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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0346; FRL–9927–25]

Prohexadione Calcium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prohexadione calcium in or on strawberry and watercress. Inter-Regional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 8, 2015. Objections and requests for hearings must be received on or before September 8, 2015, 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–2014–0346, 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0346 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 September 8, 2015. 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–2014–0346, 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 August 1, 2014 (79 FR 44729) (FRL–9911–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8264) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08450. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide prohexadione calcium, calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate, in or on strawberry at 0.3 parts per million (ppm) and watercress at 2.0 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has amended the tolerance for watercress from what the petitioner requested. The reason for this change is 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 prohexadione calcium 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.

The most sensitive effect in the prohexadione toxicity database by oral exposure is kidney toxicity in dogs both for subchronic and chronic durations. Minor hematological changes (decreased white blood cell counts in males), and fore-stomach hyperplasia were seen only at very high doses in rodents. No dermal toxicity was observed up to the limit dose of 1,000 milligram/kilogram/day (mg/kg/day). There was no evidence of neurotoxicity in either of the neurotoxicity screening batteries up to or exceeding the limit dose.

In rats and rabbits, no increased quantitative or qualitative pre- or postnatal susceptibility was observed. In rats, no maternal or developmental toxicity was observed up to the limit dose (1,000 mg/kg/day). Three developmental studies in rabbits are available in the toxicological database for prohexadione calcium. In one study, late abortions occurred during GD 24–29 at 200 mg/kg/day, with increased mortality in maternal animals (GD 15–24) also noted at this dose. In another rabbit developmental study, two premature deliveries (on GD 24 and 26) were noted at the highest dose tested (350 mg/kg/day) with no developmental effects observed. No maternal or developmental effects were seen in a third rabbit developmental study up to 150 mg/kg/day. In the 2-generation reproductive toxicity study with rats, parental toxicity (minimal mortality) occurred at a dose well below the dose that caused decreases in offspring body weight (3, 850 mg/kg/day).

Prohexadione calcium is classified as not likely to be carcinogenic to humans based on 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 document Prohexadione Calcium. Section 3 Registration for Use on Strawberry and Watercress. Human Health Risk Assessment on pages 11–14 in docket ID number EPA–HQ–OPP–2014–0346.

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 (U/SF) 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 the Table of this unit. Since the assessment in 2011, (November 18, 2011) (76 FR 71459) (FRL–9326–4), the Agency has reevaluated the endpoints and determined that the previously identified dermal endpoints are no longer appropriate.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROHEXADIONE CALCIUM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations).	No endpoint attributable to a single dose and appropriate for the U.S. general population was seen in the prohexadione calcium toxicological database; therefore, an acute dietary point of departure for the general U.S. population was not established.		
Chronic dietary (All populations).	NOAEL = 20 mg/kg/day .... UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Chronic RfD = cPAD = 0.20 mg/kg/day.	Chronic toxicity—Dog. LOAEL = 200 mg/kg/day based on histopathological changes in the kidneys (dilated basophilic tubules) and increased urinary volume and sodium concentration.
Incidental oral short-term (1 to 30 days) and intermediate-term. (1 to 6 months)	NOAEL= 80 mg/kg/day ..... UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100	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.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROHEXADIONE CALCIUM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Short-term and intermediate-term dermal endpoints were not selected since there were no adverse dermal or systemic effects observed in the 28-day dermal study in rats. There was also no evidence of increased quantitative or qualitative pre- or postnatal sensitivity in the prohexadione calcium database. Therefore no concern for any duration of dermal exposure and no dermal endpoints are required		
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 40 mg/kg/day ..... UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x ..... Inhalation assumed equivalent to oral.	LOC for MOE = 100	Prenatal Developmental Toxicity—Rabbit. Maternal LOAEL = 200 mg/kg/day based on increased mortality, and abortions.
Cancer (Oral, dermal, inhalation).	''Not likely to be carcinogenic to humans'' based upon lack of evidence of carcinogenicity in rats and mice. No evidence of carcinogenic potential, therefore, cancer risk assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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 USDA Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis assumed Dietary Exposure Evaluation Model (DEEM) (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 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/oppefed1/models/water/index.htm.*

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) model, the estimated drinking water concentrations (EDWCs) of prohexadione calcium for chronic exposures for non-cancer assessments are estimated to be 170 parts per billion (ppb) for surface water and 0.137 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 170 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. EPA assessed residential exposure using the following assumptions: Short-term residential handler exposures may result from adults applying prohexadione calcium to residential lawns and ornamentals. The Agency assessed inhalation exposures for adult handlers applying manually-pressurized handwand applications to bedding plants. Short-term exposure is also possible for post-application incidental oral exposures of children 1–<2 years old. The Agency assessed hand-to-mouth exposures and incidental soil ingestions from applications to turf for children. Intermediate- and long-term exposures are not expected since there are no registered or proposed uses of prohexadione calcium that result in intermediate- or long-term residential exposures. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for prenatal and postnatal toxicity and there is no evidence of increased qualitative or quantitative susceptibility of any kind for fetuses and offspring in both rats and rabbits.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for prohexadione calcium is complete.

ii. There is no indication that prohexadione calcium 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 prohexadione calcium 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 PCT, tolerance-level residues, and DEEM (Ver 7.81) default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prohexadione calcium in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed 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 for chronic exposure, EPA has concluded that chronic exposure to prohexadione calcium from food and water will utilize 19% 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 14,000 for adults and 2,100 for children. 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).

An intermediate-term adverse effect was identified; however, prohexadione calcium is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for prohexadione calcium.

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 (BASF Analytical Method D9601 and 564/0) is available to enforce the tolerance expression for residues of prohexadione calcium in watercress and strawberry samples.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural

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

The Codex has not established a MRL for prohexadione calcium in/on strawberries and watercress.

C. Response to Comments

One comment was received in response to the notice of filing of IR–4's petition. The commenter stated this use should be denied due to toxicity to bees and that all use of chemicals should be stopped. The comment primarily appears directed to the registration of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but to the extent the comment is directed at the present tolerance action, the Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. As to bees the EPA will consider impacts to the environment and non-target species under the authority of FIFRA.

D. Revisions to Petitioned-For Tolerances

The tolerance on watercress has been revised from what was proposed in the initial petition. EPA is increasing the proposed tolerance for residues in/on watercress from 2 ppm to 4.0 ppm based on the available watercress field trial data and the OECD tolerance calculation procedure.

V. Conclusion

Therefore, tolerances are established for residues of prohexadione calcium, calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate, in or on strawberry at 0.30 ppm and watercress at 4.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) 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: June 22, 2015.

Daniel J. Rosenblatt,

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 § 180.547, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.547 Prohexadione calcium; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Strawberry	0.30
Watercress	4.0

* * * * *

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