

requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal

governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule. VIII. Submission to Congress and the Comptroller General.

VIII. Submission of Report to Congress and 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 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 the rule in the Federal Register. This 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: February 2, 1999.

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. 346a and 371

2. In §180.480, by revising paragraph (a)(1) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) *General.* (1) Time-limited tolerances, to expire on December 31, 2001, are reestablished for combined residues of the fungicide fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, expressed as fenbuconazole, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/revocation date
Bananas (whole fruit) ...	0.3	12/31/01
Pecans	0.1	12/31/01
Stone fruit crop group (except plums and prunes)	2.0	12/31/01

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[FR Doc. 99-3519 Filed 2-16-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300769; FRL-6049-9]

RIN 2070-AB78

Cinnamaldehyde; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biochemical cinnamaldehyde in or on all food commodities when applied as a broad spectrum fungicide/insecticide/algacide in accordance with good agricultural practices. The Interregional Research Project No. 4 (IR-4) submitted a petition to EPA on behalf of Proguard, Inc., under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of cinnamaldehyde. The Agency also removes the mushroom-specific

tolerance exemption for cinnamaldehyde (40 CFR 180.1156) and considers this tolerance to be reassessed, as required by the FQPA.

DATES: This regulation is effective February 17, 1999. Objections and requests for hearings must be received by EPA on or before April 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300769], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300769], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300769]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Diana M. Horne, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 902, Crystal Mall #2

1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308-8367; e-mail: horne.diana@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1998 (63 FR 46017) (FRL-6024-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition (PP 7E4904) by the Interregional Research Project No. 4 (IR-4), on behalf of Proguard, Inc. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of cinnamaldehyde.

I. Risk Assessment and Statutory Findings

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..." 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.

A. 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.

B. Mammalian Toxicology Profile

Acute toxicity. The oral LD₅₀ for cinnamaldehyde is greater than 5,000 milligram/kilogram (mg/kg), while the dermal LD₅₀ is greater than 2,000 mg/kg. Cinnamaldehyde is also minimally toxic via the inhalation route, since the LC₅₀ is greater than 2.09 mg/L. Cinnamaldehyde is a mild skin and eye irritant. All sub-chronic, teratology and mutagenicity testing requirements have been waived since this substance is (1) a biochemical pesticide possessing a low order of toxicity, (2) applied at very low rates, (3) currently used in foods, such as nonalcoholic beverages, ice creams, candy, baked goods, condiments and meats, as a flavoring agent, and (4) considered GRAS (Generally Recognized as Safe) by the FDA. In addition, cinnamon oil (which contains 55-90% cinnamaldehyde is also classified as a GRAS substance and is extensively used in the food and flavoring industry, as well as in perfumery and cosmetic products. Cinnamon oil was also recently exempted from pesticidal regulation under FIFRA section 25(b).

II. Aggregate Exposures

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

A. Dietary Exposure

1. *Food.* Currently, dietary exposure to cinnamaldehyde occurs from its use as a food flavoring agent, and there exists a tolerance exemption on mushrooms (40 CFR 180.1156). Since flavoring agents are added in very small quantities, dietary exposure is expected to be minimal. In addition, dietary exposure to residues of cinnamaldehyde as a result of uses covered under this tolerance exemption is also expected to be insignificant.

2. *Drinking water exposure.* Cinnamaldehyde residues in drinking water are expected to be minimal due to its low application rate, expected rapid

biodegradation in soil, and its insolubility in water.

B. Other Non-Occupational Exposure

There may be minor amounts of non-dietary exposure to cinnamaldehyde from the use of cinnamon oil in cosmetics and perfumes. Cinnamon oil contains 55-90% cinnamaldehyde. However, cinnamon oil is also classified as a GRAS substance for use as a flavoring agent on food (21 CFR 182.10) and was recently exempt from pesticide regulation under FIFRA section 25(b). Based on the small amount of cinnamaldehyde and cinnamon oil used in these instances, very minimal non-dietary exposure is expected.

III. Cumulative Effects

Because of the low toxicity and use rates of cinnamaldehyde, EPA does not believe that there is any concern regarding the potential for cumulative effects of cinnamaldehyde and other substances that have a common mechanism of toxicity.

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

The use of products containing cinnamaldehyde, which is of low toxicity and is used in low concentrations, is compatible with the Agency's objectives to register reduced risk pesticides. Based on its low toxicity, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to residues of cinnamaldehyde. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. An inconsequential increase in dietary exposure is expected to result from the application of cinnamaldehyde to growing crops. Cinnamaldehyde is applied at low rates, and with its proven low toxicity and its history of safe use, does not pose a safety concern.

V. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that cinnamaldehyde has any negative impact on the immune system, or is active hormonally.

B. Analytical Method(s)

An analytical method for the detection of residues of cinnamaldehyde is not applicable to this tolerance exemption.

C. Codex Maximum Residue Level

There are no approved CODEX maximum residue levels (MRL's)

established for residues of cinnamaldehyde.

VI. Objections and Hearing Requests

The new FFDCA 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) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 19, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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). 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300769]. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). 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) (Pub. L. 104-4). Nor does it require any 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In additions, since tolerance exemptions that are established on the basis of a petition under section 408(d) of the 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. 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 the rule in the **Federal Register**. This 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: January 19, 1999.

Kathleen Knox,

Acting 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. 346a and 371.

2. Section 180.1156 is revised to read as follows:

180.1156 Cinnamaldehyde; exemption from the requirement of a tolerance.

Cinnamaldehyde (3-phenyl-2-propenal) is exempted from the requirement of a tolerance in or on all food commodities, when used as a fungicide, insecticide, and algicide in accordance with good agricultural practices. The existing tolerance exemption on mushrooms (40 CFR 180.1156) is hereby removed.

[FR Doc. 99-3663 Filed 2-16-99; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL MARITIME COMMISSION

46 CFR Parts 502, 545 and 571

[Docket No. 98-21]

Miscellaneous Amendments to Rules of Practice and Procedure

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission is making corrections and changes to existing regulations to update and improve them, and to conform them to and implement the Ocean Shipping Reform Act of 1998. This rule modifies part 502 (Rules of Practice and Procedure) and redesignates part 571 as part 545 (Interpretations and Statements of Policy).

DATES: Effective May 1, 1999.

FOR FURTHER INFORMATION CONTACT: Bryant L. VanBrakle, Secretary, Federal Maritime Commission, 800 North Capitol St., NW., Room 1046, Washington, DC 20573-0001, (202) 523-5725, E-mail: secretary@fmc.gov.

SUPPLEMENTARY INFORMATION:

The Ocean Shipping Reform Act of 1998 ("OSRA"), Pub. L. 105-258, 112 Stat. 1902, which made numerous changes to the Shipping Act of 1984 ("1984 Act"), Pub. L. 98-237, 98 Stat. 67 (46 U.S.C. app. secs. 1701 through