Toxicity Risk Assessment.'' **Federal Register** 61: 56274–56322.

16b. U.S. Environmental Protection Agency. ''Guidelines for Developmental Toxicity Risk Assessment.'' **Federal Register**. 56: 63798–63826.

16c. ''An Evaluation and Interpretation of Reproductive Endpoints For Human Health Risk Assessment.'' International Life Science Institute. Health and Environmental Sciences Institute. Developmental and Reproductive Toxicity Committee. November 1998.

17. Health Effects Division, Office of Pesticide Programs, US EPA, ''Data Evaluation Record: Reproduction and Fertility Effects Study – Rat; BAS 910 F'' (March 23, 2002) (EPA Reviewer: Alan Levy).

18. Office of Prevention, Pesticides and Toxic Substances, U. S. EPA, Memorandum from Alan Levy to Yan Donovan, ''BAS 510 F - Report of the Hazard Identification Assessment Review Committee'' (March 7, 2003).

19. Health Effects Division, Office of Pesticide Programs, US EPA, ''Data Evaluation Record: Prenatal Developmental Toxicity Study – Rabbit; BAS 910 F'' (March 23, 2002) (EPA Reviewer: Alan Levy).

List of Subjects in 40 CFR Part 180

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

Dated: January 17, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. E8–1523 Filed 1–29–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0481; FRL–8341–6]

Fluopicolide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance 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, 2,6-dichlorobenzamide (BAM), in or on grape at 2.0 parts per million (ppm); grape, raisin at 6.0 ppm; vegetable, cucurbit, group 9 at 0.50 ppm; vegetable, fruiting, group 8 at 1.6 ppm; vegetable, leafy, except brassica, group 4 at 25 ppm; and vegetable, tuberous and corm, subgroup, except potato, 1D at 0.02 ppm. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 30, 2008. Objections and requests for hearings must be received on or before March 31, 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–2006–0481. 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: Janet Whitehurst, Registration Division (7505P), 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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–2006–0481 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 March 31, 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–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'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 14, 2006 (71 FR 34345) (FRL–8071–4), 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 5F7016) by Valent U.S.A. Company, 1600 Riviera Ave., Walnut Creek, CA 94596–8025. The petition requested that 40 CFR 180.627 be amended by establishing a tolerance for residues of the fungicide fluopicolide, 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide, in or on grape at 2.0 ppm; raisin at 6.0 ppm; vegetable, leafy (except brassica) (group 4) at 20.0 ppm; vegetable, fruiting (group 8) at 0.8 ppm; vegetable, cucurbit (group 9) at 0.4 ppm; potato at 0.02 ppm; sweet potato, roots at 0.02 ppm; wheat, forage at 0.2 ppm; wheat, grain at 0.02 ppm; and wheat, hay and straw at 0.5 ppm. That notice referenced a summary of the petition prepared by Valent U.S.A. Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the tolerances proposed for vegetable, leafy, except brassica, group 4; vegetable, fruiting, group 8; and vegetable, curcurbit, group 9. The appropriate tolerances for vegetable, leafy, except brassica, group 4; vegetable, fruiting, group 8; and vegetable, curcurbit, group 9 are 25, 1.6, and 0.50 ppm, respectively. These tolerances were 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 (*http://www.pmra-arla.gc.ca/english/pdf/pro/pro2005–04-e.pdf*).

For the reasons stated in Unit V., EPA is not establishing at this time the following petitioned-for tolerances: Potato; wheat, forage; wheat, grain; and wheat, hay and straw.

The existing tolerances for imported grape at 2.0 ppm, and grape, raisin at 6.0 ppm now apply to all imported and U.S. domestic grapes. Additionally, the residue definition in paragraph (a) of the tolerance expression is being changed from only fluopicolide, to: 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, 2,6-dichlorobenzamide (BAM).

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. . . .'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance 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 metablite, BAM, on grape at 2.0 ppm; grape, raisin at 6.0 ppm; vegetable, cucurbit, group 9 at 0.50 ppm; vegetable, fruiting, group 8 at 1.6 ppm; vegetable, leafy, except brassica, group 4 at 25 ppm; and vegetable, tuberous and corm, subgroup, except potato 1D at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. 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 in the document entitled *Fluopicolide: Human Health Risk Assessment for Proposed Uses 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* at regulations.gov. BAM (AE C653711) is a common metabolite and/or environmental degradate of fluopicolide as well as the herbicide dichlobenil. Because the toxicological endpoints of BAM and fluopicolide are different, a separate human health risk assessment was conducted for BAM residues. The BAM risk assessment considered 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 dichlobenill uses. 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.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which 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 is sometimes used for risk assessment. Uncertainty (UFs)/ safety factors are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

A summary of the toxicological endpoints for fluopicolide used for human risk assessment can be found at regulations.gov in the document entitled *Fluopicolide: Human Health Risk Assessment for Proposed Uses 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 Code: 027412, Petition No: 5F7016 (71 FR 34345) (FRL–8071–4) in docket ID number EPA–HQ–OPP–2006–0481). 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, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopicolide tolerances in (40 CFR 180.627). EPA assessed dietary exposures from fluopicolide 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 assessments EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 Continuing Surveys of Food Intakes by Individuals (CSFII). 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 parent fluopicolide. The carcinogenic potential of BAM has been evaluated in only one species, the rat. That study showed 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, BAM's cancer risk is based on the chronic risk assessment and no separate cancer risk or exposure assessment has been conducted.

iv. *Anticipated residue and PCT information.* Anticipated residues and PCT information were used for the acute and chronic dietary risk assessments for BAM. Maximum residues of BAM from fluopicolide field trials on tuberous and corm vegetables (except potato) leafy vegetables (except brassica), fruiting vegetables, cucurbit vegetables, grapes (domestic and imported), and from dichlobenil field trials on food commodities with established/pending tolerances (40 CFR 180.231) were included in the assessments. The assessments assumed 100% CT 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 lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for fluopicolide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on

the environmental fate 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) 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. The EECs for chronic (non cancer) exposures are estimated to be 8.34 ppb for surface water and 0.64 ppb for ground water. The EECs for chronic (cancer) exposures are estimated to be 6.14 ppb for surface water and 0.64 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 8.34 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 assessments.

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 proposed for registration on the following residential non-dietary sites: Residential turfgrass 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 postapplication 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 postapplication activities on treated turf.

While it is necessary to evaluate residential exposure from all sources of fluopicolide's metabolite BAM, the use pattern for dichlobenil is not expected to result in scenarios with significant residential/non-occupational exposure. Therefore, BAM exposure estimates are based on fluopicolide use only.

Residential handler exposure was evaluated for parent fluopicolide only because the metabolite BAM is believed to form slowly in plants and soil after the product containing the parent (fluopicolide) has been applied.

Residential postapplication 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 (turf grass), and soil ingestion) during postapplication activities on treated turf.

Residential short-term/intermediate-term postapplication MOEs were estimated for ''Day 0'' exposure (i.e., the day of application).

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluopicolide and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluopicolide 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Fluopicolide and dichlobenil can form the common metabolite, BAM. To support existing tolerances and to establish new tolerances for fluopicolide, EPA conducted a human health risk assessment for exposure to BAM resulting from the use of all current and pending uses of fluopicolide and the herbicide dichlobenil. The risk assessment is conservative in terms of potential dietary and non-dietary exposures. In addition, the Agency retained the additional tenfold (10X) FQPA safety factor (SF) for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those composed of infants and children. The Agency's complete risk assessment can be found at regulations.gov, docket ID number EPA–HQ–OPP–2006–0481.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional 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 SF. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA SF value based on the use of traditional UFs and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity*. Since there was evidence of increased susceptibility of offspring following exposure to fluopicolide in rat developmental study, a Degree of Concern Analysis was performed to:

i. Determine the level of concern for the effects observed when considered in the context of all available toxicity data.

ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for this chemical.

EPA concluded that there is low concern for the qualitative susceptibility because: The offspring toxicity was well characterized and was accompanied by maternal toxicity; there was a clear NOAEL/LOAEL for offspring toxicity; and because the dose/endpoint selected for long-term risk assessments is considerably lower and would address the concerns for offspring toxicity seen in this study. Therefore, there are no residual uncertainties for prenatal and/or postnatal toxicity.

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 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. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of fluopicolide. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure data bases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. Conservative ground water and surface water modeling estimates were used. Similarly conservative Residential Standard Operating Procedues (SOPs) were used to assess postapplication exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. EPA does not expect that fluopicolide will pose an acute risk because an endpoint attributable to a single dose was not identified from the available data for fluopicolide.

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*. The chronic dietary exposure estimates for fluopicolide are 6% cPAD for the general U.S. population and 9% cPAD for children 1–2 years old, the most highly exposed subgroup. Based on the use pattern, 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 (< 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 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 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. *Long-term aggregate risk*. In examining long-term aggregate risk, the Agency has assumed that the only pathway of exposure relevant to that time frame is dietary exposure (i.e., any non-dietary exposures are short-term and/or intermediate-term in duration). Therefore, the long-term aggregate risk is composed of exposures to fluopicolide residues in food and drinking water and is equivalent to the chronic dietary risk. The chronic risk estimates are below the Agency's level of concern for all population subgroups.

6. *Aggregate cancer risk for U.S. population*. Fluopicolide has been classified as ''not likely to be carcinogenic to humans'' and, is thus not expected to pose a cancer risk. As explained in Unit III. the chronic risk assessment for BAM is protective of any potential cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, the Liquid Chromatography/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

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

C. Response to Comments

One comment was received from B. Sachau. Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to fluopicolide, including all anticipated dietary exposures and other exposures for which there is reliable

information. This comment as well as her comments regarding animal testing have been responded to by the Agency on several occasions. For examples, see the **Federal Register** issues of January 7, 2005 (70 FR 1349) (FRL–7691–4) and October 29, 2004 (69 FR 63083) (FRL–7681–9).

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 grape at 2.0 ppm; grape, raisin at 6.0 ppm; vegetable, cucurbit, group 9 at 0.50 ppm; vegetable, fruiting, group 8 at 1.6 ppm; vegetable, leafy, except brassica, group 4 at 25 ppm; and vegetable, tuberous and corm, except potato, subgroup 1D at 0.02 ppm. Additional livestock feeding studies and livestock tolerance enforcement methods are needed to support tolerances for: Potatoes and wheat. Tolerances for these commodities are not established at this time.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this 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 6, 2000) do not apply to this rule. In addition, This 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: January 17, 2008.

Debra Edwards,

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 revising paragraph (a) to read as follows:

180.627 Fluopicolide; tolerances for residues.

(a) *General.* 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, 2,6-dichlorobenzamide (BAM).

Commodity	Parts per million
Grape	2.0
Grape, raisin	6.0
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8	1.60
Vegetable, leafy, except brassica, group 4	25
Vegetable, tuberous and corm (except potato), subgroup 1D	0.02

* * * * *

[FR Doc. E8–1525 Filed 1–29–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing