1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerances 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: April 25, 2000.

James Jones,

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), 346(a) and 371.

§ 180.516 [Amended]

2. In § 180.516, by amending the table in paragraph (b) by changing the date for apricots, nectarines, peaches, and plums from ''12/31/99'' to read ''12/31/01''.

[FR Doc. 00–11031 Filed 5–2–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300998; FRL–6555–2]

RIN 2070–AB78

Prohexadione Calcium; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the raw agricultural commodities peanuts, peanut hay, pome fruit group, kidney, and meat byproducts. K-I Chemical U.S.A. Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 3, 2000. Objections and requests for hearings, identified by docket control number OPP–300998, must be received by EPA on or before July 3, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300998 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker (PM 22), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7740; and e-mail address: Giles-Parker.Cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production. Animal production. Food manufacturing. Pesticide manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to

the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300998. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 5, 1998 (63 FR 41828) (FRL–5799–6) and August 24, 1999 (64 FR 46191) (FRL–6069–6), EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a as amended by FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F4941) for tolerance by K-I Chemical U.S.A. Inc., Westchester Financial Center, 11 Martine Avenue, 9th Floor, White Plains, NY, 10606. These notices included a summary of the petition prepared by K-I Chemical U.S.A. Inc., the registrant. There were no comments received in response to the notices of filing.

The petition requested that 40 CFR 180 be amended by establishing a tolerance for residues of the plant growth regulator, prohexadione calcium (cyclohexanecarboxylic acid, 3, 5-dioxo-4-(1-oxopropyl)-, ion(1-), calcium, calcium salt) in or on the raw agricultural commodities peanut nutmeat at 1.0, peanut hay at 0.6, pome fruit at 3.0, and cattle meat byproduct (kidney) at 0.1 parts per million (ppm). EPA is editorially correcting the tolerance expressions to read prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the raw agricultural commodities peanuts at 1.0 ppm, peanut hay at 0.6 ppm, pome fruit crop group at 3.0 ppm, kidney of cattle, goats, hogs, horses, and sheep at 0.10 ppm and meat byproducts except kidney of cattle, goats, hogs, horses and sheep at 0.05 ppm.

Section 408(b)(2)(A)(i) of the 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) 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) 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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for a tolerance for residues of prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the raw agricultural commodities peanuts at 1.0 ppm, peanut hay at 0.60 ppm, pome fruit group at 3.0 ppm, kidney of cattle, goats, hogs, horses, and sheep at 0.10 ppm and meat byproducts except kidney of cattle, goats, hogs, horses and sheep at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 nature of the toxic effects caused by prohexadione calcium are discussed in this unit.

1. A rat acute oral study with a lethal $dose_{50}$ (LD_{50}) greater than 5,000 milligrams (mg)/kilogram (kg) for males and females. None of the acute toxicity studies showed significant toxicity in the battery of tests (acute toxicity categories III and IV for all routes of exposure).

2. A 90-day rat feeding study with a No Observed Adverse Effect Level (NOAEL) of: 73.1 mg/kg/day for males and 80.4 mg/kg/day for females and a Lowest Observed Adverse Effect Level (LOAEL) of 734 mg/kg/day for males and 815 mg/kg/day for females based on squamous cell hyperplasia of the forestomach.

3. A 90-day mouse feeding study with a NOAEL of equal to or greater than 10,244 mg/kg/day for males and equal to or greater than 11,916 mg/kg/day for females, highest dose tested (HDT).

4. A 90-day dog dietary study with a NOAEL of 80 mg/kg/day and a LOAEL of 400 mg/kg/day based on moderate cortical areas of dilated basophilic tubules in the kidneys and decreased potassium levels.

5. A 1-year dog chronic feeding study with a NOAEL of 20 mg/kg/day and a LOAEL of 200 mg/kg/day based on histopathological changes in the kidneys and increased urinary volume and sodium concentrations.

6. A rat chronic feeding/carcinogenicity study with a NOAEL for systemic toxicity of 93.9 mg/kg/day and a LOAEL of 469 mg/kg/day based on decreased white blood cells (WBC) in males. There is no evidence of carcinogenicity under conditions of the study.

7. A mouse carcinogenicity study with a NOAEL for systemic toxicity of 279 mg/kg/day and a LOAEL of 2,847 mg/kg/day based on decreased body weight gain and food utilization and microscopic changes in the stomachs of males. There was no evidence of carcinogenicity under conditions of the study.

8. A 2-generation rat reproduction study with a parental systemic NOAEL of 35.5 mg/kg/day and parental systemic LOAEL of 385 mg/kg/day based on increased mortality and a reproductive NOAEL equal to or greater than 3,850 mg/kg/day (HDT) and an offspring NOAEL of 385 mg/kg/day and an offspring LOAEL of 3,850 mg/kg/day based on decreased pup body weight.

9. A rat developmental study with a maternal and developmental NOAEL

equal to or greater than 1,000 mg/kg/day (HDT).

10. A rabbit developmental study with a maternal NOAEL of 40 mg/kg/day and a maternal LOAEL of 200 mg/kg/day based on increased mortality, abortions, and decreased maternal body weight gain and a developmental NOAEL equal to or greater than 200 mg/kg/day (HDT). A second rabbit developmental study with a maternal and developmental NOAEL equal to or greater than 150 mg/kg/day (HDT). A third rabbit developmental study with a maternal NOAEL of 100 mg/kg/day and a maternal LOAEL of 350 mg/kg/day based on premature deliveries and a developmental NOAEL equal to or greater than 350 mg/kg/day (HDT).

11. A acute neurotoxicity screening battery with a NOAEL equal to or greater than 2,000 mg/kg (HDT). A subchronic neurotoxicity screening battery with a NOAEL equal to or greater than 1,148 mg/kg/day for males and 1,348 mg/kg/day for females (HDT).

12. Prohexadione calcium was negative for mutagenic/genotoxic effects in a Bacterial reverse mutation assay (Ames test), an *In vitro* mammalian gene mutation assay, an *In vitro* mammalian chromosome aberration (Chinese hampster ovary (CHO) cells) study, an *In vivo* mammalian chromosome aberration (rat bone marrow cells) study, a Mammalian erythrocyte micronucleus test, an unscheduled DNA synthesis (UDS) in primary rat hepatocytes study, and a Rec assay with *Bacillus subtilis* study.

13. Following oral treatment of rats, prohexadione calcium was rapidly absorbed with highest tissue/carcass concentrations obtained within 30 minutes; however, absorption became saturated at the highest dose. The test material did not accumulate in the tissues. For low dose animals, renal excretion was the primary route of elimination. At the high dose, fecal excretion became the primary route of elimination. The primary excreta metabolite was identified as the free acid.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available toxicological studies.

2. *Chronic toxicity*. EPA has established the Chronic Reference Dose (cRfD) for prohexadione calcium at 0.80 mg/kg/day. This cRfD is based on both the subchronic and chronic toxicity studies in dogs. Since a similar endpoint of equal severity (minimal and moderate dilation of basophilic tubules) was observed in both studies, the results of the two studies can be evaluated using a single dose-response curve. The NOAEL of 80 mg/kg/day from the subchronic study due to the wider dose spread than in the 1-year study and an uncertainty factor of 100 (10x for interspecies extrapolation, 10x for intraspecies variability) were used to establish the cRfD. The NOAEL of 80 mg/kg/day was based on histopathological changes (dilated basophilic tubules) in the kidneys and clinical chemical changes seen at the LOAEL of 200 mg/kg/day. No additional uncertainty factor is needed because there is no increase in the severity of the lesions over time in the chronic study as compared to the subchronic study. Since an FQPA safety factor of 1x is applicable for chronic dietary risk assessment, the chronic population adjusted dose (cPAD) is equivalent to the cRfD of 0.80 mg/kg/day.

3. *Carcinogenicity*. The Health Effects Division HIARC has classified prohexadione calcium as ''not likely to be carcinogenic to humans'' based on the lack of carcinogenicity in rats and mice.

C. Exposures and Risks

1. *From food and feed uses*. No tolerances have been previously established (40 CFR part 180) for the residues of prohexadione calcium, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from prohexadione calcium as follows:

Chronic exposure and risk. The cPAD for prohexadione calcium is 0.8 mg/kg/day. A chronic dietary exposure analysis for prohexadione calcium was performed using the Dietary Exposure Evaluation Model (DEEM™). Tolerance level residues were used and 100% crop treated was assumed for all pome fruit and peanut commodities. The chronic analysis was conducted for the U.S. population and all population subgroups. The chronic exposure estimates (food only) for the U.S. population and all population subgroups were less than 5% of the cPAD.

2. *From drinking water*. The estimated environmental concentration (EEC) for ground water is 0.001 part per billion (ppb) (from screening concentration in ground water (SCI–GROW) modeling). The EECs for surface water (from generic expected environmental concentration (GENEEC) modeling) are 36 ppb for the acute (peak) concentration and 2.6 ppb for the 56-day value (with 3x adjustment factor).

3. *From non-dietary exposure*. There are no non-food uses of prohexadione calcium currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. No non-dietary exposures are expected for the general population.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether prohexadione calcium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, prohexadione calcium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that prohexadione calcium has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available toxicological studies.

2. *Chronic risk*. Using the DEEM chronic exposure assumptions described in this unit, EPA has concluded that aggregate exposure from food will utilize less than 1% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is all infants (< 1 year old) which utilizes 2.3% of the cPAD. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The drinking water level of comparisons (DWLOCs) for chronic exposure to prohexadione calcium in drinking water calculated for the U.S. population was 28,000 ppb, for females, 13–50 years old, was 24,000 ppb and for all infants the DWLOC was 8,000 ppb. The EEC for

ground water is 0.001 ppb (from SCI–GROW modeling). The EEC for surface water (from GENEEC modeling) is 2.6 ppb for the 56-day value (with 3x adjustment factor). EPA's chronic DWLOC are well above the estimated exposures for prohexadione calcium in water for the subgroups of concern. Conservative model estimates (GENEEC and SCI–GROW) of the concentrations of prohexadione calcium in surface and ground water indicate that exposure will be minimal.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate risk assessments were not performed because there are no residential uses proposed for prohexadione calcium.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to prohexadione calcium residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of prohexadione calcium, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The prenatal and postnatal toxicology data base for prohexadione calcium is adequate. The results of these studies indicated no quantitative or qualitative increase in susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to prohexadione. No developmental effects were seen at doses up to the limit dose (1,000 mg/kg/day) in the rat developmental toxicity study or up to the highest doses tested (150, 200, and 350 mg/kg/day) in three rabbit developmental toxicity studies. In the 2-generation reproduction study in rats, the effects in the offspring were observed only at treatment levels which resulted in evidence of parental toxicity.

A developmental neurotoxicity (DNT) study is not required. No neuropathology or central nervous system (CNS) malformations were seen in the developmental toxicity studies. In the 2-generation reproduction study in rats, there were no findings in pups that were suggestive of changes in neurological development, although no functional assessment was performed. Additionally, there was no evidence of neurotoxicity in either the acute or subchronic neurotoxicity studies in rats and no evidence of neurotoxicity in other studies.

The Agency concluded that an extra safety factor to protect infants and children is not needed based on the following considerations:

i. The prenatal and postnatal toxicology data base is complete, there is no indication of increased susceptibility, and a developmental neurotoxicity study is not required.

ii. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children from the use of prohexadione calcium (currently there are no proposed residential uses and, therefore, non-occupational exposure is not expected).

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

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in peanuts, pome fruit crop group, and livestock is adequately understood. The residues of concern for the tolerance expression are parent. Based on the results of animal metabolism studies, tolerances established for kidney and meat byproducts will cover any secondary residues that would occur in animal commodities from the use on peanuts and pome fruits.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography and mass selective detector) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

The qualitative nature of the residue of prohexadione calcium in plants is adequately understood for the purpose of this petition. The metabolism of prohexadione calcium in apples and peanuts is similar. Prohexadione calcium is rapidly metabolized to prohexadione and parent-like oxidative intermediates and ultimately to tricarballylic acid (TCA), citric acid, and other natural products from the plant carbon pool. Only the parent compound needs to be included in the tolerance expression for pome fruit and peanuts and is the only compound to be included in the dietary risk assessments.

D. International Residue Limits

There are no Codex Alimentarius Commission (Codex), Canadian, or Mexican Maximum Residue Levels (MRLs) for prohexadione calcium.

E. Rotational Crop Restrictions

No tolerances for inadvertent residues of prohexadione calcium are required in rotational crops at this time.

V. Conclusion

Therefore, the tolerances are established for residues of prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the raw agricultural commodities peanuts at 1.0 ppm, peanut hay at 0.60 ppm, pome fruit crop group at 3.0 ppm, kidney of cattle, goats, hogs, horses, and sheep at 0.10 ppm, and meat byproducts except kidney of cattle, goats, hogs, horses and sheep at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178.

Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300998 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 3, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300998, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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). 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.*, or 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). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: April 26, 2000.

Susan B. Hazen,

Acting Director, 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 added to read as follows:

§ 180.547 Prohexadione calcium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, kidney	0.10
Cattle, mbyp (except kidney)	0.05
Goats, kidney	0.10
Goats, mbyp (except kidney)	0.05
Hogs, kidney	0.10
Hogs, mbyp (except kidney)	0.05
Horses, kidney	0.10
Horses, mbyp (except kidney)	0.05
Peanuts	1.0
Peanut hay	0.60
Fruit, pome, group	3.0
Sheep, kidney	0.10
Sheep, mbyp (except kidney)	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00–11030 Filed 5–2–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300984; FRL–6497–4]

RIN 2070–AB78

Harpin Protein; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide harpin protein on all food commodities when applied/used in agricultural fields and greenhouses for the management of plant diseases, the significant improvement in growth and yields, and the suppression of certain insects and other pests. EDEN Bioscience Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of harpin protein.

DATES: This regulation is effective May 3, 2000. Objections and requests for hearings, identified by docket control number OPP–300984, must be received by EPA, on or before July 3, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300984 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Diana M. Horne, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8367; and e-mail address: horne.diana@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that