

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<sup>T</sup>; 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<sup>T</sup> 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<sup>T</sup> 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](mailto: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:

- 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](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.
- **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 March 10, 2010 (75 FR 11171) (FRL-8810-8), 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 9F7674) by Marrone Bio Innovations, Inc., 2121 Second Street, Suite B-107, Davis, CA 95618. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>. This notice referenced a summary of the petition prepared by the petitioner, Marrone Bio Innovations, Inc., which is available in the docket via <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 exemption 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 EPA consider "available information concerning the cumulative effects of [a particular pesticide's] \* \* \* residues and other substances that have a common mechanism of toxicity."

EPA 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 of *Chromobacterium subtsugae* Strain PRAA4-1<sup>T</sup>

*Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> is a naturally occurring, gram-negative, violet-pigmented bacterium that was isolated from soil under an eastern hemlock (*Tsuga canadensis*) in the Catocin Mountain region of central Maryland. The United States Department of Agriculture found this isolate of *Chromobacterium subtsugae* to be orally toxic to Colorado potato beetle (*Leptinotarsa decemlineata*) larvae, small hive beetle (*Aethina tumida*) larvae, southern corn rootworm (*Diabrotica undecimpunctata*) larvae and adults, and southern green stink bug (*Nezara viridula*) adults. Additional testing has shown that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>-treated diet resulted in reduced feeding in beet armyworm (*Spodoptera exigua*), cabbage looper (*Trichoplusia ni*), tobacco budworm (*Heliothis virescens*), diamondback moth (*Plutella xylostella*), and southern corn rootworm, suggesting this microbe's insecticidal activity is due to reduction in weight or inhibition of feeding. In light of the demonstrated insecticidal and miticidal capabilities of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>, Marrone Bio Innovations, Inc. has proposed to register pesticide products that could be applied to agricultural and greenhouse crops, including vegetables, fruit, flowers, bedding plants, ornamentals, and turf, to control certain insect and mite pests.

### B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the request for an exemption from the requirement of a

tolerance for residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> in or on all food commodities have been fulfilled with data submitted by the petitioner or data waiver requests that have been granted by EPA. The toxicity tests (acute oral, dermal, and inhalation toxicity) and irritation tests (acute eye and primary dermal irritation), which addressed potential routes of exposure to the active ingredient, were all classified in Toxicity Category IV (see 40 CFR 156.62). Moreover, an acute injection toxicity/pathogenicity test indicated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic, infective, and/or pathogenic via the intravenous route of exposure, a worst-case scenario whereby the skin is bypassed as a barrier. Finally, *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> is not recognized as a dermal sensitizer, and the petitioner has reported that no hypersensitivity incidents occurred during development and testing of this bacterium. The overall conclusions from all toxicological information submitted by the petitioner are described below, while more in-depth synopses of the study results can be found in the associated Biopesticides Registration Action Document provided as a reference in Unit IX. (Ref. 1).

1. *Acute oral toxicity—rat* (Harmonized Guideline 870.1100; Master Record Identification Number (MRID No.) 479450-03). An acceptable acute oral toxicity study demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic to female rats when dosed at 5,000 milligrams per kilogram (mg/kg). The median lethal dose (LD<sub>50</sub>) (i.e., a statistically derived single dose that can be expected to cause death in 50% of test animals) was greater than 5,000 mg/kg (Toxicity Category IV).

2. *Acute oral toxicity/pathogenicity* (Harmonized Guideline 885.3050; MRID No. 479450-23). Upon consideration of results of other definitive toxicological data submitted by the petitioner, EPA waived acute oral toxicity/pathogenicity testing for *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>. An acute oral toxicity study conducted on rats (MRID No. 479450-03) demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic (LD<sub>50</sub> greater than 5,000 mg/kg; Toxicity Category IV), while an acute injection toxicity/pathogenicity study conducted on rats (MRID No. 479450-11) showed that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic, infective, and/or pathogenic when the skin was bypassed as a barrier. EPA believes these data, when taken together, clearly

indicate that this bacterium would not be toxic, infective, and/or pathogenic through the oral route of exposure and that further testing is not necessary.

3. *Acute inhalation toxicity—rat* (Harmonized Guideline 870.1300; MRID No. 479450-05). An acceptable acute inhalation toxicity study demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic to male and female rats when exposed to 2.12 milligrams per liter (mg/L). The median lethal concentration (LC<sub>50</sub>) (*i.e.*, a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals) was greater than 2.12 mg/L (Toxicity Category IV).

4. *Acute pulmonary toxicity/pathogenicity* (Harmonized Guideline 885.3150; MRID No. 479450-23). Upon consideration of results of other definitive toxicological data submitted by the petitioner, EPA waived acute pulmonary toxicity/pathogenicity testing for *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>. An acute inhalation toxicity study conducted on rats (MRID No. 479450-05) demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic (LC<sub>50</sub> greater than 2.12 mg/L; Toxicity Category IV), while an acute injection toxicity/pathogenicity study conducted on rats (MRID No. 479450-11) showed that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic, infective, and/or pathogenic when the skin was bypassed as a barrier. EPA believes these data, when taken together, clearly indicate that this bacterium would not be toxic, infective, and/or pathogenic through the inhalation route of exposure and that further testing is not necessary.

5. *Acute injection toxicity/pathogenicity (intravenous)—rat* (Harmonized Guideline 885.3200; MRID No. 479450-11). An acceptable acute injection toxicity and pathogenicity (intravenous) demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic, infective, and/or pathogenic to rats when dosed intravenously at  $3.1 \times 10^6$  colony-forming units per animal.

6. *Acute dermal toxicity—rat* (Harmonized Guideline 870.1200; MRID No. 479450-04). An acceptable acute dermal toxicity study demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not toxic to rats when dosed at 5,050 mg/kg. The LD<sub>50</sub> was greater than 5,050 mg/kg (Toxicity Category IV).

7. *Acute eye irritation—rabbit* (Harmonized Guideline 870.2400; MRID No. 479450-06). An acceptable acute eye irritation study demonstrated that *Chromobacterium subtsugae* strain

PRAA4-1<sup>T</sup> was minimally irritating to the eyes of rabbits (irritation symptoms cleared by 24 hours; Toxicity Category IV).

8. *Primary dermal irritation—rabbit* (Harmonized Guideline 870.2500; MRID No. 479450-07). An acceptable primary dermal irritation study demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was slightly irritating to the skin of rabbits (irritation symptoms cleared by 24 hours; Toxicity Category IV).

9. *Dermal sensitization—guinea pig* (Harmonized Guideline 870.2600; MRID No. 479450-08). An acceptable dermal sensitization study demonstrated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> was not a dermal sensitizer to guinea pigs.

#### IV. Aggregate Exposure

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 this microbial pesticide may occur (more likely through food than drinking water); however, the lack of acute oral toxicity, as exhibited in a toxicology test on rats, and the rationales justifying the waiver of acute oral toxicity/pathogenicity testing (see Unit III.B.), support the establishment of a tolerance exemption for residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>.

1. *Food exposure.* Any exposure to this naturally occurring soil bacterium is anticipated to be negligible. Although *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> may be applied directly to food, it is not expected to persist or accumulate in any reservoirs on plants or food commodities (the phyllosphere) because, as a soil microorganism, it is best adapted to more favorable conditions underground. Rather, after application, it likely will degrade due to predation by other biological organisms (*e.g.*, protists) and exposure to particular environmental factors (*e.g.*, sunlight and varying temperatures) (Refs. 2 and 3). Should this microbial pesticide be present on food, the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity and/or pathogenicity is likely to occur with any exposure level of *Chromobacterium subtsugae* strain

PRAA4-1<sup>T</sup> (see additional discussion in Unit III.B.).

2. *Drinking water exposure.* Exposure of humans to residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> in consumed drinking water is unlikely. The proposed use patterns for *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> do not include direct application to aquatic environments, thereby limiting contact with surface water. Furthermore, ground water is not expected to have significant exposure to *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> since, like other microorganisms, this bacterium would likely be filtered out by the particulate nature of many soil types (Refs. 4, 5, and 6) and is not known to survive in water or deep soil. If *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> were to be transferred to surface or ground waters that are intended for eventual human consumption (*e.g.*, through spray drift or runoff) and directed to wastewater treatment systems or drinking water facilities, it likely would not survive the conditions water is subjected to in such systems or facilities, including high temperatures, chlorination, pH adjustments, and/or filtration (Refs. 7 and 8). In the remote likelihood that this microbial pesticide is present in drinking water (*e.g.*, in water not subject to treatment systems or facilities), the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity and/or pathogenicity is likely to occur with any exposure level of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> (see additional discussion in Unit III.B.).

##### B. Other Non-Occupational Exposure

Dermal and inhalation non-occupational exposure to *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> is not expected as all proposed pesticide applications will take place in distinct agricultural settings. Even if dermal and inhalation non-occupational exposures were to occur, such exposures would not exceed EPA's level of concern given testing that indicated that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> is not toxic (acute inhalation and dermal toxicity), is only slightly irritating (primary dermal irritation), is not a sensitizer (dermal sensitization), and is not pathogenic or infective (acute injection toxicity/pathogenicity) (see additional discussion in Unit III.B.).

#### 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 exemption, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] \* \* \* residues and other substances that have a common mechanism of toxicity.”

EPA has not found *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> to share a common mechanism of toxicity with any other substances, and *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> that need to be considered. 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>.

#### VI. Determination of Safety for 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 (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 that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. 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.

Based on the acute toxicity and pathogenicity data/information discussed in Unit III.B., EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>. Such exposure

includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because, considered collectively, the data (e.g., lack of toxicity noted for oral, dermal, and inhalation routes of exposure) available on *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> do not demonstrate toxic, pathogenic, and/or infective potential to sensitive populations from exposure to this microbial pest control agent. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

#### VII. Other Considerations

##### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since EPA 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. In this context, 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 *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>.

#### VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>. Therefore, an exemption from the requirement of a tolerance is established for residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices.

#### IX. References

1. U.S. EPA. 2011. *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> Biopesticides Registration Action Document dated July 2011 (available as “Supporting & Related Material” within docket ID number EPA-HQ-OPP-2010-0058 at <http://www.regulations.gov>).
2. U.S. EPA. 1996. Microbial Pesticide Test Guidelines—Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from [http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series885.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm).
3. Lindow SE, Brandl MT. 2003. Microbiology of the phyllosphere. *Applied and Environmental Microbiology* 69:1875–1883.
4. Pang L, McLeod M, Aislabie J, Simunek J, Close M, Hector R. 2008. Modeling transport of microbes in ten undisturbed soils under effluent irrigation. *Vadose Zone Journal* 7:97–111.
5. Aislabie J, Smith JJ, Fraser R, McLeod M. 2001. Leaching of bacterial indicators of faecal contamination through four New Zealand soils. *Australian Journal of Soil Research* 39:1397–1406.
6. DeFelice K, Wollenhaupt N, Buchholz D. 1993. Aquifers and Soil Filter Effect. Available from <http://extension.missouri.edu/p/WQ24>.
7. U.S. EPA. 2004. Primer for Municipal Wastewater Treatment Systems. EPA 832-R-04-001. Available from <http://www.epa.gov/npdes/pubs/primer.pdf>.
8. Centers for Disease Control and Prevention. 2009. Drinking Water—Water Treatment. Available from [http://www.cdc.gov/healthywater/drinking/public/water\\_treatment.html](http://www.cdc.gov/healthywater/drinking/public/water_treatment.html).

#### 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 EPA. 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA 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, EPA 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 EPA 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: August 26, 2011.

**Steven Bradbury**,  
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 180.1305 is added to subpart D to read as follows:

### § 180.1305 *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup>; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Chromobacterium subtsugae* strain PRAA4-1<sup>T</sup> in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices.

[FR Doc. 2011-22868 Filed 9-6-11; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2007-0099; FRL-8870-8]

### Flubendiamide; Pesticide Tolerances; Technical Amendment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; technical amendment.

**SUMMARY:** This document is being issued to correctly revise tolerance levels, for the pesticide, flubendiamide in or on the meat and meat byproducts of cattle, goat, hog, horse, and sheep. The tolerance levels were inadvertently transcribed incorrectly in a final rule printed in the **Federal Register** on March 23, 2011.

**DATES:** This final rule is effective September 7, 2011.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0099. All documents in the docket are listed in the docket index available in <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:

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### SUPPLEMENTARY INFORMATION:

#### I. Does this action apply to me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### II. What does this technical amendment do?

In the **Federal Register** of March 23, 2011 (75 FR 16301) (FRL-8863-8), EPA issued a final rule establishing new tolerances and revising existing tolerances for residues of flubendiamide (40 CFR 180.639) on certain food and livestock commodities. Inadvertently, a few of the tolerance levels were transcribed incorrectly, and consequently, 40 CFR 180.639(a)(2) provides an incorrect tolerance value for the established tolerances for cattle, meat (0.60 ppm); cattle, meat byproducts (0.08 ppm); goat, meat (0.60 ppm); goat, meat byproducts (0.08 ppm); hog, meat (0.15 ppm); hog, meat byproducts (0.03 ppm); horse, meat (0.60 ppm); horse, meat byproducts (0.08 ppm); sheep, meat (0.60 ppm); and sheep, meat byproducts (0.08 ppm). As supported by recalculated beef and dairy cattle, swine, and poultry dietary burdens, and re-evaluation of previously submitted animal feeding studies, these tolerance values should be revised to 0.08 ppm; 0.60 ppm; 0.08 ppm; 0.60