

does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: April 20, 2004.

**James W. Newsom,**

*Acting Regional Administrator, Region III.*

■ 40 CFR part 52 is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

*Authority:* 42 U.S.C. 7401 *et seq.*

#### Subpart XX—West Virginia

■ 2. Section 52.2520 is amended by adding paragraph (c)(59) to read as follows:

#### § 52.2520 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(59) Revisions to the West Virginia Regulations to attain and maintain the National Ambient Air Quality Standards (NAAQS) for sulfur dioxide in the City of Weirton, including Clay and Butler Magisterial Districts, in Hancock County, West Virginia, submitted on December 29, 2003, by the West Virginia Department of Environmental Protection:

(i) Incorporation by reference.

(A) Letter of December 29, 2003, from the West Virginia Department of Environmental Protection, transmitting a revision to the State Implementation Plan (SIP) for attainment and maintenance of the sulfur dioxide NAAQS for the City of Weirton, including the Clay and Butler Magisterial Districts in Hancock County, West Virginia.

(B) The following Companies' Consent Order and Operating Permit:

(1) Wheeling-Pittsburgh Steel Corporation, Operating Permit R13-1939A, effective August 19, 2003.

(2) Weirton Steel Corporation Consent Order, CO-SIP-C-2003-28, effective August 4, 2003.

(ii) Additional Material.

(A) Remainder of the State submittal pertaining to the revision listed in paragraph (c)(59)(i) of this section.

(B) Letter of February 10, 2004, from the West Virginia Department of Environmental Protection providing

clarification to permit R13-1939A, condition B.4. issued to the Wheeling-Pittsburgh Steel Corporation.

■ 3. Section 52.2525 is amended by adding paragraph (b) to read as follows:

#### § 52.2525 Control strategy: Sulfur oxides.

\* \* \* \* \*

(b) EPA approves the attainment demonstration State Implementation Plan for the City of Weirton, including the Clay and Butler Magisterial Districts area in Hancock County, West Virginia, submitted by the West Virginia Department of Environmental Protection on December 29, 2003.

[FR Doc. 04-10095 Filed 5-4-04; 8:45 am]

BILLING CODE 6560-50-P

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2004-0097; FRL-7356-5]

#### 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 harpin protein on all food commodities when applied/used to enhance plant growth, quality and yield, to improve overall plant health, and to aid in pest management. EDEN Bioscience Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), 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 5, 2004. Objections and requests for hearings must be received on or before July 6, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket ID number OPP-2004-0097. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other

material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Diana M. Horne, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8367; e-mail address: [horne.diana@epa.gov](mailto:horne.diana@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

##### B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

## II. Background and Statutory Findings

In the **Federal Register** of January 28, 2004 (69 FR 4151) (FRL-7339-2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6765) by EDEN Bioscience Corporation, 3830 Monte Villa Parkway, Bothell, WA 98021-6942. 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 a temporary exemption from the requirement of a tolerance for residues of harpin protein.

Section 408(c)(2)(A)(i) of 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 exemption is "safe." Section 408(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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) of FFDCA 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.

## III. 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.

This final rule amends the previously established exemption from the requirement of a tolerance for harpin protein published in the **Federal Register** of May 3, 2000 (65 FR 25660) (FRL-6497-4). Research on other harpin proteins that are similar to this active ingredient indicates that many of these proteins also exhibit activities of commercial value in crop production. Because the existing tolerance exemption codified in 40 CFR 180.1204 does not specify the scope of harpin proteins that are exempt, this final rule clarifies the existing exemption by specifying the criteria a protein must meet in order to be subject to the exemption. Harpin proteins exhibit no adverse effects in Tier I mammalian toxicity studies; therefore, Tier II and III study requirements are waived. Acute oral and dermal toxicity LD<sub>50</sub> values for products containing harpin protein are greater than 5,000 grams/kilograms (g/kg) in the rat (Toxicity Category IV, least toxic). Inhalation studies in the rat on products containing harpin protein resulted in an LC<sub>50</sub> of greater than 2 milligrams/liter (mg/L) (Toxicity Category IV). In addition, no adverse effects are observed in eye irritation studies in the rabbit at 100 mg (Toxicity Category IV). There have been no reported incidents of hypersensitivity in individuals exposed to products containing harpin protein during research, production, and/or field testing, and there are no published reports indicating that harpin proteins are toxic. Further, harpin proteins have a non-toxic mode of action and work by activating the treated plant's own growth and defense systems. In order to be exempt from the requirement of a tolerance, a harpin protein must meet the following specification:

1. Consists of protein less than 100 kD in size, that is acidic (pI<7.0), glycine rich (>10%), and contains no more than one cystine residue.

2. The source(s) of genetic material encoding the protein are bacterial plant pathogens not known to be mammalian pathogens.

3. Elicits the hypersensitive response (HR) which is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves.

4. Possesses a common secondary structure consisting of  $\alpha$  and  $\beta$  units that form an HR domain.

5. Is heat stable (retains HR activity when heated to 65°C for 20 minutes).

6. Is readily degraded by a proteinase representative of environmental conditions (no protein fragments >3.5 kD after 15 minutes degradation with Subtilisin A).

7. Exhibits a rat acute oral toxicity (LD<sub>50</sub>) of greater than 5,000 mg product/kg body weight.

## IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

### A. Dietary Exposure

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.* Products containing harpin protein are applied at very low rates of application (grams of active ingredient per acre). Harpin proteins are also rapidly degraded in the environment by common proteinases, ultraviolet (UV) irradiation, and oxidizing agents. No residues of active ingredient are detectable, using available methods, on treated crops even immediately after application. Therefore, the Agency believes that dietary exposure to harpin protein 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 protein is highly sensitive to small amounts of chlorine or similar oxidizing agents 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, with the exception of turf and ornamentals, the proposed use sites are primarily commercial agricultural and horticultural, as opposed to domestic settings. Increased non-dietary exposures to harpin protein via home and garden uses is not considered likely because of the typically low-use rates and lack of persistence in the environment.

1. *Dermal exposure.* Products containing harpin protein are classified as Toxicity Category IV (least toxic) for dermal exposure, and are not expected to pose any risk via the dermal route.

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

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency to consider the cumulative effects of exposure to harpin protein and to other substances that have a common mode of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Because of the lack of demonstrable toxicity of harpin protein in acute toxicity studies, lack of information indicating that any toxic effects, if they existed, would be cumulative with any other compounds, extremely low-use rates, and rapid degradation in the environment, the Agency does not expect any cumulative or incremental effects from exposure to residues of this product when used as directed on the label.

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

Harpin protein's lack of toxicity has been demonstrated by the results of acute toxicity testing in mammals in which harpin protein caused no adverse effects when dosed orally, dermally, and via inhalation at the limit dose for each study. Therefore, EPA concludes that there is a reasonable certainty that no harm to the U.S. population in general, and to infants and children, specifically, will result from aggregate exposure to

residues of harpin protein. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Accordingly, exempting harpin proteins that meet the criteria specified in this preamble is considered safe and poses no risk. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects, to account for prenatal and postnatal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty factors. Here, based on all the available information and for all the reasons already set forth in this final rule, the Agency finds that there are no threshold effects of concern to infants, children, and adults when harpin protein is used as labeled, and that the provision requiring an additional margin of safety is not necessary to protect infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of harpin protein.

#### VII. Other Considerations

##### A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA has determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, harpin protein may be subjected to

additional screening and/or testing to better characterize effects related to endocrine disruption. Based on available data, no endocrine system-related effects have been identified with consumption of harpin protein. To date, there is no evidence to suggest that harpin protein affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

##### B. Analytical Method(s)

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 protein's demonstrated lack of toxicity, and instability in the environment. Accordingly, the Agency has concluded that an analytical method is not needed for enforcement purposes for harpin protein residues.

##### C. Codex Maximum Residue Level

There is currently no CODEX Maximum Residue Limit set for food use of this active ingredient.

#### VIII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP-2004-0097 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 6, 2004.

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 issue(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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

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](mailto: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, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0097, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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

This final rule establishes an exemption from the tolerance requirement under section 408(d) of FFDCFA 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive

Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 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); or 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 section 408(d) of FFDCFA, 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### X. Congressional Review Act

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 23, 2004.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1204 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 individual harpin proteins that meet specified physiochemical and toxicological criteria when used as biochemical pesticides on all food commodities to enhance plant growth, quality and yield, to improve overall plant health, and to aid in pest management. The physiochemical and toxicological criteria identifying harpin proteins are as follows:

(a) Consists of a protein less than 100 kD in size, that is acidic (pI<7.0), glycine rich (>10%), and contains no more than one cystine residue.

(b) The source(s) of genetic material encoding the protein are bacterial plant pathogens not known to be mammalian pathogens.

(c) Elicits the hypersensitive response (HR) which is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves.

(d) Possesses a common secondary structure consisting of  $\alpha$  and  $\beta$  units that form an HR domain.

(e) Is heat stable (retains HR activity when heated to 65°C for 20 minutes).

(f) Is readily degraded by a proteinase representative of environmental conditions (no protein fragments > 3.5 kD after 15 minutes degradation with Subtilisin A).

(g) Exhibits a rat acute oral toxicity (LD<sub>50</sub>) of greater than 5,000 mg product/kg body weight.

[FR Doc. 04-10212 Filed 5-4-04; 8:45 am]

BILLING CODE 6560-50-S

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Parts 0 and 97

[WT Docket No. 04-140; FCC 04-79]

#### Amendment of Part 97 of the Commission's Rules Governing the Amateur Radio Services

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document makes minor amendments to various rule sections to

clarify or eliminate duplicative language, or conform them with other rule sections. This action will allow current Amateur Radio Service licensees to contribute more to the advancement of the radio art, reduce the administrative costs that the Commission incurs in regulating this service, streamline our licensing processes, and promote efficient use of spectrum allocated to the Amateur Radio Service.

**DATES:** Effective June 4, 2004.

#### FOR FURTHER INFORMATION CONTACT:

William T. Cross,  
*William.Cross@fcc.gov*, Public Safety and Critical Infrastructure Division, Wireless Telecommunications Bureau, (202) 418-0680, or TTY (202) 418-7233.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order, WT Docket No. 04-140, FCC 04-79, adopted March 31, 2004, and released April 15, 2004. The full text of this document is available for inspection and copying during normal business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via e-mail *qualexint@aol.com*. The full text may also be downloaded at <http://www.fcc.gov>. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418-7426, or TTY (202) 418-7365, or at *brian.millin@fcc.gov*.

1. In the Notice of Proposed Rulemaking and Order (NPRM) the Commission proposed to revise operating privileges for amateur radio service licensees as well as to eliminate obsolete and duplicative rules in the Amateur Radio Service. Additionally, on its own motion, the Commission adopted changes to its part 0 and 97 rules to clarify or eliminate duplicative language, or conform them with other rule sections.

#### I. Regulatory Matters

##### A. Paperwork Reduction Act

2. The Order does not contain any new or modified information collection.

3. The Regulatory Flexibility Act (RFA) requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." 5 U.S.C. 605(b). In the NPRM and Order,