requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, 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 by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing section 111(d) submissions, EPA's role is to approve state plans, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state plan submission, to use VCS in place of a state plan submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 13, 2006. Interested parties should comment in response to the proposed rule rather than petition for judicial review, unless the objection arises after the comment period allowed for in the proposal. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides, Waste treatment and disposal.

Dated: September 2, 2006.

Robert W. Varney,

Regional Administrator, EPA New England.

■ 40 CFR Part 62 is amended as follows:

PART 62—[AMENDED]

■ 1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart UU—Vermont

■ 2. Subpart UU is amended by adding a new § 62.11490 and a new undesignated center heading to read as follows:

Air Emissions From Existing Other Solid Waste Incineration Units

§ 62.11490 Identification of Plan-negative declaration.

On June 30, 2006, the Vermont Department of Environmental Conservation submitted a letter certifying that there are no existing other solid waste incineration units in the state subject to the emission guidelines under part 60, subpart EEEE of this chapter.

[FR Doc. E6–15198 Filed 9–12–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0695; FRL–8089–7]

Eucalyptus Oil; 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 eucalyptus oil on honey and honeycomb when applied at 2 g or less eucalyptus oil per hive to suppress varroa mites. Brushy Mountain Bee farm, c/o IR-4 Project 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 eucalyptus oil in honey and honeycomb.

DATES: This regulation is effective September 13, 2006. Objections and requests for hearings must be received on or before November 13, 2006, 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–2006–0695. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: *benmhend.driss@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?

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 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. 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–2006–0695 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 November 13, 2006.

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–2006–0695, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 19, 2006 (71 FR 41018) (FRL–8077–8), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition PP 6E7082 by Brushy Mountain Bee farm, c/o IR-4 Project Rutgers University, 681 U.S. Highway 1 South, North Brunswick, New Jersey 08902. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of eucalyptus oil. This notice included a summary of the petition prepared by the petitioner Brushy Mountain Bee farm, c/o IR-4 Project Rutgers. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption 6efrom 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 the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), 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), 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 the 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 the 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.

Eucalyptus oil (EO) is an essential oil that is obtained from steam distillation of the leaves of *Eucalyptus globulus*. Eucalyptus oil has a long history of safe medicinal uses and has been classified by FDA as a GRAS substance and permitted as a direct additive to foods for human consumption (21 CFR 172.510). It is used as a component of decongestant products, as an expectorant component of cough and cold products, in various oral dosages from (e.g., lozenges and syrups), and as an inhalant in vapor baths, etc. In 2002, 100,000 tons of Halls cough drops were consumed. There are no incident reports of adverse effects associated with exposures to EO.

There is limited information in the public literature and information reported by the FDA that provides a limit to the levels of EO that can be present in foods and or medicines. One exception however, is that EO is currently allowed at 1.2 to 1.3% (12,000 to 13,000 mg/kg) as a topical antitussive drug in mixtures with camphor and menthol (21 CFR 341.14(b); 341.40(u); 341.74(b),(c),(d)). A topical antitussive is defined as a drug that relieves cough when inhaled after being applied topically to the throat or chest in the form of an ointment or from a steam vaporizer or when dissolved in the mouth in the form of a lozenge for a local effect (21 CFR 341.3(c). Eucalyptus oil can be used orally in cough drops at 162 to 2,000 mg/kg (Ref. 1). There is information in the public literature that EO is known to be toxic at high levels. However, based on the most likely use pattern for EO as a pesticide, the Agency has determined that EO, when used as a pesticide, will be safe because it is likely to be used at very low levels. The lack of information in the public literature on the levels of EO that is present in certain foods and medicines is due to a lack of an available method to detect residues of eucalyptus oil in foods and medicines. This is primarily due to the fact that most essential oils from plants such a *Eucalyptus* spp. contain many components and therefore, may be difficult to characterize the actual oil component. Eucalyptus oil from *Eucalyptus globulus* is composed eucalyptol, triterpenes, monoterpenes, sesquiterpenes, aldehydes and ketones of which eucalyptol (1,8-cineole) makes up to 80% or more of EO. Since there is no method of detection for EO in foods, the Agency has conducted a dietary risk assessment in order to estimate the exposure to eucalyptus oil when used as a pesticide in or on honey and honey comb.

Toxicity data requirements were satisfied by the registrant with data and/or information from the public literature and requests to waive toxicity testing for the studies below. Data waiver rationales were provided and were acceptable and therefore data waivers were granted by the Agency.

A. Acute and Short-term Toxicity

Information submitted by the applicant demonstrated that acute oral LD_{50} values for EO is 4,400 mg/kg body weight in rats, 3,320 mg/kg body weight in mice, and a dermal LD_{50} of > 5,000 mg/kg body weight in rabbits. These classify EO as Toxicity Category IV for acutely toxic oral and dermal effects. EO is also a mild dermal irritant (Ref. 2). Embryotoxicity and fetotoxicity were not observed in a teratogenicity study in which mice were dosed with EO (from *Eucalyptus globulus*) subcutaneously during days 6-15 of gestation (Ref. 1).

Acute inhalation toxicity and primary eye irritation studies on EO were waived because the product requires personal protective equipment equivalent to Toxicity Category I. Inhalation and eye irritation only apply to workers using the product and not to people consuming the honey because the EO residue levels in honey are so low (0.125 ppm) when applied at 2g or less EO per hive. In addition, EO has a long history of safe use as a common ingredient in ointments applied to the skin and steam vaporizer solution for the relief of cold and flu symptoms. Hypersensitivity incidents must be reported to the Agency. No incidents have been reported during the last few years when EO in combination with other compounds has been used under the FIFRA section 18 program to control Varroa mites in bees.

B. Genotoxicity / Mutagenicity

Data submitted supported the waiver request for genotoxicity. No genotoxicity was observed following exposure of eucalyptus oil to *Salmonella* strains TA100, TA1535, TA1537, TA98 in tests with or without activation by rat and hamster liver S9 fractions (Ref. 3). An additional study (Ref. 4) also reported that eucalyptol, the main component of eucalyptus oil, was negative for mutation in *S. typhimurium* strains TA100, TA97A, TA98, TA102 both with and without metabolic activation (via rat liver S-9). Other *in vitro* studies show a weak positive to positive increases in sister chromatid exchanges were reported in Chinese hamster ovary (CHO) cells without metabolic activation (Ref. 5). Equivocal or weakly positive increases in chromosome aberrations were observed in CHO cells with S9 metabolic activation (Ref. 5). Overall, the weight of evidence suggests that EO is not genotoxic or mutagenic.

C. Subchronic Toxicity

Oral subchronic studies are typically required when the pesticidal use requires a tolerance or an exemption from the requirement of a tolerance, a food additive regulation, or its use results in repeated human oral exposure. Dietary subchronic exposure to EO in honey is probable. EO residues are found in other food items at significantly higher concentrations than those resulting from pesticidal treatments. Because the dietary contribution of EO from honey is expected to be negligible compared to that already in the diet, subchronic studies are not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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).

The Agency believes that establishing a tolerance exemption for residues of eucalyptus oil in or on honey or honey comb will not cause any new exposure that would not be safe. As mentioned in Unit III., the U.S. population in general is already exposed to EO from the consumption of cough lozenges and other food products at levels which are equivalent to the limit levels for this tolerance exemption without any reports of adverse effects. Further, the daily exposure to EO from honey consumption is negligible when compared to the level ingested for therapeutic use. In order to validate the determination that any new exposure from the use of eucalyptus oil is safe, the Agency conducted a dietary risk assessment using magnitude of residue data measuring eucalyptol and adjusted by 20 percent because eucalyptol is 80 percent of EO. As a result of this risk assessment, the Agency concludes that the use of EO when used as a pesticide on honey or honey comb to suppress varroa mites when applied at 2g or less EO will not add any new exposures or risks and is considered safe.

A. Dietary Exposure

A dietary risk was estimated by comparing theoretical exposures using the EO residues approved for use by FDA in cough drops as stated above.

These theoretical exposures were compared to the current consumption of eucalyptol, the therapeutic dose of eucalyptol. Comparisons were not calculated for the infant population because honey is generally not recommended for infant consumption due to the dangers it can pose to infants. Before comparisons could be made, exposures had to be put into terms of EO, not the marker analyte eucalyptol as described above. The amount of eucalyptus oil allowed in cough drops is 2,000 ppm which is 16,000 times that found in the honey submitted residue trial (Ref. 6).

Based on the dietary risk assessment conducted by the Agency, it has been determined that daily exposures to EO from honey consumption would be orders of magnitude less than the level ingested for therapeutic use. Therefore, the Agency concludes that residues of EO in honey when applied at 2g or less per hive are of no dietary concern to the U.S. population including children.

1. *Food.* Eucalyptus oil is commonly found in numerous food items such as yellow cake, vanilla ice cream, cola beverages, and caramel candy. In 2002, people consumed 100,000 tons of Halls drops (*http://www.cadburyschweppes.com/EN/Brands/About/Confectionery/factsheet_halls.htm*); while in the Northern Hemisphere these are sold as cough drops, other parts of the world consume them as candy. The daily exposure to EO from honey consumption when used at 2g or less is orders of magnitude less than the level ingested for therapeutic use (Ref. 1). Therefore, residues of EO in honey are not considered a dietary concern. Conservative exposure estimates and the use of lowest toxicity concentrations ensure that residues of EO present a reasonable certainty of no harm. Therefore, no adverse effects associated with exposures to EO by oral route are expected from the use of EO as a pesticide when used at 2g or less EO per hive.

2. *Drinking water exposure.* No exposure to EO residues in drinking water is expected because 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.

3. *Magnitude of the Residue in/on Honey and Honeycomb.* The end-use product, ApiLife VAR, has acceptable magnitude of the residue data on eucalyptol in honey and honeycomb when used as a treatment for Varroa mites in bee hives (Ref. 6; Ref. 7). Eucalyptol is the marker analyte for EO and comprises 80% (v/v) of the original mixture. Residue estimates and dietary exposures estimated with eucalyptol (0.1 mg/kg) were modified to account for the percentage of eucalyptol in EO (80%). Essentially, this meant increasing these estimates by 20% (equivalent to 0.125 mg/kg EO residues). The dietary exposure of eucalyptol in honey is below EPA's levels of concern for all population subgroups (Ref. 1).

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to EO residues for the general population, including infants and children, is unlikely because the proposed use-site is limited to beehives.

V. Cumulative Effects

There is no indication that the toxic effects of EO are cumulative. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA 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 EO 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 EO and any other substances and EO 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 EO 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

There is a reasonable certainty that no harm will result to the U.S. population including children from aggregate exposure to residues of EO as a result of its use as a pesticide in or on honey and honey comb when used at 2g or less EO per hive since no toxicity is expected and the U.S. population in general is already exposed to EO from the consumption of cough lozenges at much higher levels without any reports of adverse effects. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The anticipated residues in honey are at 0.125 ppm, which is more than 16,000 times lower than the established acceptable level in cough lozenges. Moreover, at high levels, EO gives off an undesirable or ill taste to the palate when consumed at levels which far exceed those levels reported for medicinal uses such as teas. For these reasons, it is unlikely that EO will be consumed at levels exceeding those reported here based on the undesirable taste alone. In addition, there is very little potential for exposure to EO from drinking water since the product will volatize or exposure and is limited to beehives or from non dietary, non occupational exposure since its use is limited to beehives. Therefore, based on its long history of safe use therapeutic and medicinal agents without any reports of any toxic or adverse effects and the fact that EO is classified by FDA as a substance that is generally recognized as safe (GRAS) when used as a direct additive to foods for human consumption, the Agency believes that the health risk to humans is negligible and concludes that there is a reasonable certainty that no harm will result from aggregate exposures to EO.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the 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 was scientific basis 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 FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA 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).

At this time, the Agency is not requiring information on the endocrine effects of this active ingredient, EO. Based on the weight of the evidence of available data and the absence of any reports to the Agency of sensitivity or other adverse effects, no endocrine system related effects are identified for EO and none is expected because of its use. To date there is no evidence that EO affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this proposed rule to establish an exemption from the requirement of a tolerance for residues of EO used at 2g or less EO per hive.

B. Analytical Method

Through this action the Agency proposes to establish an exemption from the requirement of a tolerance for EO on honey and honeycomb when used at 2g or less EO per hive to suppress varroa mites. This decision was reached based on the reasons stated above which include low toxicity to mammals and negligible exposure from the pesticidal use of products containing EO. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for EO.

C. Codex Maximum Residue Level

There are no CODEX maximum residues levels for EO.

VIII. Conclusions

Based on the data submitted and other information available to the Agency, there is a reasonable certainty that no harm will result from the aggregate exposure to residues of EO to the U.S. population, including infants and children, under reasonable foreseeable circumstances, when the biochemical pesticide EO is used in accordance with the product label directions and at 2 g or less eucalyptus oil per hive. 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 publicly available) demonstrating relatively low toxicity of EO. As a result, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of EO in or on honey, honeycomb and honeycomb with honey when used at 2g or less EO per hive.

IX. References

1. August 8, 2006. EPA Memo: Api Life VAR: Toxicology Review and a Dietary Exposure Assessment for Eucalyptus Oil (CAS No. 6000–48–4) in Support of an Exemption for the Requirement of a Tolerance. Kent Carlson to Driss Benmhend.

2. Inchem. 2004. Aliphatic and Aromatic Ethers. Chapter 2.2.2 Toxicological Studies. JEFCA. 52

3. National Toxicology Program. 1982. *Salmonella* assay for genetic toxicity from exposure to 1,8 cineole. Study 246429.

4. Gomes-Carneiro. R. 1998. Mutagenicity testing ()-camphor, 1,8 cineole, citral, citronellol, (-)-menthol, and terpineol with the Salmonella microsome assay. Mutation Research. 416(1-2). 129-136.

5. National Toxicology Program. 1982. CHO cell cytogenetics; chromosome aberrations and sister chromatid exchanges from exposure to 1,8 cineole. Study 590755.

6. July 25, 2005. MRID 466828-01. Thymol, Eucalyptol, Campho: Magnitude of the Residue on honey and beeswax. IR-$ PR No. 08661. 251pp.

7. June 29, 2006. EPA Memo: Apilife VAR: Dietary Exposure Assessment Involving Review of Toxicology and Exposure Data to Address Application to Bee Hives. Kent Carlson to Driss Benmhend.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of the 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 the FFDCA, such as the exemption from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure

''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule

XI. 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: August 31, 2006.

James Jones,

Director, Office of Pesticides 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 180.1271 is added to subpart D to read as follows:

§ 180.1271 Eucalyptus oil; exemption from the requirement of a tolerance.

An exemption from the requirement of tolerance is established for residues of eucalyptus oil in or on honey, honeycomb, and honeycomb with honey when used at 2g or less eucalyptus oil per hive, where the eucalyptus oil contains 80% or more eucalyptol.

[FR Doc. E6–14995 Filed 9–12–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0024; FRL– 8085–1]

Difenoconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole), when used as a seed treatment in or on barley, hay; barley, straw; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; cotton, gin byproducts; cotton, undelinted seed; and as a foliar treatment on fruit, pome, group 11 (import); and on grape (import). Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This rule also revises the chemical name of the active ingredient, difenoconazole, from [(2S,4R)/(2R/4S)]/[(2R/4R)]/(2S,4S) 1-(2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1H-1,2,4-triazole, to the following, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole). EPA is also deleting certain difenoconazole tolerances that are no longer needed as result of this action.

DATES: This regulation is effective September 13, 2006. Objections and requests for hearings must be received on or before November 13, 2006, 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–2006–0024. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9443; e-mail address: *kish.tony@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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**.