

requirement on all food commodities 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 in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies

that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCa. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: April 19, 2004.

**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 180.1248 is added to subpart D to read as follows:

#### § 180.1248 Exemption of citronellol from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide citronellol in or on all food commodities.

[FR Doc. 04-9618 Filed 4-27-04; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2004-0068; FRL-7351-1]

#### Geraniol; 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 geraniol on all food commodity when applied/used to control Tetranychid mites. Natural Plant Protection S.A. 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 geraniol.

**DATES:** This regulation is effective April 28, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0068, must be received on or before June 28, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a

docket for this action under Docket ID number OPP-2004-0068. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. 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, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Raderrio Wilkins, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-1259; e-mail address: [wilkins.raderrio@epa.gov](mailto:wilkins.raderrio@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)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number

OPP-2004-0068. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>, a beta site currently under development. The OPPTS harmonized test guidelines referenced in this document are available at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

**II. Background and Statutory Findings**

In the **Federal Register** of May 23, 2000 (65 FR 33318) (FRL-6557-1), 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 0F6073) by Natural Plant Protection S.A., 4061 North 156th Drive, Goodyear, AZ 85338. This notice included a summary of the petition prepared by the petitioner Natural Plant Protection S.A.. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of geraniol. Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a

tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the 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.

Geraniol is a monoterpene alcohol found in over 250 essential oils, and is widely used as a fragrance component in the manufacture of detergents, soaps, creams, lotions, cosmetics, and aromatherapy products. This chemical is also used as a synthetic flavoring agent in beverages, ice cream, and candies, and is generally regarded as safe (GRAS) under section 409 of the FFDCA (21 CFR 182.60). The toxicity

studies submitted in support of this tolerance exemption are referenced below.

1. Acute oral toxicity (OPPTS 870.1100; 152-10; MRID 45262003). Male and female Sprague-Dawley rats were tested with a single exposure to a pesticide product containing an active ingredient, geraniol, at 0.42% of the product. The pesticide was tested at doses ranging from 2,500 to 5,500 mg/kg of body weight and observed for 14 days. The oral LD<sub>50</sub> for males and females were 5,242 mg/kg and 3573 mg/kg, respectively. Classification: Acceptable. Toxicity Category III, based on the LD<sub>50</sub> of female Sprague-Dawley rats.

2. Acute dermal toxicity (OPPTS 870.1200; 152-11; MRID 45262004). Male and female New Zealand White rabbits were given 5,050 mg/kg of a pesticide product containing an active ingredient, geraniol, at 0.42% of the product, and observed for 14 days. Classification: Acceptable. Toxicity Category: IV.

3. Acute inhalation toxicity (OPPTS 870.1300; 152-12; MRID 45262005). Male and female Sprague-Dawley rats were exposed for 4 hours to an atmospheric concentration of 2.64 mg/L of a pesticide product containing geraniol as an active ingredient and observed for 14 days. The acute inhalation LC<sub>50</sub> was > 2.64 mg/L. Classification: Acceptable. Toxicity Category: IV.

4. Primary eye irritation (OPPTS 870.2400; 152-13; MRID 45262006). An acute eye irritation study was conducted in male and female albino New Zealand white rabbits using a pesticide product containing an active ingredient, geraniol, at 0.42% of the product. The test substance was moderately irritating to the eyes of the test animals, causing corneal opacity (cloudiness) and conjunctivitis (redness) that cleared within 10 days following this exposure. Classification: Acceptable. Toxicity: Category II.

5. Primary dermal irritation (OPPTS 870.2500; 152-14; MRID 45262007). The shaved skin of male and female New Zealand White rabbits was exposed to a single 0.5 mL dose of a pesticide product containing the active ingredient, geraniol, at 0.42% of the product, for 4 hours and observed for 14 days for signs of skin irritation. The test substance was moderately irritating to the skin of the test animals, causing very slight to well-defined erythema (skin redness) that cleared within 14 days following exposure. Classification: Acceptable. Toxicity Category: III.

6. Hypersensitivity (OPPTS 870.2500; 152-15; MRID 45262008). The shaved

skin of male and female Hartley guinea pigs was treated once weekly for 3 weeks with a pesticide product containing the active ingredient, geraniol, at 0.42% of the product. Skin redness (irritation) followed each treatment cleared within 48 hours. A challenge dose was given to an untreated site, and the animals observed for signs of allergic reaction (hypersensitivity) to the test material. The treated test and naive control animals showed no allergenicity (swelling, redness) at 24 and 48 hours after this challenge dose. The pesticide product was not a dermal sensitizer in Hartley guinea pigs. Classification: Acceptable.

The pesticide registrant requested waivers of the required studies on the technical grade of the active ingredient for acute toxicity, genotoxicity, reproductive toxicity, developmental toxicity, subchronic, toxicity in mammalian species, and acute toxicity to non-target species. The waivers were based on the ubiquity of geraniol in nature; the long history of use in cosmetics, fragrances, detergents, and household cleaners; the natural occurrence in fruits and beverages; the wide use as a synthetic flavoring agent and adjuvant; and the low anticipated exposure to humans and the environment due to the very low concentration of geraniol (0.42%) in the pesticide product. In addition, data on the toxicity of geraniol from publicly available technical literature was presented to the Agency (MRID 452620-10) for acute oral toxicity in the rat (Toxicity category III), acute dermal toxicity (Toxicity category IV, no species indicated), dermal irritation (severe in humans), dermal sensitization (weak sensitizer, variable response, species not indicated), subchronic oral toxicity in the rat (no effects at 10,000 ppm in the diet for 16 weeks, no effects at 1,000 ppm for 26 weeks), and mutagenicity/genotoxicity (negative in the Ames assay in *Salmonella typhimurium* strains tested at 100 µg). Data for geranyl acetate (and other esters of geranyl), which is used as a flavoring agent and is readily hydrolyzed to geraniol in the intestines of mammals, were also submitted. This data demonstrated an acute oral Toxicity category IV; no adverse effects at 1,000 mg/kg/day for 14 days and 13 weeks in mice, and no adverse effects in a chronic dietary/carcinogenicity study in rats fed 1,000 mg/kg/day for 103 weeks. Further, according to the World Health Organizations (WHO), dietary intake of geraniol is estimated based on the quantity of geranyl acetate consumed in the diet (Food Additives Series 40; 49<sup>th</sup>

meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA), 1998). Based on the data from the pesticide product submitted, the Agency, the data on geraniol from the public literature, and the data from geranyl acetate, the no adverse effects to humans would be anticipated via acute, subchronic, or chronic dietary exposures to geranyl acetate, particularly at the low levels of geraniol in the pesticide product under consideration for registration by the Agency.

#### 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).

##### A. Dietary Exposure

1. *Food.* Dietary exposure is expected to occur for most, if not all individuals to geraniol primarily from the consumption of fruits, beverages, food seasonings and its use as a flavoring agent/adjuvant in a wide variety of foods. The end-use product contains a low concentration of citronellol (0.42%) which is further reduced by dilution with water (no less than approximately 1:156 v/v) prior to application. Based on the extremely low application rate required to achieve the desired pesticidal effects, the Agency concluded that dietary exposure resulting from the proposed use on agricultural and greenhouse crops will be minimal and lower than levels of citronellol currently consumed in foods where it is naturally-occurring and/or present as a food additive.

2. *Drinking water exposure.* Geraniol residues in drinking water are expected to be minimal from its use as a pesticide. The pesticide product has a low use rate and the concentration of citronellol in the pesticide product is only 0.42%. The product is not intended for aquatic uses. Geraniol is insoluble in water and biodegrades rapidly in the soil, precluding its entry into ground and/or surface waters. Therefore, the Agency has concluded that it is highly unlikely that any residues resulting from the pesticidal use of citronellol would migrate into drinking water from natural sources.

## B. Other Non-Occupational Exposure

1. *Dermal exposure.* Non-occupational dermal exposures to geraniol from its pesticidal use are expected to be minimal to non-existent. Human dermal exposures to geraniol occur primarily from its use as a fragrance in cosmetics, soaps, detergents, creams, and lotions, not from the agricultural use as a pesticide.

2. *Inhalation exposure.* Non-occupational inhalation exposures to geraniol from its pesticidal use are expected to be minimal to non-existent. The main sources of human exposure to geraniol by this route are from its use as a fragrance in cosmetics, soaps, detergents, creams and lotions.

## V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider the "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 geraniol has a common mechanism of toxicity with any other substances. Its mode of action is as a repellent, which is considered by the Agency as a non-toxic mode of action on target pest species. Further, geraniol does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purpose of this tolerance exemption action, EPA has not assumed that geraniol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanisms 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 reasonable certainty that no harm will result from aggregate exposure to residues of geraniol to the U.S. population. This includes all anticipated dietary exposures and other exposures for which there is reliable information. The Agency arrived at this conclusion based

on the anticipated low acute exposure estimates from its pesticidal use, the low mammalian toxicity of geraniol and the widespread use of geraniol in the human diet, cosmetics and fragrances found in a variety of food products and beverages, and that geraniol is considered GRAS under 21 CFR 172.515 as a synthetic flavoring and adjuvant permitted to be added directly to food for human consumption.

2. *Infants and children.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of exposure for infants and children in the case of threshold effects. Margins of exposure are often referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness of the data base. Based on available data and other information, EPA may determine that a different margin of exposure will be safe for infants and children or that a margin of exposure approach is not appropriate. Based on all the available information the Agency reviewed on geraniol, including a lack of threshold effects, the Agency concluded that geraniol is practically non-toxic to mammals, including infants and children. Since there are no effects of concern, the provision requiring an additional margin of safety does not apply.

## VII. Other Considerations

### A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with consumption of geraniol. It is naturally occurring and a food additive in a variety of food products, and is widely used as a fragrance in the cosmetic industry. In addition, there is no evidence to suggest that geraniol affects the immune system's function in any manner.

### B. Analytical Method(s)

The Agency proposed to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including geraniol low toxicity. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for geraniol.

### C. Codex Maximum Residue Level

There are no codex maximum residue levels established for residues of geraniol.

## VIII. Objections and Hearing Requests.

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this

regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0068 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 June 28, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through

Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at

[tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.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 OPP-2004-0068, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in ADDRESSES. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **IX. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the tolerance requirement on all food commodities 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 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 the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

Thus, Executive Order 13175 does not apply to this rule.

#### X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: April 19, 2004.

**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 180.1251 is added to subpart D to read as follows:

#### § 180.1251 Geraniol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide geraniol in or on all food commodities.

[FR Doc. 04-9577 Filed 4-27-04; 8:45 am]

BILLING CODE 6560-50-S

### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Parts 0, 43, 63, and 64

[IB Docket Nos. 02-324 and 96-261, FCC 04-53]

#### In the Matter of International Settlements Policy Reform and International Settlement Rates

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document is a summary of the *Report and Order* adopted by the Commission in this proceeding. The Commission exempted the application of the International Settlements Policy (ISP) from U.S.-international routes that complied with its Benchmarks Policy. The Commission also eliminated its International Simple Resale (ISR) Policy. The Commission maintained the application of its Benchmarks Policy to all U.S.-international routes. The Commission committed to developing and releasing a Notice of Inquiry regarding the nature and effect of high foreign mobile termination rates on U.S. consumers.

**DATES:** Effective May 28, 2004 except for §§ 43.51(d), 43.51(e), 64.1001, and 64.1002(c) which contain information requirements that have not yet been approved by Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of those sections. OMB, the general public, and other Federal agencies are invited to comment on the information collection requirements on or before June 28, 2004.

**ADDRESSES:** In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov), and to Kristy L. LaLonde, OMB Desk Officer, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to [Kristy\\_L.\\_LaLonde@omb.eop.gov](mailto:Kristy_L._LaLonde@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:** James Ball, Chief, Policy Division, International Bureau, or Alexandra Field, Assistant Chief, Policy Division, International Bureau at (202) 418-1460. For additional information regarding the Paperwork Reduction Act information collections contact Judith B. Herman at 445 12th Street SW., Rm. 1-C804, Washington, DC, 20554 or via internet at [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov); phone (202) 418-0214.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Report and Order* in IB Docket No. 96-261 & 02-324; FCC 04-53, adopted March 11, 2004 and released on March 30, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The document is also available for download over the

Internet at [http://hraunfoss.fcc.gov/edocs\\_public/attachmatch/FCC-04-53A1.pdf](http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-04-53A1.pdf). The complete text may also be purchased from the Commission's copy contractor, Qualex International, in person at 445 12th Street, SW., Room CY-B402, Washington, DC 20554, via telephone at (202) 863-2893, via facsimile at (202) 863-2898, or via e-mail at [qualexint@aol.com](mailto:qualexint@aol.com). This Report and Order contains new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-3. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the modified information collections contained in this proceeding.

#### Summary of Report and Order

On October 10, 2002, the Commission adopted a Notice of Proposed Rulemaking in this proceeding 67 FR 65527 (Oct. 25, 2002) to obtain comment on proposals to modify the application of its International Settlements Policy (ISP), the competitive status of the U.S.-international telecommunications market, the success and effectiveness of Benchmarks Policy, and the issue of foreign mobile termination rates. On March 11, 2004 the Commission adopted a *Report and Order* in this proceeding. In the *Report and Order*, the Commission finds that the U.S.-international telecommunications market has been undergoing changes in recent years. There has been increasing competition on many U.S.-international routes accompanied by lower settlement rates and calling prices to U.S. customers. There also exists the potential for further development of competition as a result of emerging means of routing international traffic that do not involve the traditional carrier settlement process. At the same time, settlement rates on most routes continue to be above cost and there exists the continued potential for anticompetitive conduct and other forms of market failure. On balance, the Commission finds that the changes now unfolding in the U.S.-international market permit us to adopt a more limited application of our regulatory framework accompanied by competitive safeguards to protect U.S. customers against anticompetitive behavior. The Commission stated that, where there is vigorous competition, market forces are causing international termination rates to move toward cost on many routes.

The Commission concludes that reforming our rules to remove our International Settlements Policy (ISP)