

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. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

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

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

Dated: March 14, 2005.

**Lois Rossi,**

*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), 346a and 371.

■ 2. Section 180.571 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.571 Mesotrione; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Corn, sweet, forage .....	0.5
Corn, sweet, kernel plus cob with husks removed .....	0.01
Corn, sweet, stover .....	1.5

\* \* \* \* \*

[FR Doc. 05-5719 Filed 3-22-05; 8:45 am]  
BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2005-0011; FRL-7699-3]

**Thiophanate-methyl; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of thiophanate-methyl and its metabolite methyl 2-benzimidazolyl carbamate (MBC) in or on cotton and cotton, gin byproducts. 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 cotton. This regulation establishes a maximum permissible level for residues of thiophanate-methyl in these feed commodities. These tolerances will expire and are revoked on December 31, 2007.

**DATES:** This regulation is effective March 23, 2005. Objections and requests for hearings must be received on or before May 23, 2005.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP-2005-0011. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

**FOR FURTHER INFORMATION CONTACT:** Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

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 production (NAICS 111)
- Animal production (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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions discussed above. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

## 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 tolerances for combined residues of the fungicide thiophanate-methyl, and its metabolite MBC, in or on cotton at 0.05 parts per million (ppm) and cotton gin byproducts at 5.0 ppm. These tolerances will expire and are revoked on December 31, 2007. 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 the 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 Exemption for Thiophanate-methyl on Cotton and FFDCA Tolerances

On July 20, 2004, the State of Florida utilized the crisis exemption authority as provided under FIFRA section 18 for use of thiophanate-methyl on cotton. According to the State, fusarium hardlock of cotton has been identified as a severe economic disease during the last 4 years. This disease has become a problem since the state began to grow primarily genetically modified (GMOs) varieties of cotton. Cotton yields have been reduced up to 50% as a result of the disease. To date, thiophanate-methyl is the only pesticide that has been identified to control this disease on cotton. EPA has authorized under FIFRA section 18 the use of thiophanate-methyl on cotton for control of fusarium hardlock in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of thiophanate-methyl in or on cotton. 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 these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2007, 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 cotton and cotton gin byproducts 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 these tolerances at the time of that application. EPA will take

action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether thiophanate-methyl meets EPA's registration requirements for use on cotton or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of thiophanate-methyl by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Florida 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 exemption 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 November 26, 1997 (62 FR 62961 (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 combined residues of thiophanate-methyl in or on cotton at 0.05 ppm and cotton, gin byproducts at 5.0 ppm.

Residue data were submitted for cotton. Cotton is not consumed by humans, any inadvertent exposure to residues of thiophanate-methyl from this emergency exemption will result from the consumption of meat or milk since cotton gin byproducts and cottonseed (meal, hulls) are animal feed items. Currently there are tolerances for residues of thiophanate-methyl in or on milk and ruminant meat, meat byproducts, liver, and fat. Since there is

an established dry apple pomace tolerance at 40 ppm and peanut forage/hay tolerances exist at 15 ppm, the Agency has determined that adding cotton feed items to the animal diet will not increase the dietary burden and therefore, the current tolerances on animal commodities are adequate.

The Agency conducted dietary exposure assessments for the cotton use under section 18 of FIFRA. Using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™-FCID version 2.02) an analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to thiophanate-methyl for each commodity. The addition of cotton did not result in any increase in dietary exposure compared to existing uses. Further, there are no new residential uses being proposed since the Agency's previous risk

assessment. Therefore, establishing tolerances for residues of thiophanate-methyl in or on cotton and cotton gin byproducts will not increase the most recent estimated aggregate risks resulting from use of thiophanate-methyl, as discussed in the **Federal Register** of July 23, 2003 (68 FR 43465) (FRL–7317–5) final rule establishing a time-limited tolerance for combined residues of thiophanate methyl and its metabolite MBC in or on fruiting vegetables. Refer to the July 23, 2003 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. Additionally, a summary of the toxicological dose and endpoints for thiophanate methyl for use in human risk assessment is discussed in the final rule published in the **Federal Register** of August 28, 2002 (67 FR 55137) (FRL–7192–1). EPA relies upon these risk assessments and the findings made in the July 23, 2003 **Federal Register** document in support of this action. Below is a summary of the aggregate risk assessments.

The acute and chronic dietary risk estimates for thiophanate methyl were less than 100% of the acute and chronic Population Adjusted Doses (aPAD and cPAD) at the 99.9<sup>th</sup> exposure percentile for the general U.S. population and all population subgroups. The acute and chronic dietary risk estimates for MBC +2-AB were also less than 100% of the aPAD and cPAD at the 99.9<sup>th</sup> exposure percentile for the general U.S. population and all population subgroups. EPA generally has no concern for exposures below 100% of the PADs, because the PADs represent the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The most highly exposed subgroup for all risk estimates calculated was children 1–2 years. Table 1 summarizes the percentages of aPADs and cPADs for all scenarios for the overall U.S. population and for the most highly exposed population subgroup (children 1–2 years).

TABLE 1.—ACUTE AND CHRONIC DIETARY RISK ESTIMATES FOR THIOPHANATE METHYL EXISTING AND PROPOSED USE

Population Subgroup	aPAD Utilized	cPAD Utilized		
		TM	MBC +2-AB	TM
U.S. population	6%	2%	<1%	<1%
Children (1–2 years old)	22%	58%	2%	10%

The acute drinking water assessment, based on simultaneous dietary exposure to both MBC and thiophanate methyl (which was converted to MBC equivalents) resulted in Drinking Water Levels of Concern (DWLOCs) for the Overall U.S. Population of 5,833 parts per billion (ppb), and for children (1–2 years) of 72 ppb (the population subgroup with the lowest DWLOC). All acute DWLOCs were well above the acute Estimated Environmental Concentrations (EECs) for groundwater and surfacewater, at 3 and 44 ppb, respectively.

The chronic drinking water assessment, based on simultaneous dietary exposure to both MBC and thiophanate methyl (which was converted to MBC equivalents) resulted in chronic DWLOCs for the Overall U.S. Population of 870 ppb, and for children (1–2 years) of 22 ppb (the population subgroup with the lowest DWLOC). All chronic DWLOCs were well above the chronic EEC for groundwater of 3 ppb. The chronic DWLOCs were also above the chronic EEC for surfacewater of 23–24 ppb, except for that of the most

highly exposed subgroup, children (1–2 years), which is slightly below the EEC with a chronic DWLOC of 22 ppb. However, given the conservative nature of the screening-level approach to estimated drinking water risks, and the equivalent levels of the chronic DWLOC and EEC (22–23–24 ppb), the Agency does not believe this represents a significant risk or concern for chronic aggregate exposures.

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 uses 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 paint 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–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 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.

The total thiophanate methyl and MBC+2-AB dietary cancer risk is  $1.1 \times 10^{-6}$  for existing and proposed new uses. The cancer risk from non-occupational residential exposure is  $1.1 \times 10^{-6}$ .

Therefore, aggregate cancer risk is  $2.2 \times 10^{-6}$ . This risk estimate includes cancer risk from both thiophanate methyl and MBC+2-AB on food including all existing 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 for drinking water is based on the highest EEC, which is also a very high-end risk estimate since it is based on the maximum rate being applied every season for 70 years. The risk estimate calculations also assumed that the modeled surface water EEC is equivalent to concentrations in finished drinking water. Thus, food plus water plus non-occupational residential cancer risk is  $2.2 \times 10^{-6}$  which is within the range considered as negligible. 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 residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits for residues of thiophanate-methyl in or on cotton or byproducts of cotton. Therefore, harmonization is not an issue.

## VI. Conclusion

Therefore, tolerances are established for combined residues of thiophanate-methyl, thiophanate-methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC), in or on cotton at 0.05

ppm and cotton, gin byproducts at 5.0 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-2005-0011 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 23, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564-6255.

2. *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 **ADDRESSES**. Mail your copies, identified by the docket ID number OPP-2005-0011, 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 **ADDRESSES**. 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. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances 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 tolerances 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. Congressional Review Act**

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: February 25, 2005.

**Lois Rossi,**

*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), 346a and 371.

■ 2. Section 180.371 is amended by alphabetically adding commodities 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
Cotton	0.05	12/31/07
Cotton, gin byproducts	5.0	12/31/07

\* \* \* \* \*

[FR Doc. 05-5720 Filed 3-22-05; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 271**

[FRL-7888-3]

**North Carolina: Final Authorization of State Hazardous Waste Management Program Revision****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Immediate final rule.

**SUMMARY:** North Carolina has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for Final authorization, and is authorizing the State's changes through this immediate final action. EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we get written comments which oppose this authorization during the comment period, the decision to authorize North Carolina's changes to their hazardous waste program will take effect. If we get comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

**DATES:** This Final authorization will become effective on May 23, 2005, unless EPA receives adverse written comment by April 22, 2005. If EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

**ADDRESSES:** Send written comments to Thornell Cheeks, North Carolina Authorizations Coordinator, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA 30303-3104; (404) 562-8479. You may also e-mail your comments to [Cheeks.Thornell@epa.gov](mailto:Cheeks.Thornell@epa.gov) or submit your comments at <http://www.regulation.gov>. Copies of North Carolina's applications may be viewed from 9 a.m. to 4 p.m. at the following addresses: North Carolina Department of

Environment and Natural Resources, 401 Oberlin Rd., Suite 150, Raleigh, North Carolina 29201, (919)733-2178; and EPA Region 4, Atlanta Federal Center, Library, 61 Forsyth Street, SW., Atlanta, Georgia 30303; (404) 562-8190, John Wright, Librarian.

**FOR FURTHER INFORMATION CONTACT:** Thornell Cheeks, North Carolina Authorizations Coordinator, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA 30303-3104; (404) 562-8479.

**SUPPLEMENTARY INFORMATION:****A. Why Are Revisions to State Programs Necessary?**

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

**B. What Decisions Have We Made in This Rule?**

We conclude that North Carolina's applications to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant North Carolina Final authorization to operate its hazardous waste program with the changes described in the authorization applications. North Carolina has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in North Carolina, including issuing permits, until the State is granted authorization to do so.

**C. What Is the Effect of Today's Authorization Decision?**

The effect of this decision is that a facility in North Carolina subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. North Carolina has enforcement responsibilities under its State hazardous waste program for violations of such program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Do inspections, and require monitoring, tests, analyses or reports.
- Enforce RCRA requirements and suspend or revoke permits.
- Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which North Carolina is being authorized by today's action are already effective, and are not changed by today's action.

**D. Why Wasn't There a Proposed Rule Before Today's Rule?**

EPA did not publish a proposal before today's rule because we view this as a routine program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register** we are publishing a separate document that proposes to authorize the State program changes.

**E. What Happens if EPA Receives Comments That Oppose This Action?**

If EPA receives comments that oppose this authorization, we will withdraw this rule by publishing a document in the **Federal Register** before the rule becomes effective. EPA will base any further decision on the authorization of the State program changes on the proposal mentioned in the previous paragraph. We will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

If we receive comments that oppose only the authorization of a particular change to the State hazardous waste program, we will withdraw that part of this rule but the authorization of the program changes that the comments do not oppose will become effective on the date specified above. The **Federal**