ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0805; FRL–9353–5]

Pasteuria spp. (*Rotylenchulus reniformis* nematode)—Pr3; 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 in or on all food commodities when applied as a nematicide and used in accordance with label directions and 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 under the FFDCA.

DATES: This regulation is effective July 9, 2012. Objections and requests for hearings must be received on or before September 7, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0805, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

Some documents cited in this final rule are located in a different docket (docket ID number: EPA–HQ–OPP–2010–0808) associated with notices of receipt of applications for pesticide products containing a new active ingredient, *Pasteuria reniformis*—Pr3 (now recognized as *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 instead), under the Federal Insecticide, Fungicide, and Rodenticide Act. Such documents include the draft Biopesticides Registration Action Document (BRAD) and environmental risk assessment listed in Unit IX. of this final rule.

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 OCSPP 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–2010–0805 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 7, 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–2010–0805, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statue.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

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 FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 0F7745) 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 reniformis*—Pr3 [SD–5834]. 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.

Based upon review of data and other information supporting the petition, EPA modified the active ingredient name. In addition, EPA also changed the commodity to be reflected in the tolerance expression from ''in or on all raw agricultural crops'' to ''in or on all food commodities.'' The reasons for these changes are explained in Unit VII.D.

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 FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), 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, FFDCA section 408(b)(2)(D) 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 a pesticide. 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 FFDCA section 408(b)(2)(D), EPA 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 also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Pasteuria spp. *(Rotylenchulus reniformis nematode)—Pr3*

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), June 30, 2010 (75 FR 37734) (FRL–8831–9), and February 15, 2012 (77 FR 8736) (FRL–9337–2) for final rules that established tolerance exemptions for residues of the nematicides, *Pasteuria penetrans* (40 CFR 180.1135), *Pasteuria usgae* (40 CFR 180.1290), and *Pasteuria nishizawae*—Pn1 (40 CFR 180.1311), 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 (Refs. 1 and 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. 1, 3, 4, and 5). *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was specifically isolated from soil samples collected in the southeastern United States (Ref. 1).

Endospores of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 attach to *Rotylenchulus* species nematodes at all life stages, except eggs (Ref. 1). After an endospore attaches to the cuticle of a nematode host, a germ tube penetrates the cuticle, and growth and sporogenesis begin in the pseudocoelom of the nematode (Ref. 1). The nematode is eventually filled with cells, mycelial hyphae, and sporangia, which leads to its death (Ref. 1). In light of the demonstrated nematicidal capabilities and host specificity of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3, Pasteuria Bioscience, Inc. proposed to register pesticide products intended for use on several food and nonfood crops, primarily as seed or soil treatments, to control the reniform nematode (*Rotylenchulus reniformis*).

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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3, and these studies received a Toxicity Category IV or III classification (see 40 CFR 156.62). Although infectivity and clearance of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 were not evaluated in the acute oral, pulmonary, and injection toxicity/pathogenicity studies, the results indicated that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was not toxic and/or pathogenic via the tested routes of exposure. 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 draft BRAD provided as a reference in Unit IX. (Ref. 1).

1. *Acute oral toxicity/pathogenicity—rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 481460–09).* A supplemental acute oral toxicity/pathogenicity study demonstrated that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was not toxic and/or pathogenic to laboratory rats when administered by oral gavage in a single dose of 1.5×10^9 spores per animal.

2. *Acute pulmonary toxicity/pathogenicity—rat (Harmonized Guideline 885.3150; MRID No. 481460–10).* A supplemental acute pulmonary toxicity/pathogenicity study demonstrated that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was not toxic and/or pathogenic to laboratory rats when administered by intratracheal instillation in a single dose of 1.5×10^8 spores per animal.

3. *Acute injection toxicity/pathogenicity (intravenous)—rat (Harmonized Guideline 885.3200; MRID*

No. 481460–11). A supplemental acute injection toxicity/pathogenicity study demonstrated that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was not toxic and/or pathogenic to laboratory rats when administered intravenously in a single dose of 1×10^7 spores per animal.

4. *Hypersensitivity incidents (Harmonized Guideline 885.3400; MRID No. 481460–12).* 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3.

5. *Acute dermal toxicity—rabbit (Harmonized Guideline 870.1200; MRID No. 481460–14).* An acceptable acute dermal toxicity study demonstrated that a test substance containing *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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 III).

6. *Primary dermal irritation—rabbit (Harmonized Guideline 870.2500; MRID No. 481460–16).* An acceptable primary dermal irritation study demonstrated that a test substance containing *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 was essentially non-irritating to the skin of rabbits (Toxicity Category IV).

IV. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3, a naturally occurring soil bacterium (Ref. 1), is anticipated to be negligible. For optimal control of the target pest (reniform nematode), *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 residues on above-ground commodities. That is, although *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 is a more likely scenario. Regardless of the situation, however, should residues of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 result in or on food when used as a pesticide in accordance with label directions and good agricultural practices, its lack of toxicity and pathogenicity (as demonstrated in the available data) indicate that no adverse effects are likely to occur with respect to any exposures to such residues (see additional discussion in Unit III.).

2. *Drinking water exposure.* Exposure to residues of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 in consumed drinking water is possible but not likely. The proposed use patterns for *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3, given that this microbial pesticide would likely be filtered out by the particulate nature of many soil types as are other microorganisms (Refs. 6, 7, and 8). If *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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. 9 and 10). In the remote likelihood that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 is present in drinking water (e.g., water not subject to certain conditions in treatment systems and facilities), its lack of toxicity and pathogenicity demonstrated by the available data indicate that no toxicity, pathogenicity, and/or infectivity is likely to occur with respect to any exposures to residues of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 in drinking water that might result from pesticide applications made in accordance with label directions and good agricultural practices (see additional discussion in Unit III.).

B. Other Non-Occupational Exposure

Given *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3's natural presence in soil (Ref. 1), non-occupational exposure to the bacterium almost certainly is already occurring. Additional non-occupational exposure to *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 due to pesticidal applications is not expected because all proposed pesticide end-use products are labeled for use in distinct agricultural settings. Even if additional non-occupational exposures were to occur (e.g., eventual expansion of use sites), the lack of toxicity, pathogenicity, and irritation demonstrated in the available data indicate that no adverse effects are likely to occur with respect to any exposures to such residues that might result from pesticide applications made in accordance with label directions and good agricultural practices (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* spp. (*Rotylenchulus reniformis* nematode)—Pr3, and *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 does not appear to produce a toxic metabolite against the target pest. For the purposes of this tolerance action, therefore, EPA has assumed that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine chemicals that 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 or no safety factor when reliable data are available to support a different additional or no safety factor.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., as well as *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3's host specificity for *Rotylenchulus* species nematodes, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 is used as labeled in accordance with good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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 Unit VI. 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 United Nations 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3.

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 reniformis*—Pr3 (now recognized as *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 instead), that were described in the **Federal Register** of February 4, 2011 (76 FR 6465) (FRL–8858–7). 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3 is not toxic and/or pathogenic at the doses administered orally, intratracheally, intravenously, and dermally to rats or rabbits (see Unit III.B.). Moreover, since no mechanism of toxicity in mammals has been identified for *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3, and *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 does not appear to produce a toxic metabolite against the target pest, EPA has assumed that *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 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* spp. (*Rotylenchulus reniformis* nematode)—Pr3. 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, after Pasteuria Bioscience, Inc. petitioned EPA to establish a tolerance exemption for *Pasteuria reniformis*—Pr3 [SD–5834], EPA reviewed the submitted product identification data and made the following determinations:

1. The active ingredient name was not included in any acceptable taxonomic scheme and

2. Insufficient information was provided to show how this taxonomic position was established as a new species (i.e., *reniformis*).

Thus, Pasteuria Bioscience, Inc. submitted additional product identification data and revised the active ingredient name from *Pasteuria reniformis*—Pr3 [SD–5834] to *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 to accurately represent what was described in this new data (e.g., identification down to this isolate's genus and of its primary target pest, the reniform nematode). With this modification to the active ingredient name, inclusion of the American Type Culture Collection accession number (i.e., SD–5834) was also dropped

because Pasteuria Bioscience, Inc. already created a unique isolate identifier (i.e., Pr3). Use of just *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 throughout this document, particularly in the tolerance exemption expression, is now supported by data, is consistent with the representation of this active ingredient in other associated regulatory documents, and should assist in preventing confusion regarding this active ingredient's 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 tolerances or tolerance exemptions for residues of pesticide chemicals under the FFDCA.

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* spp. (*Rotylenchulus reniformis* nematode)—Pr3. Therefore, an exemption from the requirement of a tolerance is established for residues of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 in or on all food commodities when applied as labeled as a nematicide and used in accordance with good agricultural practices.

IX. References

1. U.S. EPA. 2011a. Draft *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 Biopesticides Registration Action Document dated May 8, 2012 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0808 at *www.regulations.gov*).
2. U.S. EPA. 2011b. Environmental Risk Assessment of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 (PC 016456) for a Section 3 Registration of the Technical Product (EPA File Symbol 85004–U) and Two End Use Products (EPA File Symbols 85004–L and 85004–I) for Control of the Reniform Nematode. Memorandum from S. Borges to J. Kausch dated March 26, 2012 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0808 at *www.regulations.gov*).
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. 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.
7. 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.
8. DeFelice K, Wollenhaupt N, Buchholz D. 1993. Aquifers and Soil Filter Effect. Available from *http://extension.missouri.edu/p/WQ24.*
9. Centers for Disease Control and Prevention. 2009. Drinking Water—Water Treatment. Available from *http://www.cdc.gov/healthywater/drinking/public/water_ treatment.html.*
10. 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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: June 13, 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 180.1316 is added to subpart D to read as follows:

§ 180.1316 Pasteuria spp. (Rotylenchulus reniformis nematode)—Pr3; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode)—Pr3 in or on all food commodities when applied as a nematicide and used in accordance with label directions and good agricultural practices.

[FR Doc. 2012–16695 Filed 7–6–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 76

[MB Docket No. 11–93; FCC 11–182]

Implementation of the Commercial Advertisement Loudness Mitigation (CALM) Act

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts rules to implement the Commercial Advertisement Loudness Mitigation (''CALM'') Act. Among other things, the CALM Act directs the Commission to incorporate into its rules by reference and make mandatory a technical standard, developed by an industry standards development body, that is designed to prevent digital television commercial advertisements from being transmitted at louder volumes than the program material they accompany. As mandated by the statute, the rules apply to digital TV broadcasters, digital cable operators, and other digital multichannel video programming distributors (''MVPDs''). Also per the statute, the rules will take effect one year after adoption, and will therefore be effective as of December 13, 2012. The rules adopted are designed to protect viewers from excessively loud commercials and, at the same time, permit broadcasters and MVPDs to implement their obligations in a minimally burdensome manner. The Commission will require broadcast stations and MVPDs to ensure that all commercials are transmitted to consumers at the appropriate loudness level in accordance with the industry standard.

DATES: Effective December 13, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 13, 2012.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Evan Baranoff, *Evan.Baranoff@fcc.gov,* or Lyle Elder, *Lyle.Elder@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120 or Shabnam Javid, *Shabnam.Javid@fcc.gov,* of the Engineering Division, Media Bureau at (202) 418–7000.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order* (R&O), FCC 11–182, adopted and released on December 13, 2011. The full text of this document is available electronically via ECFS at *http://fjallfoss.fcc.gov/ecfs/* or may be downloaded at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2011/db1214/FCC-11-182A1.doc.* (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Room CY–B402, Washington, DC 20554. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Document Summary

I. Introduction

1. With this Report & Order (*R&O*), we adopt rules to implement the Commercial Advertisement Loudness Mitigation (''CALM'') Act.[1] Among other things, the CALM Act directs the Commission to incorporate into its rules by reference and make mandatory a technical standard, developed by an industry standards development body, that is designed to prevent digital television commercial advertisements from being transmitted at louder volumes than the program material they accompany.[2] As mandated by the statute, the rules apply to digital TV broadcasters, digital cable operators, and other digital multichannel video programming distributors (''MVPDs'').[3] Also per the statute, the rules will take effect one year after adoption, and will therefore be effective as of December 13, 2012.[4] The rules we adopt today are designed to protect viewers from excessively loud commercials and, at the same time, permit broadcasters and MVPDs to implement their obligations in a minimally burdensome manner. As described below, we will require broadcast stations and MVPDs to ensure that all commercials are transmitted to consumers at the appropriate loudness level in accordance with the industry standard. In the event of a pattern or trend of complaints, stations and MVPDs will be deemed in compliance with regard to their locally inserted commercials if they demonstrate that they use certain equipment in the ordinary course of business.[5] For the

[1] Public Law 111–311, 124 Stat. 3294 (2010) (codified at 47 U.S.C. 621). The CALM Act was enacted on December 15, 2010 (S. 2847, 111th Cong.). The relevant legislative history includes the Senate and House Committee Reports to bills S. 2847 and H.R. 1084, respectively, as well as the Senate and House Floor Consideration of these bills. *See* Senate Commerce, Science, and Transportation Committee Report dated Sept. 29, 2010, accompanying Senate Bill, S. 2847, 111th Cong. (2010), S. REP. 111–340 (''*Senate Committee Report to S. 2847*''); House Energy and Commerce Committee Report dated Dec. 14, 2009, accompanying House Bill, H.R. 1084, 111th Cong. (2009), H.R. REP. 111–374 (''*House Committee Report to H.R. 1084*''); Senate Floor Consideration of S. 2847, 156 Cong. Rec. S7763 (daily ed. Sept. 29, 2010) (bill passed) (''*Senate Floor Debate*''); House Floor Consideration of S. 2847, 156 Cong. Rec. H7720 (daily ed. Nov. 30, 2010) (''*House Floor Debate of S. 2847*'') and H7899 (daily ed. Dec. 2, 2010) (bill passed); House Floor Consideration of H.R. 1084, 155 Cong. Rec. H14907 (daily ed. Dec. 15, 2009). The Senate and House Committee Reports were prepared before the bill was amended to add Section 2(c) of the CALM Act (the compliance provision). *See Senate Floor Debate* at S7763–S7764 (approving ''amendment No. 4687''). *See also House Floor Debate of S. 2847* at H7720 (Rep. Eshoo stating that ''[w]ith the passage of this legislation, we will end the practice of consumers being subjected to advertisements that are ridiculously loud, and we can protect people from needlessly loud noise spikes that can actually harm their hearing. This technical fix is long overdue, and under the CALM Act, as amended by the Senate, consumers will be in the driver's seat.''). We note that our action herein satisfies the statutory mandate that the Commission adopt final rules in this proceeding on or before December 15, 2011.

[2] *See* Advanced Television Systems Committee (''ATSC'') A/85: ''ATSC Recommended Practice: Techniques for Establishing and Maintaining Audio Loudness for Digital Television,'' (July 25, 2011) (''RP'' or ''the RP''). To obtain a copy of the RP, visit the ATSC Web site: *http://www.atsc.org/cms/standards/a_85-2011a.pdf. See also* CALM Act sec. 2(a); *Senate Committee Report to S. 2847* at 1; *House Committee Report to H.R. 1084* at 1.

[3] *See* CALM Act sec. 2(a).

[4] *See* CALM Act sec. 2(b)(1).

[5] ''Locally inserted'' commercials are commercials added to a programming stream by a station or MVPD prior to or at the time of transmission to viewers. In contrast, commercials that are placed