FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Field and External Affairs Division, (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460–0001; *telephone number:* (703) 305–6304; *e-mail address: boyle.kathryn@epa.gov,* or contact Scott Drewes, same address; telephone number (703) 347–0107; *e-mail address: drewes.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general. It simply announces the submission of a draft final rule to the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) and does not otherwise affect any specific entities. This action may, however, be of particular interest if you are a producer of pesticide products (NAICS 32532), antifoulants (NAICS 32551), antimicrobial pesticides (NAICS 32561), wood preservatives (NAICS 32519), importers of such products, or any person or company who seeks to register an antimicrobial, antifoulant coating, ballast water treatment, wood preservative pesticide, or to obtain a tolerance for such a pesticide. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding this action, consult one of the persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. What action is EPA taking?

Section 25(a)(2) of FIFRA requires the Administrator to provide the Secretary of Agriculture with a copy of any final regulation at least 30 days before signing it for publication in the **Federal Register**. Similarly, section 21(b) of FIFRA provides that the Administrator must provide the Secretary of Health and Human Services with a copy of any draft final rule pertaining to a public health pesticide at least 30 days before signing it for publication in the **Federal Register**. The draft final rule is not available to the public until after it has been signed by EPA. If either Secretary comments in writing regarding the draft final rule within 15 days after receiving it, the Administrator shall include the comments of the Secretary, if requested by the Secretary, and the Administrator's response to those comments in the final rule when published in the **Federal Register**. If the Secretary does not comment in writing within 15 days after receiving the draft final rule, the Administrator may sign the final rule for publication in the **Federal Register** anytime after the 15–day period.

III. Do any statutory and executive order reviews apply to this notification?

No. This document is not a rule; it is merely a notification of submission to the Secretaries of Agriculture and Health and Human Services. As such, none of the regulatory assessment requirements apply to this document.

IV. Will this Notification be Subject to the Congressional Review Act?

No. This action is not a rule for purposes of the Congressional Review Act (CRA), 5 U.S.C. 804(3), and will not be submitted to Congress and the Comptroller General. EPA will submit the final rule to Congress and the Comptroller General as required by the CRA.

List of Subjects

40 CFR Part 158

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

40 CFR Part 161

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

Dated: April 7, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2011–9292 Filed 4–19–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0481; FRL–8859–9]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the fungicide, fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide], including its metabolites and degradates. Compliance with the tolerance levels specified is to be determined by measuring only fluopicolide in or on the commodity. The fluopicolide metabolite, 2,6-dichlorobenzamide (BAM), is regulated with its own set of tolerances. This regulation establishes tolerances for residues of fluopicolide and its metabolites in or on multiple commodities which are identified and discussed later in this document. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 20, 2011. Objections and requests for hearings must be received on or before June 20, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0481. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Janet Whitehurst, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6129; e-mail address: *whitehurst.janet@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. 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.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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–2006–0481 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 June 20, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2006–0481, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of February 4, 2010 (75 FR 5790) (FRL–8807–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 9F7617 and 9F7568 by Valent U.S.A, 1600 Riviera Ave., Walnut Creek, CA 94596–8025). The petitions requested that 40 CFR 180.627 be amended by establishing tolerances for residues of the fungicide, fluopicolide, and its metabolites, in or on *Brassica,* leafy greens, subgroup 5B at 20 parts per million (ppm) (9F7617). Additionally, Valent U.S.A. has proposed establishing tolerances for residues of the fluopicolide metabolite, BAM on cattle, goat, horse and sheep meat at 0.02 ppm; cattle, goat, horse and sheep fat at 0.05 ppm; cattle, goat, horse and sheep meat byproducts at 0.05 ppm; and milk at 0.01 ppm (9F7568). These notices referenced a summary of the petitions prepared by Valent U.S.A., the registrant, which is available in the docket, *http://www.regulations.gov.*

Valent U.S.A. previously submitted petition 5F7016 to the Agency for consideration of uses on tuberous and corm vegetables and tolerance for indirect or inadvertent tolerances resulting from rotation to wheat. The Interregional Research Project No 4 (IR–4) submitted petition 7E7172 which included uses on root and tuber vegetables. In the **Federal Register** of May 28, 2008 (73 FR 30492) (FRL–8363–7), and the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8133–4), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of these petitions. The Agency reviewed the submitted petitions and concluded that due to data deficiencies, commodities that had associated animal feed items were not, at that time, supported by adequate data. Therefore, while the Agency approved the majority of new uses requested in the petition 5F7016, the Agency did act on the request for uses on potato, sugar beets and carrots, and on the request to allow rotation to wheat.

Valent U.S.A. subsequently submitted additional data to address deficiencies cited in the Agency reviews for the petition 5F7016, including supporting data for the animal metabolism study, a BAM feeding study, confirmatory analytical method and documentation that a BAM reference standard is available; and requests that 40 CFR 180.627 be amended by establishing tolerances for residues of the fungicide fluopicolide in or on vegetable, tuberous and corm subgroup 1C at 0.02 ppm; potato, processed potato waste at 0.05 ppm; vegetable root, subgroup 1A at 0.15 ppm. The petitioner also requested the establishment of tolerances for indirect or inadvertent residues of fluopicolide in or on wheat, forage at 0.20 ppm; wheat, grain at 0.02 ppm; wheat, hay at 0.50 ppm; wheat, milled byproducts at 0.07 ppm; wheat, straw at 0.50 ppm; wheat, aspirated grain fractions at 0.07 ppm. Concurrently with establishing the crop subgroup 1A tolerance, the petitioner proposed to delete the current tolerance on the "vegetable root, subgroup 1A, except sugar beet and carrot" since the new 1A unrestricted tolerance will cover the existing commodity tolerances as well as tolerances needed for the new uses on sugar beets and carrots. Additionally, concurrently with establishing the crop supgroup 1C "vegetable, tuberous and corm subgroup," the petitioner proposed to delete the current tolerance on "vegetable, tuberous and corm (except potato) subgroup 1D tolerance, since the new 1C subgroup tolerance will cover the existing commodity tolerances listed under 1C as well as the tolerance needed for the new use on potatoes.

There were no comments received in response to these notices of filings.

Based upon review of the data supporting the petition, EPA has modified the tolerances proposed for vegetable, brassica (cole) leafy subgroup 5B. The appropriate tolerance for vegetable brassica (cole) leafy subgroup 5B is 18 ppm. The reason for this change is explained in Unit IV.D. EPA has not established the requested BAM tolerances because the relevant data showed that no new tolerances for BAM are required for animal commodities. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 and separately for the fluopicolide metabolite, BAM, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopicolide and separately, the fluopicolide metabolite BAM follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data for fluopicolide and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological database indicates that technical grade fluopicolide has relatively low acute toxicity. Fluopicolide is not a dermal sensitizer, primary eye irritant, or primary skin irritant. The subchronic and chronic toxicity studies showed that the primary effects of fluopicolide are in the liver. Kidney and thyroid toxicity were observed in rats only. Fluopicolide is not neurotoxic, carcinogenic, nor mutagenic. Developmental toxicity in the rabbit occurred only at doses that caused severe maternal toxicity (including death). In the rat, developmental effects were seen only at high dose levels (700 milligrams/kilogram/day (mg/kg/day)) in the presence of maternal toxicity. Similarly, offspring effects (body weight, kidney) occurred only at levels causing toxicity in parents of the multi-generation reproductive toxicity study. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* or postnatal exposure to fluopicolide. No toxic effects were observed in studies in which fluopicolide was administered by the dermal routes of exposure. The toxicological profile for fluopicolide suggests that increased durations of exposure do not significantly increase the severity of observed effects. The rabbit developmental and rat chronic/cancer studies were therefore considered for all exposure scenarios.

Specific information on the studies received and the nature of the adverse effects caused by fluopicolide 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 its Metabolite, 2,6–Dichlorobenzamide (BAM). Human Health Risk Assessment to Support New Section 3 Uses on Brassica Leafy Greens Subgroup 5B, Potatoes, Sugar Beets, Carrots and to Allow Rotation to Wheat* in the docket ID number EPA–HQ–OPP–2006–0481.

BAM (AE C653711) is a common metabolite and/or environmental degradate of fluopicolide as well as the herbicide dichlobenil. Because the toxicological endpoints for BAM and fluopicolide are different, a separate human health risk assessment is required which addresses risks from exposure to BAM residues. The BAM risk assessment considers residues resulting from both fluopicolide and dichlobenil uses. However, BAM residues generated from fluopicolide uses are expected to be significantly lower than BAM residues from dichlobenil uses.

EPA has evaluated the available toxicity data for BAM and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The BAM toxicity database indicates that BAM has 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 were also observed. There is no evidence that BAM is either mutagenic or clastogenic nor is there evidence of endocrine mediated toxicity. BAM is considered to be neurotoxic. In the absence of carcinogenicity study data for a second species, the Agency 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." Quantification of cancer risk for BAM 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. Specific information regarding the metabolite of fluopicolide can be found in the document entitled *2,6-Dichlorobenzamide (BAM) as a Metabolite/Degradate of Fluopicolide and Dichlobenil. Human Health Risk Assessment for Proposed Uses of Fluopicolide on Tuberous and Corm Vegetables, Leafy Vegetables (except brassica), Fruiting Vegetables, Cucurbit Vegetables, Grapes, Turf, and Ornamentals, and for Indirect or Inadvertent Residues on the Rotational Crop Wheat (PC Codes: 027402 BAM and 027412 (fluopicolide), Petition No: 5F7016* at regulations.gov*).* Both referenced documents are available in the docket established for this action, which is described under **ADDRESSES**, and is identified as docket ID number EPA–HQ–OPP–2006–0481. A quantitative reassessment of the BAM risk for the new uses associated with the petitions 9F7617 and 9F7568 was not conducted because the new uses do not add significantly to the BAM dietary exposure; therefore, the conclusions from the most recently conducted BAM human health risk assessment remain unchanged.

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.*

The selected toxicological endpoints used for fluopicolide are presented below.

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

Exposure/scenario	Point of departure	Uncertainty/ FQPA safety factors	RfD, PAD, level of concern 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	Chronic RfD = 0.2 mg/kg/day cPAD = 0.2 mg/kg/day.	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 decreased body weight gain and increased thyroid weight and increased incidence of thyroid lesions.
Incidental Oral Intermediate-Term (1–6 months)	Maternal NOAEL = 20 mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1X	MOE = 100 (occupational). MOE = 100 (residential).	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-, Intermediate- and Long-Term (1–30 days, 1–6 months, and > 6 months)	Maternal NOAEL = 20 mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1X 37% dermal absorption.	MOE = 100 (occupational). MOE = 100 (residential).	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 decreased body weight gain and increased thyroid weight and increased incidence of thyroid lesions.
Inhalation Short-, Intermediate- and Long-term (1–30 days, 1–6 months, and > 6 months)	Maternal NOAEL = 20 mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1X (inhalation and oral toxicity are assumed to be equivalent).	MOE = 100 (occupational). MOE = 100 (residential).	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 decreased body weight gain and increased thyroid weight and increased incidence of thyroid lesions.
Cancer (oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans."			

FQPA SF = FQPA Safety Factor.
LOC = level of concern.
LOAEL = lowest observed adverse effect level.
MOE = margin of exposure.
N/A = not applicable.
NOAEL = no observed adverse effect level.
PAD = population adjusted dose (a = acute, c = chronic).
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.
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).

A summary of the toxicological endpoints for BAM used for human risk assessment can be found at regulations.gov in the document entitled *Fluopicolide and its Metabolite, 2,6-Dichlorobenzamide (BAM). Amended Human Health Risk Assessment to Support New Section 3 Uses on Brassica Leafy Greens Subgroup 5B, Potatoes, Sugar Beets, Carrots and to Allow Rotation to Wheat* in docket ID number EPA–HQ–OPP–2006–0481.

The selected toxicological endpoints used for BAM are presented below.

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 2,6–DICHLOROBENZAMIDE (BAM) FOR USE IN DIETARY, RESIDENTIAL, AND OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

Exposure scenario	Point of departure	Uncertainty/ FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute Dietary (General population, including infants and children)	LOAEL = 100 mg/kg/day.	UF_A = 10X UF_H = 10X FQPA SF[4 5] = 10X (includes UF_L and UF_{DB}).	aRfD = aPAD = 0.1 mg/kg/day.	Dose-range finding assay for *in vivo* mouse erythrocyte micronucleus assay. LOAEL = 100 mg/kg/day based on lethargy after a single oral dose.
Acute Dietary (Females 13–49 years of age)	NOAEL = 30 mg/kg/day.	UF_A = 10X UF_H = 10X FQPA SF[4] = 10X (includes UF_{DB}).	aRfD = aPAD = 0.03 mg/kg/day.	Developmental toxicity (rabbit) Offspring LOAEL = 90 mg/kg/day based on increased incidences of late abortion and skeletal (bipartite interparietal bone) and visceral (postcaval lung lobe agenesis) anomalies
Chronic Dietary (All populations)	NOAEL = 4.5 mg/kg/day.	UF_A = 10X UF_H = 10X FQPA SF[4] = 10X (includes UF_{DB}).	cRfD = cPAD = 0.0045 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[4] = 10X (includes UF_{DB}).	Residential LOC for MOE = 1000.	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-, Intermediate-, and Long-Term (1–30 days, 1–6 months, and > 6 months)	NOAEL = 25 mg/kg/day.	UF_A = 10X UF_H = 10X FQPA SF = 1X (residential uses only).	Residential and Occupational LOC for MOE = 100.	5-day dermal *using dichlobenil*[6] (mouse; literature study[1]). LOAEL = 50 mg/kg/day based on olfactory epithelial damage.
Inhalation Short-, Intermediate-, and Long-Term (1–30 days, 1–6 months, and > 6 months)	NOAEL = 3.1 mg/kg/day[2]	UF_A = 10X UF_H = 10X FQPA SF = 1X (residential uses only).	Residential and Occupational LOC for MOE = 100.	28-day inhalation *using dichlobenil*[6] (rat) LOAEL = 5.5 mg/kg/day[3] based on nasal degeneration.
Cancer	Classification: Formally unclassified; parent herbicide dichlobenil classified as "Group C, possible human carcinogen" with RfD approach utilized for quantification of human risk.			

FQPA SF = FQPA Safety Factor.
LOAEL = lowest observed adverse effect level.
LOC = level of concern.
NOAEL = no observed adverse effect level.
MOE = margin of exposure.
N/A = Not Applicable.
PAD = population adjusted dose.
RfD = reference dose (a = acute, c = chronic).
UF = uncertainty factor.
UF_A = extrapolation from animal to human (interspecies).
UF_{DB} = to account for the absence of key data.
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
UF_L = use of a LOAEL to extrapolate a NOAEL.

[1] *Deamer NJ, O'Callaghan JP, Genter MB.* (1994). Olfactory toxicity resulting from dermal application of 2,6-dichlorobenzonitrile (dichlobenil) in the C57Bl mouse. Neurotoxicology 15(2):287–93.

[2] Calculated as follows: (NOAEL) × (m^3/1000 L) × (10.26 L/hr) × 6 hr/day × (1/0.236 kg), where NOAEL = 12 mg/m^3 from 28-day inhalation toxicity study (Sprague Dawley rat).

[3] Calculated as follows: (LOAEL) × (m^3/1000 L) × (10.26 L/hr) × 6 hr/day × (1/0.236 kg), where LOAEL = 21 mg/m^3 from 28-day inhalation toxicity study (Sprague Dawley rat).

[4] The FQPA SF has been retained in the form of a UF_{DB} for the lack of neurotoxicity data, including olfactory toxicity data.

[5] The FQPA SF has been retained in the form of a UF_L and UF_{DB} for the use of a LOAEL to extrapolate a NOAEL and for the lack of olfactory toxicity data.

[6] In the absence of route-specific data, endpoints for all dermal and inhalation exposure scenarios were identical to those for dichlobenil (parent), since olfactory toxicity has been observed following i.p. administration of BAM in mice [*Brittebo EB, Eriksson C, Feil V, Bakke J, Brandt I.* (1991). Toxicity of 2,6-dichlorothiobenzamide (chlorthiamid) and 2,6-dichlorobenzamide in the olfactory nasal mucosa of mice. *Fundam Appl Toxicol* 17(1):92–102].

A summary of the toxicological endpoints for BAM used for human risk assessment can be found at regulations.gov in the document entitled *2,6-Dichlorobenzamide BAM as a Metabolite/Degradate of Fluopicolide and Dichlobenil. Human Health Risk Assessment for Proposed Uses of Fluopicolide on Tuberous and Corm Vegetables, Leafy Vegetables (except brassica), Fruiting Vegetables, Cucurbit Vegetables, Grapes, Turf, and Ornamentals, and for Indirect or Inadvertent Residues on the Rotational Crop Wheat (PC Codes: 027402 BAM and 027412 Fluopicolide, Petition No: 5F7016 (71 FR 34345) (FRL–8071–4)* in docket ID number EPA–HQ–OPP–2006–0481).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopicolide and its metabolites, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopicolide tolerances in 40 CFR 180.40. EPA assessed dietary exposures from fluopicolide and separately, its metabolite, BAM 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. No such effects were identified in the toxicological studies for fluopicolide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

A conservative acute dietary exposure assessment for the metabolite of fluopicolide, BAM, was conducted. Maximum residues of BAM from fluopicolide field trials on tuberous and corm vegetables, leafy vegetables (except brassica), fruiting vegetables, cucurbit vegetables, grapes (domestic and imported), (except potato), and from dichlobenil field trials on food commodities with established/pending tolerances (40 CFR 180.231) were included in the assessments. The assessments used 100 percent crop treated (PCT) except for apples, blueberries, cherries, cranberries, peaches, pears, and raspberries.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the U.S. Department of Agriculture 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals. As to residue levels in food, two chronic assessments were conducted: One assessment for parent fluopicolide (including residues of concern other than the metabolite BAM) and one assessment for BAM. As to residue levels in food, EPA assumed for the parent fluopicolide assessment that all foods for which there are tolerances were treated and contain tolerance-level residues. A conservative chronic dietary exposure assessment for the metabolite of fluopicolide, BAM, was conducted as described in Unit III.C.1.i. for the acute assessment.

iii. *Cancer.* Fluopicolide is not likely to be carcinogenic to humans; therefore, a cancer risk assessment was not conducted for the parent fluopicolide. The carcinogenic potential of BAM has been evaluated in only one species, the rat. That study showed an increased incidence of hepatocellular adenomas in high-dose females that was marginally statistically significant. To be conservative, EPA has assumed that BAM's potential for carcinogenicity is similar to the parent having the greatest carcinogenic potential. As noted, fluopicolide has been classified as not likely to be carcinogenic to humans; dichlobenil is classified as "Group C, possible human carcinogen" with the reference dose (RfD) approach utilized for quantification of human risk. Accordingly, EPA has assessed BAM's cancer risk by comparing BAM exposure to the dichlobenil RfD. For this assessment, EPA relied on BAM chronic exposure assessment as described in Unit III.C.1.ii.

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

EPA used anticipated residues and PCT information for the acute and chronic dietary risk assessments for BAM. 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 (DCIs) 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.

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 may be applied in a particular area.

The assessments assumed 100 PCT for fluopicolide and dichlobenil, except for the following dichlobenil-treated crops:

a. For the acute assessment: Apples (2.5%), blueberries (2.5%), cherries (2.5%), peaches (2.5%), pears (2.5%), and raspberries (5%).

b. For the chronic assessment: Apples (1%), blueberries (1%), cherries (1%), cranberries (45%), peaches (1%), pears (1%), and raspberries (5%).

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://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the surface water concentrations estimated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS); and Screening Concentrations in Ground Water (SCI–GROW) models, the estimated environmental concentrations (EECs) of fluopicolide for acute exposures are estimated to be 25.50 parts per billion (ppb) for surface water and 0.5 ppb for ground water.

The EECs for chronic exposures (non-cancer) assessments are estimated to be 24.14 ppb for surface water and 0.5 ppb for ground water.

The EECs for chronic exposures (cancer) assessments are estimated to be 22.36 ppb for surface water. The EECs for acute and chronic assessments are estimated to be 0.5 ppb in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 24.14 ppb was used to access the contribution to drinking water.

Considering residues of BAM in drinking water from uses of dichlobenil and fluopicolide, the uses on dichlobenil will result in the highest residues in drinking water. Therefore, the results from dichlobenil (from the use of nutsedge at 10 lb dichlobenil active ingredient/Acre (ai)/(A)) are used in this assessment, *i.e.,* 56.2 ppb was used as the value of BAM residues in drinking water in the dietary assessment for both the acute and chronic assessment.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fluopicolide is currently registered for the following uses that could result in residential exposures: Residential turf grass and ornamental plants. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short–term dermal and inhalation exposure to fluopicolide when mixing, loading, and applying the formulations. Residential post-application exposure via the dermal route is likely for adults and children entering treated lawns. Toddlers may also experience exposure via incidental non-dietary ingestion (*i.e.,* hand-to-mouth, object-to-mouth (turfgrass), and soil ingestion) during post-application activities on treated turf. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 fluopicolide or the fluopicolide metabolite, BAM to share a common mechanism of toxicity with any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluopicolide and BAM do not have a common mechanism of toxicity with other substances. Residues of BAM resulting from both the use of fluopicolide as well as from dichlobenil were evaluated to support the requested new uses. 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 Web site 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. *Prenatal and posnatal sensitivity.* For fluopicolide, there is no evidence of quantitative susceptibility following *in utero* and/or postnatal exposure in the rabbit and rat developmental toxicity studies or in the 2-generation rat reproduction study. Qualitative susceptibility was observed in the rat developmental toxicity study. Fetal effects (reduced growth and skeletal defects) and late-term abortions were observed. There is low concern for this qualitative susceptibility, because the fetal effects, and late-term abortions have been well characterized and only occurred at a dose level near the limit dose. Protection of the maternal effects also protects for any effects that may occur during development. There are no residual uncertainties concerning prenatal and postnatal toxicity for fluopicolide.

For BAM, there is no evidence of quantitative susceptibility following *in utero* and/or postnatal expsoure in the rabbit developmental toxicity study or in the 3-generation rat reproduction study. Qualitative susceptibility was not observed in the 3-generation reproduction study. Qualitative susceptibility was observed in the rabbit developmental toxicity study. Fetal effects (skeletal and visceral anomalies) and late-term abortions were observed. There is low concern for this qualitative susceptibility, because the fetal effects and late-term abortions have been well-characterized and occurred at dose levels where significant maternal toxicity (severe body weight gain decrements and decreased food consumption) was observed. Protection of the maternal effects also protects for any effects that may occur during development. There are no residual uncertainties concerning prenatal and postnatal toxicity for BAM.

3. *Conclusion.* As to fluopicolide, EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1X. That decision is based on the following findings:

i. The toxicity database for fluopicolide is largely complete, lacking only an immunotoxicity study. EPA has evaluated the available toxicity data for fluopicolide and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. The most sensitive endpoint in the database was decreased food consumption, decreased body weight gain, abortions/premature deliveries, and death. No definitive cross-species target organ was identified for fluopicolide; however, liver toxicity, kidney toxicity, and thyroid toxicity were observed in the database. No treatment-related changes indicative of potential immunotoxicity were seen in hematology parameters, organ weights (thymus, spleen), gross necropsy (enlarged lymph nodes), or histopathology (spleen, thymus, lymph nodes) when tested up to the limit dose in mice and rats. Therefore, EPA does not believe that conducting a special harmonized test guideline series 870.7800 immunotoxicity study will result in a NOAEL less than 20 mg/kg/day, which is presently used as the

point of departure for chronic risk assessment.

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. The degree of concern for prenatal and/or postnatal toxicity is low.

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. Conservative ground water and surface water modeling estimates were used. Similarly conservative residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

EPA has retained the 10X FQPA SF for BAM for those exposure scenarios that do not rely on dichlobenil toxicity data. These scenarios are acute dietary for the general population (including infants and children) and females 13–49 years of age; chronic dietary; and incidental oral non-dietary. Although EPA has developmental, reproduction, and subchronic and chronic toxicity studies for the metabolite BAM, and a structure activity analysis indicates EPA has identified its principal toxicological effects and level of toxicity, EPA is retaining the FQPA 10X SF due to remaining questions regarding the systemic neurotoxic potential of BAM, including olfactory toxicity via the oral route of exposure and the use of a LOAEL in assessing acute dietary risk for the general population. For the dermal and inhalation routes of exposures, for which the Agency is relying on dichlobenil toxicity data, EPA has reduced the FQPA SF for BAM toxicity to 1X, based on a comparison of toxicity via the intraperitoneal route of exposure showing that higher doses of BAM are needed to induce levels of olfactory toxicity that are similar to those caused by dichlobenil. Olfactory toxicity, the most sensitive endpoint, was the endpoint chosen for these exposure scenarios. Other factors EPA considered in the FQPA SF decisions for BAM include the following:

a. To compensate for deficiencies in the toxicology database for BAM, EPA performed a comparative analysis of the toxicity of BAM and the parent compounds, dichlobenil and fluopicolide, using the available animal data and DEREK analysis (Deductive Estimation of Risk from Existing Knowledge). DEREK is a toxicology application that uses structure-activity relationships to predict a broad range of toxicological properties based on a comprehensive analysis of a compound's molecular structure. Based on the available animal data and DEREK analyses, BAM does not appear to cause different organ-specific toxicities compared to fluopicolide and dichlobenil. The kidney and liver toxicities are common to all three compounds. With respect to relative toxicity, conclusions from the evaluation of the animal studies appear to confirm that both fluopicolide and dichlobenil appear to be more or equally toxic compared to BAM. A full discussion of EPA's comparative toxicity analysis of BAM, dichlobenil and fluopicolide can be found at *http://www.regulations.gov* in the document *Comparative Toxicity Using Derek Analysis for Dichlobenil, Fluopicolide and BAM* in docket ID number EPA–HQ–OPP–2007–0604. Based on the results of the available animal data and the DEREK analysis, EPA concludes that the safety factors discussed in the previous paragraph are adequate.

b. There is no evidence that BAM results in increased susceptibility of *in utero* rabbits in the prenatal developmental toxicity study.

c. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were refined using reliable PCT information and anticipated residue values calculated from residue field trial results. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to BAM in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by 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. Therefore, fluopicolide is not expected to pose an acute risk.

The acute dietary exposure estimates for BAM at the 99.9th percentile of the exposure distribution are 11% of the aPAD for the general U.S. population and 28% aPAD for all infants 1 year old, the most highly exposed group.

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 13% of the cPAD for children 1–2 years of age 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 is not expected.

The chronic dietary exposure estimates for BAM are 29% of the chronic cPAD for the general U.S. population and 93% cPAD for all infants (< 1 year old), the most highly exposed group, which is not of concern to the Agency.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluopicolide is proposed for registration for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fluopicolide. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures result in aggregate MOEs greater than the LOC of 100 for all population groups, and the aggregate short-term risk estimates for fluopicolide are below the Agency's level of concern. Short-term exposures for fluopicolide's metabolite BAM, may occur as a result of activities on treated turf. Incidental oral exposures related to turf activities have been combined with chronic dietary exposure estimates to assess short-term aggregate exposure for BAM. Since aggregate MOEs for BAM are greater than the LOC, they represent risk estimates that are below the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered

to be a background exposure level). Fluopicolide is proposed for registration for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for fluopicolide. The intermediate-term aggregate risk for fluopicolide and BAM is the same as calculated above for the short-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopicolide is not expected to pose a cancer risk to humans. The chronic risk assessment for BAM is protective of any potential cancer risk. Fluopicolide has been classified as "not likely to be carcinogenic to humans."

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Liquid Chromatography/Tandum Mass Spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail 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 U.N. 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.

A Codex tolerance for fluopicolide has been established at 0.2 ppm for the straw and fodder (dry) of cereal grains. However, this level is lower than residues values seen in wheat straw in U.S. field trials. Since the Codex MRL would not cover residues of fluopicolide in wheat straw resulting from the allowed use pattern in the U.S., the Agency has used the NAFTA MRL calculator to determine an appropriate tolerance level. There are no other Codex, Canadian, or Mexican MRLs which have been established for the other uses which are the subject of this action.

C. Revisions to Petitioned-for Tolerances

The proposed tolerance for vegetable, brassica (cole) leafy subgroup 5B should be changed from 20 ppb to 18 ppb. This tolerance was determined considering residue/processing data and, as applicable, recent agency guidance ("NAFTA Guidance Document for Guidance for Setting Pesticide Tolerances Based on Field Trial Data," Regulatory Proposal PRO2005–04, U.S. EPA and Health Canada, Pest Management Regulatory Agency, 2005.

The Agency has considered the submitted BAM animal feeding study, has calculated maximum reasonably balanced diets for livestock commodities based on existing and new uses of fluopicolide and concludes that BAM tolerances are not required to support the requested new uses.

V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, in or on vegetable, tuberous and corm subgroup 1C at 0.02 ppm; potato, processed potato waste at 0.05 ppm; vegetable root, subgroup 1A at 0.15 ppm; vegetable, brassica leafy greens subgroup 5B at 18 ppm; wheat, forage at 0.20 ppm; wheat, grain at 0.02 ppm; wheat, hay at 0.50 ppm; wheat, milled byproducts at 0.07 ppm; wheat, straw at 0.50 ppm; wheat, aspirated grain fractions at 0.07 ppm. Since the established tolerances for subgroup "1A, except sugar beets and carrots," and crop subgroup 1D (vegetable, tuberous and corm, except potato) are subsumed by the new unrestricted crop subgroup 1A tolerance and the subgroup 1C (vegetable, tuberous and corm) tolerance, the Agency will delete these tolerances concurrently with establishing the tolerances above.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, such as the tolerances 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: April 8, 2011.

G. Jeffrey Herndon,

Acting 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. Section 180.627 is amended by:
■ i. Removing the entries "Vegetable root, subgroup 1A, except sugar beet and carrot" and "Vegetable, tuberous and corm (except potato) subgroup 1D" from the table in paragraph (a).
■ ii. Revising (a) introductory text.
■ iii. Adding alphabetically commodities to the table in paragraph (a).
■ iv. Revising paragraph (d) to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

(a) *General.* 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, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified below is to be determined by measuring only fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] in or on the commodity.

Commodity	Parts per million
* * * * *	
Potato, processed waste	0.05
* * * * *	
Vegetable, brassica (cole) leafy subgroup 5B	18
* * * * *	
Vegetable root, subgroup 1A	0.15
Vegetable, tuberous and corm subgroup 1C	0.02

* * * * *

(d) *Indirect or inadvertent residues.* 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, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified below is to be determined by measuring only fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] in or on the commodity.

Commodity	Parts per million
Wheat, aspirated grain fractions	0.07
Wheat, forage	0.20
Wheat, grain	0.02
Wheat, hay	0.50
Wheat, milled byproducts	0.07
Wheat, straw	0.50

[FR Doc. 2011–9435 Filed 4–19–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket ID FEMA–2011–0002]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified BFEs will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Maps (FIRMs) in effect for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below of the modified BFEs for each community listed. These modified BFEs have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this final rule includes the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection.

The modified BFEs are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.