Implementation Plan revision have been approved.

(4) The revised commitment to perform a mid-course review and submit the results by December 31, 2004 included in the April 8, 2003 SIP revision is approved.

[FR Doc. 03–18853 Filed 7–22–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0242; FRL–7317–5]

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-benzimidazoyl carbamate (MBC) in or on fruiting vegetables. 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 fruiting vegetables. 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, 2005.

DATES: This regulation is effective July 23, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0242, must be received on or before September 22, 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–2003–0242. 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,* 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-benzimidazoyl carbamate, in or on vegetables, fruiting, group 8 at 0.5 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2005. 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 Exemptions for Thiophanate Methyl on Fruiting Vegetables and FFDCA Tolerances

Benomyl has historically been used to control the disease caused by *sclerotinia sclerotiorum*, more commonly known as white mold, timber rot, or sclerotinia stem rot, in fruiting vegetables, including tomatoes. The recent cancellation of benomyl has left fruiting vegetable producers in Florida, and tomato producers in New Jersey and Virginia without sufficient means to control this disease, and the applicants claim that there are no other registered fungicides or alternative control practices which are effective to control this disease. Thiophanate methyl is related to benomyl, and degrades to the same active compound as benomyl. Field trial data also shows thiophanate methyl to be significantly effective at controlling white mold. It is expected that a similar level of control would be achieved with thiophanate methyl as that achieved in the past with benomyl. 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 fruiting vegetables in Florida, and tomatoes only in New Jersey and Virginia, for control of white mold, also known as timber rot, or sclerotinia stem rot (*sclerotinia sclerotiorum*). After having reviewed the 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 fruiting vegetables. 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, 2005, 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 fruiting vegetables 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 fruiting vegetables 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 States other than Florida, New Jersey, or Virginia 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 residues of thiophanate methyl in or on fruiting vegetables at 0.5 ppm.

The most recent estimated aggregate risks resulting from the use of thiophanate methyl, are discussed in the **Federal Register** ofAugust 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. In that prior action, risk was estimated assuming tolerance level residues in all commodities for established and proposed tolerances. Available residue data indicate that the use pattern for these emergency exemptions will not result in residues of thiophanate methyl in fruiting vegetables over 0.5 ppm. Therefore, a tolerance is being established for this crop group at this level. The risk assessment related to incremental addition of these items at this level to dietary exposure is discussed below. Refer also to the August 28, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies in part 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 published in the **Federal Register** of August 28, 2002 (67 FR 55137) (FRL–7192–1). 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, 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 United States Department of Agriculture (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 overestimate thiophanate methyl residues.

Monitoring data on benomyl from the PDP were used to estimate dietary exposure to MBC, for apples, apple juice, bananas, succulent beans, cantaloupes, cucumbers, peaches, strawberries, citrus, and fruiting vegetables.

EPA assessed risk scenarios for thiophanate methyl under acute, chronic, and short-term and intermediate-term exposures. Risk estimates were calculated for the residues of toxicological concern, the parent compound thiophanate methyl, and its metabolites methyl 2-benzimidazolyl carbamate plus 2-amine-1-H-benzimidazole (MBC+2-AB).

To update the previous risk assessment, thiophanate-methyl acute and chronic dietary exposure assessments were conducted using the most current version of the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™-FCID), Version 1.3), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996/98. The 1998 CSFII survey focused on children from birth to 9 years old and greatly expanded (by several fold) the number of children aged birth to 4 years. Importantly, the supplemental survey was designed in a manner such that the results from the 1998 CSFII survey could be combined with the 1994–96 survey. The data in this newer CSFII survey (termed the 1994–1996/98 CSFII) are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days and is considered to be a more appropriate and more robust data set than the 1989–91 CSFII survey, which was used in the previous assessment.

The most current version of DEEM™-FCID was used for all dietary risk estimates calculated, and existing uses, as well as the proposed section 18 uses (blackberries, tomatoes and fruiting vegetables) were included. When calculating risk estimates from MBC+2-AB, an FQPA safety factor of 10 was applied for all infant and children population subgroups. Percent of crop treated information was also incorporated for most established uses and for all of the section 18 uses.

The acute and chronic dietary risk estimates for thiophanate methyl were <100% of the acute and chronic Population Adjusted Doses (aPAD and cPAD) at the 99.9th 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 <100% of the aPAD and cPAD at the 99.9th 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 USES

Population Subgroup	aPAD Utilized		cPAD Utilized	
	TM	MBC +2-AB	TM	MBC +2-AB
U.S. population	6%	2%	<1%	<1%
Children (1–2 years)	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 Comparison (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 ground water and surface water, 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 ground water of 3 ppb. The chronic DWLOCs were also above the chronic EEC for surface water 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. Prior to the application rate change agreed to by the registrants in connection with the Agency's reregistration process evaluation of thiophanate methyl, MOEs for aggregate exposure to MBC from the use of MBC as an in-can paint preservative were 670 for dermal exposure and 770 for exposure via inhalation. As a result of negotiated mitigation measures related to the reregistration review of this chemical, the registrant has now lowered the application rate for the in-can paint uses to the extent that the MOEs are now acceptable (>1,000). 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). The aggregate short-term exposure to MBC and thiophanate methyl resulting from food, water and residential use exceeds the Agency's level of concern for children (infants, and 1–6 years), and females 13–50 years, due primarily to post-application exposures on turf. Registrants are performing a hand press study and have submitted a 5–day inhalation study to help refine this assessment. Based on these mitigation measures, and the conservative method of exposure estimation, the risks do not exceed the Agency's level of concern.

Aggregate cancer risk for U.S. population. The total thiophanate methyl and MBC+2-AB dietary cancer risk is 1.1×10^{-6} for existing and proposed new uses (incorporating the refinements and amortizations as previously described). The cancer risk from non-occupational residential exposure is 1.1×10^{-6}. Therefore, aggregate cancer risk is 2.2×10^{-6}. This risk estimate includes cancer risk from both thiophanate methyl and MBC+2-AB 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 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 2.2×10^{-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 and MBC+2-AB residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology 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*.

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 5.0 ppm Codex MRL for thiophanate methyl on tomatoes. The 0.5 ppm tolerance for fruiting vegetables, including tomatoes, being established by this document will not harmonize with Codex.

C. Conditions

The pesticide, thiophanate methyl may be applied using ground equipment, at a rate of 1 lb. of formulated product (0.7 lb. active ingredient (a.i.)) per acre, not to exceed 4 lbs. (2.8 lbs. a.i.) per acre per crop. A maximum of four applications per crop may be made at 7 to 14 day intervals, and a 2–day pre-harvest interval must be observed. Applications may not be made through any type of irrigation system.

VI. Conclusion

Therefore, the tolerance is established for residues of thiophanate methyl and its metabolite, MBC, expressed as thiophanate methyl, in or on vegetables, fruiting, group 8 at 0.5 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–2003–0242 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 September 22, 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*, 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–2003–0242, 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*. 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 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. 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: July 10, 2003.

Deborah McCall,

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 following commodity 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
* * * * * * *		
Vegetable, fruiting, group 8	0.5	12/31/05

* * * * *

[FR Doc. 03–18499 Filed 7–22–03; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 401

[USCG–2002–12840]

RIN 1625–AA74 (Formerly 2115–AG46)

Basic Rates and Charges on Lake Erie and the Navigable Waters From Southwest Shoal to Port Huron, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; change of effective period.

SUMMARY: The Coast Guard is extending the effective period for the temporary final rule on basic rates and charges on Lake Erie and the navigable waters from Southwest Shoal to Port Huron, MI (District Two, Area 5), to December 24, 2003. Extension of the effective period ensures that the pilotage rates in District Two, Area 5, remain at the current rate while the Coast Guard completes its pending ratemaking project.

DATES: Effective July 18, 2003, § 401.407(b), suspended at 67 FR 47466, July 19, 2002, effective July 19, 2002, until July 21, 2003, will continue to be suspended through December 24, 2003; and § 401.407(c), temporarily added at 67 FR 47466, July 19, 2002, effective July 19, 2002, until July 21, 2003, will continue to be extended through December 24, 2003.

ADDRESSES: The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Tom Lawler, Project Manager, Office of Great Lakes Pilotage, Coast Guard, Commandant (G–MW–1), at 202–267–1241. If you have questions on viewing to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, at 202–366–5149.

SUPPLEMENTARY INFORMATION:

Regulatory History

On July 19, 2002, we published a temporary final rule entitled ''Basic Rates and Charges on Lake Erie and the Navigable Waters From Southeast Shoal to Port Huron, MI'' in the **Federal Register** [67 FR 47464].

Background and Purpose

On July 12, 2001, the Coast Guard published a final rule in the **Federal Register** [66 FR 36484] amending the ratemaking for the Great Lakes Pilotage. The new rates became effective August 13, 2001. Those rates were challenged in District Court by the Lake Pilots Association, representing the pilots in District Two. While preparing our defense, we discovered that we had inadvertently accounted for delay and detention hours in District Two differently from how we had in Districts One and Three. We also noticed minor errors in computing the rates in District Two. The Coast Guard has recently completed a study that addresses, among other things, the issue of how we should count hours of delay and detention when computing bridge-hours in all three Districts. Also the Coast Guard is currently in the process of adjusting the pilotage rates in all three Districts. *See* [USCG–2002–11288].

Discussion of Temporary Rule

We did not publish a notice of proposed rulemaking (NPRM) in order to extend this temporary final rule, and it takes effect immediately. Delay in implementing this rule would be contrary to the public interest. This rulemaking will maintain the status quo allowing litigation and associated rulemaking to be completed.

While not agreeing with the allegations contained in the complaint of the Lakes Pilots' Association, for the