Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards. We received no comments with regard to this rule and no changes have been made to this rule as proposed in the NPRM.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves the establishment of a special local regulation issued in conjunction with a permitted powerboat race event. The environmental analysis conducted for the powerboat race event permit included an analysis of the impact of the special local regulation. Based on our preliminary determination, there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental checklist and categorical exclusion determination is not required for this rule.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a new temporary § 100.T09–0238 as follows:

§ 100.T09–0238 Special Local Regulation; Detroit APBA Gold Cup; Detroit River; Detroit, MI.

(a) *Location.* The following is a temporary special local regulation area: All waters of the Detroit River, between Detroit, MI and Belle Isle, within an area bound on the west by a north-south line created by the Belle Isle Bridge, starting on land in Detroit at position 42°20′07″ N; 083°00′00″ W and extending south to a point on Belle Isle at position 42°20′04″ N; 082°59′08″ W, and bound on the east by a north-south line starting on land in Detroit at position 42°21′03″ N; 082°57′07″ W, and extending south to a point on Belle Isle at position 42°21′00″ N; 082°57′07″ W. (DATUM: NAD 83).

(b) *Effective Period.* This regulation is effective from 7 a.m. on July 7, 2010, to 7 p.m. on July 11, 2010. This regulation will be enforced daily from 7 a.m. until 7 p.m. on July 7–11, 2010.

(c) *Regulations.*

(1) In accordance with the general regulations in Section 100.35 of this part, entry into, and transiting or anchoring within this special local regulation area is prohibited unless authorized by the Captain of the Port Detroit, or his designated on-scene representative.

(2) This special local regulation area is closed to all vessel traffic, except as may be permitted by the Captain of the Port Detroit or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the special local regulation area shall contact the Captain of the Port Detroit or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the special local regulation area must comply with all directions given to them by the Captain of the Port or his on-scene representative.

Dated: June 14, 2010.

J.E. Ogden,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2010–16716 Filed 7–7–10; 11:15 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0237; FRL–8831– 4]

Terpene Constituents of the Extract of Chenopodium *ambrosioides* near *ambrosioides* (α-Terpinene, d-Limonene and p-Cymene) as Synthetically Manufactured; 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 Terpene Constituents of the Extract of Chenopodium *ambrosioides* near *ambrosioides* (α-terpinene, d-limonene and p-cymene) as Synthetically Manufactured in or on all food commodities when applied/used as a biochemical insecticide and acaricide. AgraQuest, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Terpene Constituents of the Extract of Chenopodium *ambrosioides* near *ambrosioides* (α-terpinene, d-limonene and p-cymene) as Synthetically Manufactured under FFDCA.

DATES: This regulation is effective July 9, 2010. Objections and requests for hearings must be received on or before September 7, 2010, 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–2009–0237. All documents in the docket are listed in the docket index available at *http://www.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 Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0031; e-mail address: *pfeifer.chris@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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2009–0237 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 7, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0237, by one of the following methods:

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

II. Background and Statutory Findings

In the **Federal Register** of May 6, 2009 (74 FR 20946) (FRL–8411–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7551) by AgraQuest, Incorporated, 1540 Drew Avenue, Davis, CA 95618–6320. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Terpene Constituents of the Extract of Chenopodium *ambrosioides* near *ambrosioides* (α-terpinene, d-limonene and p-cymene) as Synthetically Manufactured. The notice referenced a summary of the petition prepared by the petitioner, AgraQuest, Incorporated, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview

This active ingredient is a synthetic blend of the pesticidally active terpene constituents that are found in the Extract of Chenopodium *ambrosioides* near *ambrosioides*. Plant extracts are comprised of many constituents, some of which give the extract its pesticidal effects. The concentration of each of the terpene constituents is the same as that of the natural extract.

There are non-terpene constituents in this synthetically manufactured extract. These non-terpene constituents are pesticidally inactive and virtually non-toxic. Likewise, there are non-terpene constituents that are found in the natural extract. The non-terpene constituents found in both the natural extract and this synthetically manufactured extract have been assessed by EPA and determined not to be of toxicological concern when used in pesticide products applied to various food crops.

The terpene constituents of this synthetically manufactured extract and the natural extract are the same and therefore this tolerance exemption document focuses only on the terpene constituents. In addition, based on this determination, the toxicological information submitted in support of the tolerance exemption for Extract of Chenopodium *ambrosioides* near *ambrosioides* were used to bridge to satisfy the data requirements for this synthetically manufactured extract (74 FR 629, January 7, 2009).

B. Constituents of ECANA as Synthetically Manufactured

The three major terpene constituents of this synthetically manufactured extract are α-terpinene, p-cymene, and d-limonene. These terpene constituents occur naturally in fruits, vegetables, herbs, spices, and other foods and beverages. These three terpene constituents are found naturally in food, permitted as food and fragrance additives in the United States (U.S.) and Europe, and have been fully characterized by EPA and assessed for their uses in pesticide products applied to various food crops (Science Review in Support of the Registration of the Active Ingredient ECANA, February 2008; Science Review and Tolerance Exemption Petition Review in Support of the Registration of Requiem, October 2008). A summary description of the Agency's dietary exposure to the terpene constituents follows:

1. α-Terpinene is found in the essential oils of a variety of plants, including citrus, peppermint, thyme, basil, and papaya. Per 21 CFR 172.515, α-terpinene is permitted for direct addition to food for human consumption.

2. d-Limonene is a major terpene constituent of lemon oil, orange oil, and grapefruit oil; a minor terpene constituent of other fruits, vegetables, meats, and spices; widely used as a flavor and fragrance; and generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) as a food additive or flavoring and as a fragrance additive (21 CFR 182.60). Furthermore, d-limonene is a federally registered active ingredient in 15 pesticide products with a tolerance per 40 CFR 180.539. It is also used as a solvent or fragrance in 14 other food use pesticide products, where it is exempt from the requirement of a tolerance as an inert ingredient (40 CFR 180.910 and 40 CFR 180.930).

3. Humans regularly consume p-cymene through such foods as butter, carrots, nutmeg, orange juice, oregano, raspberries, lemon oil, and spices. p-Cymene is permitted by FDA for direct addition to food as a flavoring substance (21 CFR 172.515).

The general public is exposed daily to low levels of these terpene constituents via ingestion, dermal contact, and inhalation through consumption of foods and beverages, as well as through dermal contact with cosmetics, in excess of any exposure expected to result from the pesticidal use of this synthetically manufactured extract, all without toxicological incident to humans. The per capita daily consumption of these terpene constituents as food additives alone amounts to 13.325 milligrams (mg) in the U.S. and 40.397 mg in Europe (Ref. 4), amounts far in excess of any potential dietary exposures resulting from exposure to residues from this pesticidal extract.

C. Biochemical Pesticide Human Health Assessment Data Requirements

Acute toxicity data were submitted for this synthetically manufactured extract; all other toxicity information submitted in support of the registration and food use of this synthetically manufactured extract were bridged from the natural extract summaries of the toxicological data supporting this exemption from the requirement of a tolerance are as follows:

1. *Acute toxicity*. Acute toxicity studies, submitted to support the registration of the end-use product (EP) containing this synthetically manufactured extract indicate a low toxicity profile and support the finding that this active ingredient poses no significant human health risk with regard to food use.

a. The acute oral median lethal dose (LD_{50}) in rats for this synthetically manufactured extract was greater than 2,000 milligrams per kilogram (mg/kg) and confirmed negligible toxicity through the oral route. There were no observed toxicological effects on the test subjects in the the acute oral. (Master Record Identification Number (MRID No.) 4762704). This synthetically manufactured extract is Toxicity Category III for acute oral toxicity.

b. The acute dermal LD_{50} in rats was greater than 2,000 mg/kg for this synthetically manufactured extract. No toxic endpoints were established. These data substantiated this synthetically manufactured extract's relative dermal nontoxicity to the general public (MRID No. 4762705). This synthetically manufactured extract is Toxicity Category III for acute dermal toxicity.

c. The acute inhalation median lethal concentration (LC_{50}) for this synthetically manufactured extract was greater than 2.03 milligrams per liter (mg/L) in rats and showed no significant inhalation toxicity. No toxic endpoints were established. This synthetically manufactured extract was tested to a limit dose of 5.14 mg/L (MRID No. 48064401). This synthetically manufactured extract is Toxicity Category IV for acute inhalation toxicity.

d. Skin irritation studies on rabbits indicated that this synthetically manufactured extract was an irritant to the skin (MRID No. 48064403). This synthetically manufactured extract is Toxicity Category IV for dermal irritation.

e. Data indicated this synthetically manufactured extract is not a dermal sensitizer (MRID No. 48064404).

Data indicate that this synthetically manufactured extract is not acutely toxic. No toxic endpoints were established, and no significant toxicological effects were observed in any of the acute toxicity studies.

2. *Mutagenicity*. Three mutagenicity studies, using the natural extract as the test substance, were bridged to support this synthetically manufactured extract. These studies are sufficient to confirm that there are no expected dietary or non-occupational risks of mutagenicity with regard to new food uses for this synthetically manufactured extract. Although the natural extract and this synthetically manufactured extract have non-terpene constituents that are different, none of the constituents have been shown to present any mutagenicity or any impact on mutagenicity and therefore, the data submitted to support the natural extract demonstrates the lack

of mutagenicity of this synthetically manufactured extract.

a. The Reverse Mutation Assay (MRID No. 46456301) showed that the natural extract did not induce mutant colonies relative to control groups.

b. The *In vitro* Mammalian Cells in Culture Assay (MRID No. 46396214) demonstrated that the natural extract did not damage chromosomes in human lymphocyte cells.

c. A Deoxyribonucleic Acid (DNA) Repair Assay (MRID No. 46396215) indicated no unscheduled DNA repair in rat hepatocytes exposed to the natural extract.

3. *Subchronic toxicity*. When used as a contact insecticide, residues of this synthetically manufactured extract are not expected to result in any repeated and/or long-term exposure by the oral, dermal, or inhalation routes. As a result, waiver requests for the subchronic toxicity studies were approved, for the most part, based upon three residue studies for the natural extract, which confirm the rapid degradation of the terpene constituents in this synthetically manufactured extract.

a. A residue decline study on primrose (MRID No. 47209101) demonstrated that, when an EP containing the natural extract was applied at four times the labeled application rate, the terpene constituents were not detectable 10 minutes after application.

b. In another study, an EP containing the natural extract was applied to tomatoes four times and at twice the labeled application rate (MRID No. 46858903); residues of the terpene constituents were below the limit of quantitation (LOQ) of 0.01 mg/kg when plant samples were collected and checked at 0, 3, 6, and 24–hour intervals.

c. In the final study (MRID No. 47548301), an EP containing the natural extract was applied to mustard greens three times and at twice the labeled application rate; residues of the terpene constituents had dissipated to below the LOQ of 0.05 parts per million (ppm) at 1–4 hours after the last application.

These residue decline studies on the natural extract support the finding that there is little potential for dermal or inhalation exposure to residues of this synthetically manufactured extract based on the rapid degradation of the terpene constituents that are the principal constituents in the natural extract and this synthetically manufactured extract. Therefore, no subchronic testing is needed.

4. *Developmental toxicity*. The Agency bridged from information on the natural extract to support this synthetically manufactured extract. The information from the open scientific literature characterizes the developmental toxicity of the terpene constituents and satisfies the data requirements for developmental and reproductive toxicity for this synthetically manufactured extract (Refs. 1, 2, 3, and 4). The information established that none of the terpene constituents in this synthetically manufactured extract are developmental or reproductive toxicants. The data submitted to support the natural extract appropriately demonstrates the lack of developmental toxicity of this synthetically manufactured extract.

The information established a conservative maternal no observable adverse effect level (NOAEL) of 60 mg/kg per day and a developmental NOAEL of 30 mg/kg per day. These levels greatly exceed any potential dietary exposure, as discussed above in Unit III.C.3., from the use of this synthetically manufactured extract and confirm the lack of risk for developmental toxicity, even in a worst-case scenario.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary exposure to the residues of this synthetically manufactured extract is expected to be virtually nonexistent. Even in the event of exposure, the information supporting this tolerance exemption demonstrates that any dietary risks would be negligible.

1. *Food*. The pesticidal use of this synthetically manufactured extract is not expected to result in any dietary exposure. Three residue decline studies on the natural extract show that rapid degradation of the terpene constituents of this synthetically manufactured extract. A detailed discussion of those studies can be found in Unit III.C.3. In sum, these data demonstrate that, by the time this synthetically manufactured extract has dried on the plant, there is no detectable residual product.

2. *Drinking water exposure*. Exposure of humans to this synthetically manufactured extract in drinking water is unlikely because associated pesticide products are labeled for applications directly to terrestrial plants and because any residues would have significantly degraded in the advance of any rainfall event. Low application rates and rapid biodegradation in water (an aqueous half life of 36.11 hours for the natural extract) further reduce the potential for drinking water exposure.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because this synthetically manufactured extract is not approved for residential uses and the active ingredient is applied directly to food commodities and degrades rapidly.

1. *Dermal exposure*. Non-occupational dermal exposures to this synthetically manufactured extract are expected to be negligible because of its directed agricultural use. In the event of dermal exposure to residues, because of the non-toxic profile of this synthetically manufactured extract (as described in Unit III.), use of this synthetically manufactured extract is not expected to result in any risks through this route of exposure.

2. *Inhalation exposure*. Non-occupational inhalation exposures are not expected to result from the agricultural uses of this synthetically manufactured extract. Any inhalation exposure associated with this agricultural use pattern is expected to be occupational in nature.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found this synthetically manufactured extract to share a common mechanism of toxicity with any other substances, and this synthetically manufactured extract does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that this synthetically manufactured extract does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

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

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold 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 safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Health risks to humans, including infants and children, are considered negligible with regard to the pesticidal use of this synthetically manufactured extract. Toxicity information submitted in support of the application for this synthetically manufactured extract demonstrates that the active ingredient has negligible toxicity. In addition, the terpene constituents of this synthetically manufactured extract are ubiquitous in nature and present in a multitude of fruits and vegetables and, to date, there is no history of toxicological incident involving their consumption. As discussed earlier, the terpene constituents of this synthetically manufactured extract are approved as direct food additives by the FDA. Most importantly, however, exposure to the residues of this synthetically manufactured extract are not expected. Pesticidal applications are applied directly to commercial crops, and data confirm that detectable residues do not persist beyond the time for this synthetically manufactured extract to dry on to foliar surfaces. As such, the Agency has determined that this food use of this synthetically manufactured extract poses no foreseeable risks to human health or the environment. There is a reasonable certainty that no harm will result to the general U.S. population, including infants and children, from aggregate exposure to residues of this synthetically manufactured extract.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for Terpene Constituents (α-terpinene, d-limonene and p-cymene) of the Extract of Chenopodium *ambrosioides* near *ambrosioides* as Synthetically Manufactured.

VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of this synthetically manufactured extract. Therefore, an exemption is established for residues of Terpene Constituents (α-terpinene, d-limonene and p-cymene) of the Extract Chenopodium *ambrosioides* near *ambrosioides* as Synthetically Manufactured in or on all food commodities.

IX. References

1. Araujo IB, Souza CAM, De-Carvalho RR, Kuriyama SN, Rodrigues RP, Vollmer RS, Alves EN, Paumgartten FJR. 1996. Study of the embryofoetotoxicity of α-terpinene in the rat. Food and Chemical Toxicology 34:477–482.

2. Cornell University. 2008. Medicinal Plants Website. Medicinal Plants for Livestock, Beneficial or Toxic? Available from *http://www.ansci.comell.edu/plants/medicinal/plants.html*.

3. Flavor and Fragrance High Production Volume Consortia (FFHPVC). 2002. The Terpene Consortium: Test Plan for Aromatic Terpene Hydrocarbons.

4. World Health Organization (WHO). 2005. Evaluation of Certain Food Additives. WHO Technical Report Series No. 928. Sixty-third Report of the Joint FAO/WHO Expert Committee on Food Additives.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between

the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not 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: June 30, 2010.

Martha Monell,

Acting 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 180.1296 is added to subpart D to read as follows:

§ 180.1296 Terpene Constituents α-terpinene, d-limonene and p-cymene, of the Extract of Chenopodium *ambrosioides* near *ambrosioides* as Synthetically Manufactured; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the biochemical pesticide Terpene Constituents α-terpinene, d-limonene and p-cymene, of the Extract of Chenopodium *ambrosioides* near *ambrosioides* as Synthetically Manufactured when used as an insecticide/acaricide in or on all food commodities.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1187; FRL–8831–2]

Homobrassinolide; 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 homobrassinolide in or on all food commodities when applied/used as a plant growth regulator in accordance with good agricultural practices. Repar Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of homobrassinolide under the FFDCA.

DATES: This regulation is effective July 9, 2010. Objections and requests for hearings must be received on or before September 7, 2010, 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–2007–1187. All documents in the docket are listed in the docket index available at *http://www.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 Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John Fournier, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0169; e-mail address: *fournier.john@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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2007–1187 in the subject line on