Aureobasidium pullulans strains DSM 14940 and DSM 14941. Therefore, an exemption from the requirement of a tolerance is established for residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in or on all food commodities when applied as a preharvest fungicide and used in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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.

X. References

1. Chi, Z., F. Wang, Z. Chi, L. Yue, G. Liu, T. Zhang. 2009. Bioproducts from *ureobasidium pullulans,* a biotechnologically important yeast. Appl. Microbiol. Biotechnol., 82: 793–804.
2. Cooke, W.B. 1959. An ecological life history of *Aureobasidium pullulans* (De Bary) Arnaud. Mycopathologia, 12: 1–45.
3. Slepecky, R.A. and W.T. Starmer. 2009. Phenotypic plasticity in fungi: a review with observations on *Aureobasidium pullulans.* Mycologia 101: 823–832.
4. Fleet, G.H. 2002. The yeast ecology of wine grapes. Pp. 1–17 *in* Biodiversity and Biotechnol. Of Wine Yeasts (Ciani, M., *ed.*). Research Signpost, Kerala, India.
5. Fleet, G.H. 2003. Yeast interactions and wine flavor. Int. J. Food Microbiol., 86: 11–22.
6. Granado, J., B. Thurig, E. Kieffer, L. Petrini, A. Fliessbach, L. Tamm, F.P. Weibel, G.S. Wyss. 2008. Culturable fungi of stored 'Golden Delicious' apple fruits: a one-season comparison study of organic and integrated production systems in Switzerland. Microb. Ecol., 56: 720–732.
7. Gao, X.-X., H. Zhou, D.-Y. Xu, C.-H. Yu, Y.-Q. Chen, L.-H. Qu. 2005. High diversity of endophytic fungi from the pharmaceutical plant, *Heterosmilax japonica* Kunth revealed by cultivation-independent approach. FEMS Microbiol. Letters, 249: 255–266.
8. Osono, T. 2008. Endophytic and epiphytic phyllosphere fungi of *Camellia japonica:* seasonal and leaf age-dependent variations. Mycologia, 100: 387–391.
9. Slavikova, E., R. Vadkertiova, and D. Vranova. 2007. Yeasts colonizing the leaf surfaces. J. Basic Microbiol. 47: 344–350.
10. Suryanarayanan, T.S., S.K. Wittlinger, and S.H. Faeth. 2005. Endophytic fungi associated with cacti in Arizona. Mycol. Res. 109: 635–639.
11. Webb, T.A. and J.O. Mundt. 1978. Molds on vegetables at the time of harvest. Appl. Environ. Microbiol., 35: 655–658.
12. Kockova-Kratochvilova, A., M. Cernakova, and E. Slavikova. 1980. Morphological changes during the life cycle of *Aureobasidium pullulans* (de Bary) Arnaud. Folia Microbiologica, 25.
13. U.S. EPA. December 2011. DRAFT Biopesticides Registration Action Document of *Aureobasidium pullulans* strains DSM 14940 and 14941.
14. Slavikova, E. and R. Vadkertiova. 1997. Seasonal occurrence of yeasts and yeast like organisms in the river Danube. *Antonie van Leeuwenhoek* 72: 77–80, 1997.

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: January 30, 2012.

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 180.1312 is added to subpart D to read as follows:

§ 180.1312 Aureobasidium pullulans strains DSM 14940 and DSM 14941; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticides, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in or on all food commodities when applied preharvest and used in accordance with good agricultural practices.

[FR Doc. 2012–3585 Filed 2–14–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0807; FRL–9337–2]

Pasteuria nishizawae—Pn1; 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 *Pasteuria nishizawae*—Pn1 in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices. Pasteuria Bioscience, 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 *Pasteuria nishizawae*—Pn1 under the FFDCA.

DATES: This regulation is effective February 15, 2012. Objections and requests for hearings must be received on or before April 16, 2012, 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–2010–0807. 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; email 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://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–2010–0807 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 April 16, 2012. 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–2010–0807, 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 February 4, 2011 (76 FR 6465) (FRL–8858–7), 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 0F7749) by Pasteuria Bioscience, Inc., 12085 Research Dr., 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 nishizawae*—Pn1. This notice referenced a summary of the petition prepared by the petitioner, Pasteuria Bioscience, Inc., which is available in the docket via *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

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 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 Pasteuria nishizawae—Pn1

Pasteuria, a genus of bacteria, includes several species that have shown potential in controlling plant-parasitic nematodes that attack and cause significant damage to many agricultural crops (see, e.g., the **Federal Register** of December 28, 1994 (59 FR 66740) (FRL–4923–4) and June 30, 2010 (75 FR 37734) (FRL–8831–9) for final rules that established tolerance exemptions for residues of the nematicides, *Pasteuria penetrans* (40 CFR 180.1135) and *Pasteuria usgae* (40 CFR 180.1290), respectively). These gram-positive, mycelial, endospore-forming bacteria are mostly obligate parasites (i.e., organisms that depend on particular hosts to complete their own life cycle) of plant-parasitic nematodes, although one *Pasteuria* species—*Pasteuria ramosa*—is known to parasitize *Daphnia* species, which are tiny crustaceans often called ''water fleas'' due to their flea-like size and appearance (Refs. 1 and 2). *Pasteuria* species are ubiquitous in most environments and are found in nematodes in at least 80 countries on 5 continents, as well as on islands in the Atlantic, Pacific, and Indian Oceans (Ref. 2). Higher population densities often occur in areas where there is an ample supply of nematode hosts (e.g., where crops susceptible to nematodes are cultivated) (Refs. 3, 4, and 5). *Pasteuria nishizawae*—Pn1 was specifically isolated from an Illinois soybean field in the mid-2000s (Ref. 1).

Although endospores of *Pasteuria nishizawae* have been observed to attach to the cuticle of 3 nematodes of the genus *Heterodera* and 1 nematode of the genus *Globodera,* it is known only to infect and complete its life cycle within the female soybean cyst nematode (*Heterodera glycines*) (Ref. 2). In the following manner, *Pasteuria nishizawae*—Pn1 exerts a pesticidal effect on the soybean cyst nematode through parasitism that ultimately results in the death of infected females:

1. Endospores attach to the cuticle of a juvenile soybean cyst nematode female.

2. Once a soybean cyst nematode female invades soybean roots, *Pasteuria nishizawae*—Pn1 produces a germ tube that penetrates the body of the nematode.

3. Primary and secondary microcolonies of *Pasteuria nishizawae*—Pn1 develop and proliferate within the body of the nematode, causing its death (Ref. 2).

In light of the demonstrated nematicidal capabilities and host specificity of *Pasteuria nishizawae*—Pn1, Pasteuria Bioscience, Inc. has proposed to register pesticide products that could be applied to soybean or its seed to control the soybean cyst nematode.

B. Microbial Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Pasteuria nishizawae*—Pn1 in or on all food commodities have been fulfilled with data submitted by the petitioner. The results of the acute dermal toxicity and primary dermal irritation tests revealed no toxicity or irritation attributed to *Pasteuria nishizawae*—Pn1, and these studies received a Toxicity Category IV classification (see 40 CFR 156.62). Moreover, acute oral, pulmonary, and injection toxicity/pathogenicity tests indicated that *Pasteuria nishizawae*—Pn1 was not toxic and/or pathogenic via the tested routes of exposure. Although infectivity and clearance were not evaluated in any of the acute toxicity/pathogenicity tests, EPA believes that these endpoints are not a concern given the host specificity of *Pasteuria nishizawae* for the soybean cyst nematode (Refs. 1 and 2). Finally, 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 briefly described in this unit, while more in-depth synopses of some study results can be found in the associated Biopesticides Registration Action Document provided as a reference in Unit IX. (Ref. 6).

1. Acute oral toxicity/pathogenicity—rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 481517–09). A supplemental acute oral toxicity/pathogenicity study demonstrated that *Pasteuria nishizawae*—Pn1 was not toxic and/or pathogenic to laboratory rats when administered by oral gavage in a single dose of 1.6×10^9 spores per animal. Although clearance and infectivity were not measured, EPA believes these endpoints are not a concern given *Pasteuria nishizawae*—Pn1's well-established host specificity for the soybean cyst nematode (Refs. 1 and 2).

2. Acute pulmonary toxicity/pathogenicity—rat (Harmonized Guideline 885.3150; MRID No. 481517–10). A supplemental acute pulmonary toxicity/pathogenicity study demonstrated that *Pasteuria nishizawae*—Pn1 was not toxic and/or pathogenic to laboratory rats when administered by intratracheal instillation in a single dose of 1.6×10^8 spores per animal. Although clearance and infectivity were not measured, EPA believes these endpoints are not a concern given *Pasteuria nishizawae*—Pn1's well-established host specificity for the soybean cyst nematode (Refs. 1 and 2).

3. Acute injection toxicity/pathogenicity (intravenous)—rat (Harmonized Guideline 885.3200; MRID No. 481517–11). A supplemental acute injection toxicity/pathogenicity study demonstrated that *Pasteuria nishizawae*—Pn1 was not toxic and/or pathogenic to laboratory rats when administered intravenously in a single dose of 1.0×10^9 spores per animal. Although clearance and infectivity were not measured, EPA believes these endpoints are not a concern given *Pasteuria nishizawae*—Pn1's well-established host specificity for the soybean cyst nematode (Refs. 1 and 2).

4. Hypersensitivity incidents (Harmonized Guideline 885.3400; MRID No. 481517–12). The petitioner reported that no hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals, occurred during research, development, or testing of *Pasteuria nishizawae*—Pn1.

5. Acute dermal toxicity—rabbit (Harmonized Guideline 870.1200; MRID No. 481517–14). An acceptable acute dermal toxicity study demonstrated that a test substance containing *Pasteuria nishizawae*—Pn1 was not toxic to rabbits when dosed at 2,000 milligrams per kilogram (mg/kg) for 24 hours. The dermal median lethal dose, which is a statistically derived single dose that can be expected to cause death in 50% of test animals, was greater than 2,000 mg/kg for male and female rats combined (Toxicity Category IV).

6. Primary dermal irritation—rabbit (Harmonized Guideline 870.2500; MRID No. 481517–16). An acceptable primary dermal irritation study demonstrated

that a test substance containing *Pasteuria nishizawae*—Pn1 was essentially non-irritating to the skin of rabbits (Toxicity Category IV).

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

1. Food exposure. Dietary exposure to *Pasteuria nishizawae*—Pn1, a naturally occurring soil bacterium (Refs. 7, 8, and 9), is anticipated to be negligible. For optimal control of the target pest (soybean cyst nematode), *Pasteuria nishizawae*—Pn1 is applied in a manner that facilitates spore movement into or spore placement near the root zone of potentially affected plants. This requires that end users take certain actions, depending on the treatment type, that would inevitably minimize the amount of *Pasteuria nishizawae*—Pn1 residues on above-ground commodities. That is, although *Pasteuria nishizawae*—Pn1 can be applied to soil, plants, or seeds, some seeds are incorporated into the soil immediately after treatment (at-planting, hopper box, planter box, or slurry box seed treatments), and pesticide applications made to plants or the soil are always followed by irrigation to incorporate *Pasteuria nishizawae*—Pn1 into the soil. In instances where food commodities develop underground or where treated seed is diverted for food or feed purposes or to process into oil, exposure to *Pasteuria nishizawae*—Pn1 is a more likely scenario. Regardless of the situation, should *Pasteuria nishizawae*—Pn1 be present on food, its specificity for the soybean cyst nematode and available data indicate no toxicity, pathogenicity, and/or infectivity is likely to occur with any dietary exposure that results from pesticide applications made in accordance with good agricultural practices (see additional discussion in Unit III.).

2. Drinking water exposure. Exposure to residues of *Pasteuria nishizawae*—Pn1 in consumed drinking water is possible but not likely. The proposed use patterns for *Pasteuria nishizawae*—Pn1 are soil directed, soil incorporated, and/or seed directed, thereby limiting contact with surface water by drift and runoff. Furthermore, ground water is not expected to have significant exposure to *Pasteuria nishizawae*—Pn1 since, like other microorganisms, this microbial pesticide would likely be filtered out by the particulate nature of many soil types (Refs. 10, 11, and 12). If *Pasteuria nishizawae*—Pn1 were to be transferred to surface or ground waters (e.g., through spray drift or runoff) that are intended for eventual human consumption and directed to wastewater treatment systems or drinking water facilities, it may not survive some of the conditions water is subjected to in such systems or facilities, including chlorination, pH adjustments, and filtration (Refs. 13 and 14). In the remote likelihood that *Pasteuria nishizawae*—Pn1 is present in drinking water (e.g., water not subject to certain conditions in treatment systems and facilities), its specificity for the soybean cyst nematode and available data indicate no toxicity, pathogenicity, and/or infectivity is likely to occur with any drinking water exposure that results from pesticide applications made in accordance with good agricultural practices (see additional discussion in Unit III.).

B. Other Non-Occupational Exposure

Given *Pasteuria nishizawae's* natural presence in soil (Refs. 7, 8, and 9), non-occupational exposure to the bacterium is likely already occurring. Additional exposure to *Pasteuria nishizawae*—Pn1 due to pesticidal applications is not expected because all proposed pesticide end-use products are labeled for use in distinct agricultural settings. Even if non-occupational exposures were to occur (e.g., eventual expansion of use sites), such exposures would not exceed EPA's level of concern in light of *Pasteuria nishizawae*—Pn1's specificity for the soybean cyst nematode and test results that indicated *Pasteuria nishizawae*—Pn1 is not toxic (acute dermal toxicity and acute pulmonary toxicity/pathogenicity), is essentially non-irritating (primary dermal irritation), and is not pathogenic (acute pulmonary toxicity/pathogenicity) (see additional discussion in Unit III.).

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.''

No mechanism of toxicity in mammals has been identified for *Pasteuria nishizawae*—Pn1, and *Pasteuria nishizawae*—Pn1 does not appear to produce a toxic metabolite against the target pest. For the purposes of this tolerance action, EPA has assumed that *Pasteuria nishizawae*—Pn1 does not have a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) of FFDCA does not apply. 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, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, 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 discussed in Unit III.B., as well as *Pasteuria nishizawae*—Pn1's host specificity for the soybean cyst nematode, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Pasteuria nishizawae*—Pn1 is used as labeled in accordance with good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Moreover, based on the same data and EPA analysis as presented in this unit, the Agency is able to conclude 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 *Pasteuria nishizawae*—Pn1 when it is used as labeled and in accordance with good agricultural practices as a nematicide. 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 and information available on *Pasteuria nishizawae*—Pn1 do not demonstrate toxic, pathogenic, and/or infective potential to mammals, including infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated in this document and because 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 *Pasteuria nishizawae*—Pn1.

C. Response to Comments

Two comments were submitted. An anonymous commenter (EPA–HQ–OPP–2010–0012–0019) generally expressed opposition to EPA granting tolerance exemptions to several petitioners, including Pasteuria Bioscience, Inc. Specifically, this commenter mentioned concern with the prevalence of many toxic chemicals in the environment and lack of information regarding how such chemicals combine. Another commenter (EPA–HQ–OPP–2010–0905–0003) also expressed opposition to granting tolerances and tolerance exemptions for several chemicals, including *Pasteuria nishizawae*—Pn1, that were described in the **Federal Register** of February 4, 2011. This commenter stated that the food supply must be rigorously tested, that studies submitted by the chemical industry must be subjected to independent peer review, and that only long-term studies can provide data on the health impact of exposure to the chemicals in the February 4, 2011 notice of filing.

Data provided by the petitioner demonstrated that *Pasteuria nishizawae*—Pn1 is not toxic and/or pathogenic at the doses administered orally, intratracheally, intravenously, and dermally to rats or rabbits (see Unit III.B.). Although infectivity and clearance were not evaluated in any of these studies, EPA believes that these endpoints are not a concern given *Pasteuria nishizawae*—Pn1's well-established host specificity for the soybean cyst nematode (Refs. 1 and 2). Moreover, since no mechanism of toxicity in mammals has been identified for *Pasteuria nishizawae*—Pn1, and *Pasteuria nishizawae*—Pn1 does not appear to produce a toxic metabolite against the target pest, EPA has assumed that *Pasteuria nishizawae*—Pn1 does not have a common mechanism of toxicity with other substances. After conducting a comprehensive assessment of the data and information submitted by the petitioner, EPA has concluded 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 *Pasteuria nishizawae*—Pn1. Thus, under the standard in FFDCA section 408(c)(2), a tolerance exemption is appropriate.

D. Revisions to Requested Tolerance Exemption

Two modifications have been made to the requested tolerance exemption. First, since Pasteuria Bioscience, Inc. already created a unique isolate identifier (i.e., Pn1) for *Pasteuria nishizawae,* inclusion of the American Type Culture Collection accession number (i.e., SD–5833) within this microbial pesticide's taxonomic name was unnecessary. Use of just *Pasteuria nishizawae*—Pn1 throughout this document, particularly in the tolerance exemption expression, is now consistent with the representation of this active ingredient in other associated regulatory documents and should assist in preventing confusion regarding its nomenclature in the future. Second, EPA is changing ''in or on all raw agricultural crops'' to ''in or on all food commodities'' to align with the terminology the Agency currently uses when establishing tolerance exemptions for residues of other like active ingredients.

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 *Pasteuria nishizawae*—Pn1. Therefore, an exemption from the requirement of a tolerance is established for residues of *Pasteuria nishizawae*—Pn1.

IX. References

1. U.S. EPA. 2011a. *Pasteuria nishizawae* strain PN1. Memorandum from J.V. Gagliardi, Ph.D. and J.L. Kough, Ph.D. to J. Kausch dated August 16, 2011.
2. U.S. EPA. 2011b. Environmental Risk Assessment of *Pasteuria nishizawae* Pn1 (PC 016455) for a Section 3 Registration of the Technical Product (EPA File Symbol 85004–A) and Two End Use Products (EPA File Symbols 85004–T and 85004–O) for Control of the Soybean Cyst Nematode in Soybeans. Memorandum from S. Borges and G. Tomimatsu, Ph.D. to J. Kausch dated September 15, 2011 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0806).
3. Cetintas R, Dickson DW. 2004. Persistence and suppressiveness of *Pasteuria penetrans* to *Meloidogyne arenaria* Race 1. *Journal of Nematology* 36:540–549.
4. Tain B, Yang J, Zhang K–Q. 2007. Bacteria used in the biological control of plant-parasitic nematodes: Populations, mechanisms of action, and future prospects. *FEMS Microbiology Ecology* 61:197–213.
5. Noel GR. 2008. IPM of soybean cyst nematode in the USA. *In:* Integrated Management and Biocontrol of Vegetable and Grain Crops Nematodes. Eds. A. Cianio and K.G. Mukerji. Springer. Pages 119–126.
6. U.S. EPA. 2011c. Draft *Pasteuria nishizawae*—Pn1 Biopesticides Registration Action Document dated December 21, 2011 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0806).
7. Atibalentja N, Jakstys BP, Noel GR. 2004. Life cycle, ultrastructure, and host specificity of the North American isolate of *Pasteuria* that parasitizes the soybean cyst nematode, *Heterodera glycines. Journal of Nematology* 36:171–180.
8. Noel GR, Atibalentja N, Domier LL. 2005. Emended description of *Pasteuria nishizawae. International Journal of Systematic and Evolutionary Microbiology* 55:1681–1685.
9. Sayre RM, Wergin WP, Schmidt JM, Starr MP. 1991. *Pasteuria nishizawae* sp. nov.,

a mycelial and endospore-forming bacterium parasitic on cyst nematode of genera *Heterodera* and *Globodera. Research in Microbiology* 14:551–564.
10. Pang L, McLeod M, Aislabie J, Šimůnek J, Close M, Hector R. 2008. Modeling transport of microbes in ten undisturbed soils under effluent irrigation. *Vadose Zone Journal* 7:97–111.
11. 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.
12. DeFelice K, Wollenhaupt N, Buchholz D. 1993. Aquifers and Soil Filter Effect. Available from *http://extension.missouri.edu/p/WQ24.*
13. Centers for Disease Control and Prevention. 2009. Drinking Water—Water Treatment. Available from *http://www.cdc.gov/healthywater/drinking/public/water_treatment.html.*
14. 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.*

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: February 1, 2012.

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 180.1311 is added to subpart D to read as follows:

§ 180.1311 *Pasteuria nishizawae*—Pn1; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pasteuria nishizawae*—Pn1 in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices.

[FR Doc. 2012–3586 Filed 2–14–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0783; FRL–9332–9]

Spirotetramat; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of spirotetramat in or on onion, dry bulb under section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(l)(6). This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on dry bulb onions. This regulation establishes a maximum permissible level for residues of spirotetramat in or on these commodities. The time-limited tolerances expire on December 31, 2014.

DATES: This regulation is effective February 15, 2012. Objections and requests for hearings must be received on or before April 16, 2012, 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–2011–0783. 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