38 U.S.C. chapter 35 with VA within 1 year of the initial rating decision;

(3) The eligible person claims educational assistance for pursuit of an approved program of education for a period that is more than 1 year before the date VA receives his or her original claim;

(4) VA either:

(i) Received the original application on or after November 1, 2000; or

(ii) Received the original application and, as of November 1, 2000, either—

(A) Had not acted on it; or

(B) Had denied it in whole or in part, but the claimant remained entitled to pursue available administrative and judicial remedies as to the denial; and

(5) The eligible person would have been eligible to educational assistance under 38 U.S.C. chapter 35 if he or she had filed a claim on his or her eligibility date.

(Authority: 38 U.S.C. 5113; Pub. L. 106–419, 114 Stat. 1832)

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[FR Doc. E8–11726 Filed 5–27–08; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0339; FRL–8363–7]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopicolide in or on vegetable, root, subgroup 1A, except sugar beet and carrot; vegetable, leaves of root and tuber, group 2; vegetable, bulb, group 3–07; and Brassica, head and stem, subgroup 5A. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In connection with a request for new uses of the active ingredient, fluopicolide, the Agency has also evaluated the toxicity and exposure databases for 2,6-dichlorobenzamide (BAM) which is a common metabolite/degradate of dichlobenil and fluopicolide. Further characterization of fluopicolide and its metabolite BAM, will be discussed herein of this document.

DATES: This regulation is effective May 28, 2008. Objections and requests for hearings must be received on or before July 28, 2008, 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–2007–0339. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0339 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 28, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0339, 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'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. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8133–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7172) by IR-4, 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], in or on vegetable, root and tuber, group 1 at 0.2 parts per million (ppm); vegetable, leaves of root and tuber, group 2 at 12.0 ppm; vegetable, bulb, group 3 at 5.0 ppm; chive, fresh leaves at 5.0 ppm; chive, Chinese, fresh leaves at 5.0 ppm; daylily, bulb at 5.0 ppm; elegans hosta at 5.0 ppm; fritillaria, bulb at 5.0 ppm; fritillaria, leaves at 5.0 ppm; garlic, serpent, bulb at 5.0 ppm; kurrat at 5.0 ppm; lady's leek at 5.0 ppm; leek, wild at 5.0 ppm; lily, bulb at 5.0 ppm; onion, Beltsville bunching at 5.0 ppm; onion, Chinese, bulb at 5.0 ppm; onion, fresh at 5.0 ppm; onion, macrostem at 5.0 ppm; onion, pearl at 5.0 ppm; onion, potato, bulb at 5.0 ppm; onion, tree, tops at 5.0 ppm; shallot, bulb at 5.0 ppm; shallot, fresh leaves at 5.0 ppm; and brassica, head and stem, subgroup 5A at 5.0 ppm. The notice referenced a summary of the petition prepared by Valent Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has revised certain proposed tolerance levels and corrected commodity definitions as follows:

1. The Agency determined that adequate data are available to support establishing a tolerance for the bulb vegetable crop group 3–07. IR-4 petitioned for a tolerance for bulb vegetable group 3 as well as individual tolerances on chive, fresh leaves; chive, Chinese, fresh leaves; daylily, bulb; elegans hosta; fritillaria, bulb; fritillaria, leaves; garlic, serpent, bulb; kurrat; lady's leek; leek, wild; lily, bulb; onion, Beltsville bunching onion; Chinese, bulb; onion, fresh; onion, macrostem; onion, pearl; onion, potato, bulb; onion, tree, tops; shallot, bulb; and shallot, fresh leaves (PP 7E7172). In the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised bulb vegetable group 3. Changes to crop group 3 (bulb vegetable) included adding new commodities, revising existing subgroups and creating new subgroups (including bulb vegetable crop group 3–07 consisting of the commodities requested in PP 7E7172 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) that, for existing petitions for which a notice of filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on bulb vegetable crop group 3–07. Bulb vegetable crop group 3–07 consists of a variety of commodities for which tolerances were requested in PP 7E7172.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because:

i. Although the subgroup includes several new commodities, these commodities were proposed as individual tolerances and are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk;

ii. Fluopicolide exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action and

iii. The representative commodities for the revised subgroup has not changed.

2. Based upon review of the data supporting PP 7E7172, EPA has also revised the tolerance levels for vegetable, root, subgroup 1A, except sugar beet and carrot to 0.15 ppm; vegetable, leaves of root and tuber, group 2 to 15.0 ppm; and vegetable, bulb, crop group 3–07 to 7.0 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP). EPA has also determined that it is not appropriate to establish tolerances on sugar beet and carrot at this time and revised the subgroup tolerance accordingly.

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 fluopicolide 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 fluopicolide 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 fluopicolide 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 fluopicolide 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 the petitioned-for tolerances for residues of fluopicolide, [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] as an indicator of combined residues of fluopicolide and its metabolite BAM on vegetable, root, subgroup 1A, except sugar beet and carrot at 0.15 ppm; vegetable, leaves of root and tuber, group 2 at 15.0 ppm; vegetable, bulb, crop group 3–07 at 7.0 ppm; and brassica, head and stem, subgroup 5A at 5.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follow.

A. Toxicological Profile

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

information on the studies received and the nature of the adverse effects caused by fluopicolide and its metabolite 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 documents entitled *Floupicolide: Human Health Risk Assessment for the Establishment of Tolerances* for use on root vegetables (subgroup 1A), leaves of root and tuber vegetables (group 2), bulb vegetables (group 3), and head and stem brassica (subgroup 5A) on pages 29–35; and *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 on pages 54–62. Each of these risk assessments is contained within in docket ID number EPA–HQ–OPP–2007–0339.

In general, the toxicology studies conducted on fluopicolide demonstrate few or no biologically significant toxic effects at relatively low-dose levels in animal studies and only mild or no toxic effects at high doses. The subchronic and chronic toxicity studies showed that the primary effects of fluopicolide are in the liver. 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. Fluopicolide is also not neurotoxic, carcinogenic, nor mutagenic. Fluopicolide is not a developmental or reproductive toxicant. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* or post-natal exposure to fluopicolide. No toxic effects were observed in studies in which fluopicolide was administered by the dermal routes of exposure.

The rabbit developmental and rat chronic/carcinogenicity studies were considered co-critical for endpoint selection. The toxicological profile for fluopicolide suggests that increased durations of exposure (i.e., 90–day versus chronic) does not significantly increase the severity of observed effects. The rabbit developmental and rat chronic/cancer studies were therefore considered for all exposure scenarios.

BAM is a metabolite and/or environmental degradate of both the fungicide fluopicolide and the herbicide dichlobenil. Residues of BAM from uses of both fluopicolide and dichlobenil were considered when assessing BAM as a metabolite/degradate resulting from proposed uses of fluopicolide. BAM was assessed separately since there is no common toxicological effect for BAM and other fluopicolide residues of concern. The submitted acute and chronic studies on BAM were sufficient to evaluate human hazard potential. 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 were also observed but at doses of BAM that were higher than those of dichlobenil. 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 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.'' 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 dichlobenil and therefore to BAM.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fluopicolide and its metabolite BAM used for human risk assessment can be found at *http://www.regulations.gov* in documents entitled: *Fluopicolide Human Health Risk Assessment for the Establishment of Tolerances* for use on root vegetables (subgroup 1A), leaves of root and tuber vegetables (group 2), bulb vegetables (group 3), and head and stem brassica (subgroup 5A) on pages 10–11; and *BAM as a Metabolite/Degradate of Fluopicolide and Dichlobenil. Human Health Risk Assessment for proposed uses of Fluopicolide* on root vegetables (subgroup 1A), leaves of root and tuber vegetables (group 2), bulb vegetables (group 3), and head and stem brassica (subgroup 5A) on pages 3–4. Each of these risk assessments is contained within in docket ID number EPA–HQ–OPP–2007–0339.

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 and its metabolite BAM tolerances in 40 CFR 180.627 and the exposures from BAM from existing dichlobenil tolerances under 180.231. EPA assessed dietary exposures from fluopicolide and 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.

a. *Fluopicolide*. No effects were identified in the toxicological studies for fluopicolide; therefore, a quantitative acute dietary exposure assessment was not conducted.

b. *BAM*. In estimating acute dietary exposure to BAM, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, maximum residues of BAM from fluopicolide and dichlobenil field trials on food commodities with established/pending tolerances were included in the assessment. The assessments used 100 percent crop treated (PCT) except for apples, blueberries, cherries, peaches, pears, and raspberries. No livestock tolerances are established or proposed for either fluopicolide or dichlobenil.

ii. *Chronic exposure*.—a. *Fluopicolide*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances or for which tolerances are being established contain tolerance-level residues and 100 PCT.

b. *BAM*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed, maximum residues of BAM from fluopicolide and dichlobenil field trials on food commodities with established/pending tolerances were included in all foods for which there are tolerances. The assessments used 100 PCT except for apples, blueberries, cherries, cranberries, peaches, pears, and raspberries. No livestock tolerances are established or proposed for either fluopicolide or dichlobenil.

iii. *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. Therefore, a separate cancer exposure assessment was not conducted.

iv. *Anticipated residue and 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 pursuant to FFDCA section 408(f)(1) require 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 this tolerance.

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:

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 such pesticide residue.

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

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.

The Agency used PCT information as follows:

For the BAM acute assessment, maximum PCT estimates were used for the following commodities: Apples (2.5%), blueberries (2.5%), cherries (2.5%), peaches (2.5%), pears (2.5%) and raspberries (2.5%).

For the BAM chronic assessment, average PCT estimates were used for the following commodities: Apples (1%), blueberries (1%), cherries (1%), peaches (1%), pears (1%), raspberries (1%) and cranberries (45%).

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, State, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. 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 Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed in this unit 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 information on the regional consumption of food to which BAM may be applied 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, 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*.

No monitoring data were available for fluopicolide or BAM. Drinking water residues of fluopicolide (parent) were modeled for exposures resulting from uses on grapes, vegetables, and turf, which are the uses that are expected to yield the highest estimated environmental concentrations (EECs).

Drinking water residues for BAM were modeled for exposures resulting from the use currently registered on dichlobenil for control of nutsedge. This use is expected to yield the highest EECs for BAM.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW), the estimated drinking water concentrations (EDWCs) of fluopicolide for acute exposures are estimated to be 26.81 parts per billion (ppb) for surface water and 0.64 ppb for ground water. Chronic exposures are estimated to be 8.34 ppb for surface water and 0.64 ppb for ground water. Based on the PRZM/EXAMS and SCI-GROW models, the EDWCs of BAM for acute exposures are estimated to be 20.9 ppb for surface water and 56.2 for ground water. Chronic exposures are estimated to be 8.61 ppb for surface water and 56.2 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 56.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 8.34 ppb and 56.2 were used to assess the contribution to drinking water for fluopicolide and BAM, 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.The labels do not prohibit homeowners from using these products; therefore, residential handlers may receive short-term dermal and inhalation exposure to fluopicolide when mixing, loading and applying the formulations. Dermal exposure is likely for adults and children entering treated lawns. Toddlers may also experience exposure via incidental non-dietary ingestion during postapplication activities on treated turf.

EPA assessed residential exposure for fluopicolide using the following assumptions:

i. Handler exposure scenarios resulting from residential lawn applicators were assessed for 1. mix/load and spot application of liquid formulation (low-pressure hand sprayer), and 2. mix/load and broadcast application of liquid formulation (garden hose-end sprayer).

Post-application exposure scenarios resulting from lawn treatment were assessed for 1. adult and toddler postapplication dermal exposure, 2. toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer, 3. toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass, and 4. toddlers' incidental ingestion of soil from pesticide-treated residential areas. There are short and intermediate term exposures for fluopicolide.

BAM exposure estimates are based on fluopicolide use only since the use pattern for dichlobenil is not expected to result in scenarios with significant residential/non-occupational exposure. Exposure to BAM from fluopicolide uses on residential turfgrass and recreational sites, such as golf courses, has been evaluated. Residential handler exposure was not evaluated because the metabolite BAM is believed to form slowly in plants and soil after the product containing the parent (fluopicolide) has been applied.

EPA assessed residential exposure for BAM using the following assumptions:

ii. Post-application exposure scenarios resulting from lawn treatment were assessed for 1. adult and toddler postapplication dermal exposure, 2. toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer, 3. toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass, and 4. toddlers' incidental ingestion of soil from pesticide-treated residential areas. Short and intermediate term exposures for fluopicolide are expected.

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 (parent) and its metabolite BAM, and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluopicolide (parent) and its metabolite BAM has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses or pups to *in utero* or post-natal exposure to fluopicolide.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. 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 that fluopicolide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

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 postapplication exposure of children as well as incidental oral

exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

BAM: EPA is retaining 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, females 13–49 years of age, chronic dietary, and incidental oral non-dietary. This is due to the incompleteness of the data base with regard to the systemic neurotoxic potential of BAM, including olfactory toxicity via the oral route of exposure.

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. The reasons for this are that, 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 (Brandt *et al.* 1990; Brittebo *et al.* 1991; Eriksson and Brittebo 1995). Olfactory toxicity was the endpoint chosen for these exposure scenarios.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute 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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to BAM will occupy 28% of the aPAD for all infants <1 year old and females 13–49 years old, the population groups 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 11% of the cPAD for children 1–2 years old, and chronic exposure to BAM from food and water will utilize 93% of the cPAD for all infants <1 year 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 and its metabolite is not expected.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-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 and intermediate term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to fluopicolide. Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term and intermediate-term food, water, and residential exposures aggregated for fluopicolide result in aggregate MOEs of 300 for children 1–2 years.

As discussed in the unit for short-term and intermediate-term exposures, exposures to BAM may result based on use of fluopicolide only since the use pattens for dichlobenil are not expected to result in scenarios with significant residential/non-occupational exposure. Exposure to BAM from fluopicolide uses on residential turfgrass and recreational sites, such as golf courses, has been evaluated. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short and intermediate term residential exposures to BAM. Using the exposure assumptions described in this unit for short-term and intermediate-term exposures for BAM, EPA has concluded the combined short and intermediate term food, water, and residential exposures aggregated result in aggregate MOEs of 3200 for all infants <1 year old and 5,400 for children 1–2 years old.

4. *Aggregate cancer risk for U.S. population.* Fluopicolide has been classified as ''not likely to be carcinogenic to humans.'' As such, an estimate of cancer risk is not warranted for parent fluopicolide.

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 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 and its metabolite BAM residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography mass spectrometry ((LC/MS/MS) method, Method RM-43C-2) is available to enforce the tolerance expression for fluopicolide. 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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue limits (MRLs) or tolerances have been established for fluopicolide.

V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, [2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] as an indicator of combined residues of fluopicolide and its metabolite BAM on vegetable, root, subgroup 1A, except sugar beet and carrot at 0.15 ppm; vegetable, leaves of root and tuber, group 2 at 15.0 ppm; vegetable, bulb, crop group 3–07 at 7.0 ppm; and brassica, head and stem, subgroup 5A at 5.0 ppm.

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, *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 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 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) (Public Law 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: May 14, 2008.

Donald Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.627 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

(a) * * *

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	5.0
* * * * *	
Vegetable, bulb, crop group 3–07	7.0
* * * * *	
Vegetable, leaves of root and tuber, group 2	15.0
Vegetable, root, subgroup 1A, except sugar beet and carrot	0.15
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0309; FRL–8365–2]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of hexythiazox in or on corn, field, grain; corn, field, stover; and corn, field, forage. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 28, 2008. Objections and requests for hearings must be received on or before July 28, 2008, 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–2005–0309. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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