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 (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 (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: August 25, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the 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 § 180.614 add paragraph (b) to read as follows:

§ 180.614 Kasugamycin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of kasugamycin, including metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified is to be determined by measuring only kasugamycin (3-O-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetradeoxy-α-D-arabino-hexopyranosyl]-D-chiro-inositol) in or on the commodity. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Almond	0.04	December 31, 2023.
Almond, hulls ..	0.4	December 31, 2023.

* * * * *

[FR Doc. 2020–19761 Filed 10–7–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0416 and EPA–HQ–OPP–2019–0101; FRL–10003–93]

Afidopyropen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide afidopyropen, including its metabolites and degradates, in or on multiple food and animal commodities identified and discussed later in this document. BASF Corporation and the Interregional Research Project #4 requested these tolerances under section 346a of the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 8, 2020. Objections and requests for hearings must be received on or before December 7, 2020, 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 dockets for this action, identified by docket identification (ID) numbers EPA–HQ–OPP–2016–0416 and EPA–HQ–OPP–2019–0101, are available at *http://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 Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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. 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 numbers EPA–HQ–OPP–2016–0416 and EPA–HQ–OPP–2019–0101 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 December 7, 2020. 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 numbers EPA–HQ–OPP–2016–0416 and EPA–HQ–OPP–2019–0101, by one of the following methods:

- *Federal eRulemaking Portal: http://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 Avenue NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of May 9, 2019 (84 FR 20320) (FRL–9992–36), 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 8E8732) by the Interregional Research Project #4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. This petition requested that 40 CFR 180.700 be amended by establishing permanent tolerances 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 Strawberry at 0.15 parts per million (ppm) and Vegetable, fruiting, group 8–10 at 0.30 ppm. This petition also requested the removal of the existing tolerance for Vegetable, fruiting, group 8–10 upon establishment of the new group 8–10 tolerance. This document referenced a summary of the petition prepared by the IR–4, which is available in docket ID EPA–HQ–OPP–2019–0101, which can be found at *http://www.regulations.gov.* Comments were received on this notice of filing related to the IR–4 petition (8E8732). EPA's response to these comments is discussed in Unit IV.C.

In addition, in the **Federal Register** of February 11, 2020 (85 FR 7708) (FRL–10005–02), EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8734) by BASF Corporation (BASF), 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. This petition requested that 40 CFR 180.700 be amended by establishing permanent tolerances 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 Alfalfa, seed at 0.30 ppm; Almond, hulls at 0.30 ppm; Animal feed, nongrass, group 18, forage at 4.0 ppm; Animal feed, nongrass, group 18, hay at 9.0 ppm; Animal feed, nongrass, group 18, straw at 5.0 ppm; Cattle, meat at 0.25 ppm; Cattle, meat byproducts at 0.15 ppm; Egg at 0.02 ppm; Goat, meat at 0.25 ppm; Goat, meat byproducts at 0.15 ppm; Grain, aspirated fractions at 20 ppm; Grass, forage, fodder and hay, group 17 at 10.0 ppm; Hog, meat at 0.02 ppm; Hog, meat byproducts at 0.06 ppm; Horse, meat at 0.25 ppm; Horse, meat byproducts at 0.15 ppm; Milk at 0.04 ppm; Poultry, meat byproducts at 0.02 ppm; Sheep, meat at 0.25 ppm; Sheep, meat byproducts at 0.15 ppm; Sorghum, grain, forage at 0.30 ppm; Sorghum, grain, grain at 0.20 ppm; Sorghum, grain, stover at 0.30 ppm; Sorghum, sweet, grain at 0.20 ppm; Sorghum, sweet, forage at 0.30 ppm; Sorghum, sweet, stalk at 0.30 ppm; Sorghum, sweet, stover at 0.30 ppm; Soybean, forage at 0.15 ppm; and Soybean, hay at 0.40 ppm. This document referenced a summary of the petition prepared by BASF, which is available in docket ID EPA–HQ–OPP–2016–0416 at *http://www.regulations.gov.* There were no substantive comments received in response to the notice of filing related to the BASF petition (PP 9F8734).

Based upon review of the data supporting these petitions and in accordance with its authority under FFDCA section 408(d)(1)(A)(i), EPA is establishing tolerances that vary from what the petitioners sought. The reasons for these changes are explained in detail in Unit IV.D.

III. 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has enough 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 follows.

A. Toxicological Profile for Afidopyropen and Its Metabolite, Cyclopropane Carboxylic Acid (CPCA)

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.

Applications of afidopyropen result in pesticide chemical residues of concern in or on food of both the parent compound afidopyropen and its metabolite cyclopropane carboxylic acid (CPCA). Because the parent and degradate have different toxicities, EPA assessed aggregate exposure from afidopyropen and from CPCA separately as part of the effort to evaluate the safety of afidopyropen tolerances. Detailed information on the studies received and the nature of the adverse effects caused by afidopyropen and CPCA can be found in the following documents: (1) ''Afidopyropen. Human Health Risk Assessment for Section 3 Requests for a New Active Ingredient,'' dated April 4, 2018; (2) ''Afidopyropen. Human Health Risk Assessment for the Section 3 Request for New Use on Animal Feed, Nongrass (Crop Group 18); Grass, forage, fodder and Hay (Crop Group 17); and Sorghum, and a Request for Increased Application to Tree Nuts,'' dated December 9, 2019; and (3) ''Afidopyropen. Human Health Risk Assessment for Section 3 Request for Greenhouse Use on Cucumber, Strawberry and Vegetable, Fruiting (Group 8–10),'' dated October 30, 2019, by going to *http://www.regulations.gov.* The first two listed documents are available in docket ID EPA–HQ–OPP–2016–0416. The third listed document is available in docket ID EPA–HQ–OPP–2019–0101.

B. 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 (LOC) 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 *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological doses and endpoints selected for use in the human health risk assessment for afidopyropen and CPCA is shown in Tables 1 and 2 of this Unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AFIDOPYROPEN FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (General population).	An endpoint was not identified because effects of concern for this population were not observed in the toxicology database.		
Acute Dietary (Females 13–49 years old).	NOAEL = 16 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.16 mg/kg/day. aPAD = 0.16 mg/kg/day	Rabbit Prenatal Developmental Study: Maternal and developmental LOAEL = 32 mg/kg/day, based on increased early resorptions per litter.
Chronic Dietary (All populations including females 13–49 years old).	NOAEL = 8 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.08 mg/kg/day. cPAD = 0.08 mg/kg/day	2 Co-critical Studies: 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. 2-Generation Rat Reproduction Study: Offspring LOAEL = 41 mg/kg/day, based on decreased absolute body weight, and decreased spleen and thymus weights of male rats.
Dermal, Short-term (1–30 days)	NOAEL = 8 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100 Dermal absorption = 15%.	2-Generation Rat Reproduction Study: Offspring LOAEL = 41 mg/kg/day, based on decreased absolute body weight, and decreased spleen and thymus weights of male rats.
Cancer (Oral, Dermal, Inhalation).	Classification: ''*Suggestive Evidence of Carcinogenic Potential.*'' The chronic RfD will be protective of potential carcinogenicity.		

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CPCA FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary	An endpoint was not identified because effects of concern for this population were not observed in the toxicology database.		

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CPCA FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic Dietary	NOAEL = 10 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 10x	Chronic RfD = 0.1 mg/kg/day. cPAD = 0.01 mg/kg/day	Subchronic Rat Study: LOAEL = 30 mg/kg/day, based on clinical chemistry alterations, as well as microscopic findings in the liver, thymus heart, and pancreas.
Cancer (Oral, Dermal, Inhalation).	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.		

Tables 1 and 2 abbreviations: Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. 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) as the toxicological endpoints are different for these compounds. In evaluating dietary exposure to afidopyropen and the metabolite CPCA, EPA considered exposure under the petitioned-for tolerances and existing tolerances as described below.

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 (food + drinking water) exposure for afidopyropen, EPA used food consumption information from the Dietary Exposure Evaluation Model–Food Commodity Intake Database (DEEM–FCID™, Version 3.16), which incorporates 2003–2008 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 recommended 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 assessment, EPA used DEEM–FCID™, Version 3.16, which incorporates 2003–2008 consumption data from the USDA's NHANES/WWEIA. The chronic dietary assessments for afidopyropen and CPCA were conducted using recommended tolerance-level residues and 100 PCT assumptions. Empirical and default processing factors were also used.

iii. *Cancer.* 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 and/or CPCA; 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 any anticipated residue or PCT information in the dietary assessment for afidopyropen or CPCA. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for afidopyropen and CPCA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of afidopyropen and/or CPCA.

Afidopyropen and/or CPCA may be transported to surface water and groundwater via runoff, leaching, or spray drift. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling, taking into account data on the physical and fate characteristics of afidopyropen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

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. Due to differences in both structure and mode of action, CPCA is not included in the TTR analysis for afidopyropen, and EDWCs were calculated for CPCA separately.

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) and a Percent Cropped Area (PCA) of 1.0 that are listed on current afidopyropen labels. For afidopyropen in surface water, the highest EDWC for the acute assessment is 7.1 ppb and for the chronic assessment is 3.9 ppb; for CPCA, the highest EDWCs are 3.6 ppb for acute assessment and 2.7 ppb for chronic assessment. For afidopyropen in groundwater, the highest EDWCs are negligible for acute assessment and not expected for chronic assessment; for CPCA, the highest EDWCs are 54 ppb for acute assessment and 35 for chronic assessment.

For acute dietary risk assessment for afidopyropen, the EDWC value of 7.1 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. An acute dietary risk assessment was not conducted for CPCA since an acute dietary endpoint was not identified. Therefore, the only EDWC used for assessing the contribution to

drinking water for CPCA is 35 ppb for the chronic dietary risk assessment.

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 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.

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.''

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.

D. Safety Factor for Infants and Children

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

2. *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.

3. *Conclusion for CPCA.* EPA is 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 CPCA toxicity. No developmental or reproductive toxicity studies are available for CPCA to assess pre- and/or post-natal toxicity.

E. 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 CPCA as the toxicological endpoints are different for these compounds.

1. *Acute risk.* An acute endpoint for afidopyropen was not identified for the U.S. general population because acute effects of concern for this population subgroup were not observed in the toxicology database; therefore, an acute dietary exposure assessment was not conducted for these populations. An acute endpoint for afidopyropen was identified for females 13–49 year old, though. Using the exposure assumptions discussed in this Unit for acute exposure, the estimated acute dietary exposure (food + drinking water) for afidopyropen is 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 LOC (<100% of the aPAD). An acute dietary endpoint is not identified for CPCA; therefore, the Agency does not expect acute risk from exposure to CPCA.

2. *Chronic risk.* Using the exposure assumptions discussed in this Unit for chronic exposure, the estimated chronic dietary (food + drinking water) risk for afidopyropen and for CPCA is below the LOC (<100% of the cPAD) for the U.S. general population and all population

subgroups. The most highly exposed population subgroup is for children 1–2 years old at 6.5% of the cPAD. The estimated chronic dietary (food + drinking water) risk for CPCA is below the LOC (<100% of the cPAD) for the U.S. general population and all subgroups. The most highly exposed population subgroup is children 1–2 years old at 30% of the cPAD. Residential exposures to afidopyropen or CPCA is 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 considers 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 exposure assessment applies only to afidopyropen since residential exposure to CPCA is not expected. The short-term aggregate exposure assessment combines residential exposures (adults and children (6 to <11 years old contacting previously treated ornamentals) and average dietary (food + drinking water) exposures. The short-term aggregate MOEs for adults (1,900) and children (1,200) are above the LOC (<100) and are not 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 and CPCA are not expected to pose an intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* As indicated in Unit III.A., afidopyropen and/or CPCA 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/or CPCA; 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, including CPCA 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 new acceptable enforcement method (using LC–MS/MS) has been submitted for determining afidopyropen and CPCA 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 in livestock commodities.

Analytical standards for afidopyropen and CPCA are currently unavailable 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, 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). Codex has no established MRLs for afidopyropen.

C. Response to Comments

Three comments were received in response to the notice of filing for the IR–4 petition (PP 8E8732). Two comments opposed the proposed tolerances on strawberry and vegetable, fruiting, crop group 8–10 as being too high; the other comment was not related to the afidopyropen tolerances. The commenters who were concerned that the tolerances were too high incorrectly misread the petitioned-for tolerances as 15 ppm rather than 0.15 ppm and 20 ppm rather than 0.20 ppm. The Agency is not establishing tolerances at those higher levels. Regardless, the comments seek even lower tolerances values, essentially no residues of the pesticide on strawberries and fruiting vegetables. 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 these afidopyropen tolerances are safe. The commenters have provided no information to indicate that afidopyropen is not safe.

D. Revisions to Petitioned-For Tolerances

Several petitioned-for tolerance levels are different from those being established by EPA. Many of these differences are attributable to the petitioned-for levels not being consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice. The Sorghum, grain, grain and Sorghum, sweet, grain tolerance levels are lower than the petitioned-for level due to the differences in the number of significant figures used in the MRL calculation. EPA is establishing a higher tolerance for Grain, aspirated fractions based upon calculations using the highest average field trial (HAFT) from Sorghum, grain (0.10 ppm) and multiplying that figure by the calculated aspirated grains processing factor (PF) of 560x and then rounding up using OECD rounding class practice to the tolerance value of 60 ppm.

Tolerances being established for livestock commodities vary from the petitioned-for tolerances due to different models used in determining dietary burden and anticipated residues. The petitioner proposed tolerances using different models to determine dietary burden and scaled anticipated residues from the feeding study at different dose levels (transfer factor approach) to calculate a proposed tolerance. EPA has determined the appropriate tolerance value using the Dietary Burden Calculator PMRA v.2.8 to calculate dietary burden and Langmuir Model v.1.5 to determine tolerance level. The difference in dietary burden calculations for poultry and swine lead to EPA's conclusion that egg, poultry meat byproducts, and hog meat/meat byproducts had no reasonable expectation of finite residues, and that tolerances are not currently needed for these commodities.

A tolerance level of 0.30 ppm was proposed for Vegetable, fruiting, group 8–10 based on the OECD MRL calculator using the greenhouse pepper data,

although the petitioner pointed out that all residues in the greenhouse pepper study were below the current tolerance of 0.20 ppm for Vegetable, fruiting, group 8–10. Based on the submitted field trial data, residues of afidopyropen in greenhouse-grown commodities in the vegetable, fruiting, group 8–10 are not expected to exceed the current tolerance of 0.20 ppm. Further, maintaining the current tolerance level harmonizes with PMRA's proposed MRL of 0.2 ppm. Therefore, EPA is maintaining the tolerance at the current level of 0.20 ppm for Vegetable, fruiting, group 8–10 while revising the value to 0.2 ppm to be consistent with OECD rounding class practice.

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 Alfalfa, seed at 0.3 ppm; Almond, hulls at 0.3 ppm; Animal feed, nongrass, group 18, forage at 4 ppm; Animal feed, nongrass, group 18, hay at 9 ppm; Animal feed, nongrass, group 18, straw at 5 ppm; Cattle, meat at 0.2 ppm; Cattle, meat byproducts at 0.2 ppm; Goat, meat at 0.2 ppm; Goat, meat byproducts at 0.2 ppm; Grain, aspirated fractions at 60 ppm; Grass, forage, fodder and hay, group 17 at 10 ppm; Horse, meat at 0.2 ppm; Horse, meat byproducts at 0.2 ppm; Milk at 0.04 ppm; Sheep, meat at 0.2 ppm; Sheep, meat byproducts at 0.2 ppm; Sorghum, grain, forage at 0.3 ppm; Sorghum, grain, grain at 0.15 ppm; Sorghum, grain, stover at 0.3 ppm; Sorghum, sweet, grain at 0.15 ppm; Sorghum, sweet, forage at 0.3 ppm; Sorghum, sweet, stalk at 0.3 ppm; Sorghum, sweet, stover at 0.3 ppm; Soybean, forage at 0.15 ppm; Soybean, hay at 0.4 ppm; Strawberry at 0.15 ppm, and Vegetable, fruiting, group 8–10 at 0.2 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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, 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) or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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 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 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).

VII. 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: September 16, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 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:

■ a. Dedesignate paragraph (a) introductory text as paragraph (a)(1) and revise newly designated paragraph (a)(1) introductory text;

■ b. In the table in newly designated paragraph (a)(1):

■ i. Add a heading for the table;

■ ii. Add an entry for ''Alfalfa, seed'' in alphabetical order;

■ iii. Revise the entry for ''Almond, hulls;''

■ iv. Add entries for ''Animal feed, nongrass, group 18, forage,'' ''Animal feed, nongrass, group 18, hay,'' and ''Animal feed, nongrass, group 18, straw'' in alphabetical order;

■ v. Revise the entry for ''Grain, aspirated fractions;''

■ vi. Add entries for ''Grass, forage, fodder and hay, group 17,'' ''Sorghum, grain, forage,'' ''Sorghum, grain, grain,'' ''Sorghum, grain, stover,'' ''Sorghum, sweet, forage,'' ''Sorghum, sweet, grain,'' ''Sorghum, sweet, stalk,'' ''Sorghum, sweet, stover,'' ''Soybean, forage,'' ''Soybean, hay,'' and ''Strawberry'' in alphabetical order; and

■ vii. Revise the entry for ''Vegetable, fruiting, group 8–10;'' and

■ c. Add paragraph (a)(2).

The additions read as follows:

§ 180.700 Afidopyropen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of afidopyropen, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in this paragraph (a)(1) 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,5,6a,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 following food commodities:

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa, seed	0.3
Almond, hulls	0.3
Animal feed, nongrass, group 18, forage	4
Animal feed, nongrass, group 18, hay	9
Animal feed, nongrass, group 18, straw	5
* * * * * * *	
Grain, aspirated fractions	60
Grass, forage, fodder and hay, group 17	10
* * * * * * *	
Sorghum, grain, forage	0.3
Sorghum, grain, grain	0.15
Sorghum, grain, stover	0.3
Sorghum, sweet, forage	0.3
Sorghum, sweet, grain	0.15
Sorghum, sweet, stalk	0.3
Sorghum, sweet, stover	0.3
Soybean, forage	0.15
Soybean, hay	0.4
* * * * * * *	
Strawberry	0.15
* * * * * * *	
Vegetable, fruiting, group 8–10	0.2
* * * * * * *	

(2) Tolerances are established for residues of afidopyropen, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in this paragraph (a)(2) is to be determined by measuring only the sum of afidopyropen, [(3*S*,4*R*,4a*R*,6*S*,6a*S*,12*R*,12a*S*,12b*S*)-3-[(cyclopropylcarbonyl)oxy]-1,3,4,4a,5,6a,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 and its metabolite cyclopropanecarboxylic acid carnitine (CPCA-carnitine), calculated as the stoichiometric equivalent of afidopyropen in or on the following animal commodities:

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Goat, meat	0.2

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Goat, meat byproducts	0.2
Horse, meat	0.2
Horse, meat byproducts	0.2
Milk	0.04
Sheep, meat	0.2
Sheep, meat byproducts	0.2

* * * * *

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.200623–0167; RTID 0648–XA519]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer From NH to NC

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfer.

SUMMARY: NMFS announces that the State of New Hampshire is transferring a portion of its 2020 commercial bluefish quota to the State of North Carolina. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the