

Commodity	Parts per million
Squash/cucumber subgroup ...	0.5

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300993; FRL-6554-6]

RIN 2070-AB78

**Thiabendazole; Extension of Tolerance for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation extends a time-limited tolerance for residues of the fungicide thiabendazol and its metabolites in or on lentils at 0.1 part per million (ppm) for an additional 20-month period. This tolerance will expire and is revoked on December 31, 2001. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on lentils. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

**DATES:** This regulation is effective April 26, 2000. Objections and requests for hearings, identified by docket control number OPP-300993, must be received by EPA on or before June 26, 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 III. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300993 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9356; and e-mail address: beard.andrea@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 codes	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-300993. 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**

EPA issued a final rule, published in the **Federal Register** of February 25, 1998 (63 FR 9435) (FRL-5767-6), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), it established a time-limited tolerance for the residues of thiabendazole and its metabolites in or on lentils at 0.1 ppm. Subsequently, EPA extended that tolerance, published in the **Federal Register** of December 4, 1998 (63 FR 66994) (FRL-6044-5) with an expiration date of April 30, 2000. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of thiabendazole on lentils for this year's growing season due to the situation remaining an emergency. The Applicants (Idaho, Washington, North Dakota, and Montana) state that the ascochyta blight fungus has only occurred in the United States in recent years, and presently available fungicides do not adequately control its spread in lentils, to prevent significant economic loss. Additionally, a recently-discovered sexually-reproducing strain is of even greater concern, as this sexual stage releases spores, capable of traveling long distances on the wind. This disease was

initially of isolated occurrence in the U.S. until the last several years. The sexual strain has potential to lead to significant widespread infection of lentils, and without the requested use of thiabendazole to control this disease, significant economic losses are expected. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18, the use of thiabendazole on lentils for control of ascochyta blight in lentils.

EPA assessed the potential risks presented by residues of thiabendazole in or on lentils. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of February 25, 1998 (63 FR 9435). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 20-month period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on lentils after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

### III. 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-300993 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 June 26, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please

identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](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 III.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 control number OPP-300993, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](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).

#### IV. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process

to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

#### V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 12, 2000.

**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. 321(q), 346(a) and 371.

#### § 180.242 [Amended]

2. In § 180.242, amend the entry for "Lentils" in the table under paragraph (b) by revising "4/30/00" to read "12/31/01".

[FR Doc. 00-10041 Filed 4-25-00; 8:45 am]

**BILLING CODE 6560-50-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Parts 1001, 1003, 1005 and 1006

RIN 0991-AA90

#### Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From Public Law 104-191

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the OIG's civil money penalty (CMP) authorities, in conjunction with new and revised provisions set forth in the Health Insurance Portability and Accountability Act of 1996. Among other provisions, this final rulemaking codifies new CMPs for excluded individuals retaining ownership or control interest in an entity; upcoding and claims for medically unnecessary services; offering inducements to beneficiaries; and false certification of eligibility for home health services. This rule also codifies a number of technical corrections to the regulations governing OIG's sanction authorities.

**EFFECTIVE DATE:** These regulations are effective on April 26, 2000.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, (202) 619-0089 OIG Regulations Officer.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. *The Health Insurance Portability and Accountability Act of 1996*

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, included a number of changes to the OIG's authorities intended to curtail and eliminate health care fraud and abuse. With regard to the sanction authorities, HIPAA expanded the scope of certain basic fraud authorities by extending the application of current CMP provisions beyond those programs funded by the Department of Health and Human Services (the Department) to include all Federal health care programs. The HIPAA also significantly revised and strengthened the OIG's existing CMP authorities pertaining to violations under Medicare and the State health care programs.

Among other provisions related to the OIG's CMP authority, HIPAA (1) increased the maximum penalty amounts per false claim from \$2,000 to \$10,000; (2) allowed CMPs to be