DATES: This withdrawal of the direct final action is made as of June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Butensky, Environmental Planner, (617) 918–1665; *butensky.jeff@epa.gov.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: May 28, 2003.

Ira W. Leighton,

Acting Regional Administrator, EPA New England.

[FR Doc. 03–14189 Filed 6–5–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0002; FRL–7308–1]

Thymol and Eucalyptus Oil; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited exemptions from the requirement of a tolerance for residues of thymol and eucalyptus oil on honey and honeycomb. 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 these pesticides in beehives. This regulation eliminates the need to establish a maximum permissible level for residues of thymol and eucalyptus oil in or on honey and honeycomb. These time-limited exemptions from the requirement of a tolerance for residues of the thymol and eucalyptus oil will expire and are revoked on June 30, 2005.

DATES: This regulation is effective June 6, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0002, must be received on or before August 5, 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: 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.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a Federal or State government agency involved in administration of environmental quality programs. Potentially affected entities may include, but are not limited to:

•Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

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–2003–0002. 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 time-limited exemptions from the requirement of a tolerance for residues of thymol and eucalyptus oil in or on honey and honeycomb. These time-limited exemptions from the requirement of a tolerance for residues of the thymol and eucalyptus oil will expire and are revoked on June 30, 2005. EPA will publish a document in the **Federal Register** to remove the revoked exemptions 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 an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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 Thymol and Eucalyptus Oil on Honey and Honeycomb and FFDCA Tolerances

The varroa mite is an ectoparasite of honey bees. It was first detected in the continental United States in Maryland in 1979, and found in Florida and Wisconsin by 1987. Currently, it is the most important pest of honey bee colonies. The mites feed on the hemolymph of the developing bee larva, pupa, and adult bees. Dead or dying newly emerged bees have malformed wings, legs, abdomens, and thoraces. Recent anecdotal evidence suggests that bee viruses and varroa mites are closely linked. The mites have been shown to activate some of these viruses; causing virus outbreaks that ultimately lead to colony mortality.

Fluvalinate is currently registered for the control of varroa mites; however, populations of varroa mites have developed resistance to fluvalinate. Varroa mite resistance to fluvalinate has been well documented by the United States Department of Agriculture (USDA), Agricultural Research Service (ARS). According to USDA, ARS many hives treated with fluvalinate have resulted in wholesale colony losses. Due to the destructive nature of this pest coupled with the importance of honey bees (for honey production and pollination of numerous agricultural crops) to the U.S. economy, it is imperative that alternative means of controlling the varroa mite be developed.

The Agency has authorized the use of coumaphos in beehives to control varroa mites under section 18 of FIFRA since 1999 in up to 46 states. During the 2001 use season there were limited reports of mites resistant to coumaphos in Maine and Florida. Resistance to coumaphos in Florida was confirmed by the USDA's Texas Bee Lab in December of 2001. In Maine, bees are primarily imported during the growing season from Florida. South Carolina has indicated that the beekeeping industry is migratory in nature, especially in the coastal region of the state and subject to the introduction of coumaphos resistant mites from Florida. Therefore, the states have requested use of the unregistered product ApiLife VAR, containing thymol and eucalyptus oil to control mites resistant to coumaphos. EPA has authorized under FIFRA section 18 the use of thymol and eucalyptus oil in beehives for control of varroa mites in Maine, Minnesota, Mississippi, Utah, Indiana, and South Carolina. After having reviewed the submission, 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 thymol and eucalyptus oil in or on honey and honeycomb. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary exemptions from the requirement of a 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 exemptions without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these exemptions from the requirement of a tolerance will expire and are revoked on June 30, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide in the tolerance remaining in or on honey and honeycomb after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these exemptions earlier if any experience with, scientific data on, or other relevant information on these pesticides indicate that the residues are not safe.

Because these exemptions from the requirement of a tolerance are being approved under emergency conditions, EPA has not made any decisions about whether thymol and eucalyptus oil meets EPA's registration requirements for use on honey and honeycomb or whether permanent exemptions for this use would be appropriate. Under these circumstances, EPA does not believe that these exemptions from the requirement of a tolerance serve as a basis for registrations of thymol and eucalyptus oil by a State for special local needs under FIFRA section 24(c). Nor do these exemptions serve as the basis for any State other than Maine and South Carolina to use these pesticides in beehives 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 thymol and eucalyptus oil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety for Thymol

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 thymol and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for exemptions from the requirement of a tolerance for residues of thymol in or on honey and honeycomb. EPA's assessment of the dietary exposures and risks associated with establishing these exemptions from the requirement of a tolerance follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by thymol is discussed in this unit.

The EPA has not received nor does it have available any guideline studies on the mammalian toxicity of thymol. Thymol is found naturally occurring in

thyme herb (e.g., *Thymus vulgaris, T. zygis*). Thyme herb is used as a food seasoning ingredient, and is generally recognized as a safe (GRAS) natural seasoning by the Food and Drug Administration (FDA) (21 CFR 182.10). Thyme oil also is recognized as a GRAS essential oil by FDA (21 CFR 182.20).

In September of 1993, the EPA issued a Reregistration Eligibility Decision (RED) for thymol. At that time the Agency concluded that thymol is an active ingredient that should be considered for a broad waiver of generic data requirements. This conclusion was based on the following information:

Thymol is a component of many non-pesticidal consumer products currently marketed in the United States. Thymol is listed as a food additive by the Food and Drug Administration (21 CFR 172.515; synthetic flavoring substances and adjuvants). Thymol is rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the pesticide is applied.... The phenols of thymol are considered GRAS as set forth in 21 CFR 172.515 (synthetic flavoring substances and adjuvants)....

Thymol toxicity data reported available literature cite acute oral LD_{50} values as 980 milligrams/kilogram (mg/kg) and 880 mg/kg for the rat and guinea pig, respectively (Sax, 1984). The acute oral toxicity reported for the rat and guinea pig, respectively corresponds to Toxicity Category III. The Material Safety Data Sheet (MSDS) for the manufacture of technical grade thymol cites human health effects as irritating when exposed by inhalation, dermal or eye contact. The MSDS also estimates a human ingestion LD_{50} at 2 grams of the synthetic thymol. Based upon an estimated thymol dermal toxicity LD_{50} of greater than 2,000 mg/kg, the dermal toxicity would be Toxicity Category III. (Refer to pages 6 and 7 of the RED)

A summary of the submitted information on thymol toxicity allows for the statements that the acute oral LD_{50} in the rat is 980 mg/kg and in the mouse is 640 to 1,800 mg/kg. Thymol is corrosive to the rabbit eye and skin, and is not reported as a dermal sensitizer in the guinea pig. Thymol is readily absorbed from the gastrointestinal tract and is essentially excreted in the urine as a glucuronate and sulfate conjugate of the parent compound. Dosing of rats with thymol in the feed at 667 mg/kg body weight/day (highest dose tested) for 19 weeks did not produce any harmful effects. Thymol is not mutagenic in Salmonella, but gives statistically significant positive results in an Unscheduled DNA synthesis and Sister Chromatid Exchange tests, and in a cell transformation test with Syrian hamster embryonic cells. Multiple malformations are noted when thymol is injected into the air bubble or yolk sac of embryonic chickens.

B. Exposure Assessment

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*—i. *Food*. Thymol is found naturally occurring in thyme herb (e.g., *Thymus vulgaris, T. zygis*). Thyme herb is used as a food seasoning ingredient, and is generally recognized as a safe (GRAS) natural seasoning by FDA (21 CFR 182.10). Thyme oil also is recognized as a GRAS essential oil by FDA (21 CFR 182.20). The volatile oil component of thyme herb is about 2% to 5% content, and thyme oil is reported to contain from 30% to 75% thymol, and even up to 90%. Thymol may be safely used in foods as a synthetic flavoring substance when used in the minimum quantity to produce the intended effect (21 CFR 172.515). Levels of thymol reported in foods where it is permitted as a direct food additive have been stated as 44 ppm in ice cream, ices, etc.; 2.5 ppm to 11 ppm in non-alcoholic beverages; 9.4 ppm in candy, 5 ppm to 6.5 ppm in baked goods, and 100 ppm in chewing gum. Thymol is a natural component of lime blossom honey, where the maximum thymol content has been determined to be 0.16 mg/kg.

Studies in Europe showed that when ApiLife Var was used for 8 weeks in the autumn over 1 to 5 years the maximum thymol residue observed was 0.48 mg/kg. The average (median) residue value for thymol was 0.16 mg/kg in honey. When export and import tonnage values of honey are taken into consideration with U.S. honey production, the average yearly per capita intake of honey is about 2 pounds, roughly equivalent to 1 kg. If all the honey contained 0.5 mg/kg thymol then the per capita intake of thymol would be about 1.4 µg/day. For a 60 kg adult the chronic exposure value is about 0.022 µg/kg body weight/day. If a 60 kg adult consumed 1 kg of honey containing 0.5 mg thymol in 90 days the subchronic dietary exposure to thymol would be about 2 µg/kg body weight/day. Even if all 2 kg of the thymol-containing honey were consumed in one sitting, the acute exposure to thymol still would be as low as 83 µg.

2. *Drinking water exposure*. No drinking water exposure is expected from the pesticidal use of thymol which is confined to placement in beehives. Thymol is currently registered for use on ornamental plants, shrubs and grasses so there is some potential for exposure to water. However, thymol is a constituent of a mixture of organic compounds known to be rapidly degraded in the environment to elemental compounds by normal biological, physical and/or chemical processes. In the RED, the Agency concluded that the registered uses of thymol will result in negligible exposure of the environment and nontarget organisms (refer to page 7 of the RED). Therefore, thymol is not expected to be found in drinking water.

3. *Other non-occupational exposure*. The potential for non-dietary exposure to thymol residues for the general population, including infants and children, is unlikely because the proposed use site is limited to beehives. Thymol is a normal constituent of the human diet, as a component of thyme and thyme oil, and as a direct food additive. Therefore, while there exists a great likelihood of prior exposure for most, if not all individuals to thymol, any increased exposure due to the proposed use would be negligible. Thyme, which contains thymol, is a pesticide active ingredient for the control of aphids on ornamental plants. Thyme and thyme oil are considered minimum risk pesticides, and are exempted as active ingredients under FIFRA [40 CFR 152.25(g)].

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether thymol has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thymol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this exemption from the requirement of a tolerance, therefore, EPA has not

assumed that thymol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

The dietary exposure to residues of thymol to the U. S. population from use of ApiLife Var is not likely to add significantly to current dietary exposure to thymol. For instance, thymol has been measured in chewing gum at 100 mg/kg, in candy at 9.4 mg/kg, and in ice cream at 44 mg/kg. These values respectively are 200–, 20–, and 100–fold greater than the highest level of thymol (i.e., 0.48 mg/kg) measured in honey treated with ApiLife Var. In addition, thymol as measured in ice cream is about 300–fold higher than the average residue level of thymol (i.e., 0.16 mg/kg) in hives treated with ApiLife Var. Additionally, it is typical for language to appear on labels of honey that states ''Do not feed to infants under 1 year,'' so there likely would be no exposure of this population to residues of thymol in the honey. Older children likely have been exposed to thymol residues from consumption of candy, ice cream, and baked goods. Consumption of honey from hives treated with ApiLife Var is unlikely to significantly increase exposure to thymol. Therefore, based on the long history of use of thyme, thyme oil, and thymol in the diet with no known adverse effects, it is reasonable to conclude that no harm will result from exposure to thymol in honey from beehives treated with ApiLife Var. Accordingly, EPA finds that exempting thymol from the requirement of a tolerance will be safe.

V. Aggregate Risk Assessment and Determination of Safety for Eucalyptus Oil

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 eucalyptus oil and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for exemptions from the requirement of a tolerance for residues of eucalyptus oil in or on honey and honeycomb. EPA's assessment of the dietary exposures and risks associated with establishing these exemptions from the requirement of a tolerance follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by eucalyptus oil is discussed in this unit.

The EPA has not received nor does it have available any guideline studies on the mammalian toxicity of eucalyptus oil. Eucalyptus oil is obtained from steam distillation of the leaves of Eucalyptus globulus and, in addition to cineole, contains triterpenes, monoterpenes, sesquiterpenes, aldehydes and ketones. Information submitted by the applicant allows for the statements that acute oral LD_{50} value for eucalyptus oil in rats is 2,480 mg/kg. Eucalyptol (1,8-cineole) which makes up 70% or more of eucalyptus oil may be safely used in foods as a synthetic flavoring substance when used in the minimum quantity to produce the intended effect (21 CFR 172.515). Eucalyptus globulus leaves also may safely be used in foods (21 CFR 172.510).

B. Exposure Assessment

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.*—i. *Food.* Eucalyptus oil is obtained from steam distillation of the leaves of Eucalyptus globulus and, in addition to cineole, contains triterpenes, monoterpenes, sesquiterpenes, aldehydes and ketones. Levels of eucalyptus oil reported in foods where it is permitted as a direct food additive have been stated as 0.5 to 50 ppm in ice cream, ices etc.; 1.7 ppm in non-alcoholic beverages; 1.0 ppm in alcoholic beverages; 130 ppm in candy; and 76 ppm in baked goods. Cineole in foods has been reported at 0.13 ppm in non-alcoholic beverages; 0.50 ppm in ice cream, ices, etc.; 15 ppm in candy; 0.5 to 4.0 ppm in baked goods, and 190 ppm in chewing gum.

Studies in Europe showed that when ApiLife Var was used for 8 weeks in the autumn over 1 to 5 years, residues of eucalyptus oil (measured as 1,8-cineole) were less than the limit of detection, i.e., <0.01 ppm.

ii. *Drinking water exposure.* No drinking water exposure is expected from the pesticidal use of eucalyptus oil which is confined to placement in beehives. Further, there are no products registered that will result in exposure to drinking water. Therefore, eucalyptus oil is not expected to found in drinking water.

2. *Other non-occupational exposure.* The potential for non-dietary exposure to eucalyptus oil residues for the general population, including infants and children, is unlikely because the proposed use-site is limited to beehives. Eucalyptus oil is a constituent of the human diet as a direct food additive. Eucalyptus oil is used as a component of decongestant products, as an expectorant component of cough and cold products, in various oral dosage forms (e.g., lozenges and syrups), and as an inhalant in vapor baths. It is used in dermally applied products for burns, blisters, and for muscle and joint aches. It may be a component of toothpaste, soaps, detergents and toiletries. It is reported to be used internally at 0.3 to 0.6 grams/day, and externally at 5% to 20% in paraffin, jelly, or vegetable oil bases. Oil of eucalyptus has antimicrobial properties, and has been registered as an active pesticide ingredient in an herbal flea collar pet product (active ingredient is in the product at 1.00%).

3. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether eucalyptus oil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, eucalyptus oil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this exemption from the requirement of a

tolerance, therefore, EPA has not assumed that eucalyptus oil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

The dietary exposure to residues of eucalyptus oil to the U.S. population from use of ApiLife Var is not likely to add significantly to current dietary exposure to eucalyptus oil. This is because no residues of eucalyptus oil were detectable (i.e., <0.01 ppm; measured as 1,8-cineole) when ApiLife was used in hives in the autumn in Europe for up to 5 years. Even if oil of eucalyptus residues were found in honey from hives treated with Apilife Var, they would have to be present at 5,000 times greater than the limit of detection to reach the level reported in ice cream (i.e., 50 mg/kg) and 170 times greater than the limit of detection to reach the level reported in non-alcoholic beverages (i.e., 1.7 mg/kg). Therefore, based on the long history of use of eucalyptus oil in the diet with no known adverse effect, coupled with the expectation of no to minimal residues from use of ApiLife Var in hives, it is reasonable to conclude that no harm will result from this pesticidal use. Accordingly, EPA finds that exempting eucalyptus oil from the requirement of a tolerance will be safe.

VI. Other Considerations

A. Analytical Enforcement Methodology

The Agency has not reviewed the method, nor its accuracy or reliability, used to previously analyze thymol and eucalyptus oil residues in honey; nor has it confirmed that prior use of ApiLife Var in European hives will give equivalent residues in hives in the United States. However, review of information submitted on a gas chromatographic method of analysis to measure thymol and eucalyptus oil in European hives, and the similarity of the European hives to U.S. hives allow for the conclusion that thymol and eucalyptus oil residues in honey from these hives will not be significantly greater, provided ApiLife Var is applied at the same rates to overwintering hives in the United States as was done previously in Europe.

The method may be requested from: 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.

B. International Residue Limits

No Codex Maximum Residue Levels (MRL) are established for thymol. However, Switzerland has established an MRL of 0.8 mg/kg, apparently not from a safety finding, but rather arising from legislation that prohibits foreign odors or tastes in honey. According to the World Health Organization, thymol residues in food are safe to consumers at up to 50 mg/kg. According to European Union regulation Nr. 2377/90, thymol is in group II of the non-toxic veterinary drugs which do not require a MRL. No Codex Maximum Residue Levels (MRL) are established for eucalyptus oil.

VII. Conclusion

Therefore, time-limited exemptions from the requirement of a tolerance are established for residues of thymol and eucalyptus oil in or on honey and honeycomb.

VIII. 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–2003–0002 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 5, 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–2003–0002, 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).

IX. Statutory and Executive Order Reviews

This final rule establishes a time-limited exemption from the tolerance requirement 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 exemption 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.

X. 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: May 23, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1240 is added to subpart D to read as follows:

§ 180.1240 Thymol; exemption from the requirement of a tolerance.

Time-limited exemptions from the requirement of a tolerance are established for residues of thymol in or on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of the thymol will expire and are revoked on June 30, 2005.

■ 3. Section 180.1241 is added to subpart D to read as follows:

§ 180.1241 Eucalyptus oil; exemption from the requirement of a tolerance.

Time-limited exemptions from the requirement of a tolerance are established for residues of eucalyptus oil in or on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of the eucalyptus oil will expire and are revoked on June 30, 2005.

[FR Doc. 03–14198 Filed 6–5–03; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

Fisheries of the Northeastern United States

CFR Correction

In Title 50 of the Code of Federal Regulations, Part 600 to End, revised as of October 1, 2002, § 648.21 is corrected by removing paragraph (e) appearing on page 337 and reinstating the paragraph (e) appearing on page 316 in the 2000 edition. The reinstated text reads as follows:

§ 648.21 Procedures for determining initial annual amounts.

* * * * *

(e) *Inseason adjustments.* The specifications established pursuant to this section may be adjusted by the Regional Administrator, in consultation with the MAFMC, during the fishing year by publishing notification in the Federal Register stating the reasons for such an action and providing a 30–day public comment period.

* * * * *

[FR Doc. 03–55515 Filed 6–5–03; 8:45 am]

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