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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0049; FRL-9954-69]

### Oxathiapiprolin; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of oxathiapiprolin in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation amends the established tolerance for vegetable, tuberous and corm, subgroup 1C; and removes existing tolerances for *Brassica*, head and stem, subgroup 5A, and leafy greens subgroup 4A that are superseded by this action. Interregional Research Project Number 4 (IR-4), E.I. du Pont de Nemours & Company (DuPont), and Syngenta Crop Protection, LLC (Syngenta) 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-2016-0049, 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 L. Goodis, Acting Director, 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](mailto: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](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-2016-0049 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-2016-0049, 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 April 25, 2016 (81 FR 24044) (FRL-9944-86) and May 19, 2016 (81 FR 31581) (FRL-9946-02), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PPs) by DuPont (PP# 5F8435); Interregional Research Project Number 4 (PP# 5E8437) and Syngenta (PP# 5F8441), respectively.

The petition, 5F8437, requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on basil, dried leaves at 80 parts per million (ppm); basil, fresh leaves at 10 ppm; *Brassica* head and stem vegetable group 5-14 at 1.5 ppm; *Brassica* leafy greens subgroup 4-14B at 10 ppm; caneberry subgroup 13-07A at 0.5 ppm; leafy greens subgroup 4-14A at 15 ppm; and stalk and stem vegetable subgroup 22A at 2 ppm. The notice of filing for petition, PP# 5E8437, proposed a tolerance for individual crops included in designated crop group/subgroups under a proposed rule, "Tolerance Crop Grouping Program IV" on November 14, 2014 (79 FR 68153). This rule proposed certain revisions to EPA's pesticide tolerance crop grouping regulations. The final rule establishing tolerances for these crop groups/subgroups "Pesticide Tolerance Crop Grouping Program Amendment IV" published on May 3, 2016 (81 FR 26471).

The Syngenta petition, 5F8441, requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on: citrus oil at 2.0 ppm; citrus, pulp at 0.09 ppm; fruit, citrus, group 10-10 at 0.06 ppm; potato, wet peel at 0.07 ppm; and requested revising the existing 0.01 ppm tolerance on vegetable, tuberous and corm, subgroup 1C to 0.04 ppm.

The Dupont petition, 5F8435, requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on: soybean at 0.01 ppm, and sunflower at 0.01 ppm.

A summary of the petitions prepared by IR4 and the registrants, DuPont and Syngenta, are available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filings. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the subject petitions, EPA has revised the proposed tolerance level for certain crops and corrected commodity definitions, as needed, to be consistent with current EPA policy. The reason for these changes are explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in

support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for oxathiapiprolin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with oxathiapiprolin follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their 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 toxicity studies for oxathiapiprolin, no treatment-related effects were seen in any species at doses up to the limit dose (1,000 milligrams/kilogram (mg/kg)/day). No treatment-related effects were seen in subchronic or chronic oral toxicity (rats, mice, or dogs), dermal toxicity, neurotoxicity, or immunotoxicity studies. Additionally, there was no evidence of carcinogenicity in cancer studies with rats or mice. No treatment-related effects were seen in maternal or fetal animals in rat or rabbit developmental toxicity studies. Treatment-related effects were observed in offspring animals in rat reproduction studies (decreased body weight and delayed preputial separation); however, the effects were only observed at doses above the limit dose. Such high doses are not relevant for human health risk. The lack of observed treatment-related oxathiapiprolin toxicity effects is consistent with the low to moderate oral absorption and lack of bioaccumulation reported in the rat metabolism studies. In acute lethality studies, exposure to oxathiapiprolin resulted in low toxicity via the oral, dermal, and inhalation routes of exposure. Oxathiapiprolin was not a dermal or eye irritant, or a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by oxathiapiprolin 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, “Oxathiapiprolin—New Active Ingredient Human Health Risk Assessment of Uses on Turf, Ornamentals, and a Number of Crops” dated June 25, 2015, in docket ID number EPA-HQ-OPP-2014-0114.

*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>.

The majority of the toxicity studies for oxathiapiprolin did not demonstrate treatment-related effects, with the exception of the reproduction study. The effects in the reproduction study were minimal and seen at doses (above the limit dose) not relevant for human exposure. There were no adverse acute or chronic effects identified for any population groups (including

infants and children). Therefore, due to the limited toxicity in the oxathiapiprolin toxicological database, toxicity endpoints and points of departure were not selected for oxathiapiprolin exposure scenarios and a quantitative risk assessment was not conducted.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to oxathiapiprolin, EPA considered exposure under the petitioned-for tolerances as well as all existing oxathiapiprolin tolerances in 40 CFR 180.685. There is likely to be dietary exposure to oxathiapiprolin from its use as a pesticide on food. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of oxathiapiprolin.

2. *Dietary exposure from drinking water.* Exposure to oxathiapiprolin via drinking water from the proposed uses is expected to be minimal due to rapid foliar uptake and limited quantities available in spray drift. No adverse effects were observed in the submitted toxicological studies for oxathiapiprolin regardless of the route of exposure.

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).

Oxathiapiprolin is not proposed or registered for any specific use pattern that would result in residential handler exposure. However, some of the uses could involve commercial application in areas where residential post-application activities could occur (i.e., individuals playing on treated golf courses, commercial landscapes or treated ornamentals purchased at a retail location). Since no adverse effects were observed for oxathiapiprolin in the submitted toxicological studies (regardless of the route of exposure), quantitative residential handler or post-application exposure assessments are not needed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found oxathiapiprolin to share a common mechanism of toxicity with any other substances, and oxathiapiprolin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that oxathiapiprolin 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://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.* No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits. No treatment related effects were seen in maternal or fetal animals in the studies. However, there was evidence of increased quantitative susceptibility in reproduction studies in rats at doses above the limit dose. Decreased pup weight and delayed sexual maturation (preputial separation) were seen in the studies in the absence of maternal toxicity.

3. *Conclusion.* EPA evaluated the available toxicity and exposure data on oxathiapiprolin and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies; therefore, EPA concludes that there are no threshold effects of concern to infants, children, or adults from oxathiapiprolin. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

#### *E. Aggregate Risks and Determination of Safety*

Taking into account the available data for oxathiapiprolin, EPA has concluded that given the lack of toxicity of this substance, no risks of concern are expected. Therefore, 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 oxathiapiprolin.

### **IV. Other Considerations**

#### *A. Analytical Enforcement Methodology*

Method 30422 (Supplement No. 1) was developed for plant commodities, and Method 31138 was developed for livestock commodities. Residues of oxathiapiprolin and associated metabolites are extracted from crop or livestock commodity samples using a solution of formic acid, water and acetonitrile, and diluted with acetonitrile and water. Both methods use liquid

chromatography with tandem mass spectrometry (LC/MS/MS), specifically reverse-phase liquid chromatography (LC), and detection by electrospray tandem mass spectrometry (MS/MS).

The FDA multi-residue methods are not suitable for detection and enforcement of oxathiapiprolin residues or associated metabolites. However, the European Multiresidue Method (DFG Method S19) and the QuEChERS Multiresidue Method have shown success in some matrices.

Adequate enforcement methodology (LC/MS/MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established maximum residue limits (MRLs) for oxathiapiprolin.

#### *C. Response to Comments*

A comment was received from an anonymous commenter objecting to EPA “approving additional uses of oxathiapiprolin that add to the thousands of existing toxic chemical residues as well as the undetermined synergistic effects these toxicants pose to America’s population.” The existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when the pesticide meets the safety standard imposed by that statute. As required by that statute, EPA conducted a comprehensive assessment of oxathiapiprolin, including its potential for carcinogenicity. Based on its assessment of the available data, the Agency believes that given the observed lack of toxicity of this chemical, no risks of concern are expected. Therefore, 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 oxathiapiprolin.

*D. Revisions to Petitioned-For Tolerances*

In the notice of filing for petition 5E8437, the titles of the designated new commodity group and subgroups are as listed in the “Tolerance Crop Grouping Program IV” proposal of November 14, 2014 (79 FR 68153). In the final rule which published on May 3, 2016, “Pesticide Tolerances Crop Grouping Program Amendment IV,” EPA revised the crop group/subgroup titles by roughly retaining the same name and number as the pre-existing group/subgroup, except the number is followed by a hyphen and the final digits of the year established. Hence, the title of the requested “*Brassica* leafy greens subgroup 4-14B” (due to the May 3, 2016 final rule as noted above) becomes “*Brassica* leafy greens subgroup 4-16B.” Likewise, the requested “Leafy greens subgroup 4-14A” becomes “Leafy greens subgroup 4-16A;” and the title of the requested “*Brassica* head and stem vegetable group 5-14” was revised to “Vegetable, *Brassica* head and stem, group 5-16.”

To be consistent with current EPA policy, the commodity definitions were corrected for the following crops: vegetable, stalk and stem, subgroup 22A to stalk and stem vegetable subgroup 22A; citrus fruit, crop group 10 10 to fruit, citrus, group 10-10; citrus oil to citrus, oil; citrus pulp to citrus, dried pulp; soybean to soybean, seed; and sunflower to sunflower, seed.

For certain proposed crop tolerances, the Agency corrected the proposed tolerance levels. For caneberry subgroup 13-07A, the corrected tolerance level includes an additional significant figure (0.50 ppm rather than the proposed 0.5 ppm). This is to avoid the situation where rounding of an observed residue to the level of precision of the tolerance expression would be considered non-violative (such as 0.54 ppm being rounded to 0.5 ppm). For the same reason, the corrected tolerance for stalk and stem vegetable subgroup 22A is 2.0 ppm instead of the proposed 2 ppm.

## **V. Conclusion**

Therefore, tolerances are established for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on basil, dried leaves at 80 ppm; basil, fresh leaves at 10 ppm; *Brassica* leafy greens subgroup 4-16B at 10 ppm; caneberry subgroup 13-07A at 0.50 ppm; leafy greens subgroup 4-16A at 15 ppm; citrus, dried pulp at 0.09 ppm; citrus, oil at 2.0 ppm; fruit, citrus, group 10-10 at 0.06 ppm; potato, wet peel at 0.07 ppm; soybean, seed at 0.01 ppm; stalk and stem vegetable subgroup 22A at 2.0 ppm; sunflower, seed at 0.01 ppm and vegetable, *Brassica*, head and stem, group 5-16 at 1.5 ppm. The existing 0.01 ppm tolerance on vegetable, tuberous and corm, subgroup 1C is revised to 0.04 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDC 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) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). 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 10, 2016.

Michael Goodis,  
*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. Amend the table in § 180.685(a)(1) as follows:

a. Remove the entries for “*Brassica*, head and stem, subgroup 5A”; and “Leafy greens subgroup 4A”;

b. Revise the entry for “Vegetable, tuberous and corm, subgroup 1C”; and

c. Add alphabetically the entries for “Basil, dried leaves”; “Basil, fresh leaves”; “*Brassica* leafy greens subgroup 4-16B”; “Caneberry subgroup 13-07A”; “Citrus, dried pulp”; “Citrus, oil”; “Fruit, citrus, group 10-10”; “Leafy greens subgroup 4-16A”; “Potato, wet peel”; “Soybean, seed”; “Stalk and stem vegetable subgroup 22A”; “Sunflower, seed” and “Vegetable, *Brassica* head and stem, group 5-16”.

The revisions and additions read as follows:

**§ 180.685 Oxathiapiprolin; tolerances for residues.**

(a) \* \* \*  
 (1) \* \* \*

Commodity	Parts per million
Basil, dried leaves	80
Basil, fresh leaves	10
<i>Brassica</i> leafy greens subgroup 4-16B	10
Caneberry subgroup 13-07A	0.50
Citrus, dried pulp	0.09
Citrus, oil	2.0
Fruit, citrus, group 10-10	0.06
* * * * *	
Leafy greens subgroup 4-16A	15
* * * * *	
Potato, wet peel	0.07

Soybean, seed	0.01
Stalk and stem vegetable subgroup 22A	2.0
Sunflower, seed	0.01
* * * * *	
Vegetable, <i>Brassica</i> head and stem, group 5-16	1.5
* * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.04

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