Authority: 42 U.S.C. 7401 *et seq.*

Subpart SS—Texas

■ 2. Section 81.344 is amended in the table for ''Texas—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Dallas-Fort Worth, TX'', ''Houston-Galveston-Brazoria, TX'', and ''San Antonio, TX'' to read as follows:

§ 81.344 Identification of plan.

* * * * *

TEXAS—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Dallas-Fort Worth, TX		Nonattainment	July 22, 2024	Serious.
Collin County.				
Dallas County.				
Denton County.				
Ellis County.				
Johnson County.				
Kaufman County.				
Parker County.				
Tarrant County.				
Wise County.				
* * *	*	*	*	*
Houston-Galveston-Brazoria, TX		Nonattainment	July 22, 2024	Serious.
Brazoria County.				
Chambers County.				
Fort Bend County.				
Galveston County.				
Harris County.				
Montgomery County.				
San Antonio, TX	9/24/2018	Nonattainment	July 22, 2024	Serious.
Bexar County.				
* * *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

[FR Doc. 2024–13193 Filed 6–18–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0223; FRL–12024–01–OCSPP]

Afidopyropen; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of afidopyropen, including its metabolites and degradates, in or on strawberry. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on field-grown strawberry. This regulation establishes a maximum permissible level for residues of afidopyropen in or on strawberry. The time-limited tolerance expires on December 31, 2027.

DATES: This regulation is effective June 20, 2024. Objections and requests for hearings must be received on or before August 19, 2024 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0223, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket Public Reading Room is (202) 566–1744. Please review the visitor instructions and additional information about the docket 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; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Federal Register Office's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2024–0223 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 August 19, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2024–0223, by one of the following methods:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of afidopyropen, including its metabolites and degradates, in or on strawberry at 0.3 parts per million (ppm). This time-limited tolerance expires on December 31, 2027.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Afidopyropen on Strawberry and FFDCA Tolerance

The California Department of Pesticide Regulation (CDPR) has requested a specific emergency exemption for use of afidopyropen in field-grown strawberry to control lygus bugs (Western Tarnished Plant Bugs). The applicant asserts that significant losses have occurred due to unprecedented infestations of lygus bugs in California strawberry, and an urgent and nonroutine situation is occurring. The applicant cites various factors leading to the current situation, including lack of commercially and environmentally viable alternative controls due to restrictions for using neonicotinoid pesticides, and ongoing resistance development to pyrethroid pesticides. Additionally, extreme wet conditions over the last several years have contributed to higher levels of weeds in nearby areas, hosting high populations of lygus bugs which then migrate to the neighboring strawberry fields. Despite the use of available controls, the applicant states that lygus bugs have not been adequately controlled and strawberry growers are facing significant economic losses without an effective control, such as the requested afidopyropen.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of afidopyropen on field-grown strawberry for control of lygus bug in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of afidopyropen in or on strawberry. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2027, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on strawberry after that

date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke the time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether afidopyropen meets FIFRA's registration requirements for use on field grown strawberry or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of afidopyropen by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than California to use this pesticide on field-grown strawberries under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for afidopyropen, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of the use proposed by this emergency exemption request and the time-limited tolerance for residues of afidopyropen on strawberry at 0.3 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. 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 for afidopyropen, and its metabolite of concern, cyclopropane carboxylic acid (CPCA), used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of October 8, 2020 (85 FR 63453) (FRL–10003–93). The CPCA metabolite is included as a residue of concern for ruminant commodities and drinking water.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Separate dietary exposure assessments were conducted for afidopyropen (acute and chronic) and the afidopyropen metabolite CPCA (chronic only) as the toxicological endpoints are different for these compounds. In evaluating dietary exposure to afidopyropen, EPA considered exposure under the time-limited tolerance established by this action as well as all existing afidopyropen tolerances in 40 CFR 180.700. EPA assessed dietary exposures from afidopyropen in food as follows:

i. *Acute exposure.* In estimating acute dietary exposure (for afidopyropen only), EPA used food consumption information from the Dietary Exposure Evaluation Model–Food Commodity Intake Database (DEEM–FCID™, Version 4.02), which incorporates 2005–2010 consumption data from the United States 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 tolerance-level residues and 100% crop treated (PCT) assumptions. Empirical and default processing factors were also used. An acute dietary exposure assessment was not conducted for CPCA since an acute dietary endpoint was not identified.

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

iii. *Cancer.* EPA has classified afidopyropen as ''*Suggestive Evidence of Carcinogenic Potential.*'' A cancer classification for CPCA has not been determined; however, a structural-activity relationship analysis indicated no structural alerts for genotoxicity or carcinogenicity. There were no reports of a tumorigenic response in the open literature. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the

data referenced in Unit IV.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk from afidopyropen. 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 assessments 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 nor PCT information in the dietary assessment for afidopyropen and CPCA. Tolerance level residues and 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 and CPCA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of afidopyropen and CPCA. 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#aquatic.*

Because of the difference in structure and mode of action, EPA calculated separate estimated drinking water concentrations (EDWCs) for afidopyropen and CPCA. Afidopyropen degrades in soil and water to form a wide range of structurally similar transformation products. All degradates, except CPCA, are included as residues of concern in the afidopyropen total toxic residues (TTR) analysis.

The highest modeled EDWCs for afidopyropen and for CPCA used in the dietary risk assessments were entered directly into the latest version of the Pesticides in Water Calculator (PWC 1.52). EDWCs were calculated for both surface water and groundwater based on the maximum annual application rate (0.33 lb a.i./A). For afidopyropen, the highest EDWCs were for surface water. The surface water EDWCs used to assess contribution to dietary exposure and risks from drinking water were 7.1 ppb for the acute assessment and 3.9 ppb for the chronic and cancer assessments. For CPCA, an acute dietary risk assessment was not conducted since an acute dietary endpoint was not identified. For chronic dietary risk assessment, the highest EDWC for CPCA, that for groundwater of 35 ppb, was used for assessing the contribution to chronic dietary exposure through drinking water. These 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).

Afidopyropen is registered for use on residential ornamentals. Residential handler exposure is not expected because the pesticide is intended for commercial use and is not labelled for application by residential handlers. There is a potential for the registered and proposed 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.

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 consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found afidopyropen or CPCA to share a common mechanism of toxicity with any other substances. Afidopyropen and another pesticide, aminocyclopyrachlor, both produce the toxic metabolite CPCA. Drinking water is the only expected exposure pathway for CPCA from both pesticides, and co-exposures to CPCA from both pesticides are unlikely to occur based on their use patterns. For the purposes of this tolerance action, therefore, EPA has concluded that it is not appropriate to conduct a cumulative exposure assessment. 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/cumulative-assessment-risk-pesticides.*

C. 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Conclusion for afidopyropen.* EPA has determined that reliable data show that 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 toxicity 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 subchronic 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 assessments were performed based on high-end assumptions such as 100% CT and tolerance-level residues, 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 assessments for post-application exposures were conducted based on the Residential SOPs such that residential exposure and risk will not be underestimated. These assessments will not underestimate the exposure and risks posed by afidopyropen.

3. *Conclusion for CPCA.* No developmental or reproductive toxicity studies are available for CPCA to assess pre- and/or post-natal toxicity. EPA is therefore retaining the default FQPA safety factor of 10X to account for a subchronic to chronic duration extrapolation and the lack of data to assess developmental and reproductive toxicity of CPCA.

D. 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. Separate dietary assessments were conducted for afidopyropen and its CPCA metabolite, as the toxicological endpoints are different for these compounds.

1. *Acute risk.* The acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. An acute endpoint for afidopyropen was identified for females 13–49 years old. However, for all other population subgroups, including the overall U.S Population, no adverse effects for afidopyropen resulting from a single oral exposure was identified, no acute dietary endpoints were selected, and acute dietary exposure assessments were not conducted for these populations. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to afidopyropen will occupy 3.7% 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 (LOC) (<100% of the aPAD). An acute dietary endpoint was not identified for CPCA; therefore, the Agency does not expect acute risk from exposure to CPCA.

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 and for CPCA are below the LOC (<100% of the cPAD) for the US general population and all population subgroups. For afidopyropen, EPA has concluded that chronic exposure from food and water will utilize 6.4% of the cPAD for Children 1–2 years old, the population group receiving the greatest exposure, and 2.6% of the cPAD for the general U.S. population. For CPCA, EPA has concluded that chronic exposure from food and water will utilize 31% of the cPAD for Children 1–2 years old, the population group receiving the greatest exposure, and 11% of the cPAD for the general U.S population. Residential exposures to afidopyropen and CPCA are not expected to occur 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). Afidopyropen 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 afidopyropen.

The short-term aggregate exposure assessment applies only to afidopyropen since residential exposure to CPCA is not expected. The short-term aggregate exposure assessment combines residential exposures for adults and children (6 to <11 years old) contacting previously treated ornamentals) and average dietary (food + drinking water) exposures. EPA has concluded that the combined short-term aggregate exposures result in short term aggregate MOEs of 1,900 for adults and 2,100 for children. Because EPA's LOC for short term aggregate MOEs is 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effects were identified, afidopyropen and CPCA are not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* As indicated in unit IV, 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, and the chronic aggregate assessment did not result in risk estimates of concern. A cancer classification for CPCA has not been determined; however, a structural-activity relationship analysis indicated no structural alerts for genotoxicity or carcinogenicity. There were no reports of a tumorigenic response in the open literature.

6. *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 afidopyropen and CPCA residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available for plants and livestock using liquid chromatography/mass spectrometer/mass spectrometer (LC–MS/MS) analyses for analysis for afidopyropen. 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 but is not suitable for determination of CPCA in livestock commodities. However, an acceptable enforcement method (using LC–MS/MS) has been submitted for determining CPCA-carnetine in livestock commodities.

The analytical methods and standards for afidopyropen (expiration 11/1/2024) and CPCA-carnitine (expiration 04/01/2032) are currently available in the

USEPA National Pesticide Standards Repository and may be obtained by contacting: Analytical Chemistry Branch/OPP, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by 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 an MRL for residues of afidopyropen in/on strawberry that harmonizes with the permanent U.S. tolerance established to support use in greenhouse-grown strawberry, both at 0.15 ppm. However, the time-limited tolerance established by this action of 0.3 ppm afidopyropen in/on strawberry is not harmonized with the Codex MRL. Based on available residue data, use by U.S. growers consistent with the approved emergency exemption use directions could result in residues that exceed the Codex MRL. Harmonizing with the Codex MRL could put U.S. growers at risk of violative residues despite legal use of afidopyropen. Moreover, EPA's regulations require adequate time-limited tolerances be in place in order to allow a pesticide use on food under an emergency exemption. A time-limited tolerance harmonized with the Codex MRL would not be adequate to cover residues resulting from the emergency exemption use in field-grown strawberry. Since EPA has determined that this time-limited tolerance is safe, EPA is establishing this time-limited tolerance despite the lack of harmonization with the related Codex MRL.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of afidopyropen, in or on strawberry at 0.3 ppm. This tolerance expires on December 31, 2027.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 12, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

For the reasons stated in the preamble, EPA amends 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, add paragraph (b) to read as follows:

§ 180.700 Afidopyropen; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of afidopyropen, including its metabolites and degradates, in or on the commodities in table 3 to this paragraph (b). Compliance with the tolerance levels specified in this paragraph (b) is to be determined by measuring only afidopyropen, [(3*S,4R,*4a*R,*6*S,*6a*S,*12*R,*12a*S,*12b*S*)-3-[(cyclopropylcarbonyl)oxy]-1,3,4,4a,5,6a,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, in or on the

specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the dates specified in table 3 to this paragraph (b).

TABLE 3 TO PARAGRAPH (b)

Commodity	Parts per million	Expiration date
Strawberry	0.3	12/31/2027

* * * * *

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