Responses to NOSB Livestock Subcommittee Questions

1. **Additional Ingredients.** You have noted that the concentration of thymol in a footbath disinfectant solution is 0.23 percent. If synthetic thymol is added to the National List, you will need to provide complete ingredient information about any formulated product to accredited certifying agents and/or material review organizations. While you cannot submit confidential business information as part of the petition process, please clarify if the formulated product contains synthetic substances that are not included on the current National List (7 CFR 205.603).

Yes, the formulation is proprietary, but the formulated product will contain only substances that are included in the current National List (7 CFR 205.603).

2. **Manufacturing Process**. You have responded in your petition addendum that thymol is manufactured using good manufacturing practices and that the manufacturing facility follows all local and national regulations. Please provide additional information about the manufacturing process, including the steps from the basic component(s) to the final product and any environmental impacts of the manufacturing process.

Thymol is purchased in solid form, and produced by only a few suppliers, who, again, have proprietary processes, often because their competitive advantages are based on the simplicity and efficiency of the processes. Since synthetic thymol is typically used in drugs (Rx and OTC), and is very pure, there is a very controlled production process (USP, EP grade), which has little or no environmental impact to our knowledge, as is the case with almost all pharmaceutical constituents. In short, we understand the process to produce thymol to be a closed system, by mixing reagents, and then distillation to separate the thymol. The majority of non-thymol components are recaptured, repurposed and/or reused.

As an aside, the extraction process of thyme oil from thyme leaves is relatively robust in terms of environmental impact, requiring the cultivation, harvesting and transportation of the thyme plant and, then, either a steam or solvent extraction process with considerable waste by-products. This lead to a bigger carbon footprint from cultivation, transportation and energy used in high energy extraction. These are also reasons (as noted below) why thyme oil is cost prohibitive for agricultural use.

3. **Source of Petitioned Substance**. You have discussed in your petition addendum that thymol is U.S. FDA Generally Recognized as Safe (GRAS) and is naturally occurring or botanically derived. However, the thymol in the original petition is synthetically derived from coal tar using a proprietary process and proprietary other ingredients. Please clarify if you are requesting approval for synthetic thymol or naturally derived (nonsynthetic) thymol.

We are requesting approval for synthetic thymol, which is exactly the same molecule as present in thyme oil, and has the exact same chemical properties including safety, and biodegradability (in Europe we understand this type of compound would be classified with the nomenclature of "nature identical").

In fact in the publication by the EPA "*Thymol; Exemption from the Requirement of a Tolerance*" (**Annex A**) refers consistently to the chemical compound of thymol with regard to thymol's safety for food contact and consumption, and distinguishes the characteristics of thymol apart from thyme oil (with has many other compounds including phenols). The Exemption attests to the *"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. This includes all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information."* In its predicate statements, EPA also notes that *"EPA is not aware of any adverse effects to humans or the environment in the scientific literature associated with any thymol related use."* Again, the references here are regarding thymol the compound, not thyme oil. We again respectfully ask the Livestock Committee's consideration of these facts in contrast to the currently approved compound of copper sulfate, which is a hazardous, toxic and environmentally harmful, synthesized compound.

4. **Nonsynthetic Alternatives**. Please clarify if there is any difference in quality and acceptability between thymol that might be derived through essential oil distillation of plants and the synthetic process originating with coal tar noted in the original petition.

There are many differences between synthetic thymol compared with thyme oil, which results in a lower quality and less acceptable product, and thymol which "could be" derived through extraction from thyme oil which results in a cost prohibitive product, many times higher (perhaps 10 times higher). (As an aside, we are not aware of pure thymol derived from thyme oil which is available on an industrial scale).

In more detail, first, regarding the fact that thyme oil has a highly variable quality, as it is naturally derived, and contains others active compounds (typically other phenols); the thymol concentration in the thyme oil is highly variable, and sometimes as little as 30% by weight or volume. Therefore, it is virtually impossible to guarantee a high level of consistent cleaning and disinfection by using thyme oil due to this intrinsic variability of thymol content. As referenced above, isolating pure thymol from thyme oil is a commercially infeasible process for this scale, due to cost and inefficiency (the other phenols are chemically similar making distillation and other simple isolation processes impossible at a cost effective price).

Second, even by theoretically compensating for the low levels and variability of thymol in thyme oil, by increasing the levels of thyme oil several fold to increase the intrinsic thymol content, will not result in an effective footbath. As, at those levels, that quantity of thyme oil required is impossible to keep in a single phase bath (thymol and thyme oil separate out of water as an oil) and therefore, does not stay as a solution (actually a nano-emulsion) and 'bathe' the hoof.

Third, only a very stable, easily dissolvable product with a consistent antimicrobial efficacy is useful to farmers. Given the menacing problem of digital dermatitis; cows and farmers need a solution which delivers on its intended purpose, every time.

5. **Justification for Synthetic Form**. Please address why botanically derived thymol is not acceptable in your formulation for the petitioned use

1. As above, the **variable quality and lack of purity** of thyme oil, yields an unreliable disinfecting product, which could be disastrous for farmers.

2. Botanically derived ***thymol from thyme oil is cost-prohibitive.*** Thyme oil is 3-5x more expensive, and on the basis of equivalent extracted thymol content, the actual thymol is about 10X more expensive. Our polling of farmers tells us that the resulting product cost is far beyond a cost effective alternative to the current toxic chemical in use. To note, our master label, approved by EPA defines thymol as **botanically derived** (EPA #87742-1). We believe that this is yet another substantiation for the fact that there is no difference between synthetic thymol (i.e. manufactured) and naturally extracted thymol (i.e. made in a plant), which is to say that the EPA considers the molecule "thymol" to be "botanically derived", i.e. it existing in nature and not synthetic, as defined by being "man made," in terms of its atomic/elemental composition.

We also share the NOSB Livestock subcommittee's stance that natural sources of active ingredients should be used whenever feasible. We hope the subcommittee will consider that our company has actually performed field trials to grow plants and extract thymol locally, in southern Québec. This was an attempt to produce quality thymol on a commercially viable scale. It was deemed important enough to be performed in partnership with Agriculture Canada (the Canadian equivalent to the USDA). Thyme, but also Monarda (a thymol producing plant), were grown over the course of 2 years, and harvested. In the end the trials were not successful, as the yields we could obtain were not high enough to justify commercial development. Only then did we make a final decision to use synthetic thymol.

3. Today, without a better source of thymol than plants, there remains the problem of caustic exposure to humans and animals of copper sulfate used in "organic" footbaths, and the environmental toxicity to plants and fish from the disposal of millions of gallons of daily copper sulfate footbaths. Our simple and core premise for the justification of the "synthetic" form of thymol lies in the overriding logic of its "natural, proven safety" as a "botanically derived" compound, as compared to the current, grand-fathered, also synthesized, chemical compound of copper sulfate.

Annex A - Thymol; Exemption from the Requirement of a Tolerance

1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 27, 2009.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.434 is amended by revising the tolerance for pineapple and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§180.434 Propiconazole; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * *	*
Beet, garden, roots	0.30
Beet, garden, tops	5.5
* * * *	*
Cilantro, leaves	13
* * * *	*
Parsley, fresh leaves	13
Parsley, dried leaves	35
* * * *	*
Pineapple	4.5
Pineapple, process residue	7.0

* * * * *

[FR Doc. E9–6273 Filed 3–24–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0081; FRL–8404–4]

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 thymol (as present in thyme oil) in or on food commodities when applied/used in/on public eating places, dairy processing equipment, and/or food processing equipment and utensils. Sensible Life Products 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.

DATES: This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0081. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Hartman, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0734; *hartman.mark@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0081 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 26, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0081, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of July 6, 2007 (Vol. 72, No. 129 (FRL–8136–3), 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 6F7147) by Sensible Life Products (Division of LBD, Ltd.), 34-7 Innovation Dr, Ontario, Canada L9H7H9. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of thymol in or on food commodities when used as a hard surface disinfectant. 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 comment is addressed in Unit VIII.C.

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) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, 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.

Based on the following, the Agency has concluded that thymol has minimal potential toxicity and poses minimal risk:

1. Thymol is a normal constituent of the human diet and a component of many non-pesticidal consumer products currently marketed in the United States,

2. Thymol and the phenols of thymol are listed as food additives by the FDA (21 CFR 172.515; synthetic flavoring substances and adjuvants),

3. Thymol is found naturally occurring in thyme herb, a food seasoning ingredient that is generally recognized as safe (GRAS) by the FDA (21 CFR 182.10),

4. Thyme oil (for which thymol is a component) also is recognized as a GRAS essential oil by the FDA (21 CFR 182.20),

5. Thymol can be presumed non-persistent in the environment based on knowledge of its composition,

6. As a conventional pesticide, thymol repels vertebrate pests by a non-toxic mode of action,

7. The available toxicity information does not indicate toxic effects at the levels of potential exposure and

8. EPA is not aware of any adverse effects to humans or the environment in the scientific literature associated with any thymol related use.

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 found naturally in food stuffs such as 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 be at concentrations significantly higher than those levels expected from the use of thymol as a pesticidal product. For example, the U.S. population is potentially exposed to roughly 1,000 times more thymol from the consumption of foodstuffs such as ice cream, cola beverages and candy, to which thymol is intentionally added, than from thymol consumed in as a result of use as a pesticide in food handling establishments. Aggregate exposure to thymol in food, therefore, is primarily due to naturally-occurring thymol and thymol's use as a food additive.

2. *Drinking water exposure*. Exposure to thymol residues in drinking water is not expected since the use of this product is limited to application indoors and release to drinking water sources is unlikely.

B. Other Non-Occupational Exposure

The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Thymol is not registered for any specific use patterns that would result in residential exposure.

V. Cumulative Effects

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.

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. Thymol has a novel mode of cellular action (GABAA receptor, sodium, potassium, and calcium channel modulator) compared to other currently registered active ingredients. In addition, there is no indication that toxic effects of thymol would be cumulative. 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. Safety Factor for the Protection of 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. EPA has determined that a quantitative risk assessment using safety factors is not needed to assess thymol's safety for the general population due to thymol's low toxicity. For similar reasons, an additional safety factor is not necessary to protect infants and children.

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

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 presence as a naturally-occurring substance in food, and 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.

VIII. 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 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 milligrams/kilograms (mg/kg) of food grade thymol for 19 weeks. (MRID 46282803; Ref. 21).

B. Codex Maximum Residue Level

There are no CODEX maximum residues levels for thymol .

C. Public Comments

1. A commenter argued that no greater than zero residues from thymol should be allowed because embryonic chickens have multiple malformations following thymol injection into the yolk or air sac.

EPA Response: 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 (including absorption barriers and detoxification mechanisms) which are present in mammals. 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.

Developmental malformations have not been found following thymol exposure to 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).

2. A commenter argued that no greater than zero residues from thymol should be allowed because thymol is mutagenic.

EPA Response: Although the Agency understands thymol did give statistically significant positive results in an unscheduled DNA synthesis test and a Sister Chromatid Exchange (SCE) test with Syrian hamster embryonic cells, these mutagenicity studies do not comply with the Agency's current test guideline requirements either because of a lack of positive controls, or because a treatment-related dose response was not demonstrated even when statistical significance was achieved. Based on the available toxicity information, its presence in the human diet and several non-pesticidal consumer products, and its long history of use with no known adverse effects to human health and the environment.The Agency reaffirms that there is no need to establish a maximum permissible level for residue of thymol.

IX. 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. 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. Further, because thymol residues (as present in thyme oil) in or on food commodities do not pose any significant risk under reasonable foreseeable circumstances, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of thymol in or on food commodities

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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