

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 174

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

Dated: November 13, 2017.

Richard P. Keigwin, Jr.,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

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

■ 2. Add § 174.537 to subpart W to read as follows:

§ 174.537 HPPD-4 protein; exemption from the requirement of a tolerance.

Residues of the HPPD-4 protein, which is a modified protein derived from the 4-hydroxyphenylpyruvate dioxygenase enzyme of *Pseudomonas fluorescens*, in or on all food commodities are exempt from the requirement of a tolerance, when the HPPD-4 protein is used as a plant-incorporated protectant inert ingredient.

[FR Doc. 2017-26086 Filed 12-1-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0495; FRL-9970-01]

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prometryn in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 4, 2017. Objections and requests for hearings must be received on or before February 2, 2018, 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-2016-0495, 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.

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-2016-0495 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 February 2, 2018. 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-2016-0495, 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 November 30, 2016 (81 FR 86312) (FRL-9954-06), 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 6E8492) by IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of prometryn in or on the raw agricultural commodity lettuce at 0.5 parts per million (ppm); cottonseed subgroup 20C at 0.25 ppm; fennel, Florence at 0.5 ppm; leaf petiole vegetable subgroup 22B at 0.5 ppm;

sesame, oil at 0.12 ppm; sesame, seed at 0.05 ppm; and Swiss chard at 0.5 ppm.

In the **Federal Register** of April 10, 2017 (82 FR 17175) (FRL-9959-61), 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 6E8492) by IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of prometryn in or on the raw agricultural commodity celtuce at 0.5 ppm. This notice of filing corrected the November 30, 2016 notice of filing which incorrectly listed the commodity as “lettuce” not “celtuce.”

The documents referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to either notice of filing.

Based upon review of the data supporting the petition, EPA has corrected the number of significant figures used, modified one of the commodity definitions, and determined that the sesame oil tolerance was not necessary. The reason for these changes are explained in Unit IV.C.

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 prometryn including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with prometryn 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.

Following subchronic and chronic oral exposures to rabbits, mice, dogs and rats, the most consistent effects observed in the database were decreases in body weight and food consumption. Following chronic exposure, effects in the dog included degenerative hepatic changes, renal tubule degeneration, and bone marrow atrophy. In rats following chronic exposure, renal toxicity (mineralized concentrations) was observed. No adverse effects were seen in rabbits following dermal exposures up to the limit dose.

There was evidence of increased pre- and post-natal quantitative susceptibility for prometryn. While there was no evidence of susceptibility in the developmental toxicity studies in rabbits and rats, there was evidence of quantitative susceptibility in the two-generation reproduction study in rats, with offspring effects (decreased pup body weight) occurring at lower doses than those that resulted in parental effects (decreased absolute bodyweight and food consumption).

There was no evidence of neurotoxicity in the acute or subchronic neurotoxicity studies. In an immunotoxicity study in rats, there was a decreased humoral immune response using the sheep red blood cell assay, but only at a dose above the limit dose (1045 mg/kg/day).

Prometryn has been classified by EPA as “Group E:—Evidence of non-carcinogenicity for humans” based on the lack of oncogenic effects at any dose in both rats and mice. Prometryn was determined to be non-mutagenic and

non-clastogenic in *in vitro* and *in vivo* genotoxicity assays.

Specific information on the studies received and the nature of the adverse effects caused by prometryn 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 titled “Prometryn—Preliminary Human Health Risk Assessment for Registration Review and the Risk Assessment for the Section 3 Registration Request for a New Use on Sesame and Crop-Group Conversions” on pages 46–49 in docket ID number EPA-HQ-OPP-2016-0495.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for prometryn used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	Endpoint not selected as there are no adverse developmental, offspring or reproductive effects seen in the toxicological database which are attributable to a single dose.		
Acute dietary (General population including infants and children).	Endpoint not selected as there are no adverse single dose effects in the database which occur at levels relevant for human health risk assessment.		
Chronic dietary (All populations)	NOAEL = 4 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day.	Chronic Toxicity—Dog: LOAEL = 37.5 mg/kg/day based on degenerative hepatic changes, renal tubule degeneration and bone marrow atrophy.
Cancer (Oral, dermal, inhalation)	Classification: “Group E: Evidence of non-carcinogenicity for humans.”		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, 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 prometryn, EPA considered exposure under the petitioned-for tolerances as well as all existing prometryn tolerances in 40 CFR 180.222. EPA assessed dietary exposures from prometryn 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 prometryn; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 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 prometryn does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for prometryn. Tolerance level residues and 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 prometryn in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prometryn. 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 in Water Calculator (PWC) and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of prometryn for chronic exposures are estimated to be 127 parts per billion (ppb) for surface water and 433 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 433 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).

Prometryn is not registered for any specific use patterns that would result in residential exposure.

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 has not found prometryn to share a common mechanism of toxicity with any other substances, and prometryn does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that prometryn does not have 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>.

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 was evidence of increased pre- and post-natal quantitative

susceptibility for prometryn. While there was no evidence of susceptibility in the developmental toxicity studies in rabbits and rats, there was evidence of quantitative susceptibility in the two-generation reproduction study in rats, with offspring effects (decreased pup body weight) occurring at lower doses than those that resulted in parental effects (decreased absolute bodyweight and food consumption).

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 prometryn is complete.

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

iii. There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats. However, there was evidence of increased quantitative susceptibility in the two-generation reproduction study. In the two-generation reproduction study, the offspring effects (decreased absolute pup bodyweight in the F₁ generation) were observed at doses below parental toxicity (decreases in absolute bodyweight, bodyweight gain and food consumption in the F₁ generation). Concern is low since the effects are characterized by clear NOAEL and LOAEL values and the selected endpoints are protective of the observed effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prometryn in drinking water. These assessments will not underestimate the exposure and risks posed by prometryn.

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, prometryn 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 prometryn from food and water will utilize 60% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure. There are no residential uses for prometryn.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, prometryn is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short- or intermediate-term risk), no further assessment of either short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for prometryn.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the established and proposed tolerances. Prometryn is completely recovered ($\leq 80\%$ recovery)

using the Food and Drug Administration's (FDA's) Multiresidue Section 302. In addition, both Ciba-Geigy Method AG-559 (gas chromatography (GC)/flame-photometric detector (FPD)/S) and Method AG-673 (GC/nitrogen-phosphorous detector (NPD) method) are considered adequate for enforcement purposes.

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 any MRLs for prometryn.

C. Revisions To Petitioned-For Tolerances

EPA modified the tolerance levels to reflect the correct number of significant figures and to be consistent with Agency policy. Also, the commodity definition for Florence fennel was modified to read "Fennel, Florence, fresh leaves and stalk" to be consistent with Agency nomenclature. Lastly, the petitioner recommended a tolerance for residues of prometryn in/on sesame, oil at 0.12 ppm. Residues in oil at a 5x application rate were 0.1076 which when extrapolated to 1x would be 0.02 ppm. As this value is well below the proposed raw agricultural commodity (RAC) tolerance, an oil tolerance is not necessary.

V. Conclusion

Therefore, tolerances are established for residues of prometryn, including its metabolites and degradates, in or on

celtuce at 0.50 ppm; cottonseed subgroup 20C at 0.25 ppm; fennel, Florence, fresh leaves and stalk at 0.50 ppm; leaf petiole vegetable subgroup 22B at 0.50 ppm; sesame, seed at 0.05 ppm; and Swiss chard at 0.50 ppm. Additionally, the existing tolerances for the leaf petioles subgroup 4B and cotton, undelinted seed are removed as unnecessary, since they are superseded by the new tolerances.

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); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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: November 15, 2017.

Michael L. Goodis,
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 § 180.222:

■ i. Remove the entries from the table in paragraph (a) for “Cotton, undelinted seed” and “Leaf petioles subgroup 4B”.

■ ii. Add alphabetically entries to the table in paragraph (a) for “Celtuce”; “Cottonseed subgroup 20C”; “Fennel, Florence, fresh leaves and stalk”; “Leaf petiole vegetable subgroup 22B”; “Sesame, seed”; and “Swiss chard”.

The additions read as follows:

§ 180.222 Prometryn; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	*
Celtuce	0.50
* * *	*
Cottonseed subgroup 20C	0.25
* * *	*
Fennel, Florence, fresh leaves and stalk	0.50
Leaf petiole vegetable subgroup 22B	0.50
* * *	*
Sesame, seed	0.05
Swiss chard	0.50

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[FR Doc. 2017–26083 Filed 12–1–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0384; FRL–9970–05]

Quinclorac; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of quinclorac in or on the bushberry subgroup 13–07B, the caneberry subgroup 13–07A, and asparagus. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 4, 2017. Objections and requests for hearings must be received on or before February 2, 2018, 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–2016–0384, 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