to the timing requirement for submittal of an authorized tribe's first list of impaired waters pursuant to § 130.7(d)(1), the tribe's first list is due on the next listing cycle due date that is at least 24 months from the later of either:

(i) The date EPA approves the tribe's TAS application pursuant to this section; or

(ii) The date EPA-approved or EPA-promulgated water quality standards become effective for the tribe's reservation waters.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2015–0791; FRL–9951–60]**

### Fluopicolide; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends tolerances for residues of fluopicolide in or on potato, processed potato waste and vegetable, tuberous and corm, subgroup 1C and establishes a tolerance for residues of fluopicolide in or on potato, granules/flakes. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also assigns an expiration date to existing tolerances for potato, processed potato waste at 1.0 ppm and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm. Lastly, this regulation establishes a time-limited tolerance on hop, dried cones. The time-limited tolerance is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The time-limited tolerance will expire and revoked on December 31, 2019.

**DATES:** This regulation is effective September 26, 2016. Objections and requests for hearings must be received on or before November 25, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0791, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. General Information

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *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–2015–0791 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 25, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0791, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

#### II. Summary of Agency's Action

*A. Petitioned-For Tolerances*

In the **Federal Register** of March 16, 2016 (81 FR 14030) (FRL–9942–86) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8414) by Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. 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-pyridylmethyl]-benzamide, in or on potato, chips at 0.1 parts per million (ppm) and potato, granules/flakes at 0.15 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is

available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** of May 19, 2016 (81 FR 31581) (FRL–9946–02) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8414) by Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.627 be amended by amending tolerances for residues of the fungicide fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, in or on potato, processed potato waste at 0.25 ppm and vegetable, tuberous and corm, subgroup 1C at 0.10 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.*

Based upon review of the data supporting the petition, EPA is establishing tolerance levels for potato, processed potato waste and vegetable, tuberous and corm, subgroup 1C that differ from the petition requests and is not establishing a tolerance for residues on potato, chips. The reasons for these changes are explained in Unit IV.D.

*B. Tolerance for Use of Pesticide Under Emergency Exemption*

In response to a crisis exemption request filed under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) on behalf of the Michigan Department of Agriculture and Rural Development for the emergency use of fluopicolide to control downy mildew on hops grown in Michigan, EPA is establishing, pursuant to FFDCA section 408(l)(6), a time-limited tolerance for the use of fluopicolide on hop, dried cones at 30 ppm with an expiration date of December 31, 2019.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of fluopicolide on hops. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and the Agency decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2019, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on hops after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by the time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions whether fluopicolide meets FIFRA's registration requirements for use in or on hops or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance serves as a basis for registration of fluopicolide by a State for Special Local Needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Michigan to use this pesticide on hops under FIFRA sction 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for fluopicolide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopicolide including exposure resulting from the tolerances established by this action.

Fluopicolide shares a metabolite, 2,6-dichlorobenzamide (BAM), with another active ingredient, dichlobenil. Residues of BAM are considered to be of regulatory concern, and separate toxicity data and endpoints for risk assessment have been identified for BAM. Therefore, EPA has considered the aggregate, or combined risks, from food, water, and non-occupational exposure resulting from fluopicolide alone and BAM from all sources for this action. 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.

*A. Fluopicolide*

In the **Federal Register** of August 6, 2014 (79 FR 45688) (FRL–9914–37), EPA amended tolerances to raise the residue levels of fluopicolide in or on potato, processed potato waste to 1.0 ppm and vegetable, tuberous and corm, subgroup 1C to 0.3 ppm. In March of 2016, the EPA updated the dietary assessment for fluopicolide to account for the use of fluopicolide on hops under an emergency exemption. The March 2016 assessment considered the higher tolerance levels for potato, processed potato waste (1.0 ppm) and vegetable, tuberous and corm, subgroup 1C (0.3 ppm). Since this current action involves lowering the tolerances for potato, processed potato waste to 0.2 ppm and vegetable, tuberous and corm, subgroup 1C to 0.09 ppm, the EPA is relying upon the risk assessments and the findings made for fluopicolide in the August 6, 2014 **Federal Register** document, as well as an updated dietary risk assessment conducted for hops to support the lowering of the tolerances for potato, processed potato waste and vegetable, tuberous and corm, subgroup 1C.

The toxicity profile and the points of departure for evaluating human health for fluopicolide have not changed since the August 6, 2014 rule. EPA conducted a dietary risk assessment to support the Section 18 registration for use of

fluopicolide on hops grown in Michigan in March 2016. The March 2016 assessment assumed the same exposure assumptions for assessing food exposure as discussed in Unit III.C. of the 2014 rule, where the analysis assumed 100 percent crop treated (PCT) and tolerance-level residues for all proposed/registered crops except for field corn/wheat grain (rotational crop tolerances) and tuberous and corm vegetables. For these crops, the residues of concern for risk assessment include metabolites that are not included in the tolerance expression, and the analysis assumed the highest combined residues from the field trials. However, the drinking water estimates used in 2016 are higher than those used in 2014 (24.14 ppb) based on the use of the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), where residues in ground water are now estimated to be 103 ppb. The March 2016 assessment resulted in slightly higher chronic dietary exposure estimates than the August 2014 dietary risk assessment (an increase from 13% to 14% chronic population-adjusted dose (cPAD)). Since the 2016 dietary risk assessment does not take into account the tolerance reductions for potato, processed potato waste (from 1.0 ppm to 0.2 ppm) and vegetable, tuberous and corm, subgroup 1C (from 0.3 ppm to 0.09 ppm) and estimates a higher drinking water concentration (24.14 ppb to 103 ppb), EPA expects the actual chronic dietary exposure estimates to be lower than 14%. The Agency has not made any new findings concerning cumulative exposure, nor has it identified any residual uncertainties to warrant changes to the Agency's August 6, 2014 FQPA safety factor determination. EPA concludes that reliable data continue to show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X based on the same findings found in the August 6, 2014 rule and supporting documents. Therefore, relying upon the findings made in the August 6, 2014, **Federal Register** document and the 2016 dietary risk assessment, 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.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer to the August 6, 2014, **Federal Register** document and its supporting documents, available at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2014–0225, as well as document titled ''Fluopicolide. Section 18 Registration for Application of Fluopicolide to Hops Grown in Michigan. Dietary Risk Assessment.'' dated March 24, 2016, in docket ID number EPA–HQ–OPP–2015–0791.

However, since the August 6, 2014 action relied on a 2008 action for BAM, the EPA has updated the BAM assessment to revisit the percent crop treated (PCT) and account for updated food consumption data. EPA's assessment of exposures and risks associated with BAM follows.

*B. BAM*

1. 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. The toxicity profile for BAM has not changed since the 2008 assessment EPA conducted for BAM. Specific information on the studies received and the nature of the adverse effects caused by 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 in ''2,6-Dichlorobenzamide (BAM). 2,6-Dichlorobenzamide (BAM) as a Metabolite/Degradate of Fluopicolide and Dichlobenil. Human Health Risk Assessment for Proposed Uses of Rhubarb, Dichlobenil on Caneberries (Subgroup 13–07A), and Bushberries (Subgroup 13–07B).'' dated June 19, 2008, in docket ID number EPA–HQ–OPP–2007–0604.

2. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for BAM used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045) (FRL–8859–9).

3. Exposure Assessment

a. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to BAM, EPA considered exposure of BAM from petitioned-for tolerances discussed in this document, as well as all existing uses for both fluopicolide and dichlobenil. EPA assessed dietary exposures from 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 from a 1-day or single exposure.

Such effects were identified for BAM. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. EPA conducted a partially refined acute dietary exposure assessment for the metabolite BAM. As to residue levels in food, EPA assumed maximum BAM residue from either the fluopicolide or dichlobenil field trial data. Further, 100 PCT for all commodities was assumed except apples, blueberries, cherries, peaches, pears, and raspberries where EPA relied on PCT estimates based on use of dichlobenil on these commodities; fluopicolide is not registered for use on these commodities. DEEM default processing-factors were used for commodities where empirical processing data were not available.

*ii. Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the USDA NHANES/WWEIA 2003 to 2008 dietary survey. As to residue levels in food, EPA assumed maximum BAM residue from either fluopicolide or dichlobenil field trials and, further, the chronic assessment used 100 PCT for all commodities except apples. DEEM default processing-factors were used for commodities where empirical processing data were not available.

*iii. Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope-factor approach is utilized. EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to BAM.

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. Fluopicolide has been classified as not likely to be carcinogenic to humans; EPA classified dichlobenil as a Group C, possible human carcinogen, but determined that the chronic dietary risk assessment based on the cPAD would be protective of any potential cancer effects. EPA has assumed that BAM's carcinogenic potential is similar to that of dichlobenil, the parent compound having the greatest carcinogenicity potential. As with dichlobenil, the chronic dietary risk assessment based on the cPAD is expected to protect for any potential cancer effects. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.B.3.a.ii.

For additional information, refer to the summary of the toxicological endpoints for BAM used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045) (FRL–8859–9).

*iv. Anticipated residue and percent crop treated (PCT) information.* For the BAM dietary assessment, EPA used available anticipated residue levels and PCT information on apples, blueberries, cherries, peaches, pears, and raspberries where EPA relied on PCT estimates based on use of dichlobenil; fluopicolide is not registered for use on these commodities. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In the acute dietary assessment for BAM, the Agency estimated the PCT from the existing dichlobenil uses as follows: Apple, 2.5%; blueberry, 2.5%; raspberry, 20%; cherry, 2.5%; peach, 2.5%; pear, 5%. In the chronic dietary assessment for BAM, the Agency estimated the PCT from the existing dichlobenil uses as follows: Apple, 1%.

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

The Agency believes that the three conditions discussed in Unit III.B.3.a.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 fluopicolide or dichlobenil may be applied in a particular area.

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

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of BAM resulting from application of dichlobenil for acute exposures are estimated to be 25.5 parts per billion (ppb) for surface water and 67.4 ppb for ground water. The EDWCs of BAM resulting from application of dichlobenil for chronic exposures for non-cancer assessments are estimated to be 10.5 ppb for surface water and 67.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration of value 67.4 ppb was used to assess the contribution to drinking water.

c. *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, recreational sites, and ornamental plants and trees. EPA assessed residential exposure to BAM from fluopicolide uses using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposure to BAM when mixing, loading, and applying the fluopicolide formulations. Residential post-application exposure via the dermal route is likely for adults and children entering treated lawns or treated gardens and during mowing and golfing activities. Children may experience exposure via incidental non-dietary ingestion (*i.e.,* hand-to-mouth, object-to-mouth, and soil ingestion) during post-application activities on treated turf.

Residential handler exposure to BAM resulting from the application of dichlobenil is not expected. While dichlobenil is currently registered for residential uses on ornamental plants, they are approved for professional applicator use only. Post-application exposure of adults and children to dichlobenil and BAM exposure from the use of dichlobenil products on ornamental plants is expected to be negligible and, therefore, was not assessed.

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluopicolide and any other substances. Fluopicolide shares a common metabolite, BAM, with dichlobenil. Quantification of risks for residues of BAM resulting from fluopicolide and dichlobenil was completed as part of this assessment; aggregate risks from BAM are not of concern. For the purposes of this tolerance action, 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 Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*

4. Safety Factor for Infants and Children

a. *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.

b. *Prenatal and postnatal sensitivity.* For BAM, there is no evidence of quantitative susceptibility following in utero and/or postnatal exposure 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 not residual uncertainties concerning prenatal and postnatal toxicity for BAM.

c. *Conclusion.* 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 (olfactory neurotoxicity) 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 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:

i. 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.

ii. For BAM, there is no evidence of quantitative susceptibility following in utero and/or postnatal exposure 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 however, qualitative susceptibility was observed in the rabbit developmental toxicity study. Yet the concern for this qualitative susceptibility is low 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.

iii. 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 and surface water modeling used to assess exposure to BAM 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 BAM.

5. 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.

*a. Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to BAM will occupy 26% of the aPAD for females 13 to 49 years old, the population group receiving the greatest exposure.

*b. Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to BAM from food and water will utilize 95% of the cPAD for all Infants (<1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.B.3.c., regarding residential use patterns, chronic residential exposure to residues of BAM is not expected.

*c. Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered a background exposure level). Fluopicolide, is currently registered for uses that could result in short-term residential exposure to BAM, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to BAM associated with the application of fluopicolide. As noted in Unit III.B.3.c above, EPA does not expect there to be residential exposures to BAM from use of dichlobenil. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 3200 for All Infants (<1 year old) and 5,400 for children 1 to 2 years old. Because EPA's level of concern for BAM is a MOE of 1,000 or below, these MOEs are not of concern.

*d. Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered a background exposure level). An intermediate-term adverse effect was identified; however, fluopicolide is not registered for any use patterns that would result in intermediate-term residential exposure. Further, fluopicolide and dichlobenil are not registered for any use patterns that would result in intermediate-term residential exposure to BAM. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluopicolide and its metabolite, BAM.

*e. Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. See Unit III.B.5.b, *Chronic risk,* above.

*f. 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 residues of fluopicolide and its metabolite, BAM.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography/tandem mass spectrometry (LC/MS/MS)) 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; email address: *residuemethods@epa.gov.*

### *B. International Residue Limits*

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

EPA explain the reasons for departing from the Codex level. The Codex has not established an MRL for fluopicolide on the subject commodities.

*C. Response to Comments*

EPA received one comment to the Notice of Filing that stated, in part, that the citizenry of this country do not want to eat any food items that have been polluted by these toxic chemicals and to deny this exemption. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

*D. Revisions to Petitioned-For Tolerances*

EPA revised the tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. Based on evaluation of the residue data and use of the OECD calculation procedures, the Agency modified the tolerance for the vegetable, tuberous and corm, subgroup 1C from the requested level of 0.10 ppm to 0.09 ppm. The Agency also modified the tolerance for potato, processed potato waste from the requested tolerance level of 0.25 ppm to 0.2 ppm (0.075 ppm maximum residue × 2.4 processing factor for wet peel). The EPA did not establish the requested tolerance for potato, chips because the tolerance for vegetable, tuberous and corm, subgroup 1C (0.09 ppm) will cover residues in or on potato chips (0.068 ppm estimated residue).

*E. International Trade Considerations*

In this rulemaking, EPA is reducing the tolerances for vegetable, tuberous and corm, subgroup 1C from 0.3 ppm to 0.09 ppm and potato, processed potato waste from 1.0 ppm to 0.2 ppm. The petitioner requested these reductions in order to harmonize tolerances with field trial data after the tolerances were increased in 2014 to support an early season soil application to potato, which has since then been restricted. The reduction is appropriate based on available data and residue levels resulting from registered use patterns.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures Agreement, EPA notified the WTO of the request to revise these tolerances on July 19, 2016 as WTO notification G/SPS/N/USA/2861. In this action, EPA is allowing the existing higher tolerances to remain in effect for 6 months following the publication of this rule in order to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. On March 27, 2017, those existing higher tolerances will expire, and the new reduced tolerances for vegetable, tuberous and corm, subgroup 1C and potato, processed potato waste will remain to cover residues of fluopicolide on those commodities. Before that date, residues of fluopicolide on those commodities would be permitted up to the higher tolerance levels; after that date, residues of fluopicolide on vegetable, tuberous and corm, subgroup 1C and potato, processed potato waste will need to comply with the new lower tolerance levels. This reduction in tolerance is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

## V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, in or on vegetable, tuberous and corm, subgroup 1C at 0.09 ppm, potato, processed waste at 0.2 ppm, and potato, granules/flakes at 0.15 ppm. The Agency is adding an expiration date of March 27, 2017 to the existing tolerances for vegetable, tuberous and corm, subgroup 1C at 0.3 ppm and potato, processed potato waste at 1.0 ppm. Residues of fluopicolide will be covered by these higher tolerances until the expiration date, after which time, they will need to comply with the lower tolerances being established today. Lastly, this regulation establishes a time-limited tolerance for residues of fluopicolide in or on hop, dried cone at 30 ppm.

## VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning, and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

### VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

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

Dated: September 13, 2016.

**Daniel J. Rosenblatt,**

*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. In § 180.627:

■ a. In the table in paragraph (a), add alphabetically entries for ''Potato, granules/flakes'' and ''Potato, processed potato waste,'' revise the existing entry for ''Potato, processed potato waste,'' and add an entry for ''Vegetable, tuberous and corm, subgroup 1C''; and

■ b. Revise paragraph (b).

The additions and revisions read as follows:

**§ 180.627 Fluopicolide; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Potato, granules/flakes | 0.15 |
| Potato, processed potato waste | 0.2 |
| Potato, processed potato waste.[1] | 1.0 |
| * * * * * | |
| Vegetable, tuberous and corm, subgroup 1C | 0.09 |
| Vegetable, tuberous and corm, subgroup 1C[1] | 0.3 |

[1] This tolerance expires on March 27, 2017.

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the fluopicolide, including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. 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. The tolerances expire on the date specified in the table.

| Commodity | Parts per million | Expiration date |
|---|---|---|
| Hop, dried cones | 30 | December 31, 2019. |

* * * * *

[FR Doc. 2016–23184 Filed 9–23–16; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 711

**[EPA–HQ–OPPT–2009–0187; FRL–9952–64]**

**RIN 2070–AJ43**

## Chemical Data Reporting; 2016 Submission Period Extension

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is amending the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) regulations by extending the submission deadline for 2016 reports from September 30, 2016 to October 31, 2016. This is a one-time extension for the 2016 submission period only. The CDR regulations require manufacturers (including importers) of certain chemical substances included on the TSCA Chemical Substance Inventory (TSCA Inventory) to report current data on the manufacturing, processing, and use of the chemical substances.

**DATES:** This final rule is effective September 26, 2016.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0187, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Susan Sharkey, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8789; email address: *Sharkey.susan@epa.gov.*

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import and manufacture as a byproduct) chemical substances listed on the TSCA Inventory. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include but are not limited to:

- Chemical manufacturers (including importers) (NAICS codes 325 and 324110, *e.g.,* chemical manufacturing and processing and petroleum refineries).
- Chemical users and processors who may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344, *e.g.,* utilities, paper manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing).