

zone remains in effect until the LNG vessel is docked at the Eco-Electrica waterfront facility or south of Latitude 17°56.0'N.

(2) The waters within 150 feet of a LNG vessel when the vessel is alongside the Eco-Electrica waterfront facility in Guayanilla Bay, at position 17°58.55'N, 066°45.3'W. This safety zone remains in effect while the LNG vessel is docked with product aboard or is transferring liquefied natural gas.

(b) In accordance with the general regulations in 165.23 of this part, anchoring, mooring or transiting in these zones is prohibited unless authorized by the Coast Guard Captain of the Port.

(c) The Coast Guard Marine Safety Office San Juan will notify the maritime community of periods during which the safety zones will be in effect by providing advance notice of scheduled arrivals and departures of LNG vessels via a marine broadcast Notice to Mariners.

Dated: March 15, 2001.

**J.A. Servidio,**

*Commander, U.S. Coast Guard, Captain of the Port.*

[FR Doc. 01-7624 Filed 3-27-01; 8:45 am]

BILLING CODE 4910-15-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-301107; FRL-6772-1]

RIN 2070-AB78

#### **Coniothyrium minitans Strain CON/M/91-08; 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 *Coniothyrium minitans* strain CON/M/91-08 on all food commodities when applied/used according to label instructions. Prophyta Biologischer Pflanzenschutz GmbH submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) 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 *Coniothyrium minitans* strain CON/M/91-08.

**DATES:** This regulation is effective March 28, 2001. Objections and requests for hearings, identified by docket control number OPP-301107, must be received by EPA, on or before May 29, 2001.

**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-301107 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Susanne Cerrelli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8077; and e-mail address: cerrelli.susanne@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," "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301107. 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 January 24, 2000 (65 FR 3696) (FRL-6484-9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Prophyta Biologischer Pflanzenschutz GmbH, Inselstrabe 12, D-23999 Malchow/Poel, Germany. This notice included a summary of the petition prepared by the petitioner Prophyta Biologischer Pflanzenschutz GmbH.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Coniothyrium minitans* strain CON/M/91-08. Three comments were received after close of the comment period which expressed support of this registration as an additional product for controlling white mold in snap beans.

### 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.

*Coniothyrium minitans* is ubiquitous in the environment. This fungus was

first described by Campbell (1947), after being isolated from sclerotia in California. A pesticide product containing *Coniothyrium minitans* strain CON/M/91-08 is currently registered in Germany and Switzerland. No toxicological or pathogenic effects by *C. minitans* in mammals have been reported in available public literature. Furthermore, Prophyta Biologischer Pflanzenschutz GmbH has submitted several acute toxicity studies (eye, dermal, oral, and intraperitoneal) using a dose greater than  $10^7$  colony forming units (CFU) of *Coniothyrium minitans* strain CON/M/91-08, with no adverse effects being observed (NOAEL). In addition, certain biological characteristics of *Coniothyrium minitans* strain CON/M/91-08, which include, its temperature requirements for germination and mycelium growth, and its dependence on *Sclerotinia* as a host are further indications that this organism is not pathogenic to mammals. The *C. minitans* data submitted demonstrated no conidia germination at 30 °C or above, and no mycelium growth at 33 °C or above. Therefore, the use of this fungus does not appear to have any risk of adverse effects to mammals. A more detailed discussion of the data submitted in support of this tolerance exemption and the associated registration action as well as any data waivers that were granted by the Agency may be found in the Biopesticides Registration Action Document for *Coniothyrium minitans* strain CON/M/91-08, which has been placed in the official record for this action.

### V. 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 ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

#### A. Dietary Exposure

1. *Food.* Dietary exposure is expected to be minimal because the microbial product is incorporated in the soil prior to planting or after harvest. Thus no increase in fungal exposure is anticipated. In addition, standard practices of washing, peeling, cooking, or processing fruits and vegetables will reduce residues of *Coniothyrium minitans* strain CON/M/91-08 and further minimize dietary exposure. The risk posed to adults, infants and children is likely to be minimal because

of the low acute toxicity of the microbial pesticide and no reported cases in the literature of disease or injury to humans.

2. *Drinking water exposure.* A submitted study showed that the likelihood for *C. minitans* passage through a soil medium to ground water is minimal to none. Also, the survival of *C. minitans* in a municipal water treatment is unlikely. Furthermore, the results of the acute toxicity studies using a high dose of the fungus suggest there will not be any adverse effects to humans and there have been no reported cases in the literature of disease or injury to humans.

#### B. Other Non-Occupational Exposure

*Coniothyrium minitans* is a naturally-occurring fungus. Dermal and inhalation exposure to *C. minitans* pesticide product is expected to be limited to those who apply or handle the pesticide in an agricultural environment. Therefore, no other non-occupational exposure is expected.

### VI. Cumulative Effects

No mechanism of toxicity in mammals has been identified for *Coniothyrium minitans* strain CON/M/91-08. Therefore no cumulative effect with other related organisms is anticipated. Because the data demonstrate low toxicity/pathogenicity potential of the active ingredient, the likelihood of adverse dietary or cumulative effects is expected to be minimal.

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

Soil microorganisms, such as *C. minitans*, are naturally occurring and ubiquitous in the environment, with a highly probable, prior human exposure. Furthermore, the toxicity testing conducted by Prophyta Biologischer Pflanzenschutz GmbH indicates an inability of the microbe to grow at or above 33 °C and a lack of potential toxic, pathogenic, allergic effects to humans. In addition, no potential for toxic or pathogenic effects of *C. minitans* to mammals including humans was reported in published literature. Further, there is no evidence which suggests that aggregate exposure of either adults or infants and children to *C. minitans* leads to any harm. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population or any significant subpopulation, including infants and children, to residues of *Coniothyrium minitans* strain CON/M/91-08. This includes all anticipated dietary

exposures and all other exposures for which there is reliable information.

FFDCA section 408 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 data base, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that this microbial agent is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects; therefore, EPA has not used a margin of exposure (safety) approach to assess the safety of *Coniothyrium minitans* strain CON/M/91-08. As a result, the provision requiring an additional margin of exposure (safety) does not apply.

#### VIII. Other Considerations

##### A. Endocrine Disruptors

Within the available scientific literature, there are no reports to suggest or indicate that *C. minitans* has the potential to cause an adverse effects on the endocrine and/or immune systems of animals.

##### B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore the Agency has concluded that an analytical method is not required for enforcement purposes for *Coniothyrium minitans* strain CON/M/91-08.

##### C. Codex Maximum Residue Level

There are no CODEX values for *Coniothyrium minitans* strain CON/M/91-08.

#### 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-301107 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 May 29, 2001.

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](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.

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.

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-301107, 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. 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](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 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 FFDC 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 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 FFDC 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 FFDC section 408(n)(4). 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.

## 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: March 15, 2001.

**Anne E. Lindsay,**

*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 180.1213 is added to subpart D to read as follows:

#### § 180.1213 *Coniothyrium minitans* strain CON/M/91-08; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Coniothyrium minitans* strain CON/M/91-08 when used in or on all food commodities.

[FR Doc. 01-7645 Filed 3-27 -01; 8:45 am]

BILLING CODE 6560-50-S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 0, 42, 43, 61, 63, and 64

[IB Docket No. 00-202, FCC 01-93]

#### Policy and Rules Concerning the International Interexchange Marketplace and 2000 Biennial Regulatory Review

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document forbears from the requirement that U.S. non-dominant interexchange carriers file tariffs for most international services pursuant to the requirements of the Communications Act. The Commission initiated this proceeding to determine whether to extend the complete detariffing regime that it adopted for domestic, interexchange services to the international services of non-dominant commercial mobile radio services and interexchange carriers, including U.S. carriers classified as dominant due to foreign affiliations. The Commission believes that the rules and policies contained in the Order will foster competition in the U.S. international services market and benefit U.S. consumers.

**DATES:** Effective April 27, 2001. Public and agency comments on the request for emergency approval of the information