contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Effective period.* This section is effective from 11 a.m. through 9 p.m. on September 17, 2011.

Dated: August 19, 2011.

Cynthia L. Stowe,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2011–22773 Filed 9–6–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0271; FRL: 8882–4]

Lipase, Triacylglycerol; 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 lipase, triacylglycerol (CAS Reg. No. 9001–62–1) when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 500 parts per million (ppm). Novozymes North America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of lipase, triacylglycerol.

DATES: This regulation is effective September 7, 2011. Objections and requests for hearings must be received on or before November 7, 2011, 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–2010–0271 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 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: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8560 *e-mail address: fertich.elizabeth@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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–2010–0271 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 November 7, 2011. 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–2010–0271, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket 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. Petition for Exemption

In the **Federal Register** of February 25, 2011 (76 FR 1058) (FRL–8863–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7697) by Novozymes North America, Inc., P.O. Box 576, 77

Perry Chapel Church Road, Franklinton, NC 27525. The petition requested that 40 CFR 180.950 be amended by establishing an exemption from the requirement of a tolerance for residues of lipase, triacylglycerol (CAS Reg. No. 9001–62–(1), Hereafter referred to as triacylglycerol lipase, when used as an inert ingredient as an aid in the removal of lipids in antimicrobial pesticide formulations applied to food contact surfaces. That notice referenced a summary of the petition prepared by Novozymes North America, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the exemption requested by establishing an exemption from the requirement under 40 CFR 180.940(a) with a limitation of triacylglycerol lipase of 500 ppm in final pesticide formulations. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document ''PC Code 908800: Lipase, triacylglycerol lipase (CAS Reg. No. 9001–62–1); Human Health Risk Assessment and Ecological Effects Assessment to the Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations'' in docket ID number EPA–HQ–OPP–2010–0271.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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 tolerance is ''safe.'' Section 408(b)(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. Section 408(b)(2)(C) of FFDCA requires 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. * * *''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for triacylglycerol lipase including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with triacylglycerol lipase follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies 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.

The toxicology database is adequate to support the use of triacylglycerol lipase as a component of food contact sanitizing solutions. Triacylglycerol lipases are a class of lipase enzymes that catalyze the hydrolysis of fatty acid ester bonds in the triacylglycerol molecule in aqueous solutions. Like other enzymes, triacylglycerol lipase is a protein that acts as a catalyst to increase the rate of chemical reactions and is produced by all living cells.

The acute toxicity studies of triacylglycerol lipase show low toxicity. The test material is not acutely toxic by the oral or inhalation routes. It is also not a dermal irritant, eye irritant or dermal sensitizer.

Triacylglycerol lipase was also not toxic in short-term studies. In a 2 week study, Sprague-Dawley rats were dosed once daily by gavage at dose levels of 0, 0.2, 2 or 10 grams kilogram day (g/kg/day) and in a second 13 week study, Sprague-Dawley rats were administered the same test material at dose levels of 0, 0.2, 1 and 5 g/kg/day. There were no treatment related clinical signs, nor any toxicity seen in either study.

In a 2-generation reproductive toxicity study in Sprague-Dawley rats, triacylglycerol lipase was administered orally to 5 treatment groups of rats. Each group contained 24 males and 24 females and received diets containing 0, 0.5, 1.5 or 5.0% of the test material by weight in the diet (equivalent to 0, 500, 1,500 or 5,000 milligrams kilogram body weight day (mg/kg/bw/day). There were no effects of treatment with the test material on either F_0 or F_1 fertility, general reproductive performance and systemic toxicity at exposure levels of up to 5,000 mg/kg/bw/day. No treatment related effects were observed on the developmental parameters evaluated in this study at doses up to and including 5,000 mg/kg/day.

As with other proteins, inhalation exposure to lipases may lead to potential respiratory (Type 1) allergy.

Specific information on the studies received and the nature of the adverse effects caused by triacylglycerol lipase as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''PC Code 908800: Lipase, triacylglycerol (CAS Reg. No. 9001–62–1); Human Health Risk Assessment and Ecological Effects Assessment to the Support Proposed Exemption from the Requirement of a Tolerance When Used

as an Inert Ingredient in Pesticide Formulations,'' p. 7 in docket ID number EPA–HQ–OPP–2010–0271.

B. Toxicological Points of Departure/ Levels of Concern

Triacylglycerol lipase is not toxic by the oral or dermal routes. No toxicity endpoint of concern was identified in the available toxicity studies. There were also no adverse effects observed in acute toxicity studies and short-term toxicity studies at doses up to 10 kg/day. No toxicity was observed in a 2-generation reproductive toxicity study in rats at doses up to 5% (equivalent to 5,000 mg/kg/bw/day). A quantitative risk assessment for the dietary and residential exposure from the oral and dermal routes is not necessary since no endpoint of concern was identified in the available database. Inhalation exposure to enzymes, including triacylglycerol lipase, may lead to potential respiratory (Type 1) allergy.

C. Exposure Assessment

Lipases are necessary for lipid metabolism and are found in almost all living organisms, as well as being regularly consumed in foods. As with other enzymes, lipases are common in fresh and processed foods and are consumed by humans every day.

No hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), or for the short, intermediate, and long term dermal residential assessments, therefore, acute and chronic dietary and short-, intermediate-, and long-term dermal residential exposure assessments were not performed.

Residential (dermal and inhalation) exposures to triacylglycerol lipase from home uses, such as components of laundry detergents and food contact surface sanitizing solutions, are also possible. The limitation of 500 ppm for tricylglycerol lipase in final pesticide formulations will result in exposures several orders of magnitude at or below 1 nanogram per cubic meter (ng/m^3), the common level at which allergic symptoms have not been observed.

D. 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 triacylglycerol lipase to share a common mechanism of toxicity with any other substances, and triacylglycerol lipase does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triacylglycerol lipase 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

E. Safety Factor for Infants and Children

In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

No developmental toxicity studies are available in the database. However, there were no adverse effects in a 2-generation reproductive toxicity study in rats at doses up to 5% (equivalent to 5,000 mg/kg/bw/day). Also no systemic toxicity was observed at doses up to 10 g/kg/day in a 2-week, sub-acute oral toxicity study in rats and no systemic toxicity observed at 5 g/kg/day in a 13-week oral toxicity study in rats. No systemic toxicity was observed in laboratory animals at high doses, indicating relatively low hazard potential. There was no evidence of clinical signs of neurotoxicity; therefore, developmental neurotoxicity study is not required. In addition, no evidence of immunotoxicity was seen in the database; therefore, an immunotoxicity study is not required. In terms of hazard, there are low concerns and no residual uncertainties regarding prenatal and/or postnatal toxicity. Based on this information, there is no concern at this time for increased sensitivity to infants and children to triacylglycerol lipase when used as an inert ingredient in pesticide formulations and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

F. Aggregate Risks and Determination of Safety

Given the lack of concern for hazard posed by triacylglycerol lipase, EPA concludes that there are no dietary or aggregate dietary/non-dietary risks of concern as a result of exposure to triacylglycerol lipase in food and water or from residential exposure. Residues of concern are not anticipated for dietary exposure (food and drinking water) or for residential exposure (dermal) from the use of triacylglycerol lipase as an inert ingredient in pesticide products. As discussed in this unit, EPA expects aggregate exposure to triacylglycerol lipase to pose no appreciable dietary risk given that the data show a lack of systemic toxicity at doses up to 5,000 mg/kg/day and a lack of any apparent developmental effects. Inhalation exposure to enzymes, including triacylglycerol lipase, may lead to potential respiratory (Type 1) allergy. Although there is no well-defined threshold for the induction of sensitization to the potential allergic effects from exposure to enzymes such as triacylglycerol lipase, allergic symptoms have not been observed when inhalation exposure levels are at or below 1 ng/m^3. A limitation of 500 ppm of triacylglycerol lipase in final pesticide formulations will result in exposures several orders of magnitude below 1 ng/m^3. This limitation will ensure that inhalation exposures to triacylglycerol lipase will be below the threshold for adverse respiratory effects and is protective of any potential respiratory allergy concerns.

Taking into consideration all available information on triacylglycerol lipase at a maximum of 500 ppm in final pesticide formulations, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to triacylglycerol lipase under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.940(a) for residues of triacylglycerol lipase when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 500 ppm is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of triacylglycerol lipase in or on any food commodities. EPA is establishing a limitation on the amount of triacylglycerol lipase that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for which the final end use concentration of triacylglcyerol lipase in antimicrobial, food contact surface sanitizing solutions would exceed 500 ppm.

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 triacylglycerol lipase.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for residues of lipase, triacylglycerol (CAS Reg. No 9001–62–1) when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 500 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, 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 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) (Pub. L. 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).

VIII. 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: August 26, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.940(a), the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
* * *	*	* * *
Lipase, triacylglycerol	9001–62–1	When ready for use, the end-use concentration is not to exceed 500 ppm.
* * *	*	* * *

* * * * *

[FR Doc. 2011–22844 Filed 9–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0054; FRL–8887–4]

Chromobacterium subtsugae Strain PRAA4–1^T; 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 *Chromobacterium subtsugae* strain PRAA4–1^T in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices. Marrone Bio Innovations, Inc. 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 *Chromobacterium subtsugae* strain PRAA4–1^T under the FFDCA.

DATES: This regulation is effective September 7, 2011. Objections and requests for hearings must be received on or before November 7, 2011, 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–2010–0054. 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: Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8920; *e-mail address: kausch.jeannine@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:

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- 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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2010–0054 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 November 7, 2011. 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–2010–0054, 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.
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