

Commodity	Parts per million
Almond, hulls .....	80.0
Apple .....	15.0
Apple, wet pomace .....	100.0
Cherry, sweet .....	6.0
Cherry, tart .....	6.0
Citrus, dried pulp .....	100.0
Citrus, oil .....	140.0
Cucumber .....	4.0
Eggplant .....	6.0
Fruit, citrus, group 10 .....	20.0
Grape .....	5.0
Grape, raisin .....	20.0
Nut, tree, group 14 .....	0.5
Papaya .....	2.0
Peach .....	10.0
Pear .....	15.0
Plum, prune, fresh .....	4.0
Plum, prune, dried .....	20.0
Strawberry .....	10.0

(2) Tolerances are established for the combined residues of hexakis (2-methyl-2-phenylpropyl)distannoxane and its organotin metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane, and 2-methyl-2-phenylpropylstannoic acid in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat .....	0.5
Cattle, meat .....	0.5
Cattle, meat byproducts .....	0.5
Egg .....	0.1
Goat, fat .....	0.5
Goat, meat .....	0.5
Goat, meat byproducts .....	0.5
Hog, fat .....	0.5
Hog, meat .....	0.5
Hog, meat byproducts .....	0.5
Horse, fat .....	0.5
Horse, meat .....	0.5
Horse, meat byproducts .....	0.5
Milk, fat .....	0.1
Poultry, fat .....	0.1
Poultry, meat .....	0.1
Poultry, meat byproducts .....	0.1
Sheep, fat .....	0.5
Sheep, meat .....	0.5
Sheep, meat byproducts .....	0.5

\* \* \* \* \*

■ 12. Section 180.370 is amended by revising the table in paragraph (a) to read as follows:

**§ 180.370 5-Ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Barley, grain .....	0.1
Barley, hay .....	0.1
Corn, field, forage .....	0.1
Corn, field, grain .....	0.1
Corn, field, stover .....	0.1
Corn, sweet, forage .....	0.1

Commodity	Parts per million
Corn, sweet, stover .....	0.1
Cotton, gin byproducts .....	0.1
Cotton, undelinted seed .....	0.1
Peanut .....	0.1
Safflower, seed .....	0.1
Sorghum, grain, forage .....	0.1
Sorghum, grain, grain .....	0.1
Tomato .....	0.15
Vegetable, foliage of legume, group 7 .....	0.1
Vegetable, legume, group 6 .....	0.1
Wheat, forage .....	0.1
Wheat, grain .....	0.1
Wheat, straw .....	0.1

\* \* \* \* \*

**§ 180.385 [Amended]**

■ 13. Section 180.385 is amended by removing from the table in paragraph (a) the entries for “lentil, seed” and “pea seeds (dry)”.

■ 14. Section 180.395 is amended by revising the table in paragraph (a) and removing the text from paragraph (b), and reserving the paragraph designation and heading to read as follows:

**§ 180.395 Hydramethylnon; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Grass, forage .....	2.0
Grass, hay .....	2.0
Pineapple .....	0.05

(b) *Section 18 emergency exemptions.*

[Reserved]

\* \* \* \* \*

■ 15. Section 180.417 is amended by revising paragraph (a) to read as follows:

**§ 180.417 Triclopyr; tolerances for residues.**

(a) *General.* (1) Tolerances for residues of the herbicide triclopyr per se, as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Egg .....	0.05
Fish .....	3.0
Grass, forage .....	700.0
Grass, hay .....	200.0
Milk .....	0.01
Poultry, fat .....	0.1
Poultry, meat .....	0.1
Poultry, meat byproducts, except kidney .....	0.1
Rice, grain .....	0.3
Rice, straw .....	10.0

Commodity	Parts per million
Shellfish .....	3.5

(2) Tolerances for the combined residues of the herbicide triclopyr ((3,5,6-trichloro-2-pyridinyl)oxy) acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), as a result of the application/use of butoxyethyl ester of triclopyr or the triethylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat .....	0.05
Cattle, kidney .....	0.5
Cattle, liver .....	0.5
Cattle, meat .....	0.05
Cattle, meat byproducts, except kidney and liver .....	0.05
Goat, fat .....	0.05
Goat, kidney .....	0.5
Goat, liver .....	0.5
Goat, meat .....	0.05
Goat, meat byproducts, except kidney and liver .....	0.05
Hog, fat .....	0.05
Hog, kidney .....	0.5
Hog, liver .....	0.5
Hog, meat .....	0.05
Hog, meat byproducts, except kidney and liver .....	0.05
Horse, fat .....	0.05
Horse, kidney .....	0.5
Horse, liver .....	0.5
Horse, meat .....	0.05
Horse, meat byproducts, except kidney and liver .....	0.05
Sheep, fat .....	0.05
Sheep, kidney .....	0.5
Sheep, liver .....	0.5
Sheep, meat .....	0.05
Sheep, meat byproducts, except kidney and liver .....	0.05

\* \* \* \* \*

FR Doc. E7-14895 Filed 7-31-07; 8:45 am

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0289; FRL-8136-6]

**Quillaja Saponaria Extract; 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 biochemical pesticide *Quillaja saponaria* extract in or on all food commodities. Desert King

Chile, Ltd. 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 *Quillaja saponaria* extract.

**DATES:** This regulation is effective August 1, 2007. Objections and requests for hearings must be received on or before October 1, 2007, 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-2007-0289. 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 web site 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 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 Facility 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](mailto: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-2007-0289 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 October 1, 2007.

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-2007-0289, 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 March 15, 2006 (71 FR 13388) (FRL-7768-2), 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 5F6982) by Desert King Chile, Ltd., Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209 (submitted by Technology Sciences Group, Inc., 1101 17th St., NW., Suite 500, Washington, DC 20026.) The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Quillaja saponaria* extract. The notice included a summary of the petition prepared by the petitioner Desert King Chile, Ltd. 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 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.

*Quillaja saponaria*, commonly known as Soapbark tree, is a naturally occurring evergreen, originally native to the South American Andes regions. The active ingredient is a water extract from the bark of *Quillaja saponaria*. Extracts of *Quillaja saponaria* are commonly known as saponins, which belong to a group of naturally occurring glycosides produced mainly by plants that form soap-like foams in aqueous solutions. In general, saponins are found primarily in the tree bark and wood, and to a lesser extent in the leaves. They are comprised of a sugar moiety (typically glucose, galactose, glucuronic acid, xylose, rhamnose, or methylpentose) linked to a hydrophobic aglycone (sapogenin) at the C-3 (monodesmosidic) or at the C-3 and C-26 or C-28 (bidesmosidic) positions. Saponins are found in a wide variety of plants of diverse species and many are used in human food such as baked goods, candies, and soft drinks. Saponins can be used as a pesticide to inhibit the growth of pathogenic fungi

and nematodes in grapes and food crops. Saponins extracted from *Quillaja saponaria* belong to the bidesmosidic group, and are widely used in human foods.

The Food and Drug Administration (FDA) has classified *Quillaja saponaria* extract as "Generally Recognized as Safe" (GRAS). *Quillaja* extract is used in beverages and other foods with no report of any adverse effects. Other saponins are widely used in commonly consumed human food, flavoring, herbs, and spices also with no report of any adverse effects. According to the World Health Organization (WHO 2002), the established Average Daily Intake (ADI) of saponins from food additives is about 5 milligrams/kilogram body weight (mg/kg bwt). This is much higher than 0.28 mg/kg bwt which represent the calculated average daily intake of *Quillaja* saponins when used as a pesticide to treat fruits and vegetables. Moreover, up to 100 mg saponin has been measured in a kg of sugar extracted from sugar beets (*Beta vulgaris*). According to the United States Department of Agriculture, the U.S. consumption of sugar and sweeteners from sugar beet is over 80 kg a year per capita, or 8,000 mg of saponins. Furthermore, soybean flour and soybean protein has been shown to contain up to 2.5% saponin, and it has been estimated that saponins comprise the pharmacologically active components of approximately 30% of all medicinal plants.

In summary, the daily human exposure and intake of saponins for consumed foods and additives and pharmaceutical products is much higher than what would be consumed from pesticidal exposure and uses of *Quillaja* saponins. This exposure has not resulted in any adverse effects on humans. As a result, the Agency has no concerns about dietary exposure of *Quillaja* saponins.

Comprehensive reviews and risk assessment have been conducted on *Quillaja* saponins with regard to its toxicity to human health and have concluded that these saponins have low acute toxicity.

1. *Acute toxicity.* *Quillaja* saponins are in Toxicity Category III for acute oral and acute dermal toxicity, Toxicity Category I for primary eye irritation, and Toxicity Category IV for acute inhalation toxicity and primary dermal irritation. *Quillaja* saponins are not dermal sensitizers. Based on the review and analysis of the guideline studies, no additional toxicity data are required to support food or non-food uses of this compound.

2. *Mutagenicity, developmental toxicity, and immunotoxicity.* The applicant requested waivers for the mutagenicity (OPPTS Harmonized Guideline 870.5100), developmental toxicity (OPPTS Harmonized Guideline 870.3700), and immunotoxicity (OPPTS Harmonized Guideline 870.7800). *Quillaja* extracts are used as emulsifiers in baked goods, candies, frozen dairy products, gelatins, and puddings. The active ingredient is not a mutagen nor is it related to any known classes of mutagens. Chronic feeding studies have demonstrated that *Quillaja* saponins are not carcinogenic in mice or rats fed up to 2,200 mg/kg in the diet. Saponins have been demonstrated to have anticarcinogenic properties and to stimulate the immune system. Dietary levels of *Quillaja* saponin (up to 700 ppm in feed) stimulated the immune systems of piglets fed for 20 days post-weaning (Ilsey et al., 2005). Based on the information provided, the request for waivers of mutagenicity, developmental toxicity, and immunotoxicity testing requirements was granted by the Agency.

3. *Subchronic toxicity.* The requirement for a 90-day feeding study (OPPTS Harmonized Guidelines 870.3100) was satisfied by submission of a study in which *Quillaja* extract was administered to 15 CFE rats at dietary concentrations equivalent to 0, 360, 1,180, or 2,470 mg/kg bwt/day for males and 0, 440, 1,370, or 3,030 mg/kg bwt/day for females for 13 weeks. Additional groups of 5 rats were administered 0, 2.0, or 4.0% test material for 2 weeks or 6 weeks for interim evaluations. There were no treatment-related effects on mortality, clinical signs, hematology and erythrocyte osmotic fragility, clinical chemistry, urinalysis, or gross and histologic pathology. The NOAEL for the study was the highest dose tested, 2,470 mg/kg bwt/day for males and 3,030 mg/kg bwt/day for females.

### 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.* The Agency is not concerned about dietary exposure to *Quillaja* saponins because humans consume it regularly without any reports of adverse

effects. Humans are regularly exposed to *Quillaja* saponins via their use as an FDA-approved flavoring agent and food additive. Undiluted *Quillaja saponaria* extracts are used in soft drinks at levels of 100–500 mg/kg (WHO, 2002). The Joint WHO/FAO Expert Committee on Food Additives (WHO, 2002) established an acceptable daily intake (ADI) of *Quillaja* saponins of up to 5 mg/kg/day. The mean intake of *Quillaja* extracts in the U.S. just from soft drinks (the major food use) is as much as 0.54 mg/kg/day, or 11% of the ADI (WHO, 2006). According to EPA's review and calculations using a maximum use rate for up to 6 applications per season, the exposure and average daily intake of *Quillaja* saponins from treated crops is estimated to be 0.28 mg/kg bwt. This amount is well below the established ADI of 5 mg/kg bwt (WHO, 2002). Even if the use of *Quillaja* saponins exceeds the maximum proposed use rate, the Agency is not concerned about dietary exposure because of the low toxicity of this active ingredient and the history of its use without any reports of adverse effects.

2. *Drinking water exposure.* No significant drinking water exposure and residues are expected to result from the pesticidal usage of *Quillaja* saponins, especially when compared to ubiquity of the naturally occurring saponins in the environment and their widespread use at higher concentrations in food items and beverages. Moreover, saponins are widely known to biodegrade quickly in the environment. As a result, dietary and drinking water exposure to *Quillaja*'s saponins from product applications, are expected to be minimal.

#### B. Other Non-Occupational Exposure

There are no residential, school or day care uses proposed for this product. Since the proposed use pattern is for agricultural food crops, the potential for non-occupational, non-dietary exposures to *Quillaja* saponins by the general population, including infants and children, is highly unlikely.

1. *Dermal exposure.* Non-occupational dermal exposures to *Quillaja* saponins when used as a pesticide are expected to be negligible because it is limited to agricultural use.

2. *Inhalation exposure.* Non-occupational dermal exposures to *Quillaja* saponins when used as a pesticide are expected to be negligible because it is limited to agricultural use.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish an exemption from 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." These considerations include the possible cumulative effects of such residues on infants and children. EPA has considered the potential for cumulative effects of *Quillaja* saponins and other substances in relation to a common mechanism of toxicity. Common mechanisms of toxicity are not relevant to a consideration of cumulative exposure to *Quillaja* saponins because the extract is not toxic to mammalian systems. Thus, the Agency does not expect any cumulative or incremental effects from exposure to residues of *Quillaja* saponins when applied/used as directed on the label and in accordance with good agricultural practices.

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

##### A. U.S. Population

There is reasonable certainty that no harm will result from aggregate exposure to residues of *Quillaja* saponins to the U.S. population, infants, and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of *Quillaja* extract and the already widespread exposure to *Quillaja* saponins without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Moreover, *Quillaja* extracts are classified by the Food and Drug Administration (FDA) as 'Generally Recognized as Safe' (GRAS), and are also a part of the human diet when used as emulsifiers in baked goods, candies, frozen dairy products, gelatin, and puddings (WHO, 2002). Humans have had frequent physical contact with *Quillaja saponaria* with no negative health effects. Therefore, the Agency has not used a margin of exposure (safety) approach to assess the safety of saponins of *Quillaja saponaria*.

##### B. Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (also referred to as a margin of safety) for infants and children in the case of threshold effects to account for

prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all available information, the Agency concludes that *Quillaja saponaria* extract is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when *Quillaja saponaria* extract is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure approach to assess the safety of *Quillaja* saponins.

#### 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."

*Quillaja* saponins are not known endocrine disruptors nor is it related to any class of known endocrine disruptors. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this final rule for *Quillaja* saponins.

##### B. Analytical Method

Through this action, the Agency proposes to establish an exemption from the requirement of a tolerance for the saponins extracted from *Quillaja saponaria* when used on fruit and vegetable crops. For the very same reasons that support the granting of this tolerance exemption, the Agency has concluded that an analytical method is not required for enforcement purposes for these proposed uses of *Quillaja saponins*.

##### C. Codex Maximum Residue Level

There are no codex maximum residue levels established for *Quillaja* saponins.

#### VIII. Conclusions

There are no human health concerns when this food use product containing *Quillaja* saponins is applied according to label use directions. The data submitted by applicant and reviewed by the Agency support the petition for an exemption from the requirement of a tolerance for *Quillaja* saponins on food when the product is applied/used as directed on the label

and in accordance with good agricultural practices.

### IX. 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 rule has been exempted from review under Executive Order 12866, 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) 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 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.

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 6, 2000) do not apply to this rule. In addition, This 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).

### X. 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: July 15, 2007.

**Debra Edwards,**

*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 180.1278 is added to subpart D to read as follows:

#### **§ 180.1278 Quillaja saponaria extract (saponins); exemption from the requirement of a tolerance.**

Residues of the biochemical pesticide *Quillaja saponaria* extract (saponins) are exempt from the requirement of a tolerance in or on all food commodities. [FR Doc. E7-14894 Filed 7-31-07; 8:45 am]

**BILLING CODE 6560-50-S**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 1

[WT Docket No. 00-230; FCC 07-52]

### Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; clarification.

**SUMMARY:** In this document, the Federal Communications Commission ("Commission") determines that, at this time, no further revisions are necessary with regard to the existing policies and rules relating to secondary markets in radio spectrum usage rights.

**DATES:** Effective August 1, 2007.

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**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Third Report and Order (hereinafter *Third Report and Order*) in WT Docket No. 00-230, adopted on April 6, 2007, and released on April 11, 2007. This order addresses comments filed in response to the Commission's Second Further Notice of Proposed Rulemaking (*Second Further Notice*) 69 FR 77560, December 27, 2004, in this docket. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. The complete text may be purchased from the FCC's copy contractor, Best Copy & Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (800) 378-3160 or 863-2893, facsimile (202) 863-2898, or via e-mail at <http://www.bcpweb.com>. The full text is also available on the Commission's Web site at <http://www.fcc.gov>.

### Paperwork Reduction Act

This *Third Report and Order* does not contain any new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. Therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4).