

Commodity	Parts per million	Expiration/Revocation Date
Almond, hulls .....	5.0	None
Apple .....	1.5	None
Bean, snap, succulent ..	2.0	None
Birdfoot trefoil .....	2.0	None
Birdfoot trefoil, hay .....	5.0	None
Blackberry .....	2.0	None
Blueberry .....	5.0	None
Boysenberry .....	2.0	None
Broccoli .....	2.0	None
Brussels sprouts .....	2.0	None
Cabbage .....	2.0	None
Cauliflower .....	2.0	None
Celery .....	2.0	None
Cherry .....	2.0	None
Clover .....	2.0	None
Clover, hay .....	5.0	None
Cottonseed .....	0.5	None
Crabapple .....	1.5	None
Cranberry .....	0.5	None
Cucumber .....	2.0	None
Eggplant .....	0.3	None
Filbert .....	0.3	None
Fruit, citrus, group .....	2.0	None
Grape .....	4.0	None
Loganberry .....	2.0	None
Melon .....	2.0	None
Onion .....	2.0	None
Parsley, leaf .....	5.0	None
Parsley, root .....	2.0	None
Peach .....	2.0	None
Pear .....	1.5	None
Pecan .....	0.3	None
Pepper .....	0.3	None
Pistachio .....	0.3	None
Plum, prune .....	2.0	None
Potato .....	0.2	None
Quince .....	1.5	None
Raspberry .....	2.0	None
Spinach .....	2.0	None
Strawberry .....	2.0	None
Sugarcane .....	0.3	6/30/00
Tomato, postharvest ....	2.0	None
Walnut .....	0.3	None

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

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

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

#### §§ 180.154a and 180.531 [Removed]

3. By removing § 180.154a and § 180.531.

[FR Doc. 00-15725 Filed 6-21-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300924; FRL-6383-7]

RIN 2070-AB78

### Trichoderma Harzianum Rifai Strain T-39; 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 *Trichoderma harzianum* Rifai strain T-39 on all food commodities when applied/used as ground and certain foliar applications. Makhteshim Agan of North America 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 *Trichoderma harzianum* Rifai strain T-39.

**DATES:** This regulation is effective June 22, 2000. Objections and requests for hearings, identified by docket control number OPP-300924, must be received by EPA on or before August 21, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300924 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-8097; and e-mail address: bacchus.shanaz@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:

Cat-egories	NAICS	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 in the "FOR FURTHER INFORMATION CONTACT" section.

#### 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-300924. 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 June 26, 1998 (63 FR 34390–34392) (FRL–5794–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by Makhteshim Agan of North America, (hereafter referred to as MANA), 551 Fifth Avenue, Suite 1100, New York, NY 10176. This notice included a summary of the petition prepared by the petitioner, MANA. 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 *Trichoderma harzianum* Rifai strain T-39.

## 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 residue 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.

*Trichoderma harzianum* strain T-39 was considered neither toxic nor pathogenic based on the results of the Tier I toxicology studies. Tier II and Tier III studies were not required because the results from the Tier I studies were sufficient to satisfy guideline requirements. On the basis of the studies submitted, it was considered a Toxicity Category III pesticide for acute oral effects due to the amount dosed only, and Toxicity Category IV for dermal and primary dermal irritation health effects. These and additional toxicology studies are summarized below.

1. *Acute oral infectivity/pathogenicity.* Based on the submitted data, *Trichoderma harzianum* strain T-39 demonstrated a low toxicity profile. It was not infectious, pathogenic or toxic to rats when administered orally at  $1.4$  to  $2.0 \times 10^8$  colony forming units (cfu) per animal. Clearance and infectivity were evaluated in the brain, blood, lymph nodes, kidney, liver, spleen, lungs, caecum and feces. The microbe was detected only in fecal samples, and in those samples a distinct clearance pattern was demonstrated throughout the study.

2. *Acute dermal toxicity.* A single  $1,150$ – $1,570$  mg/kg dose of *Trichoderma harzianum* was applied dermally for a 24 hour exposure period to rabbits. There were no clinical signs of toxicity and no effects on mortality or body weight nor any signs of dermal irritation during the study. The available information indicates that dermal toxicity is not likely to occur with *Trichoderma harzianum* strain T-39.

3. *Primary Dermal Irritation Study.* A dermal application of  $0.5$ g of *Trichoderma harzianum* strain T-39 at  $5 \times 10^9$  cfu/g produced no dermal response in rabbits after a 4-hour exposure period. The results of this study are classified as Supplementary, but taken in conjunction with the acute dermal toxicity study, the microbial pesticide is likely to be mildly irritating to skin. The pesticide was classified as Toxicity Category IV for primary dermal irritation effects.

4. *Skin sensitization in guinea pig.* Under the conditions of this study, *Trichoderma harzianum* strain T-39 in physiological saline was applied in

occluded dermal patches. This study demonstrated potential delayed contact hypersensitivity in guinea-pigs. This study was designed to meet the requirements of the OECD Guidelines for Testing Chemicals, and was submitted in support of fulfilling EPA data requirements for hypersensitivity incidents. While the study is not a substitute for reporting hypersensitivity incidents, it was considered acceptable. However, the registrant must report any hypersensitivity incidents to the Agency. The label must indicate that products containing this active ingredient are likely to demonstrate a potential for dermal sensitization.

5. *Primary eye irritation.* Three eye irritation studies were submitted. Two acute eye irritation studies were conducted using undiluted TGAI on a single male rabbit each time. The studies indicated a potential for severe eye irritation, placing the undiluted TGAI in acute Toxicity Category I. In one study, a single dose of  $0.1$ g of the active ingredient, approximately  $5 \times 10^8$  cfu, was used to treat one rabbit. The results indicated that the microbial pest control agent (MPCA) TGAI, *Trichoderma harzianum* strain T-39, has the potential to cause serious ocular damage. The active ingredient was a severe eye irritant. In another study a single dose of  $0.1$ g was administered into the everted lower right eyelid of a sentinel male rabbit. The results of this study indicated that a 3 minute,  $180$  ml saline rinse, applied 3 minutes post dosing, had no ameliorating effect on the irritancy of the active ingredient. The adhesion of the TGAI to the conjunctivae remained a serious effect of treatment even after rinsing.

However, another eye irritation study was done in which the test material was the End-use Product (EP), Trichodex. Six male rabbits were treated with a single dose of  $0.1$  ml ( $0.04$  g) of Trichodex-EP into the everted lower right eyelid. The maximum average irritation score was determined to be  $15.3$  at 24 hours post dosing. There was no corneal involvement after 72 hours and ocular irritation was no longer present after 7 days, equivalent to a mildly irritating, or an acute Toxicity Category III rating for the EP. This study was considered acceptable and can be used for labeling of the EP. Workers, who are most likely to be exposed to the pesticide during mixing/loading, application and post application activities, are required to wear goggles to mitigate against potential eye irritation.

6. *Acute intraperitoneal toxicity/pathogenicity.* Under conditions of this study the LD<sub>50</sub> for the EP, Trichodex,

administered via intraperitoneal injection was 644 mg/Kg in male rats, 1.087 mg/Kg in female rats and 806 mg/Kg for combined results from male and female rats. The lowest dose administered,  $1.5 \times 10^7$  cfu/animal, showed no indications of significant adverse effects. This study was considered acceptable and is a substitute for the intravenous study with fungi as active pesticidal ingredients.

7. *Acute pulmonary toxicity/pathogenicity.* Small 2 mm pale raised areas were found in the lungs of some animals of both genders treated with test material containing the active fungi. However, minimal clinical signs and no deaths were observed. There were no significant macroscopic lesions found in any test animals in the other experimental groups. The active ingredient was not found in samples of liver, brain, spleen, kidneys, lymph nodes or blood. Microbial clearance through the caecum was evident. Although there was no evidence of the reproduction of the microbe in the tissues, colony forming units persisted in the lungs of animals treated with the active fungus. However, no adverse effects were seen even in the absence of lung clearance by day 21. Based on this study the TGAI was classified as Toxicity Category III. Because the predominant inert ingredient is known to have associated irritation and inhalation effects, the microbial, EP was classified as an acute Toxicity Category II pesticide or likely to be a moderate acute inhalation hazard. Workers who are most likely to be exposed during mixing/loading, application and post application activities are required to wear the recommended respirators with NIOSH prefixes, N-95, P-95 or R-95, to mitigate against exposure.

8. *Mouse Micronucleus Test.* This study is not required under the guidelines for registration of microbials but was submitted by the registrant for consideration of the application. A preliminary toxicity test using doses of 2,500 and 5,000 mg/Kg resulted in no deaths and no significant chromosome damage. Subsequently, the main study was carried out with administration of Trichodex suspended in 0.5% methyl cellulose solution by oral gavage. Doses were 200, 1,000, or 5,000 mg/kg. Under conditions of this test, there was no evidence of chromosomal damage leading to micronucleus formation in polychromatic erythrocytes of treated mice 24, 48, or 72 hours after dosing. The study was rated supplemental.

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

### A. Dietary Exposure

Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the establishment of an exemption from the requirement of a tolerance for *Trichoderma harzianum* strain T-39.

1. *Food.* The microbial pesticide can be removed from foods by washing, peeling, cooking and processing. Dietary exposure to the microbial and the risk posed to adults, infants and children are likely to be minimal, because of the low acute oral toxicity/pathogenicity potential of the microbial pesticide.

2. *Drinking water exposure.* Oral exposure, at very low levels, may occur from ingestion of drinking water. Drinking water is not being screened for *Trichoderma harzianum* as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to the fungal active ingredient through drinking water. Therefore, the potential of significant transfer of residues to drinking water is minimal to non-existent. Even if negligible oral exposure should occur through drinking water, the Agency concludes that such exposure would present no risk due to the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe.

### B. Other Non-Occupational Exposure

*Dermal and inhalation exposure.* Dermal and inhalation exposures and risks to adults, infants and children via treated lawns or recreational areas are not likely if the pesticide is applied as labeled. However, should such exposures occur, adverse effects via the dermal and inhalation routes are expected to be minimal based on the low toxicity potential of this naturally occurring, ubiquitous microbe.

## VI. Cumulative Effects

There are other species and strains of *Trichoderma* registered. The Agency has received information to distinguish strain T-39 from other registered strains.

It is not clear to the Agency whether the registered strains share a common mechanism of toxicity, or any mechanism of toxicity with strain T-39. Because the data available demonstrate a low toxicity/pathogenicity potential of the active ingredient, the likelihood of adverse dietary effects is expected to be minimal.

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

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to the U.S. population to *Trichoderma harzianum* Rifai strain T-39 residues. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has imposed appropriate risk mitigation measures to protect the at-risk worker population from potential eye irritation and acute pulmonary effects. These include goggles and appropriate dust-mist filtering respirators which comply with the Worker Protection Standards.

## VIII. Other Considerations

### A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. There is no evidence to suggest that use of *Trichoderma harzianum* strain T-39 at the proposed concentrations will adversely affect the endocrine system.

### B. Analytical Method(s)

As part of the standard Quality Control measures, the Agency is requiring microbial assays and analytical methods to identify the active ingredient and potential contaminants. Analytical methods are available and sufficient to identify metabolites and contaminants within regulatory levels. All batches containing potential human pathogens are to be destroyed.

### C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels or exemption from tolerances for the microbial active ingredient *Trichoderma harzianum* strain T-39. There is an exemption from tolerance on all food commodities except mushrooms for another strain of *Trichoderma harzianum*, Rifai strain KRL-AG2, in 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-300924 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 August 21, 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 Room C-400, 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, 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 VIII.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP-300924, 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 PRIB described in Unit I.B.2. of this preamble. 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 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 will establish an exemption from the tolerance requirement under FFDCA section 408(e). 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 action 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). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), 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. 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 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 General Accounting Office

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: May 25, 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 180.1201 is revised to read as follows:

#### **§ 180.1201 Trichoderma harzianum strain T-39; exemption from the requirement of a tolerance.**

*Trichoderma harzianum* strain T-39 is exempt from the requirement of a tolerance on all food commodities.

[FR Doc. 00-15723 Filed 6-21-00; 8:45 am]

**BILLING CODE 6560-50-F**

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 180**

**[OPP-301010; FRL-6592-4]**

**RIN 2070-AB78**

#### **Cloquintocet-mexyl; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for the combined residues of the inert ingredient (herbicide safener) cloquintocet-mexyl and its acid metabolite in or on wheat grain, forage, hay, and straw. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective June 22, 2000. Objections and requests for hearings, identified by docket control number OPP-301010, must be received by EPA on or before August 21, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301010 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Treva Alston, Registration

Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-8373; and e-mail address: alston.treva@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:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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-301010. 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