

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule 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: December 10, 2009.

G. Jeffrey Herndon,  
Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.603 is amended by revising the introductory text in paragraphs (a)(1) and (2); and alphabetically adding "Brassica, leafy greens subgroup 5B" and "Turnip, greens" to the table in paragraph (a)(1) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

(a) \* \* \* (1) Tolerances are established for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of dinotefuran and its metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on the commodities listed in the table below:

Commodity	Parts per million
* * *	* *
Brassica, leafy greens, subgroup 5B .....	15.0
* * *	* *
Turnip, greens .....	15.0
* * *	* *

(2) Tolerances are established for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the

commodities listed in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine in or on the commodities listed in the table below:

\* \* \* \* \*

[FR Doc. E9-30131 Filed 12-17-09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0773; FRL-8801-8]

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of prometryn in or on celeriac, roots; celeriac, tops; cilantro, leaves; coriander, dried leaves; leaf petioles subgroup 4B; okra; parsley, leaves; parsley, dried leaves; and increases the tolerance level for carrot, root. Additionally, the tolerance for celery is removed since it is included in the leafy petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action. Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0773. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only

available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts>.

[www.epa.gov/oppts](http://www.epa.gov/oppts) and select "Test Methods & Guidelines" on the left-side navigation menu.

### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2008-0773 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 16, 2010.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0773, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Petition for Tolerance**

In the **Federal Register** of December 3, 2008 (73 FR 73640) (FRL-8390-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8E7434 and 8E7436) by IR-4, 500 College Road East, Suite 201W, Princeton, New Jersey 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 carrots at 0.7 parts per million (ppm); celeriac, roots at 0.05 ppm; celeriac, tops at 0.05 ppm; cilantro, fresh at 4.0 ppm, cilantro, dried at 15 ppm; okra at 0.05 ppm; parsley, leaves at 0.7 ppm, (all the preceding in PP 8E7434); and leaf petiole subgroup 4B at 0.5 ppm (PP 8E7436). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, on behalf of IR-4, which is available to the public 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 modified carrot, roots from 0.7 ppm to 0.45 ppm; celeriac, tops from 0.05 ppm to 0.20 ppm; cilantro, leaves from 4.0 ppm to 3.5 ppm; coriander, dried leaves from 15.0 ppm to 9.0 ppm; parsley, leaves from 0.7 ppm to 0.60 ppm. EPA also revised several commodity terms and determined that a tolerance is required for parsley, dried leaves at 1.5 ppm. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of prometryn on carrot, roots at 0.45 ppm; celeriac, roots

at 0.05 ppm; celeriac, tops at 0.20 ppm; cilantro, leaves at 3.5 ppm; coriander, dried leaves at 9.0 ppm; leaf petioles subgroup 4B at 0.50 ppm; okra at 0.05 ppm; parsley, leaves at 0.60 ppm; and parsley, dried leaves at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Prometryn demonstrated minimal acute toxicity via the oral, dermal, and inhalation routes. Prometryn is mildly irritating to the eyes, slightly irritating to the skin, and is not a skin sensitizer.

In a 28-day feeding study in mice, prometryn caused decreased body weight and/or mortality at doses that exceed the limit dose. No evidence of local or systemic toxicity was observed in a 21-day dermal toxicity study in rabbits. In a chronic oncogenicity study in mice, decreased body-weight gain at the highest dose tested was the only adverse effect observed. In a combined chronic toxicity/carcinogenicity study in rats, decreased body weight, body-weight gains, and renal toxicity (mineralized concretions) were observed at the highest dose only. There was no evidence of carcinogenicity in either study and prometryn was non-mutagenic when tested in a battery of genotoxicity assays. Following long-term exposure of dogs to prometryn, multi-organ toxicity (degenerative hepatic changes, renal tubule degeneration, bone marrow atrophy) was observed at the highest dose tested.

Prometryn is neither a developmental nor a reproductive toxicant. Adverse effects were observed primarily at the highest doses tested; offspring toxicity was observed at the same doses as maternal/parental toxicity. In the developmental toxicity study in the rat, decreased body weight and food consumption, and clinical signs of toxicity were observed in dams; decreased fetal body weight, and incomplete ossification of sternebrae and metacarpals were observed at the same dose in offspring. In the developmental toxicity study in rabbits, decreased food consumption and increased incidence of resorptions, abortions, and post-implantation loss were observed in maternal animals that

led to a decreased number of viable litters and live fetuses at the highest dose tested. In the 2-generation rat production study, decreased food consumption, body weight, and body-weight gain were observed in parental animals, and decreased body weight was observed in offspring at the same dose. There was no evidence of toxicity to the reproductive organs in the study.

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 "Section 3 Registration Request to Add New Uses on Carrot, Celery, Cilantro, Okra, Parsley, and Leaf Petioles (Crop Subgroup 4B). Human-Health Risk Assessment," at page 36 in docket ID number EPA-HQ-OPP-2008-0773.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at <http://www.regulations.gov> in the document "Section 3 Registration Request to Add New Uses on Carrot, Celery, Cilantro, Okra, Parsley, and Leaf Petioles (Crop Subgroup 4B). Human-Health Risk Assessment," at page 19 in docket ID number EPA-HQ-OPP-2008-0773.

#### 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 (increased incidence of resorptions, abortions, and post-implantation loss and decreased number of live fetuses) were identified in the toxicological studies for prometryn for the population subgroup females 13 to 49 years old; no such effects were identified for the general population or other population subgroups.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that all food commodities contain tolerance level residues and that 100% of all crops are treated with prometryn. EPA also used the default processing factors for all processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that all food commodities contain tolerance level residues and that 100% of all crops are treated with prometryn. EPA also used the default processing factors for all processed commodities.

iii. *Cancer.* Prometryn was classified by the Agency in Group E ("Evidence of non-carcinogenicity for humans"), based on the lack of oncogenic effects at any dose in both rats and mice. Therefore an exposure assessment to evaluate cancer risks is not needed for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for prometryn. Tolerance level residues and 100% CT 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 acute exposures are estimated to be 377.4 parts per billion (ppb) for surface water and 23.2 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 157.9 ppb for surface water and 23.2 ppb for ground water.

For acute dietary risk assessment, the water concentration value of 377.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 157.9 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 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 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 showed no increased sensitivity of fetuses when compared to maternal animals following *in utero* exposures of rats or rabbits. The multi-generation reproduction study in rats showed no increased sensitivity of offspring when compared to parental animals. No evidence of developmental anomalies of the fetal nervous system was observed in the prenatal developmental toxicity studies in either rats or rabbits up to maternally toxic dose levels.

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 except for acute and subchronic neurotoxicity studies and immunotoxicity testing. Recent changes to 40 CFR part 158 make these studies (OPPTS Guideline 870.7800) required for pesticide registration; however, the toxicology database for prometryn does not show any evidence of treatment-related effects on the nervous or immune system. The overall weight-of-evidence suggests that this chemical

does not directly target the nervous or the immune system. In addition, prometryn does not belong to a class of chemicals (e.g., the organotins, heavy metals, halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Although an immunotoxicity study and acute and subchronic neurotoxicity studies are required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration, the Agency does not believe that conducting a functional immunotoxicity study or acute and subchronic neurotoxicity studies will result in a lower POD than that currently use for overall risk assessment, and therefore, a database uncertainty factor is not needed to account for lack of these studies.

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 is no evidence that prometryn 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 food exposure assessments were performed based on 100% CT 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 16% of the

aPAD for females 13 to 49 years old, the population group receiving the greatest exposure. No adverse effect resulting from a single-oral exposure was identified for the remaining population groups 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 30% of the cPAD for all infants < 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-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Prometryn is not registered for any use patterns that would result in residential exposure. Therefore, the short- and intermediate-term aggregate risk is the sum of the risk from exposure to prometryn through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.1.iii., the Agency has concluded that prometryn is not likely to be carcinogenic to humans, therefore, a cancer risk is not of concern for this chemical.

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 (gas chromatography/flame photometric detection/sulfur (GC/FPD/S)) 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; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### *B. International Residue Limits*

There are currently no established Codex MRLs for prometryn.

### *C. Revisions to Petitioned-for Tolerances*

Based upon review of the data supporting the petition, EPA has

modified carrot, roots from 0.7 ppm to 0.45 ppm; celeriac, tops from 0.05 ppm to 0.20 ppm; cilantro, leaves from 4.0 ppm to 3.5 ppm; coriander, dried leaves from 15.0 ppm to 9.0 ppm; parsley, leaves from 0.7 ppm to 0.60 ppm. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency's tolerance spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data. EPA also revised the commodity term for cilantro dried to coriander, dried leaves, to be in compliance with correct commodity definition. Additionally, EPA determined that a tolerance is required for parsley, dried leaves at 1.5 ppm. Additionally, the tolerance for celery is removed since it is included in the leaf petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action.

## V. Conclusion

Therefore, tolerances are established for residues of prometryn, 2,4-bis(isopropylamino)-6-methylthio-s-triazine, in or on celeriac, roots at 0.05 ppm; celeriac, tops at 0.20 ppm; cilantro, leaves at 3.5 ppm; coriander, dried leaves at 9.0 ppm; leaf petioles subgroup 4B at 0.50 ppm; okra at 0.05 ppm; parsley, leaves at 0.60 ppm; parsley, dried leaves at 1.5 ppm and increases the tolerance level for carrot, root to 0.45 ppm. Additionally, the tolerance for celery is removed since it is included in the leafy petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the

**Federal Register.** This final rule 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: December 8, 2009.

**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, in the table to paragraph (a) by revising the entry for "carrot, roots"; by removing footnote 1, and the entry for "celery," and by adding alphabetically entries for "celeric, roots"; "celeric, tops"; "cilantro, leaves"; "coriander, dried leaves"; "leaf petioles subgroup 4B"; "okra"; "parsley, leaves"; and "parsley, dried leaves" to read as follows, and in the table to paragraph (c) by removing the entry for "parsley, leaves."

### § 180.222 Prometryn; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
Carrot, roots .....	0.45
Celeriac, roots .....	0.05
Celeriac, tops .....	0.20
Cilantro, leaves .....	3.5
Coriander, dried leaves ..	9.0
* * *	* *
Leaf petioles subgroup 4B .....	0.50
Okra .....	0.05
Parsley, dried leaves .....	1.5
Parsley, leaves .....	0.60
* * *	* *

\* \* \*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0704; FRL-8803-4]

### Fluoxastrobin; Pesticide Tolerances

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