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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0590; FRL-9395-4]

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prometryn in or on succulent snap bean, dill oil, fresh dillweed leaves, and dried dillweed leaves. This regulation additionally removes the established tolerance with regional restrictions on dill, since it is superseded by the tolerance on fresh dillweed leaves. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2012-0590, 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), EPA West 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; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0590 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2012-0590, 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 September 28, 2012 (77 FR 59578) (FRL-9364-6), 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 2E8053) by IR-4, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.222 be amended by establishing tolerances for residues of the herbicide prometryn, 2,4-bis(isopropylamino)-6-methylthio-*s*-triazine, in or on bean, snap, succulent at 0.05 parts per million (ppm); bean, forage at 0.09 ppm; dill, leaves at 0.3 ppm; dill, dried leaves at 1.1 ppm; and dill, oil at 1.3 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has corrected the commodity terminology for certain proposed tolerances and has revised the tolerance expression for all commodities. The reasons 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.

In the subchronic oral feeding study in mice, prometryn caused decreased body weight (bwt) and/or mortality at doses that exceeded the limit dose. In chronic oral toxicity studies, effects primarily occurred only at the highest doses tested for dogs, rats, and mice, though the dog is considered the most sensitive species. Effects in the dog included degenerative hepatic changes, renal tubule degeneration, and bone marrow atrophy. In developmental studies with prometryn, fetal effects were observed primarily at the highest doses tested and in the presence of maternal toxicity. In rats, decreased bwt, decreased food consumption, and clinical signs of toxicity were observed in dams. Decreased fetal bwt and incomplete ossification of sternebrae and metacarpals were observed at the same dose in offspring. In rabbits, maternal effects included decreased food consumption and an increased incidence of resorptions, abortions, and post-implantation loss; these effects corresponded with a decreased number of viable litters and live fetuses at the same dose. In the 2-generation rat reproductive study, decreased food consumption, bwt, and bwt gain were observed in parental animals, and decreased bwts were observed in offspring at the same dose.

Preliminary review of the rat acute and subchronic neurotoxicity studies reveals lower mean total and/or ambulatory locomotor activity counts noted for both sexes on the first day of treatment in the acute study, and no signs of neurotoxicity in the subchronic study. In the immunotoxicity study, there was a decreased humoral response in the sheep red blood cell assay. No evidence of local or systemic toxicity was observed in a 21-day dermal toxicity study in rabbits.

In a combined chronic toxicity and carcinogenicity study in rats, effects included decreased bwt, bwt gains, and renal toxicity, exhibited as mineralized concretions. In a carcinogenicity study in mice, the only effect was decreased bwt gain. Prometryn has been classified with "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 document: "Prometryn: Human-Health Risk Assessment for the Proposed Uses on Snap Bean and Dill." pp. 32-34 in docket ID number EPA-HQ-OPP-2012-0590.

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 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 13-49 years of age)	NOAEL = 12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.12 mg/kg/day aPAD = 0.12 mg/kg/day	Developmental toxicity (rabbit) LOAEL = 72 mg/kg/day based on increased incidence of resorptions, abortions, and post-implantation loss leading to decreased number of viable litters and live fetuses.
Acute dietary (General population including infants and children)	No effects attributable to a single exposure were identified for the general population, including infants and children. Therefore, a dose and endpoint were not selected for this exposure scenario.		
Chronic dietary (All populations)	NOAEL= 3.75 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; dietary) LOAEL = 37.5 mg/kg/day based on degenerative hepatic changes, renal tubule degeneration, and bone marrow atrophy.
Cancer (Oral, dermal, inhalation)	Classified as “evidence of non-carcinogenicity for humans.”		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. 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. Such effects were identified for prometryn for females 13-49 years old, the only acute population subgroup of concern for this assessment. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses 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) from 2003 through 2008. As to residue levels in food, EPA used tolerance-level residues for all commodities, 100 percent crop treated (PCT) estimates, and utilized DEEM version 7.81 default processing factors when appropriate.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to

residue levels in food, EPA used tolerance-level residues for all commodities, assumed 100 PCT, and utilized DEEM default processing factors when appropriate.

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://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of prometryn for surface waters are expected to be 377.4 parts per billion (ppb) for acute exposures and 157.9 ppb for chronic exposures. For ground water, the EDWC is expected to be 23.2 ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 377.4 ppb and 157.9 ppb were used to assess the contribution of drinking water for the acute and chronic dietary risk assessments, respectively.

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.”

Prometryn is a triazine, and certain triazine pesticides were identified as a common mechanism group (CMG) by EPA in a 2002 paper entitled, “The Grouping of a Series of Triazine Pesticides Based on a Common Mechanism of Toxicity.” However, prometryn was excluded from the triazine CMG because it does not share the toxicity profile of the CMG triazines. Therefore, for the purposes of this action, EPA is assuming that prometryn does not have a common mechanism of toxicity with other substances, and prometryn does not produce a toxic metabolite known to be produced by other substances. For information regarding EPA's efforts to determine which substances have a common mechanism of toxicity and to evaluate the cumulative effects of such substances, see EPA's website 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 Food Quality Protection Act Safety Factor (FQPA 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*. Developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats are available to assess potential fetal and offspring sensitivity to prometryn, and there is no evidence of increased quantitative prenatal susceptibility following prometryn exposure in these studies. In the 2-generation rat reproductive study, no evidence of toxicity to the reproductive organs was observed and the effects that were observed in the offspring (decreased bwt) occurred at the same dose as those observed in parental animals (decreased food consumption, bwt, and bwt gain). In both rats and rabbit developmental toxicity studies, fetal and offspring effects occurred at maternal/parental doses. Fetal effects in rats included decreased fetal bwt, incomplete ossification of sternebrae and metacarpals observed at the same dose as maternal toxicity, including decreased bwt, decreased food consumption, and clinical signs of toxicity. In rabbits, fetal effects included a decreased number of viable litters and live fetuses noted in the presence of decreased food consumption and an increased incidence of resorptions, abortions, and post-implantation loss in maternal rabbits.

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. In the last final rule for prometryn, published in the **Federal Register** of December 18, 2009 (74 FR 67104) (FRL-8801-8), immunotoxicity (OCSPP Guideline 870.7800) and acute and subchronic neurotoxicity (OCSPP Guideline 870.6200) studies were reported as data gaps required in 40 CFR part 158 for pesticide registration. These studies were recently submitted to the Agency and are pending formal review. Preliminary review suggests that these studies will not affect the endpoints selected for assessing the dietary risks of concern. In the immunotoxicity study, although there was a decreased humoral response in the sheep red blood cell assay, this effect is not expected to impact the risk assessment. This effect was observed at the limit dose (1,044 milligrams/kilogram/day (mg/kg/day) and is at least one order of magnitude higher than the effects used for the acute and chronic dietary endpoints causing a very low level of concern. The preliminary review of the acute neurotoxicity study shows some indication of neurotoxicity; however, since the POD chosen for risk assessment is lower than the dose that caused the observed effects in this study, it is thus considered protective of these effects. Additionally, there were no signs of neurotoxicity observed in the subchronic neurotoxicity study. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

ii. There is no evidence that prometryn results in increased susceptibility in young rats in the 2-generation reproduction study. The effects noted in *in utero* rats and rabbits in the prenatal developmental studies do not indicate increased susceptibility because:

a. The effects are well characterized.

b. Clear NOAELs were established.

c. The developmental rabbit study is being used in endpoint selection.

iii. 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 aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prometryn will occupy 17% of the aPAD for females 13-49 years old, the population subgroup identified as having a potential acute exposure.

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 23% 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-term and Intermediate-term risks*. Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term and intermediate-term adverse effects were identified; however, prometryn is not registered for any use patterns that would result in short-term or intermediate-term residential exposures. Short-term and intermediate-term risk is assessed based on short-term and intermediate-term residential exposure plus chronic dietary exposure. Because there are no short-term or intermediate-term residential exposures 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-term risk), no further assessment of short-term or intermediate-term risks are necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risks 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

An enforcement methodology (gas chromatography/flame photometric detection/sulfur (GC/FPD/S)), Method AG-559, 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 a MRL for prometryn.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA has determined that the proposed tolerance in or on bean, forage at 0.09 ppm is not necessary. The Agency

determined that this tolerance level is not necessary because bean, forage is not a significant livestock feed item. Additionally, the Agency revised the proposed commodity terminology for dill, leaves to dillweed, fresh leaves and dill, dried leaves to dillweed, dry leaves in order to reflect the correct commodity terminology. Finally, the Agency has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of prometryn not specifically mentioned.

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of prometryn, 2,4-bis(isopropylamino)-6-methylthio-*s*-triazine, in or on bean, snap, succulent at 0.05 ppm; dill, oil at 1.3 ppm; dillweed, fresh leaves at 0.30 ppm; and dillweed, dried leaves at 1.1 ppm. This regulation additionally removes the established tolerance with regional restrictions in or on dill 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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: August 29, 2013.

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 §180.222:

a. Revise the introductory text of paragraph (a).

b. Add alphabetically “bean, snap, succulent,” “dill, oil,” “dillweed, dried leaves,” and “dillweed, fresh leaves” to the table in paragraph (a).

c. Remove and reserve paragraph (c).

d. Revise the introductory text of paragraph (d).

The amendments read as follows:

§ 180.222 Prometryn; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide prometryn, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only prometryn, 2,4-bis(isopropylamino)-6-methylthio-*s*-triazine, in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, snap, succulent	0.05
* * * * *	
Dill, oil	1.3
Dillweed, dried leaves	1.1
Dillweed, fresh leaves	0.30
* * * * *	

* * * * *

(c) *Tolerances with regional exemptions.* [Reserved]

(d) *Indirect or inadvertent residues*. Tolerances are established for indirect or inadvertent residues of the herbicide prometryn, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only prometryn, 2,4-bis(isopropylamino)-6-methylthio-*s*-triazine, in or on the following raw agricultural commodities.

* * * * *

[FR Doc. 2013-22107 Filed 09/10/2013 at 8:45 am; Publication Date: 09/11/2013]