Port Valdez at 61°05′03.6″ N, 146°25′42″ W; thence northerly to yellow buoy at 61°06′00″ N, 146°25′42″ W; thence east to the yellow buoy at 61°06′00″ N, 146°21′30″ W; thence south to 61°05′06'' N, 146°21′30″ W; thence west along the shoreline and including the area 2000 yards inland along the shoreline to the beginning point.

(2) *Tank Vessel Moving Security Zone.* All waters within 200 yards of any TAPS tank vessel maneuvering to approach, moor, unmoor or depart the TAPS Terminal or transiting, maneuvering, laying to or anchored within the boundaries of the Captain of the Port, Prince William Sound Zone described in 33 CFR 3.85–20(b).

(3) *Valdez Narrows, Port Valdez, Valdez, Alaska.* All waters within 200 yards of the Valdez Narrows Tanker Optimum Track line bounded by a line beginning at 61°05′15″ N, 146°37′18″ W; thence southwest to 61°04′00″ N, 146°39′52″ W; thence southerly to 61°02′32.5″ N, 146°41′25″ W; thence northwest to 61°02′40.5″ N, 146°41′47″ W; thence northeast to 61°04′07.5″ N, 146°40′15″ W; thence northeast to 61°05′22″ N, 146°37′38″ W; thence southeast back to the starting point at 61°05′15″ N, 146°37′18″ W.

(b) *Regulations.* (1) The general regulations in 33 CFR 165.33 apply to the security zones described in paragraph (a) of this section.

(2) Tank vessels transiting directly to the TAPS terminal complex, engaged in the movement of oil from the terminal or fuel to the terminal, and vessels used to provide assistance or support to the tank vessels directly transiting to the terminal, or to the terminal itself, and that have reported their movements to the Vessel Traffic Service, as required under 33 CFR part 161 and § 165.1704, may operate as necessary to ensure safe passage of tank vessels to and from the terminal.

(3) All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port and the designated on-scene patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a vessel displaying a U.S. Coast Guard ensign by siren, radio, flashing light, or other means, the operator of the vessel must proceed as directed. Coast Guard Auxiliary and local or state agencies may be present to inform vessel operators of the requirements of this section and other applicable laws.

Dated: January 5, 2006.

M.S. Gardiner,

Commander, United States Coast Guard, Coast Guard, Captain of the Port, Prince William Sound, Alaska.

[FR Doc. 06–449 Filed 1–17–06; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0483; FRL–7754–9]

Thymol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the thymol (5-methyl-2-isopropyl-1-phenol) on honey, honeycomb, and honeycomb with honey when applied/used as treatment to decrease the incidence of Varroa mite infestation in the honey bee. Vita (Europe) Limited, c/o Landis International Limited, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of thymol (5-methyl-2-isopropyl-1-phenol).

DATES: This regulation is effective January 18, 2006. Objections and requests for hearings must be received on or before March 20, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0483. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) 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: Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6928; e-mail address:*bryceland.andrew@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 production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 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 on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document go directly

to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of April 27, 2005 (70 FR 21773) (FRL–7707–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6752) by Vita (Europe) Limited c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of thymol (5-methyl-2-isopropyl-1-phenol). This notice included a summary of the petition prepared by the petitioner. A public comment has been received objecting to ''any tolerance, exemption, or waiver allowing more than zero residue of thymol on food.'' This objection was supported by the arguments that:

1. Embryonic chickens have multiple malformations following thymol injection into the yolk or air sac, and;

2. Switzerland has established an Maximum Residue Limit (MRL) of 0.8 milligram/kilogram (mg/kg). The commenter did not provide a specific data citation for either of these arguments.

The results from the chicken study are of questionable relevance to mammals. Currently, EPA does not use chickens (or intrayolk or intra-airsac exposure routes) as an animal model for developmental toxicity because of the differences in developmental physiology and anatomy between the two species. Developmental timing, duration, and potential environmental effects on developing young are also different in mammals and birds, again precluding this model for use in setting developmental toxicity endpoints for the regulation of pesticides (Reference 13).

Developmental malformations have not been found following thymol exposure to other mammalian species such as mice, rats, hamsters, and rabbits (Environmental Risk Management Agency of New Zealand, 2005). In addition, Mortazavi *et al.* (2003) reported no external tissue abnormalities in fetuses following dosing of female rats with an infusion of the plant *Satureja khuzestanica* (which has the components thymol and carvacrol).

Regulatory limits have been set for thymol in other countries. The Swiss Federal Department of the Interior has set a tolerance (MRL) concentration for thymol in honey as an antiparasitic agent (0.8 mg/kg; pharmacological substance active in nutrition or therapeutic application; 817.021.23). This tolerance was derived to prevent exceedance of the taste threshold for thymol in honey (1.1 - 1.3 mg/kg; Bogdanov *et al.*, 1999), not safety. Tolerances set by EPA are based on ''the reasonable certainty of no harm,'' FFDCA section 408(c)(2)(A)(ii), and therefore, are not constrained by criteria such as taste.

Section 408(c)(2)(A)(i) of 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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of 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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take intoaccount the factors set forth in section 408(b)(2)(C), which require 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. . . .'' Additionally, section 408(b)(2)(D) of FFDCA requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. 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.

Thymol is an essential oil that is extracted from thyme and mandarine and tangerine oils and is FDA approved when used as a synthetic flavoring (21 CFR 172.515), a preservative and indirect food additive of adhesives (21 CFR 175.105). Additionally, the source plant (thyme), from which thymol is extracted is acknowledged by FDA as generally recognized as safe (GRAS) (21 CFR 182.10, 21 CFR 182.20). Residues of thymol can be found in other food stuffs either naturally such as that found in lime honey or intentionally added to foods such as ice cream, non-alcoholic beverages, candy, baked goods, and chewing gum. Information from the public literature documents that levels of thymol residues in such foods are present at significantly higher concentrations than those resulting from pesticidal treatments (Refs. 1, 3, 14, 15, 16, 17, and 18). End use products containing thymol as the active ingredient will be used as a slow release treatment within the beehive itself to decrease the incidence of Varroa mite infestation in the honey bee.

Toxicity data requirements were addressed by requests for data waivers. The Agency granted data waivers based on publically available information/data submitted by the registrant and reviewed by the Agency.

1. *Acute oral toxicity waiver (OPPTS 870.1100, 152–10).* The waiver rationale submitted in support of the acute oral toxicity (870.1100) data requirement is based on oral LD_{50}s from the open literature and reviewed by the Agency. The oral LD_{50} of thymol has been reported to be 980, 640–1800, and 880 mg/kg in rats, mice, and guinea pigs, respectively (Refs. 3 and 5). Thymol occurs in various food stuffs and spices from 0.02 mg/kg to 100 mg/kg (Refs. 3, 14, 15, 16, 17, and 18). The lowest level in which there was an effect from thymol was 640 mg/kg (Refs. 3 and 5). The amount in which thymol causes an acute effect is approximately 6 times higher than the 100 mg/kg found in the food stuff with the highest amount of thymol present. The information/data described above support the waiver form the data requirement for the acute oral toxicity study.

2. *Acute dermal toxicity data waiver (OPPTS 870.1200, 152.11).* The waiver rationale submitted in support of the acute dermal toxicity data requirement is based upon information collected from a report by the Environmental Risk Management Agency (ERMA, 2005) of New Zealand and Anonymous (2000) which found dermal LD_{50}'s for thymol

greater than 2,000 mg/kg. Thymol occurs in various food stuffs and spices from 0.02 mg/kg to 100 mg/kg (Refs. 3, 14, 15, 16, 17, and 18). Dermal exposure to thymol already occurs from contact with foodstuffs and seasonings containing thymol as it is FDA approved when used as a direct food additive and is generally recognized as safe by FDA as a spice, natural oil, oleoresin, or natural extract and therefore, any additional exposure resulting from dermal contact with thymol will not result in any significant exposure. Thymol, when used as a pesticide, is to be applied to the inside of beehives. Data from U.S. and European field trials demonstrate maximum residue concentrations of 2.59 mg/kg thymol in honey (at 30 days following treatment in U.S. trials) and 4.61 mg/kg thymol in honey (at 2 days following treatment in European trials) demonstrate that, following good agricultural practices (as specified in the tolerance exemption), the amount of thymol residues remaining in the beehive after application will be well below the dermal LD_{50} and within the range of those thymol residues already present in food stuffs (MRID No.'s: 460435–10, 11, 12, and 13). Based on this information, the Agency therefore concludes that the information/data described above support the waiver from the data requirement for the acute dermal toxicity study.

Classification: Acceptable.

3. *Acute inhalation toxicity waiver (OPPTS 870.1300, 152–12)*. The waiver rationale submitted in support of the acute inhalation toxicity data requirment is based upon information from the U.S. Food and Drug Administration Center for Drug Evaluation and Research (Ref. 19). Thymol is added to the anesthetic halothane as a preservative (0.01%) and is considered inactive at this concentration (Ref. 19). Halothane is used to anesthetize dogs, cats, and other non-food animals for periods sometimes exceeding 4 hours (Ref. 19). Anesthetic induction concentrations can typically reach approximately 5% (Ref. 19). Calculation of the exposure from these factors yields a thymol atmospheric concentration of 5 milligram/liter (mg/L). Thymol is for application to the inside of beehives. Thymol occurs in various food stuffs and spices from 0.02 mg/kg to 100 mg/kg (Refs. 3, 14, 15, 16, 17, and 18). Inhalation exposure to thymol already occurs from contact with foodstuffs and seasonings containing thymol as it is FDA approved when used as a direct food additive and is generally recognized as safe by FDA as a spice, natural oil, oleoresin, or natural extract and therefore, any additional exposure resulting from inhalation contact with thymol will not result in any significant exposure The information/data described above support the waiver from the data requirement for the acute inhalation toxicity study.

Classification: Acceptable.

4. *Skin hypersensitivity study waiver (OPPTS 870.2600, 152.15)*. The waiver rationale for skin hypersensitivity is based on publically available information (Ref. 20). Using quantitative structure activity relationships, from the public literature, it was predicted that thymol is a dermal sensitizer (Ref. 20). Thymol is for application to the inside of beehives. Thymol occurs in various food stuffs and spices from 0.02 mg/kg to 100 mg/kg (Refs. 3, 14, 15, 16, 17, and 18). Dermal exposure to thymol already occurs from contact with foodstuffs and seasonings containing thymol as it is FDA approved when used as a direct food additive and is generally recognized as safe by FDA as a spice, natural oil, oleoresin, or natural extract and therefore, any additional exposure resulting from dermal contact with thymol will not result in any significant exposure. The information/data described above support the waiver from the data requirement for the skin hypersensitivity study.

Classification: Acceptable.

The information/data described above support the waiver from the data requirement for the skin hypersensitivity study. However, the registrant is obliged under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(a)(2) to notify the Agency in the events of such incidents.

Classification: Acceptable.

5. *Genotoxicity and mutagenicity study waivers, Master Record Identification Numbers (MRIDs) 46282801 and 46282802 (OPPTS 870.2300, 870.5195; 152–17, and 152.19)*. Genotoxicity and mutagenicity studies submitted on September 18th of 2003 (MRIDs 462828-01 and -02), presumably as waiver rationales for genotoxicity (870.5000) and other peer-reviewed publications retrieved by EPA (Refs. 3, 6, 7, 8, 9, 10, and 11), were used to support the waivers from the data requirements. These data demonstrate that thymol is not genotoxic and/or mutagenic. The information/data described above support the waivers from the data requirements for the genotoxicity and mutagenicity studies.

Classification: Acceptable.

6. *Immune response study waiver (OPPTS 870.3550, 152.18)*. The waiver rationale for immune response (870.3550) is based upon information presented in a peer-reviewed publication (Ref. 21). No effects were shown in this data (Ref. 21). The information/data described above support the waiver form the data requirement for the acute inhalation toxicity study.

Classification: Acceptable.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA 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).

A. Dietary Exposure

1. *Food*. Thymol is already found naturally in food stuffs such lime honey and cooking herbs and/or food stuffs derived from cranberry and mandarin and tangerine oils. Thymol is also added to food stuffs commonly consumed by humans such as ice cream, non-alcoholic beverages, candy, baked goods, and chewing gum. It is FDA approved when used as a synthetic flavoring, (21 CFR 172.515), a preservative and indirect food additive of adhesives (21 CFR 175.105) and the source plant (thyme), from which thymol is extracted is acknowledged by FDA as generally recognized as safe (GRAS) (21 CFR 182.10, 21 CFR 182.20). The information and/or data reviewed in support of this tolerance exemption demonstrate that the levels of thymol already present in foods or intentionally added to food stuffs will at concentrations significantly higher that those levels expected from the use of thymol as a pesticidal product. Because thymol is already present, either naturally or intentionally added to various food stuffs, there is a great likelihood of exposure to thymol for most, if not all individuals, including infants and children. Even if there is a significant increase in exposure to thymol due to it's use as a pesticide, the acute toxicity information from the public literature demonstrating relatively low mammalian toxicity indicate that any possible risk associated with acute exposures by the oral route would below to non-existent.

2. *Drinking water exposure*. No exposure to thymol residues in drinking water is expected since the use of this product is limited to application within the hive box in which the product is contained in a dispenser tray, where the

product is rapidly volatilized or redistributed. Because thymol has relatively low toxicity, has been approved for food use by FDA as a direct food additive and is generally recognized as safe by FDA, even if exposure through drinking water were to occur, the exposure would be far less than the exposure that humans already get from consumption of thymol thru the diet and therefore, no risk is anticipated.

B. Other Non-Occupational Exposure

The potential for non dietary exposure to residues of thymol for the general population, including infants and children, is unlikely because the uses are limited to application to certain agricultural crops within the hive box containing the bees and there is no honey present in the bee hive. Thymol is consumed by humans thru the diet and for this reason, from a dietary exposure standpoint, has been determined to have relatively low toxicity. Therefore, while the likelihood of exposure exists for most if not all individuals, any increased exposure due to the proposed product would not add any significant risks.

1. *Dermal exposure*. Dermal exposure to thymol already occurs from contact with foodstuffs and seasonings containing thymol as it is FDA approved when used as a direct food additive and is generally recognized as safe by FDA as a spice, natural oil, oleoresin, or natural extract and therefore, any additional exposure resulting from dermal contact with thymol will not result in any significant risk.

2. *Inhalation exposure*. Inhalation exposure to thymol already occurs from contact with foodstuffs and seasonings containing thymol as it is FDA approved when used as a direct food additive and is generally recognized as safe by FDA as a spice, natural oil, oleoresin, or natural extract and therefore, any additional exposure resulting from dermal contact with thymol will not result in any significant risk.

V. Cumulative Effects

Thymol has a novel mode of cellular action (GABAA receptor, sodium, potassium, and calcium channel modulator) compared to other currently registered active ingredients (Ref. 1). In addition, there is no indication that toxic effects of thymol would be cumulative (Ref. 1). Section 408(b)(2)(D)(v) of 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. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thymol and any other substances and thymol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. The Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of thymol to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the relatively low levels of mammalian dietary toxicity associated with thymol, its FDA approval as a direct food additive, a preservative and indirect food additive of adhesives and GRAS listing as a spice, natural oil, oleoresin, or natural extract and information and/or data which demonstrate that the U.S. population is potentially exposed to 938 times more thymol from the consumption of foodstuff such as ice cream, cola beverages and candy, to which thymol is intentionally added, than from thymol consumed in honey (Refs. 22, 23, and MRID 46043510). These data indicate that thymol residues found in food and foodstuffs exist at significantly higher concentrations that those residues levels resulting from the use of thymol as a pesticide. For these reasons, the Agency has determined that thymol residues in honey will not pose any significant dietary risk under reasonable foreseeable circumstances residue.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless the EPA determines that a different margin of exposure (safety) will be safe for infants and children. Based on all the reliable available information the Agency reviewed on thymol, the Agency concludes that there are no residual uncertainties for prenatal/postnatal toxicity resulting from thymol and that thymol has relatively low toxicity to mammals from a dietary standpoint, including infants and children thus, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors

No studies illustrating thymol-induced immune and endocrine toxicity were submitted by the registrant.

EPA is required under FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, thymol may be subjected to additional screening and/or testing to better characterize effects related to endocrine

disruption. Based on available data, no endocrine system-related effects have been identified with consumption of thymol. Information submitted from the public literature and reviewed by the Agency however, describe immunological endpoints in relation to short-term and chronic dosing. No effects were seen in the thymus, spleen, lymph nodes, white cell counts, red cell counts, hemoglobin counts, or hematocrits following the dosing of rats with 1,000 or 10,000 mg/kg of food grade thymol for 19 weeks. (MRID 46282803; Ref. 21). This information does not however, provide evidence to suggest that thymol affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

An analytical method for measuring thymol in honey and beeswax was submitted and reviewed by the Agency and found to be acceptable.

C. Codex Maximum Residue Level

The are no CODEX maximum residues levels for thymol.

VIII. Conclusions

Based on the information/data submitted and other information available to the Agency, there is a reasonable certainty that no harm will result from aggregate exposure to residues of thymol to the U.S. population, including infants and children, under reasonable foreseeable circumstances, when the biochemical pesticide is used in accordance with the product label directions. This includes all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information. The Agency has arrived at this conclusion based on the information/data submitted (and publically available) demonstrating relatively low toxicity of thymol. As a result, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of thymol in or on honey, honeycomb and honeycomb with honey.

IX. References

1. 12/7/05 Agency review memorandum; From Dr. Kent Carlson, Biologist; Through Dr. Russell Jones, Senior Biologist; To Andrew Bryceland, Regulatory Action Leader; Subject: Addendum to the 7/19/05 Agency review memorandum and Review of Response to Deficiency Letter, Waiver Rationales, and Product Chemistry.

2. 7/19/05 Agency review memorandum; From Dr. Kent Carlson, Biologist; Through Dr. Russell Jones, Senior Biologist; To Andrew Bryceland, Regulatory Action Leader; Review of Response to Deficiency Letter, Waiver Rationales, and Product Chemistry.

3. Environmental Risk Management Authority (ERMA). 2005. Form HS1, Application for approval to import or manufacture any hazardous substance for release (for APILIFE VAR). *www.ermanz.govt.nz*.

4. Mortazavi, S.H.R., Ebrahimi, M., Salehnia, A., and M. Abdollahi. 2003. Effects of *satureja khuzestanica* on reproduction potency of female rats. Neurotoxicology and Teratology. 25. 381–397.

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12. Environmental Protection Agency. 2001. Risk assessment guidance for superfund volume I: Human health evaluation manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim. EPA/540/R/99/005, OSWER 9285.7–02EP, PB99–963312.

13. EPA Health Effects Guidelines (OPPTS.7300, Prenatal development toxicity study, pg.1 (e)(1)).

14. FR Notice 7308–1, Vol.68, No. 109, Friday June 6, 2003.

15. Fenaroli's Handbook of Flavoring ingredients. Vol 2. Edited, translated and revised by T.E. Furia and Bellanca. 2nd edition. Cleeland: The Chemical Rubber Co., 1975., p536.

16. De Vincenzi, M., Maialetti, F., and M. Di Pasquale. 1991. Monographs on botanical flavoring substances used in food; Part 1. Fitoterapia. 62(1). 47–63.

17. Piasenzotto, L., Gracco, L., Conte, L.S., and S. Bodenov. 2002. Application of solid phase microextraction to evaluate traces of thymol in honey. Apidologie. 33. 545–552.

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19. Food and Drug Administration, April 10, 1997, NADA, Freedom of Information Summary, p3.

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23. Food and Drug Administration. FDA Total Diet Study. 1990. FDA Total Diet Study. 2003. TDS Diets, Version 1 (1990 food list + 1987–88 NFCS data), at *http://www.cfsan.fda.gov/~comm/tds-hist.html#fca*.

X. Objections and Hearing Requests

Under section 408(g) of 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 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 FFDCA provides essentially the same process for persons to ''object '' to a regulation setting an exemption from the requirement of a

tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of 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 EPA–HQ–OPP–2005–0483 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 March 20, 2006.

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 IX.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 docket ID number EPA–HQ–OPP–2005–0483, to: Public Information and Records Integrity Branch, Information Technology and Resource Management 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. 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).

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of FFDCA in response to a petition submitted to the Agency. 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 petition under section 408(d) of 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 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.

XII. 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: December 30, 2005.

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), 346a and 371.

■ 2. Section 180.1240 is amended by redesignating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

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

* * * * *

(b) An exemption from the requirement of tolerance is established for residues of Thymol (5-methyl-2-isopropyl-1-phenol in or on honey, honeycomb, and honeycomb with honey when used in accordance with good agricultural practices.

[FR Doc. 06–436 Filed 1–17–06; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 94–129; DA 05–1618]

Policies and Rules Concerning Unauthorized Changes of Consumers' Long Distance Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: A Petition for Declaratory Ruling regarding the Commission's carrier change verification rules was filed by a coalition of rural local exchange carriers (LEC Petitioners). Specifically, the LEC Petitioners asked the Commission to declare that certain carrier change verification actions do not violate the Commission's rules, which prohibits executing carriers from verifying the submission of a change request by a submitting carrier or causing an unreasonable delay in the execution of a change. In this document, the Commission denies the LEC Petitioners' request.

DATES: Effective January 18, 2006.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: David Marks, Consumer & Governmental Affairs Bureau, (202) 418–2512 (voice), *David.Marks@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Declaratory Ruling* (Order) DA 05–1618, CC Docket No. 94–129, adopted June 8, 2005 and released June 9, 2005. The Order denies a Petition for Declaratory Ruling regarding the Commission's carrier change verification rules filed by a coalition of rural local exchange carriers (LEC Petitioners) on February 1, 2005.

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, it does not contain new or modified ''information collection burdens for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, Room CY–A257, 445 12th Street, SW., Washington, DC 20054. The complete text of this decision may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact the Commission's contractor at their Web site: *http://www.bcpiweb.com* or call 1–800–378–3160. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY). The *Order* can also be downloaded in Word and Portable Document Format (PDF) at *http://www.fcc.gov/cgb/policy*.

Synopsis

On February 1, 2005, a coalition of rural local exchange carriers (LEC Petitioners) filed a Petition for Declaratory Ruling regarding the Commission's carrier change verification rules. In their Petition, LEC Petitioners set forth three main arguments that their practices do not violate the Commission's rules. First, they argue that there is no basis in law, including agency law, for the proposition that a third party (such as an executing LEC) should rely on a claim of authority of a person who the executing carrier believes to be without authorization. *See* Petition for Declaratory Ruling, CC Docket No. 94–129, filed February 1, 2005 (Petition), by 3 Rivers Telephone Cooperative, Inc., Armstrong Telephone Company Maryland, Armstrong Telephone Company New York, Armstrong, Telephone Company North, Armstrong Telephone Company Northern Division, Armstrong Telephone Company Pennsylvania, Armstrong Telephone Company West Virginia, Calaveras Telephone Company, Inc., Chester Telephone Company, Chibardun Telephone Cooperative, Inc., Chickasaw Telephone Company, Citizens Telephone Company of Higginsville, Concord Telephone Company, CTC Telcom, Inc., Darien Telephone Company, DTC Communications, Egyptian Telephone Cooperative, Five Area Telephone, Hardy Telephone Company, Horry Telephone Cooperative, Inc., HTC Communications, Lackawaxen Telecommunications Services, Inc., Lockhart Telephone Co., Margaratville