ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0179; FRL–8831–9]

Pasteuria usgae; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Pasteuria usgae*, in or on all food commodities when applied preharvest and used as a nematicide in accordance with good agricultural practices. MacIntosh and Associates Incorporated (on behalf of Pasteuria Bioscience 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 *Pasteuria usgae*.

DATES: This regulation is effective June 30, 2010. Objections and requests for hearings must be received on or before August 30, 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–2009–0179. 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), 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:

- 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*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* 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–2009–0179 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 August 30, 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–2009–0179, 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 April 8, 2009 (74 FR 15969) (FRL–8407–6), 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 9F7539) by MacIntosh and Associates Incorporated, 1203 Hartford Avenue, Saint Paul, MN 55116–1622 (on behalf of Pasteuria Bioscience Incorporated, 12085 Research Drive, Suite 185, Alachua, FL 32615). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pasteuria usgae*. This notice referenced a summary of the petition prepared by the petitioner, MacIntosh and Associates Incorporated (on behalf of Pasteuria Bioscience Incorporated), which is available in the docket, *http://www.regulations.gov*. There were no substantive 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.

Pasteuria, a genus of bacteria, includes a number of species that have shown potential in controlling plant-parasitic nematodes. These bacteria are obligate endoparasites, organisms that grow internally in a limited range of hosts. *Pasteuria usgae*, a recently discovered strain isolated from soil samples collected in Florida, is host-specific for the sting nematode [*Belonolaimus longicaudatus*]. This strain of *Pasteuria* is pending recognition by the Judicial Commission of the International Committee for Systematic Bacteriology. There is sufficient evidence from morphology, host specificity, and genomics to justify *Pasteuria usgae* as a distinct strain. In developing products for crop applications, such as uses on strawberries and a wide variety of vegetables, the difficulty of growing *Pasteuria* outside of a nematode host has always been an obstacle. This host specificity is at the core of EPA's conclusions that *Pasteuria usgae* may be granted a permanent exemption from the requirement of a tolerance for all food commodities. Additional information regarding *Pasteuria usgae* can be found in the Biopesticides Registration Action Document (BRAD) on the Biopesticides and Pollution Prevention Division (BPPD) website: *http://www.epa.gov/pesticides/biopesticides*.

Studies submitted to the Agency were issued Master Record Identification (MRID) Numbers and reviewed by BPPD scientists. The following summaries of the toxicological profile of *Pasteuria usgae* are based on an Agency risk assessment memorandum and related data evaluation records dated April 9, 2009.

a. *Acute Oral Toxicity and Pathogenicity - Rat*: Harmonized Test Guideline 885.3050; MRID No. 474267–09. *Pasteuria usgae* does not appear to be toxic and/or pathogenic in rats when dosed at 1 x 10^8 spores/animal. There were no treatment-related clinical signs or necropsy findings in rats receiving a single oral dose of 1 x 10^8 *Pasteuria usgae* spores. Three males in the microbial pest control agent (MPCA) - treated group gained weight through day 14 but lost weight by day 21. All other animals gained weight prior to scheduled sacrifice. Microbial enumeration was not performed because the testing laboratory showed that the test material would not grow on agar media. Therefore, while no significant adverse effects were seen, the typical clearance of the microbe could not be confirmed. However, because the spores are highly specific to sting nematode, infectivity is unlikely to be a concern. This study was rated "Acceptable," and *Pasteuria usgae* was classified as Toxicity Category IV.

b. *Acute Injection Toxicity and Pathogenicity - Rat*: Harmonized Test Guideline 885.3200; MRID No. 474267–11. There were no treatment-related significant adverse effects seen in the rats receiving a single intravenous dose of 10^8 *Pasteuria usgae* spores. One treated female lost weight by day 7 but gained weight prior to sacrifice on day 14. All other animals gained weight throughout the study. All animals survived and appeared normal during the study. No abnormalities were observed in any animal at necropsy or in harvested organs. No significant variations in organ weight were found between different groups or sexes. The acute intravenous median lethal dose (LD_{50}) of *Pasteuria usgae* was greater than 1 x 10^8 spores/animal in male and female rats. *Pasteuria usgae* does not appear to be toxic and/or pathogenic in rats when dosed at 10^8 spores/animal. MRID No. 474267–09 reported that microbial enumeration was not done because the test material would not grow on agar media. Since microbial enumeration was not performed, the infectivity was uncertain. However, because the spores are highly specific to sting nematode, infectivity is unlikely to be a concern. *Pasteuria usgae* was not pathogenic as tested in this study. This study was rated as "Acceptable."

c. *Acute Dermal Toxicity - Rat*: Harmonized Test Guideline 885.3100; MRID No. 474267–12. Based on the results of this study, *Pasteuria usgae* does not appear to be toxic in rats when treated with 2,000 milligrams/kilogram (mg/kg) at 10^8 spores/milliliter (mL). Thus, the acute dermal LD_{50} was greater than 2,000 mg/kg for 10^8 spores/mL in male and female rats. There were no treatment-related significant adverse effects seen in the dosed rats. Two males and one female had very slight erythema on day 1 with clearance by day 4. One male lost weight slightly during the second week and one male and two females lost weight during the first week, but all gained weight by the end of the study. All other animals gained weight throughout the study. This study was rated "Acceptable," and *Pasteuria usgae* was classified as Toxicity Category IV.

d. *Acute Pulmonary Toxicity and Pathogenicity - Rat*: Harmonized Test Guideline 885.3150; MRID No. 474267–10. In an acute pulmonary toxicity and pathogenicity assessment, there were no test substance-related significant adverse effects seen in rats receiving a single dose of approximately 1–3 x 10^8 spores of *Pasteuria usgae*. One dosed female exhibited pale lungs. Additionally, one untreated control female lost weight by day 21, and another untreated control female lost weight by day 14 but gained weight by day 21. One MPCA-treated male did not gain weight by day 7 but gained weight thereafter. All other animals gained weight throughout the study. Based on these results, *Pasteuria usgae* does not appear to be toxic and/or pathogenic in rats when dosed at approximately 1–3 x 10^8 spores/animal. Microbial enumeration was not performed because the testing laboratory showed that the

test material would not grow on agar media. Therefore, while no significant adverse effects were seen, the typical clearance of the microbe could not be confirmed. However, because the spores are highly specific to sting nematode, infectivity is unlikely to be a concern. This study was rated "Acceptable," and *Pasteuria usgae* was classified as Toxicity Category IV.

e. *Hypersensitivity Incidents*: Harmonized Test Guideline 885.3400; MRID No. 474350–02. No hypersensitivity incidents—involving *Pasteuria usgae* and occurring during fermentation, processing, formulation, or research—have been reported to the Agency. Any future hypersensitivity incidents must be reported per Harmonized Test Guideline 885.3400.

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 *Pasteuria usgae* may occur, mainly through food. However, the lack of acute oral toxicity/pathogenicity, based on the toxicology test on rats presented in Unit III., along with the inability of the bacterium to grow outside of a specific nematode host, support the establishment of a permanent exemption from the requirement of a tolerance for *Pasteuria usgae*. There is presently a temporary exemption from the requirement of a tolerance established for residues of *Pasteuria usgae* under 40 CFR 180.1290, which will expire and be revoked on December 31, 2010. *Pasteuria usgae* is exempt from the requirement of a tolerance when applied/used as a nematicide on strawberries in accordance with the terms of Experimental Use Permit 85004-EUP-1 August 5, 2009, (74 FR 38970) (FRL–8429–1). Additionally, under 40 CFR 180.1135, a similar active ingredient, *Pasteuria penetrans*, was assessed previously and granted a permanent exemption from the requirement of a tolerance in or on all raw agricultural commodities, except roots and tubers, when used as a nematicide in the production of fruits and vegetables in greenhouses December 28, 1994, (59 FR 66740) (FRL-4924–4).

1. *Food*. Dietary exposure to the naturally occurring soil bacterium, *Pasteuria usgae*, although a possibility, is anticipated to be negligible. For optimal control of sting nematode, *Pasteuria usgae* is applied in a manner that facilitates movement of spores into the root zone of the affected crop. This requires that end users take two particular actions that would inevitably minimize the amount of *Pasteuria usgae* residues on aboveground food commodities–soil-directed applications and irrigation with a specified amount of water following any such applications. For food commodities that develop underground, exposure to *Pasteuria usgae* residues is a more likely scenario, although standard post-harvest practices of washing, cooking, or processing would reduce such residues. In general, any actual dietary exposure is expected to be several orders of magnitude lower than the dose used in the acute oral toxicity/pathogenicity test referenced in Unit III., during which no toxic or pathogenic effects were observed in rats. Moreover, *Pasteuria usgae* is an obligate endoparasitic bacterium specific to the sting nematode. The Agency concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to the residues of *Pasteuria usgae* in food.

2. *Drinking water exposure*. Exposure of humans to residues of *Pasteuria usgae* in consumed drinking water is unlikely. The currently approved and proposed use patterns, use sites, and application methods for *Pasteuria usgae* do not include direct application to aquatic environments. Furthermore, given that *Pasteuria usgae* spores attach specifically to the sting nematode, which is a plant-parasitic nematode that thrives only in sandy soil environments and is dependent upon plant roots to sustain life, future proposals to add aquatic use sites to pesticide products containing this bacterium are not expected. Even if oral exposure should occur through consumed drinking water, the Agency concludes that there is a reasonable certainty that no harm will result from the exposure to the residues of *Pasteuria usgae* in all the anticipated drinking water exposures because of the lack of acute oral toxicity/pathogenicity to mammals and the host-specific nature of the bacterium, as stated previously.

B. Other Non-Occupational Exposure

Non-occupational exposure is considered unlikely for *Pasteuria usgae* as all currently approved or proposed uses occur in distinctly agricultural or commercial settings, and there are no currently approved or proposed uses for residential areas.

The only other non-occupational exposure is that which would normally be encountered as part of the natural environment (i.e., not as a result of pesticide use). As expected since *Pasteuria usgae* is an obligate endoparasite of the sting nematode, there have been no reports of adverse effects from human exposure to this bacterium that naturally occurs in sandy soils, particularly those of the southeastern and midwestern United States.

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 *Pasteuria usgae* to share a common mechanism of toxicity with any other substances, and *Pasteuria usgae* does not appear to produce a toxic metabolite as its mode of action against the target pest. For the purposes of this tolerance action, therefore, EPA has assumed that *Pasteuria usgae* 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 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 (MOE) (safety), which are often referred to as uncertainty factors (UFs), are incorporated into EPA risk assessments

either directly or through the use of a MOE analysis, or by using UF (safety) in calculating a dose level that poses no appreciable risk.

Based on the acute toxicity and pathogenicity data discussed in Unit III., EPA 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 the residues of *Pasteuria usgae*. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Pasteuria usgae* do not demonstrate toxic, pathogenic, or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply.

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 *Pasteuria usgae*.

VIII. Conclusions

Therefore, an exemption is established for residues of *Pasteuria usgae* in or on all food commodities when applied preharvest and used as a nematicide in accordance with good agricultural practices.

IX. 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).

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 11, 2010.

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. In subpart D, revise §180.1290 to read as follows:

§ 180.1290 *Pasteuria usgae;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pasteuria usgae* in or on all food commodities when applied preharvest and used as a nematicide in accordance with good agricultural practices.

[FR Doc. 2010–15465 Filed 6–29–10; 8:45 am]

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