extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Clarity of This Rule

We are required by Executive Orders 12866 (section 1(b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

List of Subjects in 36 CFR Part 2

Environmental protection, National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 2 as set forth below:

PART 2—RESOURCE PROTECTION, PUBLIC USE AND RECREATION

■ 1. The authority citation for Part 2 continues to read as follows:

Authority: 54 U.S.C. 100101, 100751, 320102.

■ 2. Amend § 2.52 as follows:

■ a. Revise the section heading.

■ b. Revise the paragraph (a) subject heading.

■ c. Add two sentences at the end of paragraph (a).

■ d. Revise paragraph (b) introductory text.

The revisions and additions to read as follows:

§ 2.52 Sale of printed matter and the distribution of printed matter and other message-bearing items.

(a) *Printed Matter and Other Message Bearing Items.* * * * The term ''other message-bearing items'' means a message-bearing item that is not ''printed matter,'' that is distributed free of charge and without asking for payment or a donation, and is not solely commercial advertising. Other message-bearing items include, but are not limited to: Readable electronic media such as CDs, DVDs, and flash drives; clothing and accessories such as hats and key chains; buttons; pins; and bumper stickers.

(b) *Permits and the small group permit exception.* The sale or distribution of printed matter, and the free distribution of other message-bearing items, is allowed within park areas if it occurs in an area designated as available under § 2.51(c)(2) and when the superintendent has issued a permit for the activity, except that:

* * * * *

Dated: October 4, 2016.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–24641 Filed 10–13–16; 8:45 am]

BILLING CODE 4312–52–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0824; FRL–9952–75]

RIN 2070–ZA16

Tebufenozide; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish tolerances for residues of tebufenozide in or on multiple commodities which are identified and discussed later in this document and amend the existing tolerance for almond, hulls under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before December 13, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2008–0824, 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 Confidential Business Information (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.*

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. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked

will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. This Proposal

EPA on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to establish tolerances for residues of the insect growth regulator tebufenozide, in or on bushberry subgroup 13–07B at 3.0 part per million (ppm); caneberry subgroup 13–07A at 3.0 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome group 11–10 at 1.0 ppm; nut, tree, group 14–12 at 0.1 ppm; sugarcane, cane at 1.0 ppm; sugarcane, molasses at 3.0 ppm; vegetable, fruiting, group 8–10 at 1.0 ppm. The Agency is also proposing to amend the existing tolerance for almond, hulls to raise the tolerance from 25 ppm to 30 ppm. Further, upon the establishment of these tolerances, the Agency is proposing to delete the existing tolerances for apple; berry, group 13; fruit, citrus, group 10; fruit, pome; nut, tree, group 14; pistachio; vegetable, fruiting, group 8; and walnut since they will be superseded by the newly established tolerances.

The EPA is proposing to establish tolerances on sugarcane, cane; and sugarcane, molasses since permanent tolerances established in a September 22, 1999 Final Rule in the **Federal Register** (64 FR 51251) were later inadvertently removed from 40 CFR 180.482. *See* 67 FR 35045 (May 17, 2002). Additionally, EPA is proposing to convert several existing crop group tolerances to updated crop group tolerances consistent with its policy as stated in its most recent crop group rulemaking. *See* 81 FR 26471, 26474 (May 3, 2016). EPA has stated that it will convert tolerances for any pre-existing crop group to tolerances with coverage under the revised crop group through the registration review process and in the course of evaluating new uses for a pesticide. *Id.* As part of the registration review for tebufenozide, EPA considered the pesticide exposures to commodities included in the updated crop groups and determined that they are safe. Finally, in order to harmonize with Codex, the following tolerance levels are proposed to be amended: fruit, citrus, group 10–10 will be increased from 0.80 to 2.0 ppm; fruit, pome, group 11–10 will be lowered from 1.5 to 1.0 ppm; and almond, hulls will be increased from 25 to 30 ppm.

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), 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, consistent with FFDCA section 408(b)(2), for tolerances for residues of tebufenozide. EPA's assessment of exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

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

The toxic effects of tebufenozide in mammalian species arise primarily from methemoglobinemia associated with denaturation of hemoglobin and concomitant Heinz body formation in erythrocytes, resulting in a rapid turnover of red blood cells with increased hematopoiesis, splenic discoloration, and other spleen effects. This type of toxicity is often typical of compounds with a hydrazine moiety, and is consistent with the structure of tebufenozide. The hematologic effects have been observed in all mammalian species tested to date (rat, mouse, dog, and rabbit), with no indication of any significant differences between sexes. There is no evidence that tebufenozide is neurotoxic, or that it causes reproductive or developmental toxicity. There is no indication of increased susceptibility of fetuses or pups (effects occur above maternally toxic doses). There was no toxicity noted in a 21-day dermal toxicity study and no immunotoxicity was observed in immunotoxicity studies in both rats and mice. Tebufenozide is classified as ''not likely to be carcinogenic to humans'' based on lack of evidence of carcinogenicity in rats and mice and no evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by tebufenozide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''Tebufenozide: Draft Human Health Risk Assessment for Registration Review'' on pages 18–24 in docket ID number EPA–HQ–OPP–2008–0824–0024.

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 toxicology 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 tebufenozide used for

human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TEBUFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	No appropriate endpoint attributable to a single dose was identified in the toxicity database.		
Chronic dietary (All populations)	NOAEL = 2.0 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day ..... cPAD = 0.02 mg/kg/day	90-day and 1-year dog studies (Cocritical) LOAEL = 8.7 mg/kg/day based on decreases in body weight gains, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen, and liver.
Incidental oral short-term (1 to 30 days).	NOAEL = 2.0 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	90-day and 1-year dog studies (Cocritical) LOAEL = 8.7 mg/kg/day based on decreases in body weight gains, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen, and liver.
Dermal (All durations)	No dermal endpoint was selected based on a lack of systemic toxicity in the dermal study and no concern for susceptibility.		
Inhalation (All durations)	Inhalation (or oral) study NOAEL= 2.0 mg/kg/day (inhalation toxicity assumed to be equivalent to oral toxicity 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	Occupational LOC for MOE = 100.	90-day and 1-year dog studies (Cocritical) LOAEL = 8.7 mg/kg/day based on decreases in body weight gains, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen, and liver.
Cancer (Oral, dermal, inhalation).	Classification: This chemical is classified as ''not likely'' to be a human carcinogen. A cancer risk assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tebufenozide, EPA considered exposure under the proposed tolerances as well as all existing tebufenozide tolerances in 40 CFR 180.482. EPA assessed dietary exposures from tebufenozide 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 tebufenozide; 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 the 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 incorporated tolerance-level residues, average percent crop treated (PCT) estimates for some commodities, and DEEM 7.81 default processing factors as appropriate.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that tebufenozide is classified as ''Not Likely to be Carcinogenic to Humans.'' Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue information in the dietary assessment for tebufenozide; tolerance level residues were assumed for all food commodities.

The Agency did use some PCT information for the dietary assessment.

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.

The Agency estimated the PCT for existing uses as follows: blueberries: 10%; cabbage, caneberries, cauliflower, celery, lettuce, parsley, pecans, peppers, tomatoes and walnuts: each at 5%; almonds, broccoli, pistachios, spinach, and turnip roots: each at 2.5%; apples, citrus, cotton, grapes and pears: each at 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.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tebufenozide may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tebufenozide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tebufenozide. 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.*

The residues of concern in drinking water was recently updated to include parent and metabolite RH–112651 for ground water and parent plus 3 metabolites, RH–112651, RH–112703, and RH–96595 for surface water. The Total Toxic Residues (TTR) approach was used, assuming presence of parent tebufenozide plus all three of its major metabolites, RH–112651, RH–112703, and RH–9659 in both ground and surface water in its assessment of tebufenozide residues in drinking water. Based on the Surface Water Concentration Calculator (SWCC) with the Provisional Cranberry Model and Pesticide Root Zone Model for Groundwater (PRZM–GW) model, the estimated drinking water concentrations (EDWCs) of tebufenozide for chronic exposures are estimated to be 105.8 parts per billion (ppb) for surface water and 107.2 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 107 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tebufenozide is currently registered for the following uses that could result in residential exposures: Ornamentals in outdoor residential areas. EPA assessed residential exposure using the following assumptions: For adult handlers, it is assumed that residential use will result in short-term (1 to 30 days) duration for dermal and inhalation exposures. However, since a dermal hazard was not identified, only the residential inhalation exposure from applications to garden/trees via backpack sprayer was assessed. Although an incidental oral endpoint was identified, incidental oral exposure is not expected based on the on application to ornamentals in outdoor residential areas.

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.*

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

EPA's Office of Pesticide Programs (OPP) has previously developed guidance documents for establishing common mechanism groups (CMGs) (Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity (1999)) and conducting cumulative risk assessments (CRAs) (Guidance on Cumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity (2002)). In 2016, EPA's Office of Pesticide Programs released another guidance document entitled Pesticide Cumulative Risk Assessment: Framework for Screening Analysis. All three of these documents can be found at *http://www.regulations.gov* in docket ID EPA–HQ–OPP–2015–0422.

The agency has utilized this framework for tebufenozide and determined that halofenozide, tebufenozide, and methoxyfenozide (diacylhydrazines) form a candidate CMG. This group of pesticides is

considered a candidate CMG because they share characteristics to support a testable hypothesis for a common mechanism of action. Following this determination, the Agency conducted a screening-level cumulative risk assessment consistent with the 2016 guidance document. This screening assessment indicates that that cumulative dietary and residential aggregate exposures for the diacylhydrazine candidate CMG, including tebufenozide, are below EPA's levels of concern. The Agency's screening level cumulative analysis can be found at *http://www.regulations.gov* in the document ''Diacylhydrazines Cumulative Screening Risk Assessment: Methoxyfenozide and Tebufenozide'' in docket ID number EPA–HQ–OPP–2008–0824.

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.* The toxicology data for tebufenozide provides no indication of enhanced sensitivity of infants and children based on the results from developmental studies conducted with rats and rabbits as well as two-generation reproduction studies conducted with rats.

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

i. The toxicity database for tebufenozide is complete.

ii. There is no indication that tebufenozide 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 tebufenozide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessment used tolerance-level residues and was only partially refined by use of PCT information. EPA does not expect post-application exposures for infants and children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tebufenozide in drinking water, which includes the use of the TTR approach. These assessments will not underestimate the exposure and risks posed by tebufenozide.

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, tebufenozide 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 tebufenozide from food and water will utilize 37% of the cPAD for children 1 to 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 tebufenozide 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).

Tebufenozide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to tebufenozide. 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 an aggregate MOE of 550 for adults. Because EPA's level of concern for tebufenozide is a MOE of 100 or below, this MOE is 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, tebufenozide 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 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 tebufenozide.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography using ultraviolet detection (HPLC–UV)) 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 US tolerances with international standards whenever possible, consistent with US 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 established MRLs for tebufenozide in or on sugarcane; fruit, citrus, group 10–10; fruit, pome, group 11–10; and almond, hulls. The proposed US tolerances would be harmonized with the Codex MRLs.

C. International Trade Considerations

In this proposed rule, EPA is proposing to reduce the tolerance in or on fruit, pome, group 11–10 from 1.5 to 1.0 ppm. The Agency is proposing this reduction in order to harmonize with the Codex MRL. 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 (SPS) Agreement, EPA will notify the WTO of its intent to revise this tolerance. In addition, the SPS Agreement requires that Members provide a ''reasonable interval'' between the publication of a regulation subject to the Agreement and its entry into force in order to allow time for producers in exporting Member countries to adapt to the new requirement. Although the WTO has determined that six months would be a reasonable interval, it has also recognized that some circumstances may warrant implementation of a regulation without the de facto six month implementation delay, *e.g.,* where exporting countries can adapt to the new requirements within a shorter interval. (Ref. 1 at 100).

EPA is proposing not to provide a reasonable interval between the publication of this rule and the date it becomes effective because it believes that exporting countries do not need time to adjust to the new requirement. With very few exceptions, all of the global maximum residue levels for tebufenozide on pome fruits are already at or below EPA's proposed level of 1.0 ppm. Although Mexico allows 1.5 ppm on crabapple, pear, and quince, Mexico defaults to the US tolerance levels. Similarly, although Hong Kong has established a maximum residue level of 1.5 ppm for pear and Asian pear, it has not exported those fruits to the United States in the past 2 years. As a result, EPA believes that a reasonable interval between the publication of this rule and the effective date of these tolerances is not necessary and proposes to make the reduction effective upon publication of the final rule.

This proposed 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

EPA proposes to establish tolerances for residues of tebufenozide in bushberry subgroup 13–07B at 3.0 ppm; caneberry subgroup 13–07A at 3.0 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome group 11–10 at 1.0 ppm; nut, tree, group 14–12 at 0.1 ppm; sugarcane, cane at 1.0 ppm; sugarcane, molasses at 3.0 ppm; and vegetable, fruiting, group 8–10 at 1.0 ppm. The Agency is also proposing to amend the existing tolerance for almond, hulls to raise the tolerance from 25 ppm to 30 ppm. Further, upon the establishment of these tolerances, the Agency is proposing to delete the existing tolerances for apple; berry, group 13; fruit, citrus, group 10; fruit, pome; nut, tree, group 14; pistachio; vegetable, fruiting, group 8; and walnut since they will be superseded by the newly established tolerances.

VI. References

Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes,* 222–23, WT/DS406/AB/R (Apr. 4, 2012) (*adopted* Apr. 24, 2012) *available at http://www.wto.org/english/tratop_e/dispu_e/406abr_e.pdf.*

VII. Statutory and Executive Order Reviews

In this proposed rule in Unit II, EPA is proposing to establish tolerances under FFDCA section 408(e), and also modify and revoke specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions (*e.g.,* establishment and modification of a tolerance and tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or 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.*). Nor does it require any special considerations as required by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This proposed rule 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). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the **Federal Register** of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL–5753–1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document is available in the docket of this proposed rule). Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Taking into account this analysis, and

available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule, and will be addressed prior to issuing a final rule. In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *''*Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

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 30, 2016.

Michael L. Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Amend the table in § 180.482(a)(1) as follows:

■ a. Remove the entries for ''Apple''; ''Berry group 13''; ''Fruit, citrus, group 10''; ''Fruit, pome''; ''Nut, tree, group 14''; ''Pistachio''; ''Vegetable, fruiting, group 8''; and ''Walnut'';

■ b. Revise the entry for ''Almond, hulls''; and

■ c. Add alphabetically the entries for ''Bushberry subgroup 13–07B''; ''Caneberry subgroup 13–07A''; ''Fruit, citrus, group 10–10''; ''Fruit, pome, group 11–10''; ''Nut, tree, group 14–12''; ''Sugarcane, cane''; ''Sugarcane, molasses''; and ''Vegetable, fruiting, group 8–10''.

The revisions and additions read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Almond, hulls	30
* * * * *	
Bushberry subgroup 13–07B	3.0
* * * * *	
Caneberry subgroup 13–07A	3.0
* * * * *	
Fruit, citrus, group 10–10	2.0
Fruit, pome, group 11–10	1.0
* * * * *	
Nut, tree, group 14–12	0.1
* * * * *	
Sugarcane, cane	1.0
Sugarcane, molasses	3.0
* * * * *	
Vegetable, fruiting, group 8–10	1.0
* * * * *	

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[FR Doc. 2016–24650 Filed 10–13–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

[LLCOF02000 L12200000.DU0000 16X]

Notice of Proposed Supplementary Rules for Public Lands in Colorado: Cache Creek Placer Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) in Colorado is proposing supplementary rules for 2,160 acres of public lands addressed in the Cache Creek Placer Area Management Plan, approved on February 23, 2016. These proposed supplementary rules would apply to public lands administered by the BLM Royal Gorge Field Office in Chaffee County, Colorado. The proposed rules would implement decisions found in the Cache Creek Placer Area Management Plan relating to the collection of mineral materials within the Cache Creek parcel.

DATES: Please send comments to the address below by December 13, 2016. Comments received or postmarked after this date may not be considered in the development of the final supplementary rules.

ADDRESSES: You may send comments by the following methods: Mail or hand deliver to Kalem Lenard, Outdoor Recreation Planner, BLM Royal Gorge Field Office, 3028 E. Main Street, Cañon City, CO 81212. You may also send comments via email to *rgfo_comments@blm.gov* (include ''Proposed Supplementary Rules'' in the subject line).

FOR FURTHER INFORMATION CONTACT: Kalem Lenard, Outdoor Recreation Planner, at the above address, by phone