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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0257; FRL-9973-44]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopicolide in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0257, 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: Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., 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-2016-0257 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2016-0257, 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 Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *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 Wednesday, June 22, 2016 (81 FR 40594) (FRL-9947-32), 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 6E8464) by IR-4 Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.627 be amended by establishing tolerances for residues of the fungicide, fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide], including its metabolites and degradates, in or on the commodities: basil, dried leaves at 200 parts per million (ppm); basil, fresh leaves at 30 ppm; bean, succulent at 0.9 ppm; citrus, dried pulp at 0.048 ppm; citrus, oil at 1.94 ppm; hop, dried cones at 15 ppm; fruit, citrus, group 10-10 at 0.02 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; and vegetable, fruiting, crop group 8-10 at 1.60 ppm. That document referenced a summary of the petition prepared by Valent, the registrant, which is available in the docket, *http://www.regulations.gov*. Two similar anonymous public comments were received in response to the notice of filing. The Agency's response to the comments is included in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing certain tolerances that differ from what the petitioner requested. 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 fluopicolide including exposure resulting from the tolerances established by this action.

Fluopicolide shares a metabolite, 2,6-dichlorobenzamide (BAM), with another active ingredient, dichlobenil. Residues of BAM are assessed independently of fluopicolide and dichlobenil because it has its own toxicity database and endpoints of concern. The BAM assessment considers residues resulting from both fluopicolide and dichlobenil uses. EPA's safety finding for fluopicolide considers the aggregate exposures to fluopicolide alone as well as the aggregate exposure to BAM from both fluopicolide and dichlobenil uses.

A. Toxicological Profile

EPA has evaluated the available toxicity database 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.

Fluopicolide. Fluopicolide has low acute toxicity by the oral, dermal, and inhalation routes. Following subchronic and chronic exposures, increased liver weights and/or liver hypertrophy were observed in rats and mice. Additional liver lesions were seen in mice, including oval cell proliferation in a 90-day oral toxicity study and altered cell foci in the

carcinogenicity study. Treatment-related effects in rats also included kidney and thyroid effects; however, these effects were not seen consistently across studies in the fluopicolide database. In the 28-day oral toxicity study in rats, there were indications of nephrotoxicity including pale kidneys and microscopic lesions (granulation, proteinaceous material, and hydronephrosis). Kidney effects were not observed in any other studies, except the reproduction toxicity study where slightly increased organ weights and kidney lesions were observed in parental animals. Thyroid toxicity was only observed in the combined chronic/carcinogenicity study in rats and consisted of increased thyroid weights, gross pathological observation of enlarged thyroids, and increased incidence of cystic follicular hyperplasia in males (slight to moderate severity).

Evidence of increased quantitative susceptibility was seen in the rat developmental toxicity study. Developmental effects (delayed ossification and fetal growth) were only seen at a relatively high dose (700 mg/kg/day) in the absence of maternal effects. There was no evidence of susceptibility in the rabbit developmental toxicity and rat reproduction toxicity studies. In the rabbit developmental toxicity study, late abortions/premature deliveries were observed at 60 mg/kg/day. Additional effects at this dose included late maternal deaths and decreased crown rump length in fetuses. In the rat reproduction toxicity study, offspring effects (decreased body weight) were seen in the presence of parental effects (kidney effects).

There is no evidence of neurotoxicity, immunotoxicity, or mutagenicity in the fluopicolide toxicity database. Due to the absence of treatment-related tumors in two adequate rodent carcinogenicity studies, fluopicolide is classified as "Not Likely to be Carcinogenic to Humans".

BAM. Acute toxicity studies on BAM demonstrated moderate acute toxicity via the oral route of exposure. In subchronic and chronic toxicity studies, the primary oral effects seen in the rat and dog were body weight changes. Adverse liver effects, including hepatocellular

alterations and increased liver weights, were also observed. Toxicity to the olfactory sensory neurons has been observed following intraperitoneal exposure of mice to BAM, indicating potential neurotoxicity; however, no effects on the olfactory system were observed via the oral route. There is no evidence that BAM is either mutagenic or clastogenic nor is there evidence of endocrine mediated toxicity. A BAM combined chronic toxicity/carcinogenicity study in the rat is available; however, in the absence of a carcinogenicity study data for a second species, EPA has assumed that BAM's carcinogenic potential is similar to that of dichlobenil, the parent compound having the greatest carcinogenicity potential. Dichlobenil is classified as "Group C, possible human carcinogen." Therefore, EPA has concluded that quantification of cancer risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to dichlobenil, and therefore, to BAM.

Specific information on the studies received and the nature of the adverse effects caused by fluopicolide and BAM, 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 at *http://www.regulations.gov* in document: Fluopicolide and 2,6-Dichlorobenzamide (BAM). Human Health Risk Assessment to Support Registration for Application of Fluopicolide on Basil, Succulent Bean, Hops, Small Vine Climbing Subgroup 13-07F, and Citrus Fruit Group 10-10 and Crop Group Conversion for Fruiting Vegetables 8-10, dated December 5, 2017 at pages 19-25 in docket ID number EPA-HQ-OPP-2016-0257.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for fluopicolide and BAM used for human risk assessment is shown in Table 1 and Table 2, respectively, of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for fluopicolide 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 (All populations)	An endpoint attributable to a single dose was not identified from the available data.		
Chronic dietary (All populations)	Maternal NOAEL = 20 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X	cRfD = cPAD = 0.2 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL (maternal) = 60 mg/kg/day based on death, abortions/ premature deliveries, and decreased food consumption. Co-critical:

			Chronic/Oncogenicity Study in Rats NOAEL = 31.5 mg/kg/day. LOAEL = 109.4 mg/kg/day based on increased thyroid weight and increased incidence of thyroid lesions.
Incidental oral short- and intermediate-term (1-30 days, and 1-6 months)	Maternal NOAEL = 20 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X	LOC for MOE <100	Developmental Toxicity Study in Rabbits LOAEL (maternal) = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption and body-weight gain.
Dermal short- and intermediate-term (1-30 days, and 1-6 months)	Maternal NOAEL= 20 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X (when applicable) DAF =5%	LOC for MOE <100	Developmental Toxicity Study in Rabbits LOAEL (maternal) = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption and body-weight gain. Co-critical: Chronic/Oncogenicity Study in Rats NOAEL = 31.5 mg/kg/day. LOAEL = 109.4 mg/kg/day based on increased thyroid weight and increased incidence of thyroid lesions.

Inhalation short- and intermediate- term (1-30 days, and 1-6 months)	Maternal NOAEL= 20 mg/kg/day Inhalation assumed equivalent to oral UF_A = 10x UF_H = 10x FQPA SF = 1X, when applicable	LOC for MOE < 100	Developmental Toxicity Study in Rabbits LOAEL (maternal) = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption. Co-critical: Chronic/Oncogenicity Study in Rats NOAEL = 31.5 mg/kg/day. LOAEL = 109.4 mg/kg/day based on and increased thyroid weight and increased incidence of thyroid lesions.
Cancer (Oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

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.
FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

Table 2. Summary of Toxicological Doses and Endpoints for 2,6-Dichlorobenzamide (BAM) 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 (All	LOAEL = 100	aRfD = aPAD = 0.1	Dose-range finding assay for *in vivo* mouse

populations)	mg/kg/day UF_A = 10x UF_H = 10x FQPA SF/UF_L= 10x	mg/kg/day	erythrocyte micronucleus assay LOAEL = 100 mg/kg/day based on lethargy after a single oral dose
Chronic dietary (All populations)	NOAEL = 4.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X	cRfD = cPAD = 0.045 mg/kg/day	Chronic toxicity (dog) LOAEL = 12.5 mg/kg/day based on decreased body weight and body weight gain
Incidental oral short- and intermediate-term (1-30 days, and 1-6 months)	NOAEL = 14 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X	LOC for MOE <100	90-day oral (rat) LOAEL = 49 mg/kg/day based on decreased body weight gain (M) and reduced skeletal muscle tone (day 4 only in males; days 91 and 92 only in females)
Dermal short- and intermediate-term (1-30 days and 1-6 months)	NOAEL = 25 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1X (when applicable)	LOC for MOE <100	5-day dermal using dichlobenil (mouse; literature study) LOAEL = 50 mg/kg/day based on olfactory epithelial damage
Inhalation Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL = 12.1 mg/m^3 UF_A = 3X UF_H = 10X FQPA SF = 1X (when applicable)	LOC for MOE <100	28-day inhalation using dichlobenil (rat) LOAEL = 21 mg/m^3 based on nasal degeneration
Cancer	Classification: unclassified; parent herbicide dichlobenil classified as "Group C, possible human carcinogen" with RfD approach utilized for quantification of human risk		

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, UF_L = use of a LOAEL to extrapolate a NOAEL, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, RfD = reference dose (a = acute, c = chronic), PAD = population-adjusted dose, MOE = margin of exposure, LOC = level of concern, N/A = not applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fluopicolide and its metabolite BAM, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopicolide tolerances in 40 CFR 180.627 and the exposures from BAM from existing dichlobenil tolerances under 40 CFR 180.231. EPA assessed dietary exposures from fluopicolide and its metabolite BAM in food as follows:

a. *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.

i. *Fluopicolide*. A toxicity endpoint attributable to a single dose has not been identified in the toxicological studies for fluopicolide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *BAM.* Such effects were identified for BAM. In estimating acute dietary exposures to BAM, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. EPA conducted a partially refined acute dietary exposure assessment. As to residue levels in food, EPA assumed maximum BAM residue from either the fluopicolide or dichlobenil field trial data. The acute assessment assumed 100% crop treated for all commodities, except apples, blueberries, cherries, peaches, pears, and raspberries. These values reflect the dichlobenil percent crop treated estimates as fluopicolide is not registered for application to these crops. Default

processing factors were used for commodities where empirical processing data were not available

b. *Chronic exposure* – i. *Fluopicolide*. In estimating chronic dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 3.16). The software uses 2003-2008 food consumption data from the U.S. Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The chronic analysis assumed tolerance-level residues or maximum field trial residues, 100% crop treated, default processing factors, and modeled drinking water estimates.

ii. *BAM*. In estimating chronic dietary exposures, EPA conducted a partially refined chronic dietary exposure assessment using DEEM-FCID (ver. 3.16) and USDA's NHANES/WWEIA (2003 through 2008). The chronic dietary assessment assumed the maximum BAM residue from either the fluopicolide or dichlobenil field trial data. The chronic assessment assumed 100% crop treated for all commodities except apple. These values reflect the dichlobenil percent crop treated estimates as fluopicolide is not registered for application to these crops. Default processing factors were used for commodities where empirical processing data were not available.

c. *Cancer*. Fluopicolide has been classified as ''not likely to be carcinogenic to humans." Therefore, a cancer dietary exposure assessment was not conducted for the parent fluopicolide. Additionally, EPA has determined BAM's potential for carcinogenicity is similar to that of dichlobenil, which is classified as ''group C, possible human carcinogen." Quantification of cancer risk is based on the reference dose (RfD) approach which requires comparison of the chronic exposure to the RfD. Using this methodology will adequately account for all chronic toxic effects, including

carcinogenicity, likely to result from exposure to BAM. Hence, a separate cancer exposure assessment to BAM was not conducted.

d. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

EPA did not use anticipated residue or PCT information in the dietary assessment for fluopicolide. Tolerance level residues or maximum field trial residues and 100 PCT were assumed for all food commodities.

EPA used anticipated residues and PCT information for the acute and chronic dietary risk assessments for BAM. The BAM acute assessment assumed 100 PCT for all commodities except apples (2.5%), blueberries (2.5%), cherries (2.5%), peaches (2.5%), pears (5%) and raspberries (20%). The BAM chronic assessment assumed 100 PCT for all commodities except apples (1%). These values reflect the dichlobenil percent crop treated estimates as fluopicolide is not registered for application to these crops. Default processing factors were used for commodities where empirical processing data were not available.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 2.5%. The maximum PCT figure is the highest observed maximum value reported within the most recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for situations in which the maximum PCT is less than 2.5%. In cases where the estimated value is less than 2.5% but greater than 1%, the average and maximum PCT used are 2.5%. If the estimated value is less than 1%, 1% is used as the average PCT and 2.5% is used as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1. iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which BAM may be found in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fluopicolide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopicolide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

No monitoring data are available for fluopicolide or BAM. Drinking water residues of fluopicolide (parent) estimates were generated using maximum annual application rate of 0.375 lbs ai/acre, and the surface water concentration calculator (SWCC version 1.106) for surface water, and the pesticide root zone model for groundwater (PRZM-GW version 1.07). The

estimated drinking water concentrations (EDWCs) of fluopicolide for non-cancer chronic exposures are 12.90 ppb for surface water and 103 ppb for ground water.

Estimates of BAM residues in drinking water were generated using the Provisional Cranberry Model (PCM) and Pesticide Water Concentration Calculator (PWC) for surface water, and the PRZM-GW model for groundwater. BAM drinking water concentrations can result from the application of dichlobenil and fluopicolide. The BAM estimates resulting from application of dichlobenil are higher than those resulting from application of fluopicolide. The acute and chronic analyses assumed a BAM drinking water concentration of 239 ppb and 206 ppb, respectively, based on the PRZM-GW model from turf use (worst case scenario).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment for BAM, the water concentration value of 239 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 206 ppb and 103 ppb were used to assess the contribution to drinking water for BAM and fluopicolide, respectively.

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).

Fluopicolide is currently registered for the following uses that could result in residential exposures: residential turf grass and recreational sites; however, all registered fluopicolide product labels with residential use sites require that handlers wear specific clothing and/or use personal protective equipment (PPE). Therefore, the Agency has concluded that these products are not intended to be used by homeowners and did not conduct residential handler assessments. There is potential for post-application exposure for individuals entering areas that

have been previously treated with fluopicolide. EPA assessed the following residential exposure scenarios for fluopicolide:

Post-application exposure to children, youth, and adults from treated lawns, turf, gardens, trees, and golf courses.

In the case of BAM, the Agency considered the potential for residential exposures to BAM from dichlobenil and fluopicolide uses. As noted above, fluopicolide is registered for use on residential turfgrass and recreational sites, such as golf courses. These uses may also result in short-term dermal post-application exposure to BAM to youth and adults from treated gardens. Post-application exposures from treated turf is not expected since BAM was not detected in turf transferable residue studies with fluopicolide.

As discussed above, residential handler assessments were not performed for fluopicolide; therefore, a residential handler assessment for BAM is also not required. Residential handler exposure to BAM resulting from the application of dichlobenil is not expected. While dichlobenil is currently registered for residential uses on ornamental plants, they are approved for professional applicator use only. Post-application exposure of adults and children to dichlobenil and BAM exposure from the use of dichlobenil products on ornamental plants is expected to be negligible and, therefore, was not assessed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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 fluopicolide and any other substances. Fluopicolide shares a common metabolite, BAM, with dichlobenil. EPA's assessment of BAM from pesticide use of fluopicolide and dichlobenil has been updated for the current assessment and no risks of concern were identified. For the purposes of this tolerance action, therefore, EPA has not assumed that fluopicolide (parent) and its metabolite BAM have a common mechanism of toxicity with other substances. 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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. *Prenatal and postnatal sensitivity*. For fluopicolide, there is no evidence of increased susceptibility in the rabbit developmental or rat reproduction toxicity studies. There was

evidence of increased quantitative susceptibility in the rat developmental toxicity study; however, the developmental effects were only seen at a relatively high dose (700 mg/kg/day), the effects are well-characterized with a clear NOAEL, and the selected endpoints are protective of the observed effects. For BAM, there was no evidence of increased susceptibility in the rabbit developmental study.

3. *Conclusion for fluopicolide*. 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. That decision is based on the following findings:

i. The toxicity database for fluopicolide is complete.

ii. There is no indication that fluopicolide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence of increased susceptibility in the rabbit developmental or rat reproduction toxicity studies. Although there is evidence of increased quantitative susceptibility in the rat developmental toxicity study, the developmental effects were only seen at a relatively high dose, the effects are well characterized with a clear NOAEL, and the selected endpoints are protective of the observed effects. There are no residual uncertainties concerning prenatal and postnatal toxicity for fluopicolide.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to fluopicolide in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by fluopicolide.

4. *Conclusion for BAM*: EPA is retaining the FQPA SF of 10X for the acute dietary exposure scenario for the general population to account for the use of a LOAEL to extrapolate to a NOAEL. For all other exposure scenarios, the FQPA SF has been reduced to 1X. That decision is based on the following findings:

i. Acute, subchronic, and chronic oral studies are available for BAM and utilized for endpoint selection. For the dermal and inhalation routes of exposures, the Agency is relying on dichlobenil toxicity data, where olfactory toxicity was observed. Based on a comparison of toxicity via the intraperitoneal route of exposure, higher doses of BAM are needed to induce levels of olfactory toxicity that are similar to those caused by dichlobenil; therefore, the endpoints based on dichlobenil are considered protective of potential BAM toxicity.

ii. Although there is potential neurotoxicity in the olfactory system from BAM exposure, concern is low since the effects are well-characterized and selected endpoints based on dichlobenil are protective of these effects.

iii. There is no evidence of increased susceptibility in the developmental rabbit study.

iv. The assessments of BAM are unlikely to underestimate exposure and risks. Acute and chronic dietary assessments assumed maximum BAM residues from field trial data as well as conservative (protective) assumptions of BAM exposure in drinking water. Similar conservative assumptions were used to assess post-application exposure of children to BAM.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected for fluopicolide. Therefore, fluopicolide is not expected to pose an acute risk.

In the case of BAM, using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to BAM will occupy 81% of the aPAD for children 1 to <2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopicolide from food and water will utilize 15% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. In the case of BAM, chronic exposure to BAM from food and water will utilize 26% of the cPAD for all infants (<1year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopicolide or BAM is not expected.

3. *Short-term/intermediate-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).

Fluopicolide is currently registered for uses that could result in short-term residential exposure and may result in post-application exposures of BAM. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluopicolide and BAM. There are no intermediate-term exposures expected for fluopicolide or BAM; however, the short-term aggregate assessment is considered protective of

intermediate-term since the same endpoints were selected to evaluate short- and intermediate-term exposures.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined fluopicolide short-term food, water, and residential exposures for children 1-2 years old and children 6-11 years old result in aggregate MOEs of 490 and 670, respectively. In addition, an aggregate assessment conducted for adults resulted in an MOE of 500. Because EPA's level of concern for fluopicolide is a MOE of 100 or below, these MOEs are not of concern. For BAM, dermal and inhalation exposures may not be combined with oral exposures due to different toxicological effects used as the basis of the selected endpoints. As a result, the aggregate risk estimates are equivalent to the dietary risk estimates and are not of concern.

4. *Aggregate cancer risk for U.S. population*. Due to the absence of treatment-related tumors in two adequate rodent carcinogenicity studies, fluopicolide is classified as "not likely to be carcinogenic to humans"; therefore, a quantitative cancer assessment is not required.

EPA has assumed BAM's potential for carcinogenicity is similar to that of dichlobenil, which is classified as ''group C, possible human carcinogen."

Quantification of cancer risk is based on the RfD approach which requires comparison of the chronic exposure to the RfD. Therefore, the chronic risks discussed in Unit III.E.2. are considered protective of both non-cancer and cancer effects.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluopicolide residues, including its metabolite.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (LC/MS/MS) enforcement method RM-43C-2) is available to enforce the tolerance expression. Enforcement methodology (LC/MS/MS Method, Methods 00782, 00782/M001, 00782/M002, and 00782/M003) is available to adequately enforce the tolerance expression for BAM.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established MRLs for basil, hop, bean, or citrus. The fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F tolerance is harmonized with Codex grape MRL. Codex established a tolerance for "Fruiting vegetables other than cucurbits" at 1.0 ppm. Based on the field trial data and the Organization for Economic Cooperation and Development (OECD) calculator, using the labeled application scenario may result in residues greater than 1.0

ppm in/on fruiting vegetables. As a result, harmonization of the vegetable, fruiting, crop group 8-10 tolerance with the Codex MRL could result in food containing residues exceeding tolerances despite legal application of the pesticide, which would not be appropriate.

C. Response to Comments on Notice of Filing

Two anonymous public comments were received on the notice of filing that center around opposing IR-4 and the uses of pesticides (toxic chemicals), such as fluopicolide, on food commodities including grape, citrus and basil, claiming these chemicals are harmful to human health.

EPA's Response: Aside from assertions that chemicals are toxic and linked to adverse human health effects, the commenters provided no information supporting these assertions that EPA could use to evaluate the safety of fluopicolide or BAM. The existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency evaluates all available data and assesses the potential for risk from aggregate exposure to the pesticide. As discussed in this rule, EPA examined all relevant data for fluopicolide and BAM and has concluded that there is a reasonable certainty that no harm will result from aggregate human exposure to fluopicolide, including residues of its metabolite BAM. The commenters have presented no information to support reconsideration of that conclusion.

D. Revisions to Petitioned-For Tolerances

The established tolerances differ from the petitioner's requests as follows:

i. EPA is establishing a tolerance for "basil fresh leaves" at 40 ppm, rather than 30 ppm, as a result of removing certain inadequate residue data from the tolerance calculation.

ii. The petitioner requested a tolerance for residues of fluopicolide for the general category of "bean, succulent" at 0.9 ppm. This term is defined in EPA's regulations as including a variety of beans in succulent form (*see* 40 CFR § 180.1(g)). At this time, EPA is establishing tolerances for only those beans included in the succulent bean definition that are also supported by the submitted snap bean field trial data. Those specific succulent beans are the following: "bean, moth, succulent", "bean, yardlong, succulent" (species of the *Vigna* genus), "bean, runner, succulent", "bean, snap, succulent", and "bean, wax, succulent" (species of the *Phaseolus* genus). Tolerances for the other beans contained within the definition of "bean, succulent" as contained in 180.1(g) are not being established at this time due to lack of adequate residue data. In addition, the Agency has adjusted the tolerance values for these beans (from 0.9 to 0.90) to be consistent with its current guidance on significant figures.

iii. Because all reported residue data on crops supporting the "fruit, citrus, crop group 10-10" were below the 0.01 ppm limit of quantitation, EPA is establishing a tolerance for this group at 0.01 ppm.

iv. The petitioner's requested tolerances for "citrus, dried pulp" at 0.048 ppm and "citrus, oil" at 1.94 ppm were based on the petitioned-for tolerance level for citrus group 10-10 at 0.02 ppm. Using the 0.01 ppm tolerance level for group 10-10 as indicated in the previous paragraph and applying appropriate processing factors yields tolerances of 0.03 for citrus, dried pulp and 1.0 for citrus, oil.

V. Conclusion

Therefore, tolerances are established for residues of the fungicide fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide], including its metabolites and degradates (determined by measuring the parent only), in or on Basil, fresh leaves at 40 ppm; Basil, dried leaves at 200 ppm; Bean, moth, succulent at 0.90 ppm; Bean,

snap, succulent at 0.90 ppm; Bean, runner, succulent at 0.90 ppm; Bean, wax, succulent at 0.90 ppm; Bean, yardlong, succulent at 0.90 ppm; Citrus, dried pulp at 0.03 ppm; Citrus, oil at 1.0 ppm; Fruit, citrus, crop group 10-10 at 0.01 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; Hop, dried cones at 15 ppm; and Vegetable, fruiting, crop group 8-10 at 1.6 ppm. Also, the tolerances for "Grape" and "Vegetable, fruiting, group 8" in the table in paragraph (a) and for "Hop, dried, cones" in the table in paragraph (b) are deleted as they are superseded by this action. Finally, in an additional housekeeping measure, the expired tolerances for "Potato, processed potato waste" at 1.0 ppm and "Vegetable, tuberous and corm, subgroup 1C" at 0.3 ppm are deleted since they have no effect anymore and have been replaced by lower tolerances for those commodities as discussed in the **Federal Register** of September 26, 2016 (81 FR 65924).

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); 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: February 20, 2018.

Michael L. Goodis,
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 § 180.627:

a. In the table to paragraph (a):

i. Add alphabetically the entries "Basil, dried leaves"; "Basil, fresh leaves"; "Bean, moth, succulent"; "Bean, runner, succulent"; "Bean, snap, succulent"; "Bean, wax, succulent"; "Bean, yardlong, succulent"; "Citrus, dried pulp"; "Citrus, oil"; "Fruit, citrus, crop group 10-10"; and "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F";

ii. Remove the entry for "Grape";

iii. Add alphabetically the entry "Hop, dried cones";

iv. Remove the entry for "Potato, processed potato waste[1]";

v. Add alphabetically the entry "Vegetable, fruiting, crop group 8-10"; and

vi. Remove the entries for "Vegetable, fruiting, group 8" and "Vegetable, tuberous and corm, subgroup 1C[1]" and footnote 1 of the table.

b. Revise paragraph (b).

The additions and revision read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

(a) * * *

Commodity	Parts per million
Basil, dried, leaves	200
Basil, fresh leaves	40
Bean, moth, succulent	0.90
Bean, runner, succulent	0.90
Bean, snap, succulent	0.90

Bean, wax, succulent	0.90
Bean, yardlong, succulent	0.90
* * * * * * *	
Citrus, dried pulp	0.03
Citrus, oil	1.0
Fruit, citrus, crop group 10-10	0.01
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
* * * * * * *	
Hop, dried cones	15
* * * * * * *	
Vegetable, fruiting, crop group 8-10	1.6
* * * * * * *	

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

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