coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone and, therefore it is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0635 to read as follows:

§ 165.T09–0635 Safety Zone; Gay Games 9 Open Swim, Lake Erie, Cleveland, OH.

(a) *Location.* This safety zone will encompass all waters of Lake Erie near the shore of Edgewater Park in Cleveland, OH within a 1000-yard radius centered around 41°29′40″ N and 081°44′24″ W (NAD 83).

(b) *Effective and enforcement period.* This section is effective and will be enforced on August 10, 2014, from 8 a.m. until 1 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: July 25, 2014.

B.W. Roche,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2014–18605 Filed 8–5–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0225; FRL–9914–37]

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. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 6, 2014. Objections and requests for hearings must be received on or before October 6, 2014, 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–2014–0225, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0225 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 October 6, 2014. 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–2014–0225, by one of the following methods:

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL–9910–29), 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* 3F8191) 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-pyridinyl]methyl]benzamide, in or on potato, processed waste at 0.3 parts per million (ppm); and vegetable, tuberous and corm, subgroup 1C at 0.3 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.* 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 revised the proposed tolerance in or on potato, processed waste from 0.3 ppm to 1.0 ppm, and has revised the commodity terminology. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

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

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. However, since increased tolerances on the commodities affected by this action do not add significantly to the BAM dietary exposure, the conclusions from the most recently conducted BAM human health risk assessment remain unchanged.

The subchronic and chronic toxicity studies for fluopicolide showed that the primary effects following exposure are in the liver. Kidney and thyroid toxicity were observed in rats only. Fluopicolide is not neurotoxic, carcinogenic, nor mutagenic. Developmental toxicity in the rabbit occurred only at doses that caused severe maternal toxicity, including death. In the rat, developmental effects were seen only at high dose levels, in the presence of maternal toxicity. Similarly, offspring effects (decreased body weight and body weight gain) in the multi-generation reproductive toxicity study occurred only at levels causing significant toxicity in parents. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* or postnatal exposure to fluopicolide. No toxic effects were observed in studies in which fluopicolide was administered by the dermal routes of exposure. The toxicological profile for fluopicolide suggests that increased durations of exposure do not significantly increase the severity of observed effects. Toxic effects observed in the rabbit developmental and rat chronic/cancer studies were selected as risk assessment endpoints for all durations of exposure. Fluopicolide is classified as not likely to be carcinogenic to humans and no quantification of cancer risks is required.

The toxicity profile for BAM has not changed since the last assessment EPA conducted for BAM; an analysis of the toxicology profile of BAM 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.

Specific information on the studies received and the nature of the adverse effects caused by fluopicolide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://w www.regulations.gov* in document: ''Fluopicolide and its Metabolite, 2,6-Dichlorobenzamide (BAEM). Human Health Risk Assessment to Support a Petition for an Increased Tolerance on Tuberous and Corm Subgroup 1C Vegetables,'' pp. 31–35 in docket ID number EPA–HQ–OPP–2014–0225.

B. Toxicological Points of Departure/ Levels of Concern

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

A summary of the toxicological endpoints for fluopicolide and 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).

C. Exposure Assessment

The fluopicolide exposure assessment considers exposure from fluopicolide only. EPA did not reassess exposures from BAM since the proposed change in use pattern does not add significantly to the BAM dietary exposure, and residues of BAM due to fluopicolide applications are significantly lower than those from dichlobenil applications. EPA is relying on conclusions from the 2008 BAM Human Health Risk Assessment, which remain unchanged. A discussion of how BAM exposures were assessed can be found in Unit III.C. of the final rule published in the **Federal Register** of August 27, 2008 (73 FR 50563) (FRL–8377–7).

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.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues. iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopicolide does not pose a cancer risk to humans. Therefore, a quantitative dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluopicolide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopicolide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the surface water concentrations estimated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS); and Screening Concentrations in Ground Water (SCI–GROW) models, the estimated environmental concentrations (EECs) of fluopicolide for chronic exposure (non-cancer) assessments are estimated to be 24.14

ppb for surface water and 0.5 ppb for ground water. Acute and cancer dietary risks were not quantified, as previously discussed.

3. *From non-dietary exposure.* i. 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).

ii. Fluopicolide is currently registered for the use on residential turf grass, recreational sites, and ornamental plants that could result in short-term residential exposures. EPA assessed residential exposure using the following assumptions:

a. Residential handler short-term dermal and inhalation exposures to fluopicolide when mixing, loading, and applying the formulations.

b. Residential post-application exposures via the dermal route for adults and children entering treated lawns or treated gardens and during mowing and golfing activities. and

c. Incidental non-dietary ingestion (i.e., hand-to-mouth, object-to-mouth, and soil ingestion) by children during post-application activities on treated turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

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. Although fluopicolide shares a common metabolite, BAM, with dichlobenil, quantification of risks for residues of BAM resulting from fluopicolide was not done as part of this assessment because they contribute an insignificant amount to the total BAM exposure. Furthermore, aggregate risks to 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at: *http://www.epa.gov/pesticides/cumulative/.*

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is no evidence of quantitative susceptibility following *in utero* and/or postnatal fluopicolide exposure in the rabbit and rat developmental toxicity studies or in the 2-generation rat reproduction study. Qualitative susceptibility was observed in the rat developmental toxicity study. In this study, fetal effects (reduced growth and skeletal defects) and late-term abortions were observed at doses at which only decreased body weight gain were observed in maternal animals. There is low concern for this qualitative susceptibility because the fetal effects and late-term abortions have been well characterized and only occurred at a dose level near the limit dose. Protection for the maternal effects also protects for any effects that may occur during development. There are no residual uncertainties concerning prenatal and postnatal toxicity for fluopicolide.

3. *Conclusion regarding fluopicolide.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluopicolide is complete.

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

iii. There is no evidence that fluopicolide results in increased susceptibility in *in utero* rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there was some evidence of qualitative susceptibility in the rat developmental toxicity study, as discussed in Unit III.D.2., the degree of concern for the prenatal and/or postnatal toxicity is low; thus, there is no need for the 10X FQPA safety factor to account for potential prenatal or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopicolide in drinking water. Although EPA has required additional data on transferable residues from treated turf for fluopicolide, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (e.g., assuming residues do not degrade over the thirty-day assessment period and assuming high-end activities on turf for every day of the assessment period). Therefore, EPA is confident that it has not underestimated postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

4. *Conclusion regarding BAM.* For reasons explained in the Unit III.D.3.ii. of the preamble to the final rule published in the **Federal Register** of August 27, 2008, EPA reduced the FQPA safety factor for BAM to 1X for inhalation and dermal exposure scenarios and retained the 10X FQPA safety factor for all other BAM exposure scenarios. EPA is relying on the findings in the preamble of the August 27, 2008 final rule and the 2008 BAM Risk Assessment for the BAM FQPA safety factor determinations for this action.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime

probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopicolide from food and water will utilize 13% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopicolide is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluopicolide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate average exposure through food and water with short-term residential exposures to fluopicolide.

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 110 for adults and 180 for children aged 6 to less than 11 years old. Because EPA's level of concern for fluopicolide is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, fluopicolide is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus average 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.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopicolide is not expected to pose a cancer risk to humans.

6. *BAM.* As noted in Unit III.C., EPA does not expect the increased tolerances in this action to increase BAM exposure above what was assessed in the June 19, 2008 BAM risk assessment. None of the results of this BAM risk assessment indicated a risk from aggregate BAM exposures, including for acute and chronic risks. Similarly, since short- and intermediate-term aggregate MOEs for BAM are greater than the LOC, they represent risk estimates that are below the Agency's level of concern. Finally, EPA has determined that BAM does not pose an aggregate cancer risk for the U.S. population. EPA has relied upon the conclusions from the June 19, 2008 BAM Risk Assessment in order to make these determinations.

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, 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 made a request to reconsider ''loosening tolerances'' for several pesticide petitions, including for fluopicolide. The commenter additionally noted that, ''It is an issue of environmental justice that our youngest citizens—our children—are disproportionately exposed to health risks.'' The commenter points to an American Academy of Pediatrics Policy statement regarding pesticide exposure in children, a Centers for Disease Control and Prevention report on human exposure to environmental chemicals, and a President's Cancer Panel regarding reducing environmental cancer risks in supporting the request to reconsider the tolerance amendments proposed for fluopicolide.

The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food, or that pesticide tolerances should be ''significantly tightened'' as the commenter notes. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when EPA determines that aggregate exposure to that pesticide is safe, i.e., that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. When making this determination, EPA considers the toxicity, including any potential carcinogenicity, of the pesticide and all anticipated dietary exposures and all other exposures for which there is reliable information. EPA also gives special consideration to the potential susceptibility and exposures of infants and children to the pesticide chemical residue when making this determination. For fluopicolide, the Agency has considered all the available data, including all available data concerning the potential for carcinogenicity of fluopicolide and its metabolites, and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm

will result from aggregate human exposure to fluopicolide and that, accordingly, the amended fluopicolide tolerances on potato, processed potato waste and vegetable, tuberous and corm, subgroup 1C, are safe.

D. Revisions to Petitioned-For Tolerances

Based on the data supporting the petition, EPA has determined that the proposed tolerance in or on potato, processed waste at 0.3 ppm should be established at 1.0 ppm. That determination was based on the following: Processing data previously provided for the use of fluopicolide on potato indicate that residues of fluopicolide concentrate in wet peels. Residues of fluopicolide found in or on potatoes are estimated to be in the range of 0.2 ppm to 0.25 ppm following directed soil application. Using the highest estimated value of residues found in or on potato and the theoretical concentration factor of 4.0X for potato processed waste (in accordance with EPA's Residue Chemistry Test Guidelines), EPA has determined that a tolerance of 1.0 ppm is appropriate for residues on potato, processed waste. Additionally, EPA has revised the commodity terminology to potato, processed potato waste in order to reflect the preferred designation.

V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide, in or on potato, processed potato waste at 1.0 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: July 29, 2014.

Lois Rossi,

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, revise the following entries in the table in paragraph (a) to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Potato, processed potato waste	1.0
* * * * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.3

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0904; FRL–9912–92]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenazate in or on multiple commodities which are identified and discussed later in this document including tolerances with regional restrictions for timothy hay and timothy forage. In addition, this regulation removes existing tolerances on ''fruit, pome, group 11'' ''vegetable, fruiting, group 8'' and existing time-limited tolerances for ''timothy, forage'' and ''timothy, hay'' that are superseded