for all afidopyropen exposure scenarios. That decision is based on the following findings:

i. The toxicology database for afidopyropen is considered complete for evaluating and characterizing toxicity, assessing children's susceptibility under FQPA, and selecting endpoints for the exposure pathways of concern.

ii. Acute oral (gavage) and sub-chronic oral (dietary) neurotoxicity studies were conducted in rats with effects seen only in the acute study at the limit dose. In subchronic studies with mice and dogs, indications of neurotoxicity were limited to vacuolation of white matter and/or spinal cord, which may have been an artifact of not preparing the tissues properly. Further, the nervous tissue vacuolation was observed at doses 7.5x–115x higher than the POD for the chronic dietary risk assessment. Thus, the potential effects are well-characterized with clearly established NOAEL/LOAEL values and the selected PODs are protective for the observed effects.

Based on the weight of the evidence and taking into consideration the PODs selected for risk assessment, a developmental neurotoxicity study is not required at this time. Clear NOAELs have been established for all life stages, the selected PODs are protective of all pre- and/or post-natal toxicity observed throughout the toxicology database, and no specific neuropathological effects were noted. A DNT with rat (the typical test species) would not be expected to contribute meaningfully to the database, as the rat is expected to be less sensitive than dogs and mice.

iii. There is evidence of increased susceptibility following pre- and/or post-natal exposure to afidopyropen. Clear NOAELs have been established for the developmental effects in rats and rabbits as well as the offspring effects in the 2-generation reproduction studies. The NOAELs chosen for all selected endpoints are protective of all developmental and offspring effects seen in the database.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment is based on high-end assumptions such as tolerance-equivalent residue levels of the parent compound and CPCA in foods, 100 PCT, default processing factors, and modeled, high-end estimates of residues in drinking water. All the exposure estimates are based on high-end assumptions and are not likely to underestimate risk. In addition, the residential exposure assessment was conducted based on the Residential SOPs such that residential exposure and risk will not 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. For the acute dietary assessment for afidopyropen, the estimated risk is 4.2% of the aPAD for females 13–49 years old (the only population subgroup for which an acute endpoint was identified), at the 95th percentile of exposure, and is below the level of concern (<100% of the aPAD). The acute aggregate risk estimates for afidopyropen include food and drinking water only and are equivalent to the acute dietary risk estimates, which are below HED's level of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, the estimated chronic dietary exposure risks from food and water for afidopyropen are below the LOC (<100% of the cPAD) for the US general population and all population subgroups. EPA has concluded that chronic exposure from food and water will utilize 6.3% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. The proposed use is for applications to lettuce grown in greenhouses and is not anticipated to result in residential exposure on a chronic basis. Therefore, the chronic aggregate risk estimates are equivalent to the chronic dietary risk estimates and are below the LOC.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). In estimating the short-term aggregate risk, EPA has aggregated the total short-term residential exposure and average dietary (food + drinking water) exposure. 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.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term exposure is anticipated, afidopyropen is not expected to pose an intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* As indicated in Unit III.A., afidopyropen is classified as having ''suggestive evidence of carcinogenicity in humans.'' Quantification of risk using a non-linear approach (*e.g.,* a cPAD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to afidopyropen; the chronic aggregate assessment did not result in risk estimates of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that 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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Suitable tolerance enforcement methods for plants and livestock using liquid chromatography-mass spectrometer/mass spectrometer (LC–MS/MS) analyses are available for the analysis of afidopyropen. In addition, a separate acceptable enforcement method (using LC–MS/MS) has been submitted and reviewed for determining afidopyropen and cyclopropanecarboxylic acid (CPCA-carnitine) in livestock commodities. The Quick Easy Cheap Effective Rugged Safe (QuEChERS) multi-residue method D1514/01 is considered suitable for the analysis of afidopyropen in plant and livestock commodities. However, this multi-residue method is not suitable for determination of CPCA-carnitine in livestock commodities.

Analytical standards for afidopyropen and CPCA-carnitine are currently available in the EPA National Pesticide Standards Repository. Supplies of analytical standards will be replenished to the repository at the following address: USEPA National Pesticide Standards Repository/Analytical Chemistry Branch, 701 Mapes Road, Fort George G. 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 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 established a MRL for afidopyropen in or on lettuce, leaf at 2 ppm.

The greenhouse-grown lettuce data supporting this petition show that residues from the domestic use of afidopyropen may exceed the Codex MRL of 2 ppm on lettuce, leaf. Therefore, the Agency is establishing a tolerance of 7 ppm for greenhouse lettuce, leaf based on the proposed use pattern and supporting data.

C. Response to Comments

One comment was received in response to the notice of filing for the IR–4 petition (PP4E9104). The commenter offers that the ''correct pesticide tolerance is zero.'' Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that this afidopyropen tolerance is safe. The commenter provided no information to indicate that afidopyropen is not safe.

D. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance for residues of afidopyropen in or on lettuce, leaf at 7 ppm as requested by the petitioner. However, the petitioner initially requested an amendment to the established leafy greens subgroup 4–16A tolerance at 2.0 ppm, to be revised to ''leafy greens subgroup 4–16A, except lettuce, leaf at 2 ppm'', upon establishment of the lettuce, leaf tolerance at 7 ppm. EPA will not amend the leafy greens subgroup 4–16A to state ''except lettuce, leaf''. Establishing an individual tolerance for residues of afidopyropen on lettuce, leaf at 7 ppm, and maintaining the established leafy greens subgroup 4–16A tolerance at 2.0 ppm covers the permitted uses and is supported by the submitted and available data.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide afidopyropen, [(3*S*,4*R*,4a*R*,6*S*,6a*S*,12*R*,12a*S*,12b*S*)-3-[(cyclopropylcarbonyl)oxy]-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(3-pyridinyl)-2*H*,11*H*-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl cyclopropanecarboxylate, including its metabolites and degradates, in or on lettuce, leaf at 7 ppm.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/regulations/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. 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: July 17, 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. Amend § 180.700 by adding in alphabetical order an entry for ''lettuce, leaf'' to the table in paragraph(a)(1) to read as follows:

§ 180.700 Afidopyropen; tolerances for residues.

(a)(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Lettuce, leaf	7
* * * * *	

* * * * *

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