888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a temporary safety zone extending 150 yards around a bridge to complete emergency repairs to the S99 Alford Street Bridge during a seven-month period when boating traffic is minimal on the Mystic River. It is categorically excluded from further review under paragraph L60(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

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: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new § 165.T01–0343 to read as follows:

§ 165.T01–0343 Safety zone, S99 Alford Street Bridge—Emergency grid replacement project, Mystic River, Charlestown and Everett, MA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Mystic River between Charlestown and Everett, Massachusetts from surface to bottom, within 150-yards of the S99 Alford Street Bridge, at mile 1.4 on the Mystic River between Charlestown and Everett, Massachusetts.

(b) *Definitions.* As used in this section:

(1) Designated representative means any Coast Guard commissioned, warrant, petty officer, or any federal, state, or local law enforcement officer who has been designated by the Captain of the Port (COTP) Boston, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) Official patrol vessel means any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessel assigned or approved by the COTP Boston to enforce this section.

(c) *Enforcement Periods.* This section is enforceable 24 hours a day from 12:01 a.m. on October 1, 2018, through 11:59 p.m. on April 30, 2019. When enforced as deemed necessary by the COTP Boston, vessels will be prohibited from entering this safety zone during the emergency grid replacement on the bridge.

(d) *Regulations.* The general regulations contained in 33 CFR 165.23, as well as the following regulations, apply:

(1) No person or vessel may enter or remain in this safety zone without the permission of the COTP Boston or the COTP's designated representatives. However, any person or vessel permitted to enter the safety zone must comply with the directions and orders of the COTP Boston or the COTP's designated representatives.

(2) To obtain permission required by this regulation, individuals may reach the COTP Boston or a COTP designated representative via Channel 16 (VHF–FM) or 617–223–5757 (Sector Boston Command Center).

(3) *Penalties.* Those who violate this section are subject to the penalties set forth in 33 U.S.C. 1232.

Dated: September 6, 2018.

Eric J. Doucette,

Captain, U.S. Coast Guard, Captain of the Port Boston.

[FR Doc. 2018–19746 Filed 9–12–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0416; FRL–9976–65]

Afidopyropen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues 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,5,6,6a,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 multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 13, 2018. Objections and requests for hearings must be received on or before November 13, 2018, 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–2016–0416, is 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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, P.E., 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 Printing 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, 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–2016–0416 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 November 13, 2018. 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–2016–0416, 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 Tolerance

In the **Federal Register** of August 12, 2016 (81 FR 53380) (FRL–9949–53), 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 6F8468) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR part 180 be amended by establishing permanent tolerances in primary crops for residues of the insecticide afidopyropen, [(3*S,4R,*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, its metabolites, and degradates, in or on the following raw agricultural and processed commodities: Almond, hulls at 0.15 parts per million (ppm); Apple, wet pomace at 0.05 ppm; Citrus, oil at 0.3 ppm; Cotton, gin byproducts at 2 ppm; Cotton, undelinted seed at 0.1 ppm; Fruit, citrus, group 10–10 at 0.15 ppm; Fruit, pome, group 11–10 at 0.03 ppm; Fruit, stone, group 12–12 at 0.03 ppm; Nut, tree, group 14–12 at 0.01 ppm; Plum, prune at 0.06 ppm; Soybean, aspirated grain fractions at 0.4 ppm; Soybean, seed at 0.01 ppm; Vegetable, brassica, head and stem, group 5–13 at 0.5 ppm; Vegetable, cucurbit, group 9 at 0.7 ppm; Vegetable, fruiting, group 8–10 at 0.15 ppm; Vegetable, leaf petioles, subgroup 22B at 3 ppm; Vegetable, leafy, subgroup 4–13A at 2 ppm; Vegetable, leafy, subgroup 4–13B at 5 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and EPA policy, the Agency has revised some of the commodity definitions and tolerance levels from the petition, and concluded that the following tolerances are appropriate for afidopyropen in or on the following commodities: Almond, hulls at 0.15 ppm; Apple, wet pomace at 0.05 ppm; Brassica, head and stem, group 5–16 at 0.50 ppm; Brassica, leafy greens, subgroup 4–16B at 5.0 ppm; Citrus, oil at 0.40 ppm; Cotton, gin

byproducts at 2.0 ppm; Cotton, undelinted seed at 0.08 ppm; Fruit, citrus, group 10–10 at 0.15 ppm; Fruit, pome, group 11–10 at 0.02 ppm; Fruit, stone, group 12–12 at 0.03 ppm; Grain, aspirated fractions at 0.15 ppm; Leafy Greens, subgroup 4–16A at 2.0 ppm; Leaf petiole vegetable subgroup 22B at 3.0 ppm; Nut, tree, group 14–12 at 0.01 ppm; Soybean, seed at 0.01 ppm; Tomato, dried at 0.50 ppm; Vegetable, cucurbit, group 9 at 0.70 ppm; Vegetable, fruiting, group 8–10 at 0.20 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm. The reasons for these changes are explained 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 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 follows.

A. 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.

Afidopyropen is classified as category III for acute oral and acute dermal, and category IV for acute inhalation, primary eye irritation, and dermal irritation. The toxicology database for afidopyropen is complete. The target organs identified following exposure to afidopyropen are the liver, heart, brain, spleen, and reproductive organs of both sexes. The liver is a main target organ in both subchronic and chronic oral toxicity studies in all three-species tested (*i.e.,* mouse, rat, and dog).

There was no evidence of neurotoxicity seen in the subchronic neurotoxicity study in rats up to the highest dose tested. Afidopyropen caused neurotoxic effects in the acute neurotoxicity study; however, only at the limit dose of 2,000 milligrams/kilogram/day (mg/kg/day).

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 included an increased incidence of skeletal variations (lumbar ribs), increased ossification of the metatarsi, and an altered sex ratio (increased percentage of male pups); however, maternal effects were not observed up to the highest dose tested. In a second developmental study in rats, adverse fetal effects (increased incidence of skeletal variations and supernumerary ribs) occurred at a lower dose as compared to maternal effects (mortality in one animal). In a developmental study in rabbits, fetal developmental and maternal effects occurred at the same dose level. Effects included a decreased number of live fetuses, increased early resorptions and completely resorbed litters, as well as increased post-implantation loss. Fetuses also exhibited an altered sex ratio (increased percentage of male pups) at this dose level.

Quantitative susceptibility was also observed in two 2-generation rat studies. In the first study, no reproductive or parental effects were observed, while offspring effects were decreased absolute body weight in both sexes and F1 pup and litter deaths. In the second study, offspring effects included decreased absolute body weight and decreased spleen and thymus weights in both sexes. Reproductive effects included effects on ovary and uterus weight, decreased implantation sites, and an altered sex ratio (increased percentage of male pups). In this study, the parental and offspring effects occurred at the same dose level.

Afidopyropen did not display systemic effects in the 28-day dermal study, even at the limit dose of 1,000 mg/kg/day. There were no adverse effects observed in the route-specific dermal toxicity study up to the limit dose; however, there is evidence of increased susceptibility following pre- and/or post-natal exposure to afidopyropen. As a result, an oral point of departure was selected since the dermal toxicity study did not evaluate developmental or reproductive endpoints. A point of departure (POD) for dermal exposures (all durations) was selected from the 2-generation reproduction study in rats, this POD reflects the most sensitive endpoint in the database, and is protective of effects observed following subchronic exposure, including the fetal effects seen in the rat and rabbit developmental studies. This POD is also selected for inhalation exposures (all durations), and incidental oral and chronic dietary exposures. Chronic dietary was set using 2 co-critical studies (chronic dog study and 2-generation rat reproduction study). For acute dietary exposure, the POD is based on maternal and developmental effects (increased early resorptions of litters) observed in the rabbit developmental study and is applicable to females of childbearing age. An acute dietary POD was not identified for the general population because acute effects of concern for this population were not observed in the toxicology database.

In an immunotoxicity study in the rat, there were no adverse effects noted up to the highest dose tested.

Afidopyropen is classified as ''*Suggestive Evidence of Carcinogenic Potential*'' based on benign hepatocellular adenomas in male rats and uterine adenocarcinomas and combined adenocarcinomas and adenomas in female rats. There is insufficient evidence to support the petition's description of a uterine tumor mode-of action (MOA) in female rats. There is no concern for mutagenicity. Quantification of human cancer risk is not required. The chronic Reference Dose (RfD) will adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to afidopyropen.

More detailed 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 Section 3 Requests for a

New Active Ingredient,'' dated April 4, 2018, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and double-click on the hyperlink for the referenced document to view the referenced information on pages 16–23 of 112.

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 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 endpoints for afidopyropen used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AFIDOPYROPEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

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+)	NOAEL = 16 mg/kg/day $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	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+).	NOAEL = 8 mg/kg/day $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	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 to 30 days)	NOAEL = 8 mg/kg/day Dermal absorption = 15% $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	LOC for MOE = 100	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.
Inhalation (All durations)	A point of departure (POD) used for inhalation exposures (all durations) was selected from the 2-generation rat reproduction study, is the most sensitive endpoint in the database, and is protective of effects observed following subchronic exposure, including the fetal effects seen in the rat and rabbit developmental studies.		
Cancer (Oral, dermal, inhalation) ..	Classification: ''*Suggestive Evidence of Carcinogenic Potential*''.		

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.* In evaluating dietary exposure to afidopyropen, EPA considered exposure under the petitioned-for tolerances, and 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 (food and drinking water) exposure, 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 was conducted using recommended tolerance-level residues and 100% crop treated assumptions. Empirical and default processing factors were used. Screening-level estimated drinking water concentrations (EDWCs)

were incorporated as point estimates, based on surface water modeling. The acute EDWC (7.1 ppb) was modeled using the Florida cabbage scenario.

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 assessment was conducted using recommended tolerance-level residues and 100% crop treated assumptions. Empirical and default processing factors were used. Screening-level EDWCs were incorporated as point estimates, based on surface water modeling. The chronic EDWC (3.9 ppb) was modeled using the California lettuce scenario.

iii. *Cancer.* As explained in unit III.A., 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.

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. 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 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of afidopyropen.

Afidopyropen may be transported to surface water and groundwater via runoff, leaching, or spray drift. Afidopyropen is a new chemical; therefore, at this point, no monitoring data are available. 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.*

Based on the latest version of the Pesticides in Water Calculator (PWC 1.52) and incorporating the Pesticide Root Zone Model for Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of afidopyropen for acute exposures are estimated to be 7.1 parts per billion (ppb) for surface water, and 3.8×10^{-4} ppb for ground water. For chronic exposures for non-cancer assessments, the EDWCs are estimated to be 3.9 ppb for surface water and 1.1×10^{-4} ppb for ground water.

Modeled estimates for drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 7.1 ppb was used to assess the contribution to drinking water. For chronic and cancer dietary risk assessment, the water concentration value of 3.9 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). The proposed use of afidopyropen on ornamentals can be in residential or recreational settings. All afidopyropen product labels require users to wear specific clothing and PPE (*i.e.,* gloves), and are assumed to be marketed for commercial use; therefore, a quantitative residential handler assessment was not conducted.

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 to share a common mechanism of toxicity with any other substances. Afidopyropen and another pesticide, aminocyclopyrachlor, both produce the common toxic metabolite CPCA; however, co-exposure to CPCA from both pesticides are unlikely to occur. Drinking water is the only expected exposure pathway for CPCA for either pesticide. The likelihood of having ground water residues of both afidopyropen and aminocyclopyrachlor at the EDWC predicted in the screening ground water modeling in the same location is miniscule for the following reasons: Ground water modeling assumes application of a chemical at the maximum rate, and the maximum number of applications, every year for up to 100 years, and because lateral flow of chemicals away from the application site is relatively slow, both chemicals would have to be applied in approximately the same location every year at the maximum application rates, at maximum numbers of applications for each, for the exposures to be additive, and this is not a feasible scenario. For the purposes of this tolerance action; therefore, EPA has assumed that afidopyropen does not have a common mechanism of toxicity with other substances or cause a cumulative effect as a result of the common metabolite with aminocyclopyrachlor. 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 *http://www.epa.gov/pesticides/cumulative.*

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. *Pre-natal and post-natal sensitivity.* 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 included an increased incidence of lumbar ribs, increased ossification of the metatarsi, and an increased percentage of male pups; however, maternal effects were not observed up to the highest dose tested. In a second developmental study in rats, adverse fetal effects (increased incidence of skeletal variations and supernumerary ribs) occurred at a lower dose as compared to maternal effects (mortality in one animal). In a developmental study in rabbits, fetal developmental and maternal effects (increased early resorptions and completely resorbed litters) were observed.

Quantitative susceptibility was also observed in two 2-generation rat studies. In the first study, no reproductive or parental effects were observed, while offspring effects were decreased absolute body weight in both sexes and F1 pup and litter deaths. In the second study, offspring effects included decreased absolute body weight and decreased spleen and thymus weights in both sexes. Reproductive effects included effects on ovary and uterus

weight, decreased implantation sites, and an altered sex ratio (increased percentage of male pups). In this study, the parental and offspring effects occurred at the same dose level.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all 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. No evidence of specific neurotoxicity was seen in the subchronic neurotoxicity study up to the highest dose tested (369/438 mg/kg/day). Afidopyropen caused neurotoxic effects in the acute study; however, only at the limit dose.

Indications of neurotoxicity in mice and dogs were limited to vacuolation of white matter and/or spinal cord. The Agency has low concern because the nervous tissues in the mouse and dog studies were not perfused in-situ; therefore, the vacuolation that was observed is more likely an artifact of not preparing the tissues properly. The nervous tissue vacuolation seen in the subchronic dog and mice (subchronic and chronic) studies occurred at doses 7.5X–115X higher than the POD for the chronic dietary risk assessment. As a result, the effects are well-characterized with clearly established NOAEL/LOAEL values and the selected PODs are protective for the observed neurotoxic 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 lifestages, the selected PODs are protective of all pre- and post-natal toxicity observed throughout the database, and no specific neuropathological effects were noted. The adverse neuropathological effects observed in the subchronic mouse and dog and the chronic mouse studies occurred at doses 7.5X–115X higher than the lowest POD, and the rat (species typically used in the DNT) is less sensitive than dogs and mice to afidopyropen's putative neurotoxic effects.

iii. There is evidence of increased susceptibility following pre- and/or post-natal exposure to afidopyropen. In pre-natal developmental studies in rats, adverse fetal effects occurred at lower doses as compared to the maternal generation. In the first 2-generation study, offspring effects were observed while no adverse reproductive or parental effects occurred. In the second 2-generation study, offspring effects occurred at a lower dose as compared to the reproductive and parental effects. Clear NOAELs have been established for the developmental effects in rats and rabbits as well as the offspring effects in the two-generation reproduction studies. The NOAEL used for the chronic dietary risk assessment (8 mg/kg/day), based on effects observed in the 2-generation reproduction study in rats, is 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 in foods, 100% CT, default processing factors, and modeled, high-end estimates of residues in drinking water. All of 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.

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.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water only to afidopyropen will occupy 3.6% of the aPAD for females, 13–49 years old. Since there was no acute endpoint identified for the general population, an acute dietary exposure assessment was not conducted for the U.S. general population and other population subgroups.

2. *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 and water) exposure. The selected residential exposure scenarios for aggregation, adults and children (6 to <11 years old) contacting treated ornamentals, represent the worst-case risk estimates and are protective of all other lifestages and exposure scenarios. The short-term aggregate MOEs for adults (2,000) and children (2,500) are above the LOC (100), and are not of concern.

3. *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.

4. *Chronic risk.* Chronic aggregate risk assessments address exposures that are likely to occur continuously for greater than six months. Using the exposure assumptions discussed in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to afidopyropen from food and water only will occupy 2.2% of the cPAD for the U.S. general population, and the population subgroup with the highest estimated risk was for children, 1–2 years old at 4.4% of the cPAD. Residential exposures to afidopyropen 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 EPA's LOC.

5. *Aggregate cancer risk for U.S. population.* Afidopyropen is classified as having ''*Suggestive Evidence of Carcinogenic Potential.*'' The cRfD (cPAD) is considered to be protective of all chronic toxicity, including carcinogenicity, that could result from exposure to afidopyropen.

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 were submitted for the analysis of afidopyropen. The reported

limit of quantitation (LOQ) of each method is 0.01 ppm for afidopyropen.

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. Maximum residue limits (MRLs) for afidopyropen have not been established by Codex.

For this pesticide, the U.S. EPA and Health Canada's Pest Management Regulatory Agency (PMRA) have conducted a joint review of the available data. That review used the Organization for Economic Co-operation and Development (OECD) calculation procedures to determine the appropriate MRLs. Therefore, the EPA tolerance levels are harmonized with MRLs to be established by Health Canada's PMRA.

C. Revisions to Petitioned-For Tolerances

Several of the tolerances requested by the petitioner are different from those established in this rule. EPA's tolerance levels are expressed to provide sufficient precision for enforcement purposes, and this may include the addition of trailing zeros (such as 0.30 ppm rather than 0.3 ppm). This is to avoid the situation where rounding of an observed violative residue to the level of precision of the tolerance expression would result in a residue considered non-violative (such as 0.34 ppm being rounded to 0.3 ppm). This revision has been made for the following: Brassica, head and stem, group 5–16; Brassica, leafy greens, subgroup 4–16B; Cotton, gin byproducts; Leafy Greens, subgroup 4–16A; Leaf petiole vegetable subgroup 22B; and Vegetable, cucurbit, group 9.

For citrus oil and cotton, undelinted seed, the levels differ because of differences in rounding the values calculated from the residue data. The pome fruit tolerance is different because of differences in the MRL calculation for pear. Two pear field trials were concluded to be replicates for calculation and the petitioner also used an additional residue value which is believed to be a transcription error. A tolerance for the processed food prunes is not needed because residues are not expected to concentrate in prunes. For fruiting vegetables, these differences are attributable to the petitioner having combined both the bell and non-bell pepper data together for calculation. In addition, the petitioner did not request a tolerance for the dried tomato processed commodity, but EPA has concluded that the tolerance for the crop group will not be adequate to cover that commodity. Finally, regarding ''Soybean, aspirated grain fractions,'' the tolerance level requested by the petitioner was not consistent with data submitted with the petition. EPA reviewed the requested use pattern and supporting data, corrected the proposed commodity definition, and has decided to establish a tolerance for commodity ''Grain, aspirated fractions.''

V. Conclusion

Therefore, tolerances are established for residues 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,5,6,6a,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 Almond, hulls at 0.15 ppm; Apple, wet pomace at 0.05 ppm; Brassica, head and stem, group 5–16 at 0.50 ppm; Brassica, leafy greens, subgroup 4–16B at 5.0 ppm; Citrus, oil at 0.40 ppm; Cotton, gin byproducts at 2.0 ppm; Cotton, undelinted seed at 0.08 ppm; Fruit, citrus, group 10–10 at 0.15 ppm; Fruit, pome, group 11–10 at 0.02 ppm; Fruit, stone, group 12–12 at 0.03 ppm; Grain, aspirated fractions at 0.15 ppm; Leafy Greens, subgroup 4–16A at 2.0 ppm; Leaf petiole vegetable subgroup 22B at 3.0 ppm; Nut, tree, group 14–12 at 0.01 ppm; Soybean, seed at 0.01 ppm; Tomato, dried at 0.50 ppm; Vegetable, cucurbit, group 9 at 0.70 ppm; Vegetable, fruiting, group 8–10 at 0.20 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 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). 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 5, 2018.

Richard P. Keigwin, Jr.,

Director, 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. Add § 180.700 to subpart C to read as follows:

§ 180.700 Afidopyropen; Tolerances for residues.

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

Commodity	Parts per million
Almond, hulls	0.15
Apple, wet pomace	0.05
Brassica, head and stem, group 5–16	0.50
Brassica, leafy greens, subgroup 4–16B	5.0
Citrus, oil	0.40
Cotton, gin byproducts	2.0
Cotton, undelinted seed	0.08
Fruit, citrus, group 10–10	0.15
Fruit, pome, group 11–10	0.02
Fruit, stone, group 12–12	0.03
Grain, aspirated fractions	0.15
Leafy Greens, subgroup 4–16A	2.0
Leaf petiole vegetable subgroup 22B	3.0
Nut, tree, group 14–12	0.01
Soybean, seed	0.01
Tomato, dried	0.50
Vegetable, cucurbit, group 9	0.70
Vegetable, fruiting, group 8–10	0.20
Vegetable, tuberous and corm, subgroup 1C	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2018–19951 Filed 9–12–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0702; FRL–9983–18]

Bacteriophage Active Against Erwinia amylovora; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of lytic bacteriophage active against *Erwinia amylovora* that are produced in *Erwinia amylovora* in or on apple and pear, when used in accordance with label directions and good agricultural practices. OmniLytics, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of bacteriophage active against *Erwinia amylovora* in or on apple and pear under FFDCA.

DATES: This regulation is effective September 13, 2018. Objections and requests for hearings must be received on or before November 13, 2018, 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–2017–0702, is 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 Bldg., Rm. 3334, 1301 Constitution Ave. 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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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 Government Printing 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 number EPA–HQ–OPP–2017–0702 in the subject line on