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]

BILLING CODE 6560–50–F

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

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–300984. 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, 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 September 9, 1999 (64 FR 49010) (FRL–6095–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (PP 9F6027) by EDEN Biosciences, 11816 North Creek Parkway N., Bothell, WA 98011–8205. This notice included a summary of the petition prepared by the petitioner EDEN Bioscience Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of harpin protein.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. . . .'' Additionally, section 408(b)(2)(D) requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

Harpin exhibits no adverse effects in Tier I mammalian toxicity studies; therefore, Tier II and III studies are not required. Acute toxicity studies indicate that Messenger is a Toxicity Category IV substance. No toxicity was observed in acute oral toxicity studies conducted with Messenger. Acute oral and dermal toxicity LD_{50} values for Messenger were greater than 5,000 grams/kilograms (g/kg) in the rat (Toxicity Category IV). The LC_{50} for Messenger was greater than 2 milligrams/liter (mg/L) in an acute inhalation study in the rat. Messenger also showed no effect in eye and dermal irritation studies. For example, the dermal irritation index for Messenger was zero at 500 mg and no eye irritation was shown in the rabbit at 100 mg. There have been no reported incidents of Messenger-induced hypersensitivity in individuals exposed to Messenger during research, production, and/or field testing and there are no published reports indicating that harpin proteins are toxic. Further, the harpin protein has a non-toxic mode of action by eliciting a systemic acquired resistance response in plants, and it has been demonstrated that the product has no direct antimicrobial effect on bacteria and fungi, for species examined to date. For a more complete discussion, see the Harpin Registration Eligibility Document.

V. Aggregate Exposures

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning dietary exposures from pesticide residues in food and drinking water and all other exposures for which there is reliable information. These other sources of exposure include such non-occupational exposures as those resulting from the use of pesticides around the home or in public areas such as parks and schools. The Agency defines acute and chronic aggregate risks to include only dietary (food and water) exposures. Short-, intermediate-, and long-term aggregate exposures are defined to include non-occupational exposures in addition to dietary exposures. Any or all of these aggregate risk assessments may be required for a pesticide depending on its registered uses.

A. Dietary Exposure

Harpin and related harpin proteins are common constituents of plant pathogenic bacteria which are often found on fruits and vegetables. Additional dietary exposure to harpin protein resulting from labeled uses is unlikely to occur because of extremely low use rates and rapid degradation in the field. Furthermore, the lack of demonstrable toxicity in acute studies, and the natural occurrence of harpins in the environment support the establishment of an exemption from the requirement of a tolerance for harpin protein.

1. *Food*. Messenger is applied at very low rates of application (generally 2 to 11.5 grams of active ingredient per acre). Harpin also degrades rapidly in sunlight, high temperatures, and in the presence of chlorine. Because of the low use rates and rapid degradation in the field, no harpin residues are detectable, using available methods, on treated crops even immediately after application. Therefore, the Agency believes that dietary exposure to harpin via consumption of treated food or feed will be negligible.

2. *Drinking water exposure*. Because harpin protein is applied at extremely low use rates and rapidly degrades in the environment, residues are unlikely to occur in ground or surface water. In addition, harpin is highly sensitive to small amounts of chlorine, as contained in many municipal water systems. Therefore, residues of harpin protein are unlikely to occur in drinking water.

B. Other Non-Occupational Exposure

The Agency believes that the potential for non-dietary exposure and attendant risks to the general population including infants and children is minimal to non-existent, due to low use rates, the instability of harpin protein in the environment, and lack of demonstrated toxicity. In addition, the label use sites are commercial, agricultural, and horticultural, as opposed to domestic settings; thus, non-occupational exposure to the general population is expected to be minimal.

1. *Dermal exposure*. Harpin is a Toxicity Category IV product, and is not expected to pose any risk via the dermal route of exposure.

2. *Inhalation exposure*. Acute inhalation tests place harpin in Toxicity Category IV, thus risk via the inhalation route is expected to be minimal to non-existent.

VI. Cumulative Effects

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.

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of harpin protein and no information that indicates that toxic effects would be cumulative with any other compounds. Moreover, harpin does not exhibit a toxic mode of action in its target pests or diseases.

VII. Determination of Safety for U.S. Population, Infants and Children

Harpin's lack of toxicity has been demonstrated by the results of acute toxicity testing in mammals in which harpin caused no adverse effects when dosed orally and via inhalation at the limit dose for each study. Thus, based on this and other information in this preamble, EPA concludes that there is a reasonable certainty that no harm to the United States population in general, or to infants or children will result from aggregate exposure to harpin residues. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

VIII. Other Considerations

A. Endocrine Disruptors

The Agency has no information regarding endocrine effects of this biochemical pesticide at this time; however, since there was no demonstrable toxicity in acute tests, there is no evidence to suggest that harpin will adversely affect the endocrine system.

B. Analytical Method

Because this notice establishes an exemption from the requirement of a tolerance, no anlytical method is necessary. The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons enumerated in this preamble, including harpin's lack of toxicity. Accordingly, the Agency has concluded that an analytical method is not needed for enforcement purposes for harpin residues.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels nor any tolerances or exemptions issued for harpin protein outside the United States.

IX. 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–300984 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 20460. 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 IX.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 number OPP–300984, 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).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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 exemption 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).

XI. 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 19, 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), 346(a) and 371.

2. Section 180.1204 is revised to read as follows:

§ 180.1204 Harpin protein; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established 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.

[FR Doc. 00–11029 Filed 5–2–00; 8:45 am]

BILLING CODE 6560–50–F