

tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal

Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VIII. 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: January 24, 2003.

**Peter Caulkins,**

*Acting 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.

2. Section 180.532 is amended by adding alphabetically the following commodities to the table in paragraph (a)(1) to read as follows:

#### § 180.532 Cyprodinil; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

| Commodity              | Parts per million |
|------------------------|-------------------|
| * * *                  | * *               |
| Bushberry subgroup 13B | 3.0               |
| Caneberry subgroup 13A | 10                |
| * * *                  | * *               |
| Juneberry .....        | 3.0               |
| Lingonberry .....      | 3.0               |
| Pistachio .....        | 0.10              |
| * * *                  | * *               |
| Salal .....            | 3.0               |
| Watercress .....       | 20                |

\* \* \* \* \*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP–2002–0355; FRL–7285–9]

#### Thiophanate Methyl; Pesticide Tolerance for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of thiophanate methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)) in or on mushrooms. This action is in response to EPA’s granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on mushroom spawn. This regulation establishes a maximum permissible level for residues of thiophanate methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2004.

**DATES:** This regulation is effective February 5, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0355, must be received on or before April 7, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: conrath.andrea@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

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

- Crop producers (NAICS 111)
- Animal producers (NAICS 112)
- Food manufacturing (NAICS 311)

- Pesticide manufacturing (NAICS 32532)

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

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0355. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available 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.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in

the system, select “search,” then key in the appropriate docket ID number.

## II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide thiophanate methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), in or on mushroom at 0.01 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2004. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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 FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18-related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish 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(b)(2)(A)(ii) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA 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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions

exist which require such exemption.” This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemptions for Thiophanate Methyl on Mushroom and FFDCA Tolerances

Benomyl has historically been used in mushroom production to control fungal pathogens, including one of the most serious, green mold (*Trichoderma aggressivum*). The registrant’s recent cancellation of benomyl has left mushroom growers in Delaware, Maryland, and Pennsylvania without sufficient means to control this disease, as there are no available alternatives. Significant economic losses are expected without the requested use of thiophanate methyl. EPA has authorized under FIFRA section 18 the use of thiophanate methyl on mushroom spawn for control of green mold in Delaware, Maryland, and Pennsylvania. After having reviewed their submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of thiophanate methyl in or on mushroom. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2004, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on mushroom after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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.

Because this tolerance is being approved under emergency conditions,

EPA has not made any decisions about whether thiophanate methyl meets EPA's registration requirements for use on mushroom or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of thiophanate methyl by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Delaware, Maryland, and Pennsylvania to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for thiophanate methyl, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of thiophanate methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of thiophanate methyl in or on mushroom at 0.01 ppm.

The most recent estimated aggregate risks resulting from the use of thiophanate methyl, are discussed in the **Federal Register** for August 28, 2002 (67 FR 55137) (FRL-7192-1), final rule establishing tolerances for residues of thiophanate methyl in/on grapes, pears, potatoes, canola, and pistachios. Available residue data did not indicate that this use pattern will result in residues of thiophanate methyl in mushrooms over the limit of quantitation (LOQ), 0.01 ppm. Therefore, a tolerance is being established for mushroom at this level. Incremental addition of mushrooms at this level to dietary exposure, from existing food/feed uses, is negligible. Additionally, the results for this section 18 use do not alter the current aggregate

exposure assessments with respect to drinking water or residential exposure. Refer to the August 28, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. A summary of the toxicological dose and endpoints for thiophanate methyl for use in human risk assessment is discussed in the final rule mentioned above, published in the **Federal Register** of August 28, 2002 (67 FR 55137).

For thiophanate methyl, the Agency recently modified the tolerance expression, so that the residues to be regulated in plant and animal commodities for purposes of tolerance enforcement will consist of the residues of thiophanate methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), expressed as thiophanate methyl.

Exposure from the use of benomyl, another pesticide which degrades under environmental conditions to MBC was not included in this assessment because the only basic registrant of benomyl requested voluntary cancellation of all benomyl-containing products in April 2001. Product cancellations were effective in early 2001 with sales and distribution of benomyl-containing products ending by December 31, 2001. However, the Agency conducted a dietary assessment using USDA Pesticide Data Program (PDP) monitoring data for benomyl, measured as MBC to estimate residues of thiophanate methyl because MBC is a common metabolite of both benomyl and thiophanate methyl. PDP data were available for apples, bananas, beans, cucurbits, peaches, and strawberries. The PDP analytical method employs a hydrolysis step that converts any benomyl present to MBC. MBC is then quantitated and corrected for molecular weight, and results are measured as the sum of benomyl and MBC. Therefore, using MBC data to estimate thiophanate methyl residues may be a conservative approach in that it may over estimate thiophanate methyl residues.

EPA assessed risk scenarios for thiophanate methyl under acute, chronic, and short- and intermediate-term exposures.

The Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

For the acute exposure assessments, maximum percent crop treated estimates and anticipated residue estimates were used.

Using these exposure assumptions, EPA concluded that acute dietary exposure to thiophanate methyl uses 10% of the acute Population Adjusted Dose (aPAD) for the general U.S. population and 25% of the aPAD for the most highly exposed population subgroup of concern, infants (< 1 year). For MBC, the acute dietary risk estimate uses 4% of the aPAD for the general U.S. population and 89% of the aPAD for the population subgroup of concern, infants (< 1 year). The total thiophanate methyl plus MBC acute dietary risk estimate for the population subgroup of concern, females (13-50 years) uses 51% of the aPAD. The drinking water assessment, based on simultaneous dietary exposure to both MBC and thiophanate methyl (which was converted to MBC equivalents) resulted in the following Drinking Water Levels of Concern (DWLOCs): Infants (< 1 year) 18 ppb; children (1-6 years) 57 ppb; females (13-50 years) 150 - 170 ppb; and general U.S. population 5,700 ppb. The lowest DWLOC for the population subgroup, infants (< 1 year) does not exceed the Estimated Environmental Concentration (EEC) for ground water (0.033 ppb); however, the DWLOC does exceed the EEC for surface water (25 ppb). Although the EEC is exceeded, the DWLOC is greatly inflated because 50% of the aPAD percentage is consumed by citrus which is a 1-year emergency use only. When citrus is removed from the DWLOC estimation, the DWLOC becomes 94 ppb which is well above the EEC of 25 ppb. The DWLOC is significantly lowered by the addition of citrus because field trial data was used which results in an overly conservative estimation.

Another indication that the addition of citrus based on field trial data results in an over estimation is the fact that benomyl PDP data available for citrus indicated that there were zero hits out of 689 Florida samples of orange juice. These data were not used to refine the DWLOC estimation because the benomyl application rate is somewhat

lower than the rate approved for thiophanate methyl in this year's emergency exemption. However, the Agency believes that most growers used the benomyl rate, because the emergency exemption was approved later in the use season and thus fewer applications than were authorized were actually used. Furthermore, if the higher rate were used, the impact would be lessened by the fact that juice is a blended commodity. Therefore, although the DWLOC is exceeded, the acute dietary risk from food and water does not exceed the Agency's level of concern.

For the chronic exposure assessments, average residues from field trial data and average percent crop treated estimates were used.

Using these exposure assumptions, EPA has concluded that exposure to thiophanate methyl and MBC will utilize the following percentages of the chronic Population Adjusted Dose (cPAD) for the U.S. population: Thiophanate methyl - 0.7%; MBC - 1.0% and total thiophanate methyl plus MBC - 1.7%. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years) and EPA has concluded that aggregate dietary exposure to thiophanate methyl and MBC will utilize the following percentages of the cPAD: Thiophanate methyl - 2.3%; MBC - 26% and total thiophanate methyl plus MBC - 28%. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The aggregate chronic DWLOC's are as follows: 858 ppb for the general U.S. population; 69 ppb for females (13-50 years); 22 ppb for infants (< 1 year); and 18 ppb for children (1-6 years). The aggregate surface water EECs for thiophanate methyl is 0.7 ppb; 14 ppb for MBC and 14.7 ppb for thiophanate methyl plus MBC. Therefore, the chronic aggregate risks do not exceed the Agency's level of concern.

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiophanate methyl and MBC are currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for thiophanate methyl and MBC.

All residential exposures are considered to be short-term. The Margins of Exposure (MOEs) (converted

to MBC equivalents) for aggregate short-term exposure to thiophanate methyl are as follows: Oral exposure of children (1-6 years) is 670; dermal exposure of children (1-6 years) is 1,000; and dermal exposure of females (13-50 years) is 1,315. The MOEs for aggregate exposure to MBC from the use of MBC as an in-can preservative are 670 for dermal exposure and 770 for exposure via inhalation. The MOEs (converted to MBC equivalents) for the total thiophanate methyl and MBC aggregate exposure are as follows: 630 for oral and dermal exposure of children (1-6 years); 770 for exposure via inhalation for females (13-50 years); and 620 for oral and dermal exposure for females (13-50 years). Although the MOEs below 1,000 exceed the Agency's level of concern, when considering the conservative method of exposure estimation previously discussed, and the negotiated risk mitigation whereby the registrant has agreed to conduct hand-press studies to help refine this assessment, the risks do not exceed the Agency's level of concern.

*Aggregate cancer risk for U.S. population.* The total thiophanate methyl and MBC dietary cancer risk is  $8.5 \times 10^{-7}$  for existing and new uses. The cancer risk from non-occupational residential exposure is  $3.7 \times 10^{-7}$ . The aggregate cancer risk is  $1.2 \times 10^{-6}$ . This risk estimate includes cancer risk from both thiophanate methyl and MBC on food including all pending uses and section 18 uses, thiophanate methyl exposure from treating ornamentals, thiophanate methyl exposure from performing post-application lawn activities, and exposure from applying paint containing MBC. This is considered to be a high-end risk scenario since it is not expected that someone would treat ornamentals, perform high exposure post-application activities, and apply paint containing MBC every year for 70 years. Therefore, this estimate is considered to be a conservative estimate. Additionally, the cancer risk estimate based on the highest EEC (thiophanate methyl plus MBC EEC) is  $9.6 \times 10^{-7}$ . This is also a very high-end risk estimate since it is based on the maximum rate being applied every season for 70 years. Thus, food plus water (assuming that the modeled surface water EEC is equivalent to concentrations in finished drinking water) plus non-occupational residential cancer risk is  $2.2 \times 10^{-6}$  which is still within the range considered as negligible. In addition, the cancer risk estimates using benomyl/MBC PDP monitoring data to estimate thiophanate methyl residues

are below  $1 \times 10^{-6}$  for thiophanate methyl existing uses, new uses, and the amortized section 18 use on citrus and blueberry. Therefore, the risks do not exceed the Agency's level of concern.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to thiophanate methyl and MBC residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

### B. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiophanate methyl residues in/on various plant and animal commodities. Codex MRLs for thiophanate methyl are currently expressed as MBC. The Codex MRL residue definition and the U.S. tolerance definition, previously expressed as only thiophanate methyl, have been incompatible and will remain incompatible even with the recent revision of the U.S. tolerance definition, since the revised tolerance definition includes both thiophanate methyl and MBC. Additionally, there is a 1.0 ppm Codex MRL for thiophanate methyl on mushroom. The 0.01 ppm tolerance being established by this document will not harmonize with Codex.

### C. Conditions

The pesticide, thiophanate methyl, is to be mixed at 1.4 lbs. active ingredient (a.i.) (2 lbs. product) with 80 to 100 lbs. of gypsum, limestone, or chalk. This mixture will then be used to coat spawn grains (approximately 1,600 units) before mixing the spawn into the mushroom growing substrate. The substrate will then be applied to bed surface before spawning.

## VI. Conclusion

Therefore, the tolerance is established for residues of thiophanate methyl and its metabolite, (methyl 2-benzimidazolyl carbamate (MBC), expressed as thiophanate methyl, in or on mushroom at 0.01 ppm.

## VII. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0355 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 April 7, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver

your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

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

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.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.1. Mail your copies, identified by the docket ID number OPP-2002-0355, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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).

## VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are

established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, 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 section 408(n)(4) of the FFDCA. For these same reasons, the

Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### 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 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: January 17, 2003.

**Debra Edwards,**

*Acting 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.

2. Section 180.371 is amended by alphabetically adding the entry for mushroom to the table in paragraph (b) to read as follows:

#### § 180.371 Thiophanate methyl; tolerances for residues.

\* \* \* \* \*

(b) \* \* \*

| Commodity      | Parts per million | Expiration/revocation date |
|----------------|-------------------|----------------------------|
| * * * * *      |                   |                            |
| Mushroom ..... | 0.01              | 12/31/04                   |

\* \* \* \* \*

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BILLING CODE 6560-50-S

#### FEDERAL EMERGENCY MANAGEMENT AGENCY

#### 44 CFR Part 64

[Docket No. FEMA-7801]

#### Suspension of Community Eligibility

**AGENCY:** Federal Emergency Management Agency, FEMA.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities, where the sale of flood insurance has been authorized under

the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**. **EFFECTIVE DATES:** The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

**ADDRESSES:** If you wish to determine whether a particular community was suspended on the suspension date,

contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

#### FOR FURTHER INFORMATION CONTACT:

Edward Pasterick, Division Director, Risk Communication Division, Federal Insurance and Mitigation Administration, 500 C Street, SW., Room 435, Washington, DC 20472, (202) 646-3443.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance