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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0780; FRL-9326-4]

Prohexadione Calcium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of prohexadione calcium in or on sweet cherry. BASF Corporation requested this tolerance 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0780. 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: Rose Mary Kearns, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5611; e-mail address: *kearns.rosemary@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 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://ecfr.gpoaccess.gov/cgi/t/text/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-2010-0780 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0780, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 27, 2010 (75 FR 66092) (FRL-8848-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7765) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.547 be amended by establishing tolerances for residues of the plant growth regulator prohexadione calcium, calcium, 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate, in or on sweet cherries at 0.50 parts per million (ppm). That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing for these changes are explained in Unit IV.D.

Based upon review of the data supporting the petition, EPA has lowered the tolerance from 0.5 ppm to 0.4 pm. The reason for these changes are explained in Unit IV.C

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prohexadione calcium 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. Prohexadione calcium is not acutely toxic by the oral, dermal, and inhalation routes. It is moderately irritating to the eyes and skin and is not a dermal sensitizer.

Following subchronic dietary exposures, no treatment-related effects were seen at doses up to the limit dose in mice, fore-stomach hyperplasia was seen only at very high doses in rats, and kidneys were the target organ for toxicity in the dogs. Following repeated dermal exposures for 28-days, no toxicity was seen at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day). There was no evidence of neurotoxicity following acute or subchronic exposure to rats.

Following chronic dietary exposures, toxicity was seen only at high doses in dogs, rats, and mice. There was no evidence of carcinogenicity in male and female mice or male and female rats.

In the rat developmental toxicity study, no treatment-related maternal or developmental toxicity was seen at the limit dose. Three rabbit developmental toxicity studies are also available. In one study, maternal toxicity manifested as increased mortality, abortions, and decreases in body-weight gain was seen at the highest dose tested. However, no developmental toxicity was seen at the dose that caused maternal toxicity. The abortions were attributed to the maternal toxicity (i.e., mortality and decreased body-weight gain) and not to toxicity of the test material. In the second developmental toxicity study in rabbits, no maternal or developmental toxicity was seen at the highest dose tested. In the third study, maternal toxicity, manifested as premature deliveries, was seen as a dose where no developmental toxicity was seen. In the

reproductive toxicity study with rats, parental toxicity (minimal mortality) occurred at a dose lower than the dose that caused decreases in body weight of the offspring. No reproductive toxicity was seen at the highest dose tested in this study. These results indicate no quantitative or qualitative increase in susceptibility of rats and rabbits to *in utero* and/or post-natal exposure to prohexadione calcium.

Prohexadione calcium was non-carcinogenic in both the rat and mouse. Prohexadione calcium has been classified as "not likely to be caricinogenic to humans" based upon lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by prohexadione calcium 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 Notice of Filing for Prohexadione Calcium at 66092 in docket ID number EPA-HQ-OPP-2010-0780. (See pages 8012 in the HED Risk Assessment in the docket number for this rule).

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 prohexadione calcium used for human risk assessment is shown in Table 1 of this unit.

Table 1. — Summary of Toxicological Doses and Endpoints for Prohexadione Calcium for Use in Human Health Risk Assessment

Exposure/Scenario	Dose Used in Risk Assessment, UFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	N/A	N/A	An appropriate endpoint attributable to a single dose (exposure) was not seen in the toxicity database.
Chronic dietary	NOAEL = 20 mg/kg/day UF_A = 10x	Chronic RfD cPAD= 0.2 mg/kg/day	Chronic toxicity dog LOAEL = 200 mg/kg/day based on histopathological

	UF_H = 10x FQPA SF = 1x		changes in the kidneys (dilated basophilic tubules) and increased urinary volumn and NA^+ ion concentrations.
Incidental oral short-term (1 to 30 days)- and Intermediate (1-6 Months)-Term	NOAEL= 80 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100 (Residential)	90 day oral toxicity dog LOAEL = 400 mg/kg/day based on moderate cortical areas of dilated basophilic tubules in the kidneys and decreased potassium levels.
Short (1-30 days)-and intermediate (1 to 6 months) – Term Dermal (Occupational/ Residential)	Oral Maternal NOAEL= 40 Estimated absorption rate 25%	LOC for MOE = 100 (Occupational/ Residential	Prenatal developmental Toxicity - rabbit LOAEL = 200 mg/kg/day based on increased mortality, abortions, and decreased maternal body-weight gain.
Short-term (1 to 30 days)- and Intermediate (1-6 months) – Term Inhalation	Oral Maternal NOAEL = 40 mg/kg/day (inhalation-absorption	LOC for MOE = 100	Prenatal developmental toxicity - rabbit LOAEL = 200 mg/kg/day based on increased mortality, abortions, and

	rate =100%)		decreased maternal body-weight gain.
Cancer (oral, dermal, inhalation	Not likely human carcinogen	N/A	No evidence of carcinogenic potential.

[1] UF = uncertainty factor, UF_A = extrapolation from animal to human (interspecies), UF_H = potential variation in sensitivity among members of the human population (intraspecies), FQPA SF = FQPA Safety Factor, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, PAD = population-adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure; LOC = level of concern; NA = not applicable.

[2] 25% Dermal-absorption factor – Derived from HIARC report 112600HA.002.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to prohexadione calcium, EPA considered exposure under the petitioned-for tolerances as well as all existing prohexadione calcium tolerances in 40 CFR 180.547. EPA assessed dietary exposures from prohexadione calcium in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for prohexadione calcium therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture

(USDA) 1994-1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed Dietary Exposure Evaluation Model (DEEM) ^{TM} (ver.7.81) default processing factors, 100 percent crop treated (PCT), and tolerance level residues for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that prohexadione calcium 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 percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for prohexadione calcium. Tolerance level residues and/or 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 prohexadione calcium in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prohexadione calcium. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppfed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models the estimated drinking water concentrations (EDWCs) of prohexadione calcium for acute exposures are estimated to be 52.4 parts per billion for surface water and .158 ppb for ground water.

For chronic exposures for non cancer assessments are estimated to be 9.1 ppb for

surface water and 0.0158 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary assessment, the water concentration value of 52.4 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 9.1 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). Prohexadione calcium is currently registered for the following uses that could result in residential exposures: Residential lawns, ornamentals, athletic fields, parks, and golf courses. There is a potential for exposure in residential settings during the application process for homeowners who use products containing prohexadione calcium. There is also a potential for exposure of adults and children from entering prohexadione calcium-treated areas. EPA assessed residential exposure using the following assumptions: It has been determined that exposure to pesticide handlers is likely during the residential use of prohexadione calcium on lawns and ornamentals. Intermediate term exposures are not likely because of the intermittent nature of applications by homeowners. Adults were also assessed for potential short-term postapplication dermal exposure from contact with treated residential and recreational turf (home lawns, recreational fields, and golf courses). Youths, ages 10-12 years old, were selected as a representative population to assess postapplication dermal exposure from contact with treated residential and

recreational turf (home lawns, fields, and golf courses). Children, ages 3-6 years old, were selected as a representative population to assess for postapplication dermal and incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposure to residential turf/home lawns. For all residential scenarios, the short-term risk estimates (MOEs) do not exceed the Agency's LOC. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 prohexadione calcium to share a common mechanism of toxicity with any other substances, and prohexadione calcium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that prohexadione calcium 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*. There is no evidence (quantitative or qualitative) evidence of increased susceptibility following *in utero* exposures to rats and rabbits and following pre-and post-natal exposures to rats. In the developmental study in rats, no maternal or developmental toxicity was seen up to the limit dose. Additionally, three developmental studies in rabbits were available, and no developmental toxicity was seen in these studies. The abortions seen in one study were not due to treatment, but rather due to the severe maternal toxicity (deaths and decreased body-weight gain) observed in the dose. In the reproductive toxicity, offspring toxicity was seen at a dose higher than the dose that caused parental/systemic toxicity.

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 prohexadione calcium is complete.

ii. There is no evidence of neurotoxcity following acute and subchronic exposures and there was no evidence of increased susceptibility following in utero and pre/post natal exposures. Therefore, a developmental neurotoxicity study is not required.

iii. The toxicology database for prohexadione calcium does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. In addition, prohexadione calcium 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 is now required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration, HED does not believe that conducting this study will result in a lower point of departure (POD) than that currently use for overall risk assessment; therefore, a database uncertainty factor (UF_{DB}) is not needed to account for lack of these studies

iv. There are no residual uncertainties for pre- and post-natal toxicity.

v. There are no residual uncertainties identified in the exposure databases. The dietary exposure analysis is conservative in that tolerance-level residues, 100% crop treated, and modeled drinking water estimates were assumed. The residential exposure analysis is conservative since it is based on the residential Standard Operating Procedures (SOPs). The dietary and residential risk assessments are thus conservative and are not expected to underestimate risk. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to prohexadione calcium in drinking water. EPA used similarly conservative assumptions to assess postapplication of children as well as incidental oral exposure of toddlers. These

assessments will not underestimate the exposure and risks exposed by prohexadione calcium.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, prohexadione calcium is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit or chronic exposure, EPA has concluded that the chronic exposure to prohexadione calcium from food and water will utilize 14% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of prohexadione calcium is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Prohexadione calcium is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is

appropriate to aggregate chronic exposure through food and water with short-term residential exposures to prohexadione calcium. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 340 or higher for all populations. Because EPA's level of concern for prohexadione calcium is a MOE of 100 or below, these MOEs are not of concern.

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

Because no intermediate-term adverse effect was identified, prohexadione calcium is not expected to pose a intermediate-term risk.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. A liquid chromatography with tandem mass spectrometry (LC/MS/MS) method (BASF Method 564/0) is available for the enforcement of the proposed tolerances

or sweet cherries. EPA has determined that BASF Method 564/0 is a suitable enforcement method for fruit commodities, as defined in SOP No. ACB-019 (9/15/08).

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*.

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 U.N. 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 prohexadione calcium.

C. Revisions to Petitioned-For Tolerances

EPA has determined that the tolerance level for prohexadione calcium residues in or on sweet cherry should be lowered from 0.50 ppm as requested in the petition to 0.40 ppm based on a review of the current prohexadione calcium database and utilizing the internationally (OECD) harmonized spreadsheet for calculating pesticide tolerances.

Additonally, the Agency is modifying the tolerance expression for prohexadion calcium to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of prohexadione calcium not specifically mentioned; and 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, a tolerance is established for residues of prohexadione calcium, calcium 3-oxido-5-oco-4-propionylcyclohex-3-enecarboxylate, in or on sweet cherry at 0.40 ppm. The tolerance expression is also being revised to include metabolites and degradates.

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: October 28, 2011.

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. Section 180.547 is amended by:

i. Revising the introductory text to paragraph (a) and;

ii. Alphabetically adding the commodity Cherry, sweet, to the table in paragraph (a) to read as follows:

§ 180.547 Prohexadione calcium, tolerances for residues.

(a) *General*. Tolerances are established for residues of the growth regulator, prohexadione calcium, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate)" in or on the following commodities.

Commodity	Parts per million
* * *	* *
Cherry, sweet	0.40
* * *	* *

* * * * *

[FR Doc. 2011-29751 Filed 11/17/2011 at 8:45 am; Publication Date: 11/18/2011]