BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Pasteuria usgae

Pesticide Chemical (PC) Code: 006545

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY

Pasteuria species are gram-positive, mycelial, endospore-forming bacteria that are endoparasitic to nematodes and water fleas. The microbial active ingredient, *Pasteuria usgae*, is host-specific to the sting nematode (*Belonolaimus longicaudatus*), which can be damaging to a wide variety of crops such as turf and strawberry. The active agent of *Pasteuria usgae* is an endospore that attaches to and infects the host nematode during all life stages (except eggs). These endospores are formed inside the host, released into the soil when the infected nematode decomposes, and considered nonmotile and stable in the soil environment for several years.

Environmental Protection Agency (EPA or the Agency) scientists reviewed product analysis, toxicology, and nontarget organism/environmental fate data and other information (40 Code of Federal Regulations (CFR) §§ 158.2120, 158.2140, and 158.2150, respectively), which were submitted to support the registration of three *Pasteuria usgae* pesticide products. It was determined that the data and other information adequately satisfy current data requirements for the purposes of particular time-limited, conditional registrations under section 3(c)(7) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for a manufacturing-use product (*Pasteuria usgae* – BL1, EPA Registration Number 85004-1) and two end-use products (Econem™, EPA Registration Number 85004-2; *Pasteuria usgae* – Liquid Formulation, EPA Registration Number 85004-3). All pesticide products containing *Pasteuria usgae* are presumed to be in the public interest as they could serve as partial replacements for conventional nematicides of continuing concern to the Agency (e.g., methyl bromide (ozone-depleting substance) and 1,3-dichloropropene (probable human carcinogen)).

For the purposes of conditional, time-limited registrations, product analysis data requirements for *Pasteuria usgae* (to include product chemistry and composition, analysis of samples, and physical and chemical characteristics) were satisfied by acceptable guideline studies. Additional product analysis data that the Agency required by specific dates include the following:

- A written description of quality control measures taken during the manufacturing process to screen for *Pasteuria* species that parasitize saprophytic nematodes. This information was submitted by the registrant in a timely manner and is being reviewed for acceptability.
- A new five-batch analysis with all batches from production level.
- Results from an ongoing twelve-month storage stability study. This information was submitted by the registrant in a timely manner and is being reviewed for acceptability.

Lastly, documentation indicating official recognition of *Pasteuria usgae* as a species by the Judicial Commission of the International Committee for Systematic Bacteriology must be submitted to the Agency when it becomes available.

Adequate mammalian toxicology data and other information were submitted to support all of the *Pasteuria usgae* pesticide products. The Tier I microbial pesticide toxicological studies showed that, at a single high dose, *Pasteuria usgae* was not toxic and/or pathogenic via any examined route of exposure (i.e., oral, dermal, pulmonary, and injection). Since microbial enumeration was not performed in some of these tests because *Pasteuria usgae* would not grow on agar media, the infectivity was uncertain. However, because *Pasteuria usgae* spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. Moreover, no hypersensitivity incidents, occurring during the testing or production of *Pasteuria usgae*, were observed by the registrant. Given the results of the Tier I toxicological studies and the absence of hypersensitivity incidents, testing at higher tiers was not required.

The Agency concluded 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*. No dietary risks are expected from use of *Pasteuria usgae* as an active ingredient in pesticide products. Significant dietary exposure (through food and drinking water) is not expected given the established use patterns, use sites, and application methods for the pesticide products, as well as standard practices for postharvest handling of food commodities (e.g., washing and cooking). In the unlikely event oral exposure should occur through food or drinking water, such exposure to *Pasteuria usgae* is expected to be several orders of magnitude lower than the dose used in the acute oral toxicity/pathogenicity test, during which no toxic or pathogenic effects were observed in rats. Finally, nonoccupational exposure is considered unlikely for *Pasteuria usgae* as all currently approved uses occur in distinctly agricultural or commercial settings.

Despite the low toxicological profile of *Pasteuria usgae*, baseline personal protective equipment (PPE) is required for handlers that may be exposed to the active ingredient, due to their occupation, for prolonged periods. Handlers working with *Pasteuria usgae* in manufacturing facilities or in occupational and agricultural settings are directed to wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health (NIOSH) standards of at least N-95, R-95, or P-95. The Agency may require additional PPE, other than the standard described above, on a product-specific basis. For example, protective eyewear is required for Econem™, the registered granular *Pasteuria usgae* formulation.

Data waiver rationales were submitted in response to data requirements for avian, freshwater fish and invertebrate, insect, and honey bee nontarget organism testing. The information provided was sufficient to satisfy the Tier I nontarget organism data requirements for the pesticide products containing *Pasteuria usgae* as an active ingredient. Further testing of nontarget organisms at higher tier levels is not required. Based on the rationales submitted, adverse effects to terrestrial animals and plants or freshwater and marine/estuarine fish, invertebrates, and plants are not expected because of exposure to labeled applications of *Pasteuria usgae*. Furthermore, the Agency has made “No Effect” (NE) determinations for direct and indirect effects to listed species and their habitat as a result of the current uses of *Pasteuria usgae*.

On October 1, 2009, the Agency announced a policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, the Agency intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; and any registration decisions for which the Agency believes there may be substantial public interest.

Consistent with the policy of making registration actions more transparent, the end-use product containing *Pasteuria usgae* as an active ingredient (*Pasteuria usgae* – Liquid Formulation, EPA Registration Number 85004-3) was subject to a 30-day comment period because the associated label allows for application to strawberry, which was considered a "first food use" for this currently registered active ingredient. During this comment period, no comments were received on the Agency's preliminary decision to register. Therefore, the Agency maintained that, based upon the risk assessment and information submitted in support of registration of *Pasteuria usgae* – Liquid Formulation, it was in the best interest of the public and the environment to issue the registration for this pesticide product with a first food use. The basis for this decision can be found in the risk assessment for *Pasteuria usgae*, which is characterized throughout this BRAD.

II. ACTIVE INGREDIENT OVERVIEW

Biological Name:	*Pasteuria usgae*
Culture Deposit:	American Type Culture Collection in Manassas, Virginia under Accession Number SD-5835
Office of Pesticide Programs (OPP) Chemical Code:	006545
Type of Pesticide:	Microbial Pesticide – Nematicide
	See Appendix B for specific information (e.g., use sites, application rates, methods of application, formulation types, and target pests) regarding the registered pesticide products containing this active ingredient.

III. REGULATORY BACKGROUND

A. Applications for Pesticide Registration

On May 5, 2008, MacIntosh and Associates, Incorporated (address: 1203 Hartford Avenue, Saint Paul, Minnesota 55116-1622), acting as the authorized agent for Pasteuria Bioscience, Incorporated (address: 12085 Research Drive, Suite 185, Alachua, Florida 32615), submitted an application to register *Pasteuria usgae* – BL1 (EPA File Symbol 85004-R) under FIFRA section 3. On August 13, 2008, the Agency announced receipt of this application to register a pesticide product containing a new active ingredient (73 Federal Register (FR) 47166) and opened a 60-day public comment period pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

Pursuant to FIFRA section 3(c)(7)(C), a conditional, time-limited registration was issued for the manufacturing-use product, *Pasteuria usgae* – BL1, on June 2, 2009 (EPA Registration Number 85004-1). The Agency announced the approval to conditionally register *Pasteuria usgae* – BL1, containing a new active ingredient, in the Federal Register of July 1, 2009 (74 FR 31426).

While the Agency was assessing the data submitted in connection with *Pasteuria usgae* – BL1, MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) submitted two additional applications for associated end-use products (Econem™, EPA File Symbol 85004-E; *Pasteuria usgae* – Liquid Formulation, EPA File Symbol 85004-G). Pursuant to FIFRA section 3(c)(7)(A), a conditional, time-limited registration was issued for Econem™, a granular end-use product applied to turf to

control sting nematode, on September 3, 2009 (EPA Registration Number 85004-2). The other end-use product was associated with a "new use" as one of the use patterns (i.e., application to strawberry) required the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (40 CFR § 152.3). Pursuant to the provisions of FIFRA section 3(c)(4), on March 5, 2010, the Agency announced receipt of the application from MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) requesting to register a new use (75 FR 10259). No comments were received following this publication. Pursuant to FIFRA section 3(c)(7)(A), a conditional, time-limited registration was issued for *Pasteuria usgae* – Liquid Formulation, a liquid end-use product applied to turf and strawberry to control sting nematode, on June 16, 2010 (EPA Registration Number 85004-3).

B. Request for an Experimental Use Permit

On January 14, 2009, receipt of an experimental use permit application was announced in the Federal Register (74 FR 2070), and a 30-day public comment period was opened. No comments were received following this publication. After the associated temporary exemption from the requirement for a tolerance was established for *Pasteuria usgae* (see section III(C)), the experimental use permit was issued on August 12, 2009 (EPA Experimental Use Permit Number 85004-EUP-1). This experimental use permit allowed the use of 59,675 pounds of formulated product (3,272.5 pounds of nematicidal active ingredient, *Pasteuria usgae*) on 385 acres of strawberry and turf to evaluate control of the sting nematode under various methods of application. The program was authorized only in the States of Alabama, Florida, Georgia, Mississippi, and North Carolina and was effective from August 12, 2009 to August 31, 2010. Issuance of this experimental use permit was announced in the Federal Register of August 27, 2009 (74 FR 43696).

C. Food Tolerance Exemptions

Concurrent with their experimental use permit application and under FFDCA section 408(d), MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) submitted a petition to establish a temporary exemption from the requirement of a tolerance for *Pasteuria usgae* (Pesticide Petition (PP) 8G7471). In the Federal Register of January 8, 2009 (74 FR 808), the Agency announced that MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) proposed to establish a temporary exemption from the requirement of a tolerance for residues of the microbial nematicide, *Pasteuria usgae*, in or on strawberries and opened a 30-day public comment period. No comments were received following this publication.

On August 5, 2009, the Agency established a temporary exemption from the requirement of a tolerance for *Pasteuria usgae* when applied/used as a nematicide on strawberries in accordance with the terms of Experimental Use Permit 85004-EUP-1 (40 CFR § 180.1290; 74 FR 38970). This temporary exemption from the requirement of a tolerance would have expired and been revoked on December 31, 2010 but was replaced by a permanent tolerance exemption (see explanation in the next paragraph).

In addition to the petition associated with the temporary exemption that was submitted with the experimental use permit, MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) also submitted a separate petition, along with their application for registration for *Pasteuria usgae* – Liquid Formulation (EPA File Symbol 85004-G), to establish a permanent exemption from the requirement of a tolerance for *Pasteuria usgae* (PP 9F7539). In the Federal Register of April 8, 2009 (74 FR 15969), the Agency announced that MacIntosh and Associates, Incorporated (on behalf of Pasteuria Bioscience, Incorporated) proposed to establish a permanent exemption from the requirement of a tolerance for residues of the microbial nematicide, *Pasteuria usgae*, in or on all food commodities and opened a 30-day public comment period. No substantive comments were received following this publication. On June 30, 2010, the Agency established a permanent exemption from the requirement of a tolerance 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 (40 CFR § 180.1290; 75 FR 37734). This exemption revised the temporary exemption established previously in conjunction with EPA Experimental Use Permit Number 85004-EUP-1.

IV. RISK ASSESSMENT

On October 26, 2007, the Agency issued a Final Rule in the Federal Register on the data requirements to support registration of biochemical and microbial pesticides and updated the definitions for biochemical and microbial pesticides (72 FR 60988). The rule became effective on December 26, 2007. The data and information evaluated for this Biopesticides Registration Action Document (BRAD) were considered in light of these requirements.

The classifications that are found for each data submission are assigned by Agency science reviewers and are an indication of the usefulness of the information contained in the documents for risk assessment. A rating of “ACCEPTABLE” indicates the study is scientifically sound and is useful for risk assessment. A “SUPPLEMENTAL” rating indicates the data provide some information that can be useful for risk assessment. The studies may have certain aspects determined not to be scientifically acceptable (“SUPPLEMENTAL: UPGRADABLE”). If a study is rated as “SUPPLEMENTAL: UPGRADABLE,” the Agency always provides an indication of what is lacking or what can be provided to change the rating to “ACCEPTABLE.” If there is simply a “SUPPLEMENTAL” rating, the reviewer will often state that the study is not required by the current 40 CFR part 158. Both “ACCEPTABLE” and “SUPPLEMENTAL” studies may be used in the risk assessment process as appropriate. An “UNACCEPTABLE” rating indicates that new data need to be submitted.

For the acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information submitted to the Agency. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the

lowest toxicity.

A. Product Analysis Assessment (40 CFR § 158.2120)

For purposes of conditional, time-limited registrations, all product analysis data requirements were satisfied by acceptable guideline studies. The Agency required additional product analysis data on *Pasteuria usgae* by specific dates.

For a comprehensive guideline-by-guideline summary of the generic product analysis data requirements described in sections IV(A)(1), IV(A)(2), and IV(A)(3), as well as additional product-specific data submitted to support individual registrations, refer to Tables 1 and 2 in Appendix A.

1. Product Chemistry and Composition (Office of Chemical Safety and Pollution Prevention (OCSPP) Guidelines 885.1100, 885.1200, and 885.1300)

Pasteuria species are gram-positive, mycelial, endospore-forming bacteria that are endoparasitic to nematodes and water fleas. The endospores of *Pasteuria* species can be identified and counted microscopically, but it is difficult to distinguish between species unless high magnification electron microscopy is used so that size and shape of the spores can be visualized and measured. Molecular techniques, such as polymerase chain reaction (PCR) methods, have been reported for *Pasteuria penetrans* but have not been developed for the other species. Therefore, host specificity assay, requiring the establishment of nematode cultures and a bioassay, is the most direct and reliable technique for species identification.

Pasteuria usgae, a recently discovered strain, is host-specific to the sting nematode (*Belonolaimus longicaudatus*), which can be damaging to a variety of crops such as turf and strawberry. Currently, full recognition of *Pasteuria usgae* as a species is still pending with the Judicial Commission of the International Committee for Systematic Bacteriology. Once *Pasteuria usgae* is recognized and removed from the category *Candidatus*, documentation indicating official recognition must be provided to the Agency.

The active agent of *Pasteuria usgae* is an endospore that attaches to and infects the host nematode during all life stages (except eggs). Increased moisture, neutral pH, temperatures above 10°C, and sandy soil seem to provide the best environments for spore attachment to the host. In laboratory studies, *Pasteuria* species were able to attach to nematodes after exposure to high temperatures and wide ranges of pH; however, at extremes, the number of attached spores per nematode was reduced and, in some cases, no infection occurred after attachment. After attachment of the endospore, a germ tube penetrates the nematode cuticle and mycelial microcolonies are formed in the pseudocoelom, leading to eventual death of the host. The endospores are formed inside the host, released into the soil when the infected nematode decomposes, and considered nonmotile and stable in the soil environment for several years.

Submitted data also adequately described the production process and potential microbial contaminants, and these requirements were satisfied for the purposes of conditional, time-limited registrations. The original manufacturing process did not describe quality control measures taken to confirm that *Pasteuria usgae* was the only *Pasteuria* species present in the master stock. A follow-up explanation, which demonstrated that batches are screened for the presence of other microbes and screened against sting nematodes to confirm the presence of *Pasteuria usgae*, still did not provide sufficient information to indicate that screening for other *Pasteuria* species is conducted during the manufacturing process. Other *Pasteuria* species, specifically those that parasitize saprophytic (non-plant pathogenic) nematodes, must be screened for during the manufacturing process. Pasteuria Bioscience, Incorporated was required to integrate quality control measures that screen for *Pasteuria* species that parasitize saprophytic nematodes, either immediately after freezing or after making seed stock, into their current manufacturing process and provide a written description of these measures to the Agency on or before October 1, 2009. This information was submitted by Pasteuria Bioscience, Incorporated in a timely manner (Master Record Identification Number (MRID No.) 478853-01) and is being reviewed for acceptability.

2. Analysis of Samples (OCSPP Guideline 885.1400)

Results of a preliminary five-batch analysis were provided and the requirement for analysis of samples was satisfied for purposes of conditional, time-limited registrations. The preliminary analysis of samples provided to the Agency revealed a wide range of concentrations, with many replicates containing 1–2 orders of magnitude fewer *Pasteuria usgae* spores than the minimum specified on the Confidential Statement of Formula (CSF) and product label (i.e., 1×10^6 spores per milliliter). A follow-up explanation, attempting to address this variability, mentioned several factors that contributed to this inconsistency and discussed how the concentration of spores could be adjusted during the manufacturing process, if necessary. Despite this additional information, a new five-batch analysis, with all batches from production level, must be submitted to the Agency on or before May 1, 2011.

3. Physical and Chemical Characteristics (OCSPP Guidelines 830.6302, 830.6303, 830.6304, 830.6313, 830.6317, 830.7000, and 830.7300)

Submitted data adequately described the physical and chemical characteristics of *Pasteuria usgae*; however, a twelve-month storage stability study was cited as ongoing with the original application. Therefore, the requirements for color, physical state, odor, stability to normal and elevated temperatures, metals, and metal ions, pH, and density/relative density/bulk density (specific gravity) were satisfied. Pasteuria Bioscience, Incorporated was required to submit the final storage stability study to the Agency on or before June 1, 2010. This information was submitted by Pasteuria Bioscience, Incorporated in a timely manner (MRID No. 479672-01) and is being reviewed for acceptability.

B. Human Health Assessment

1. Toxicology

Adequate mammalian toxicology data and other information are available to support the registration of *Pasteuria usgae* pesticide products, including the most recent end-use product (*Pasteuria usgae* – Liquid Formulation, EPA Registration Number 85004-3) registered for use on strawberry and turf. All Tier I toxicology data requirements were satisfied by guideline studies. Furthermore, Tier II and Tier III studies were not required for *Pasteuria usgae* based on the lack of acute toxicity/pathogenicity in the Tier I studies.

For a comprehensive guideline-by-guideline summary of the generic toxicology data requirements described in sections IV(B)(1)(a) and IV(B)(1)(b), as well as additional product-specific data submitted to support individual registrations, refer to Tables 3 and 4 in Appendix A.

a. Acute Toxicity/Pathogenicity – Tier I (40 CFR § 158.2140)

Acute Oral Toxicity and Pathogenicity – Rat (OCSPP Guideline 885.3050; MRID No. 474267-09): 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. *Pasteuria usgae* did not appear to be toxic and/or pathogenic in rats when dosed at 1 x 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. This study was rated "ACCEPTABLE," and *Pasteuria usgae* was classified as TOXICITY CATEGORY IV.

Acute Dermal Toxicity – Rat (OCSPP Guideline 885.3100; MRID No. 474267-12): 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. Based on the results of this study, *Pasteuria usgae* did not appear to be toxic in rats when treated with 2,000 milligrams/kilogram (mg/kg) at 10^8 spores/milliliter (mL). The acute dermal median lethal dose (LD_{50}) was greater than 2,000 mg/kg for 10^8 spores/mL in male and female rats. This study was rated "ACCEPTABLE," and *Pasteuria usgae* was classified as TOXICITY CATEGORY IV.

Acute Pulmonary Toxicity and Pathogenicity – Rat (OCSPP 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* did not appear to be toxic and/or pathogenic in rats when dosed at approximately 1–3 x 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. This study was rated "ACCEPTABLE," and *Pasteuria usgae* was classified as TOXICITY CATEGORY IV.

Acute Injection Toxicity and Pathogenicity – Rat (OCSPP Guideline 885.3200; MRID No. 474267-11): There were no treatment-related significant adverse effects seen in 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 LD_{50} of *Pasteuria usgae* was greater than 1 x 10^8 spores/animal in male and female rats. *Pasteuria usgae* did not appear to be toxic and/or pathogenic in rats when dosed at 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. This study was rated "ACCEPTABLE."

Hypersensitivity Incidents (OCSPP Guideline 885.3400; MRID No. 474350-02): No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals occurring during the testing or production of *Pasteuria usgae*, were observed by Pasteuria Bioscience, Incorporated. Any future hypersensitivity incidents must be reported to the Agency.

Cell Culture (OCSPP Guideline 885.3500): This study was not required because *Pasteuria usgae* is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).

b. Acute Toxicology and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III (40 CFR § 158.2140)

Tier II and Tier III studies were not required for *Pasteuria usgae* based on the lack of acute toxicity/pathogenicity in the Tier I studies.

c. Endocrine Disruptors

As required under FFDCA section 408(p), the Agency has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as

the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the Agency will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, the Agency issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Pasteuria usgae is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Accordingly, the Agency anticipates issuing future EDSP orders/data call-ins for all pesticide active ingredients.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/*.

2. Food Quality Protection Act (FQPA) Considerations

Section 408(c)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act allows the Agency 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 the Agency 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, the Agency must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require the Agency 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."

The Agency performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, the Agency determines the toxicity of pesticides. Second, the Agency examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, the Agency reviewed the available scientific data and other relevant information, and considered its validity, completeness, and reliability and the relationship of this information to human risk. The Agency has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Based on the acute toxicity/pathogenicity data discussed previously and presented in Table 3 in Appendix A, the data required for a FQPA risk assessment for *Pasteuria usgae* have been satisfied.

a. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs the Agency to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational 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).

Dietary Exposure and Risk Characterization: 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 postharvest 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 section IV(B)(1)(a), during which no toxic or pathogenic effects were observed in rats. Moreover, since *Pasteuria usgae* is host-specific, no toxicity or pathogenicity in humans is likely to occur. 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.

Drinking Water Risk Characterization: Exposure of humans to residues of *Pasteuria usgae* in consumed drinking water is unlikely. The currently approved 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.

Nonoccupational, Residential Risk Characterization: Nonoccupational exposure is considered unlikely for *Pasteuria usgae* as all currently approved uses occur in distinctly agricultural or commercial settings.

The only other nonoccupational 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.

b. 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."

The Agency 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, the Agency has assumed that *Pasteuria usgae* does not have a common mechanism of toxicity with other substances. For information regarding the Agency's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Agency's website at *http://www.epa.gov/pesticides/cumulative*.

c. Determination of Safety for U.S. Population, Infants, and Children

FFDCA section 408(b)(2)(C) provides that the Agency 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 the Agency 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 the Agency determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into Agency risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the acute toxicity and pathogenicity data discussed in section IV(B)(1)(a), the Agency 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.

3. Occupational Exposure and Risk Characterization

In light of the Tier I acute toxicity/pathogenicity studies, which did not show any toxic and/or pathogenic effects to rats via oral, pulmonary, dermal, and intravenous routes of exposure (see section IV(B)(1)(a)), handler exposure to *Pasteuria usgae* is not expected to pose any undue risk. Regardless, appropriate personal protective equipment and precautionary statements are required on the product label to mitigate any potential risks to pesticide handlers due to prolonged exposure. Handlers working with *Pasteuria usgae* in manufacturing facilities and applying the end-use products in commercial and agricultural settings must wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Additional PPE, other than the standard described above, may be required on a product-specific basis (e.g., protective eyewear for Econem™, the registered granular *Pasteuria usgae* formulation).

4. Human Health Risk Characterization

The Agency considered human exposure to *Pasteuria usgae* in light of the standard for registration and safety factors in FIFRA and FFDCA, as amended by the FQPA. A determination has been made that no unreasonable adverse effects to the United States population in general, and to infants and children in particular, will result from the use of *Pasteuria usgae* when used in accordance with EPA-approved labeling.

C. Environmental Assessment

Exposure of nontarget organisms is possible with application of end-use products containing *Pasteuria usgae* to turf and strawberry. Pasteuria Bioscience, Incorporated submitted data waiver rationales containing information cited in published literature to satisfy data requirements for nontarget organism testing with the technical grade of the active ingredient (TGAI). The following is a review of the rationales submitted to support the registration of the manufacturing-use product and end-use products, as well as resulting conclusions regarding environmental risks based on the submitted waiver justifications.

For a comprehensive guideline-by-guideline summary of the nontarget toxicity data requirements, refer to Table 5 in Appendix A.

1. Summary of Nontarget Organism Waiver Rationales (40 CFR § 158.2150)

Data waiver rationales were submitted in response to data requirements for avian, freshwater fish and invertebrate, insect, and honey bee nontarget organism testing requirements. Justification for these waivers is described in sections IV(C)(1)(a), IV(C)(1)(c), and IV(C)(1)(f). Some data requirements were not required based on the test notes described in 40 CFR § 158.2150(e), and explanations are provided in sections IV(C)(1)(b), IV(C)(1)(d), and IV(C)(1)(e). Overall, the information provided was sufficient to satisfy the Tier I nontarget organism data requirements for the manufacturing-use product and end-use products. Further testing of nontarget organisms at higher tier levels was not required.

a. Avian Oral Toxicity/Pathogenicity (OCSPP Guideline 885.4050)

The request to waive avian oral toxicity/pathogenicity testing was based on the rationale that exposure of birds to *Pasteuria usgae* as a result of its applications will be minimal, and that no records are available in which toxicity or pathogenicity of *Pasteuria usgae* or other *Pasteuria* species to birds is reported. *Pasteuria* species are ubiquitous in soil environments where plant-parasitic nematodes exist (Chen and Dickson 1998; Hewlett *et al*. 1994), and their population dynamics are strongly linked to parasite-prey interactions with their nematode hosts (Ciancio and Queneherve 2000; Darban *et al*. 2005). *Pasteuria usgae* is very specific to its host (Bekal *et al*. 2001; Giblin-Davis *et al*. 2001, 2003).

Extensive literature searches were performed within *Agricola* and *PubMed* databases, as well as several relevant journals, and no information was found relating exposure to naturally occurring *Pasteuria usgae* or other *Pasteuria* species to toxic or pathogenic effects in birds. The searches also did not result in finding any reports of genotoxic, carcinogenic, allergenic, mutagenic, or teratogenic effects.

An argument could be made that the absence of a record of toxicity/pathogenicity to birds is not evidence that such effects could not occur. However, since *Pasteuria usgae* is a naturally occurring and ubiquitous bacterium, there would likely have been reports in these databases if it was toxic or pathogenic to birds. Based on this information, adverse effects to avian wildlife resulting from exposure to *Pasteuria usgae* are not anticipated. Therefore, the rationale presented was acceptable and fulfilled the data requirement for avian oral toxicity/pathogenicity testing.

b. Avian Inhalation Toxicity/Pathogenicity (OCSPP Guideline 885.4100)

These data were not required as the nature of the microbial pesticide does not indicate potential pathogenicity to birds or relatedness to any known bird pathogens (refer to test note #3 of 40 CFR § 158.2150(e)).

c. Freshwater Fish Toxicity/Pathogenicity (OCSPP Guideline 885. 4200) and Freshwater Invertebrate Toxicity/Pathogenicity (OCSPP Guideline 885.4240)

The requests to waive the data requirements for freshwater fish toxicity/pathogenicity and freshwater invertebrate toxicity/pathogenicity were combined. The rationale was similar to that for birds described above, wherein exposure is expected to be limited and there are no reports of toxicity or pathogenicity of *Pasteuria usgae* to freshwater fish or invertebrates. Additionally, *Pasteuria usgae* and other *Pasteuria* species do not produce crystalline insect toxins like bacteria that are toxic to insects (e.g., *Bacillus thuringiensis*). *Pasteuria ramosa* is a closely related species to *Pasteuria usgae* that is known to parasitize *Daphnia magna* and other *Daphnia* species. However, *Pasteuria ramosa* does not infect nematode hosts typical to other *Pasteuria* species (Ebert *et al*. 1996). Furthermore, neither *Pasteuria usgae* nor *Pasteuria ramosa* are included in published fish pathogen listings. *Pasteuria usgae* is unique in the ultrastructural characteristics of its spores, and this contributes to its specificity (Ebert *et al*. 1996; Giblin-Davis *et al*. 2001).

Based on this information, adverse effects to freshwater fish or invertebrates resulting from labeled applications of *Pasteuria usgae* are not expected. The request to waive the data requirements for freshwater fish and invertebrate toxicity/pathogenicity testing was acceptable.

d. Estuarine/Marine Fish Testing and Estuarine/Marine Invertebrate Testing (OCSPP Guideline 885.4280)

These data were not required because *Pasteuria usgae* will not be applied to water and is not expected to enter marine/estuarine environments in amounts that are significantly higher than naturally occurring concentrations (refer to test note #6 of 40 CFR § 158.2150(e)).

e. Nontarget Plant Testing (OCSPP Guideline 885.4300)

These data were not required because *Pasteuria usgae* is not related to known plant pathogens, and adverse effects to plants are not expected (refer to test note #7 of 40 CFR § 158.2150(e)).

f. Nontarget Insect Testing (OCSPP Guideline 885.4340) and Honey Bee Testing (OCSPP Guideline 885.4380)

The requests to waive the data requirements for nontarget insect testing and honey bee testing were combined. The rationale was similar to that given for other nontarget taxa above, wherein exposure to nontarget insects and honey bees is expected to be limited, and neither *Pasteuria usgae* nor other *Pasteuria* species are included in published insect or honey bee pathogen listings. *Pasteuria usgae* and other *Pasteuria* species do not produce crystalline insect toxins as seen in other bacteria that are known to be toxic to insects.

Based on this information, adverse effects to nontarget insects or honey bees resulting from labeled applications of *Pasteuria usgae* are not expected, and the request to waiver these data requirements were acceptable.

2. Environmental Effects Conclusions

a. Terrestrial Animals and Plants

Data waiver rationales provided sufficient information to conclude that adverse effects are not expected in birds, nontarget insects, and honey bees as a result of exposure to *Pasteuria usgae* (MRID No. 474267-13). These rationales addressed exposure via applications of granules containing *Pasteuria usgae* to turf; however, the rationales presented are also applicable to liquid applications to turf and strawberry. *Pasteuria* species are ubiquitous in soils worldwide, and *Pasteuria usgae* is highly host-specific to the plant-parasitic sting nematode (*Belonolaimus longicaudatus*). None of the uses are expected to increase the concentrations of *Pasteuria usgae* in the soil above naturally occurring levels. Soil applications of granules to turf are expected to limit exposure in the environment. While liquid applications would result in exposure on foliar surfaces of turf and strawberry plants, no reports of terrestrial animal toxicity or pathogenicity from exposure to *Pasteuria usgae* exist in the available scientific literature.

An acute oral toxicity and pathogenicity study with laboratory rats (MRID No. 474267-09) is available with which to determine the potential effects of *Pasteuria usgae* on wild mammals. Laboratory rats were dosed with 10^8 spores/mL and were observed for 21 days. No signs of toxic or pathogenic effects were observed throughout the test or at necropsy. This study demonstrated that toxicity/pathogenicity to wild mammals is not expected from labeled applications of *Pasteuria usgae*.

Nontarget plant testing was not required because *Pasteuria usgae* is not related to any known plant pathogen. Adverse effects on plants are not expected to result from labeled applications of *Pasteuria usgae*.

Based on the above rationales, adverse effects are not expected to occur to terrestrial animals or plants as a result of labeled applications of *Pasteuria usgae*. The request to waive these data requirements was acceptable.

b. Aquatic Animals and Plants

Data waiver rationales were submitted to fulfill data requirements for and support effects conclusions for freshwater aquatic organisms (MRID No. 474267-13). These rationales addressed exposure via applications of granules containing *Pasteuria usgae* to turf; however, the rationales presented are also applicable to liquid applications to turf and strawberry. The rationales provided sufficient information to conclude that adverse effects are not expected in freshwater fish or freshwater invertebrates as a result of exposure to *Pasteuria usgae*. The rationales were similar to those presented for terrestrial

organisms in that *Pasteuria* species are ubiquitous in soils worldwide, and *Pasteuria usgae* is highly host-specific to the plant-parasitic sting nematode (*Belonolaimus longicaudatus*). Soil applications in turf only are expected to limit exposure in the aquatic environment, and runoff from both soil and liquid applications is not expected to increase the concentrations of *Pasteuria usgae* in freshwater environments above naturally occurring levels. There is no available literature documenting reports of pathogenicity or toxicity to freshwater fish or invertebrates as a result of exposure to *Pasteuria usgae*. *Pasteuria ramosa* is a closely related species to *Pasteuria usgae* that does parasitize *Daphnia magna* and other *Daphnia* species. However, *Pasteuria ramosa* does not infect nematode hosts typical to other *Pasteuria* species, and *Pasteuria usgae* is very host-specific and is not known to parasitize aquatic invertebrates.

Because the use of *Pasteuria usgae* is limited to applications to turf and strawberry and is not intended for application directly to water, exposure is not expected to be significant in aquatic environments, including marine or estuarine systems. Therefore, testing with marine/estuarine animals and testing with aquatic plants was not necessary.

Based on the rationales submitted, adverse effects to freshwater and marine/estuarine fish, invertebrates, and plants are not expected as a result of exposure to labeled applications of *Pasteuria usgae*. The request to waive these data requirements was acceptable.

3. Threatened and Endangered Species Assessment

There are no listed endangered or threatened species related to the target pest. Since it is concluded that effects are not anticipated for nontarget species exposed to *Pasteuria usgae* as a result of labeled applications, direct and indirect effects to listed species or their habitat are also not expected. Therefore, the Agency made “No Effect” (NE) determinations for direct and indirect effects to listed species and their habitat as a result of the uses of *Pasteuria usgae*.

V. ENVIRONMENTAL JUSTICE

The Agency seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment means that no group of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that (1) potentially affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public’s contribution can influence the regulatory agency’s decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out

and facilitate the involvement of those potentially affected. The Agency has this goal for all communities and persons across the United States.

At this time, the Agency does not believe the use of *Pasteuria usgae* pesticide products will cause harm or a disproportionate impact on at-risk communities.

For additional information regarding environmental justice issues, please visit the Agency's web site at *http://www.epa.gov/compliance/environmentaljustice/index.html*.

VI. PUBLIC INTEREST FINDING

The Agency determines whether conditional registration of a pesticide is in the public interest in accordance with the criteria set forth in the Federal Register of March 5, 1986 (58 FR 7268). There is a presumption that registration of a pesticide is in the public interest if (1) the use is for a minor crop, (2) the use is a replacement for another pesticide that is of continuing concern to the Agency, (3) the use is one for which an emergency exemption under FIFRA section 18 has been granted (i.e., the basis for the exemption was lack of a registered alternative product), or (4) the use is against a pest of public health significance. *Pasteuria usgae* pesticide products could serve as partial replacements for conventional nematicides of continuing concern to the Agency (e.g., methyl bromide (ozone-depleting substance) and 1,3-dichloropropene (probable human carcinogen)). Based on this information, registration of *Pasteuria usgae* pesticide products are presumed to be in the public interest.

VII. RISK MANAGEMENT AND REGISTRATION DECISIONS

A. Determination of Eligibility

1. *Pasteuria usgae* – BL1 (EPA Registration Number 85004-1)

Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act provides for the conditional registration of a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data if the following are determined:

(1) Use of the pesticide during a defined period will not cause any unreasonable adverse effect on the environment;
(2) Use of the pesticide is in the public interest; AND
(3) For data that are lacking, a reasonable period of time sufficient for generation of that data has not elapsed since the Agency first imposed the data requirements.

As discussed in this document, use of products containing *Pasteuria usgae* is not likely to result in any unreasonable adverse effects on the environment, fulfilling criterion 1. Furthermore, as mentioned in section VI, the registration of *Pasteuria usgae* – BL1 is presumed to be in the public interest because it will be used to create end-use products that could serve as partial replacements for particular conventional nematicides of continuing concern to the Agency; thus, criterion 2 has been satisfied. To satisfy criterion 3, insufficient time has elapsed since the initial imposition of the data requirements outlined in section VIII(B)(1).

2. Econem™ (EPA Registration Number 85004-2) and *Pasteuria usgae* – Liquid Formulation (EPA Registration Number 85004-3)

Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act provides for the conditional registration of a pesticide if the following are determined:

(1) The pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment AND
(2) Approving the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.

Although these end-use pesticide products are not substantially similar to the manufacturing-use product, *Pasteuria usgae* – BL1 (EPA Registration Number 85004-1), use of these products to control sting nematode in commercial and agricultural settings is not likely to result in any unreasonable adverse on the environment, a conclusion that is

supported by the information presented throughout this document. Thus, criterion 1, and by default, criterion 2 have both been satisfied.

B. Registration Review

The Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the FQPA of 1996, mandated the continuous review of existing pesticides. All pesticides distributed and sold in the United States must generally be registered by the Agency, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed in product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at *http://www.epa.gov/oppsrrd1/registration_review/*.

The Agency has implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act. *Pasteuria usgae* will be included in the schedule for registration review at the end of the Fiscal Year when schedules are updated.

C. Regulatory Decisions

1. *Pasteuria usgae* – BL1 (EPA Registration Number 85004-1)

Based on the data submitted and under FIFRA section 3(c)(7)(C), the Agency granted a conditional, time-limited registration for the manufacturing-use product, *Pasteuria usgae* – BL1, containing *Pasteuria usgae* as a new active ingredient. Although the data were satisfactory, they were not sufficient to support an unconditional registration under FIFRA section 3(c)(5). Additional data, discussed in section VIII(B)(1), are necessary for a finding of registrability under FIFRA section 3(c)(5) and are still considered terms or conditions for the purposes of this registration.

Handler exposure to *Pasteuria usgae* is not expected to pose any undue risk given the Tier I acute toxicological studies, which showed that *Pasteuria usgae* is not toxic and/or pathogenic. Regardless, appropriate personal protective equipment and precautionary statements are required on the product label to mitigate any potential risks to pesticide handlers due to prolonged exposure. Handlers working with *Pasteuria usgae* in manufacturing facilities must, at a minimum, wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.

2. Econem™ (EPA Registration Number 85004-2)

Based on the data submitted and under FIFRA section 3(c)(7)(A), the Agency granted a conditional, time-limited registration for the end-use product, Econem™. Although the data were satisfactory to make the determinations required by this section of FIFRA, they were not sufficient to support an unconditional registration under FIFRA section 3(c)(5). Additional data, discussed in section VIII(B)(2), are necessary for a finding of registrability under FIFRA section 3(c)(5) and remain as terms or conditions for the purposes of this registration. Furthermore, the registrant must submit/cite all data required to support *Pasteuria usgae* – BL1 (as outlined in its associated registration notice) as this particular manufacturing-use product serves as Econem™'s source of active ingredient.

Handler exposure to *Pasteuria usgae* is not expected to pose any undue risk given the Tier I acute toxicological studies, which showed that *Pasteuria usgae* is not toxic and/or pathogenic. Regardless, appropriate personal protective equipment and precautionary statements are required on the product label to mitigate any potential risks to pesticide handlers due to prolonged exposure. Handlers working with *Pasteuria usgae* in commercial and agricultural settings must, at a minimum, wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. In addition, because the product-specific data eye irritation data indicated that Econem™ most appropriately fit in Toxicity Category III, all handlers must also wear protective eyewear.

3. *Pasteuria usgae* – Liquid Formulation (EPA Registration Number 85004-3)

On October 1, 2009, the Agency announced a policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, the Agency intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; and any registration decisions for which the Agency believes there may be substantial public interest.

The Agency concluded that the data submitted fulfill the requirements of registration for the end-use product, *Pasteuria usgae* – Liquid Formulation, which contains *Pasteuria usgae* as a nematicidal active ingredient and is labeled for this currently registered active ingredient's first food use. Acute toxicological data for *Pasteuria usgae* demonstrated that it is not toxic and/or pathogenic via any examined route of exposure (i.e., oral, dermal, pulmonary, and injection). Moreover, because *Pasteuria usgae* spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. Product-specific data and other information placed this end-use product in either Toxicity Category III or IV. Finally, the Agency has no concerns for any nontarget organisms (to include threatened and endangered species) exposed to *Pasteuria usgae* in accordance with its currently approved uses as no toxic endpoints have been identified for mammals, birds,

plants, insects, honey bees, or aquatic organisms. Given the nontoxic character of *Pasteuria usgae* and its associated end-use product, *Pasteuria usgae* – Liquid Formulation, but also taking into consideration that certain data are still outstanding for this pesticide product's source of active ingredient (i.e., *Pasteuria usgae* – BL1, EPA Registration 85004-1), the Agency supported *Pasteuria usgae* – Liquid Formulation's registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act. Although the data were satisfactory to make the determinations required by this section of FIFRA, they were not sufficient to support an unconditional registration under FIFRA section 3(c)(5). Additional data, discussed in section VIII(B)(3), are necessary for a finding of registrability under FIFRA section 3(c)(5) and remain as terms or conditions for the purposes of this registration.

D. Labeling

The labels for the registered pesticide products containing the active ingredient, *Pasteuria usgae*, are available at *http://oaspub.epa.gov/pestlabl/ppls.home*.

VIII. ACTIONS REQUIRED BY THE REGISTRANT

A. Final Printed Labeling

Before releasing pesticide products containing *Pasteuria usgae* for shipment, the registrant is required to provide appropriate final printed labeling to the Agency.

B. Terms and Conditions of the *Pasteuria usgae* Pesticide Products

1. *Pasteuria usgae* – BL1 (EPA Registration Number 85004-1)

The Agency evaluated the data submitted in connection with the initial registration of the manufacturing-use product, *Pasteuria usgae* – BL1, containing *Pasteuria usgae* as a new active ingredient. Although it was determined that these data fulfilled current requirements for a conditional, time-limited FIFRA section 3(c)(7)(C) registration, the Agency required Pasteuria Bioscience, Incorporated to submit the following additional data and/or information in the time frames listed:

Study Type	Required Data/Information	Due Date
Analysis of Samples (OCSPP Guideline 885.1400)	The preliminary analysis of samples provided to the Agency revealed a wide range of concentrations, with many replicates containing 1–2 orders of magnitude fewer *Pasteuria usgae* spores than the minimum specified on the Confidential Statement of Formula and product label (i.e., 1 x 10^6 spores per milliliter). A follow-up explanation, attempting to address this variability, mentioned several factors that contributed to this inconsistency and discussed how the concentration of spores could be adjusted during the manufacturing process, if necessary. Despite this additional information, a new five-batch analysis, with all batches from production level, must be submitted to the Agency.	May 1, 2011

Study Type	Required Data/Information	Due Date
Manufacturing Process (OCSPP Guideline 885.1200)	The original manufacturing process did not describe quality control measures taken to confirm that *Pasteuria usgae* was the only *Pasteuria* species present in the master stock. A follow-up explanation, which demonstrated that batches are screened for the presence of other microbes and screened against sting nematodes to confirm the presence of *Pasteuria usgae*, still did not provide sufficient information to indicate that screening for other *Pasteuria* species is conducted during the manufacturing process. Other *Pasteuria* species, specifically those that parasitize saprophytic (non-plant pathogenic) nematodes, must be screened for during the manufacturing process. Pasteuria Bioscience, Incorporated must integrate quality control measures that screen for *Pasteuria* species that parasitize saprophytic nematodes, either immediately after freezing or after making seed stock, into their current manufacturing process and provide a written description of these measures to the Agency. **This information was submitted by Pasteuria Bioscience, Incorporated (MRID No. 478853-01) in a timely manner and is currently being reviewed for acceptability.**	October 1, 2009
Product Identity (OCSPP Guideline 885.1100)	Currently, full recognition of *Pasteuria usgae* as a species is still pending with the Judicial Commission of the International Committee for Systematic Bacteriology. Once *Pasteuria usgae* has been recognized and removed from the category *Candidatus*, documentation indicating official recognition must be provided to the Agency.	As soon as the specified information becomes available
Storage Stability (OCSPP Guideline 830.6317)	The storage stability study for the technical grade of the active ingredient (TGAI)/manufacturing-use product (MP) has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency. Within the discussion of these results, the test substance must be described to ensure that this data requirement has been fulfilled for both the TGAI and the MP (i.e., reference that the TGAI is equivalent to the MP for *Pasteuria usgae* – BL1). **This information was submitted by Pasteuria Bioscience, Incorporated (MRID No. 479672-01) in a timely manner and is currently being reviewed for acceptability.**	June 1, 2010

2. Econem™ (EPA Registration Number 85004-2)

The Agency evaluated the data submitted in connection with the initial registration of the end-use product, Econem™, containing *Pasteuria usgae*. Although it was determined that these data fulfill current requirements for a conditional, time-limited FIFRA section 3(c)(7)(A) registration, the Agency required Pasteuria Bioscience, Incorporated to both submit/cite all data required to support *Pasteuria usgae* – BL1 (as outlined in its associated registration notice) and submit the following additional data and/or information in the time frames listed:

Study Type	Required Data/Information	Due Date
Analysis of Samples (OCSPP Guideline 885.1400)	The preliminary analysis of samples provided to the Agency revealed a wide range of concentrations of *Pasteuria usgae* spores. A new five-batch analysis, with all batches from production level, must be submitted to the Agency.	August 1, 2011
Storage Stability (OCSPP Guideline 830.6317)	The storage stability study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency. **This information was submitted by Pasteuria Bioscience, Incorporated (MRID No. 480262-01) in a timely manner and is currently being reviewed for acceptability.**	September 1, 2010
Corrosion Characteristics (OCSPP Guideline 830.6320)	The corrosion characteristics study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency. **This information was submitted by Pasteuria Bioscience, Incorporated (MRID No. 480262-02) in a timely manner and is currently being reviewed for acceptability.**	September 1, 2010

3. *Pasteuria usgae* – Liquid Formulation (EPA Registration Number 85004-3)

The Agency evaluated the data submitted in connection with the initial registration of the end-use product, *Pasteuria usgae* – Liquid Formulation, containing *Pasteuria usgae*. Although it was determined that these data fulfill current requirements for a conditional, time-limited FIFRA section 3(c)(7)(A) registration, the Agency required Pasteuria Bioscience, Incorporated to both submit/cite all data required to support *Pasteuria usgae* – BL1 (as outlined in its associated registration notice) and submit the following additional data and/or information in the time frames listed:

Study Type	Required Data/Information	Due Date
Storage Stability (OCSPP Guideline 830.6317)	The storage stability study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency.	June 18, 2011
Corrosion Characteristics (OCSPP Guideline 830.6320)	The corrosion characteristics study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency.	June 18, 2011

C. Reporting of Adverse Effects and Hypersensitivity Incidents

Notwithstanding the information stated in the previous sections, it should be clearly understood that certain, specific data are required to be reported to the Agency as a requirement for maintaining the federal registration for a pesticide product. A brief summary of these types of data are described below.

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA section 6(a)(2). Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR § 158.2140(d).

IX. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
cSt	CentiStokes
°C	degrees Celsius
EDSP	Endocrine Disruptor Screening Program
EPA	Environmental Protection Agency (the "Agency")
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g/cm^3	grams per cubic centimeter
LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
mg/kg	milligrams per kilogram
mL	milliliter
MP	manufacturing-use product
MPCA	microbial pest control agent
MRID No.	Master Record Identification Number
NE	"No Effect"
NIOSH	National Institute for Occupational Safety and Health
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
PC Code	Pesticide Chemical Code
PCR	polymerase chain reaction
PP	Pesticide Petition
PPE	personal protective equipment
TGAI	technical grade of the active ingredient

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APPENDIX A – MICROBIAL PESTICIDE DATA REQUIREMENTS

TABLE 1. Product Analysis Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/ Manufacturing-Use Product (MP), *Pasteuria usgae* – BL1 (40 CFR § 158.2120)

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	MP	
Product Chemistry and Composition			
Product Identity (885.1100)	Not applicable	*Pasteuria usgae* is host-specific to the sting nematode (*Belonolaimus longicaudatus*), which can be damaging to a variety of crops such as turf and strawberry. The active agent of *Pasteuria usgae* is an endospore that attaches to and infects the host nematode during all life stages (except eggs). The endospores formed inside the host are released into the soil when the infected nematode decomposes. The spores are nonmotile and stable in the soil environment for several years. **Classification: Acceptable. Currently, full recognition of *Pasteuria usgae* as a species is still pending with the Judicial Commission of the International Committee for Systematic Bacteriology. Once *Pasteuria usgae* has been recognized and removed from the category *Candidatus*, documentation indicating official recognition must be provided to the Agency.**	474267-01
Manufacturing Process (885.1200)	Submitted data satisfied the requirement of manufacturing process for the TGAI/MP for the purposes of a conditional, time-limited FIFRA section 3(c)(7)(C) registration. **Classification: Supplemental: Upgradeable. Pasteuria Bioscience, Incorporated was required to integrate quality control measures that screen for *Pasteuria* species that parasitize saprophytic nematodes, either immediately after freezing or after making seed stock, into their current manufacturing process and provide a written description of these measures to the Agency on or before October 1, 2009. This information has been provided to the Agency (MRID No. 478853-01) and is being reviewed for acceptability.**		474267-02
Deposition of a Sample in a Nationally Recognized Culture Collection (Not applicable)	*Pasteuria usgae* is on deposit with the American Type Culture Collection in Manassas, Virginia under Accession Number SD-5835.	Not applicable	Not applicable

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	MP	
Discussion of Formation of Unintentional Ingredients (885.1300)	Submitted data satisfied the requirement of discussion of formation of unintentional ingredients for the TGAI/MP. **Classification: Acceptable**		474267-03
Analysis and Certified Limits			
Analysis of Samples (885.1400)	Submitted data satisfied the requirement of analysis of samples for the TGAI/MP for the purposes of a conditional, time-limited FIFRA section 3(c)(7)(C) registration. **Classification: Unacceptable. A new five-batch analysis, with all batches from production level, must be submitted to the Agency on or before May 1, 2011.**		474267-04
Certification of Limits (885.1500)	Not applicable	The certified limits for the active and inert ingredients fell within the OCSPP Guideline 830.1750 specified ranges. **Classification: Acceptable**	474267-05
Physical and Chemical Characteristics			
Color (830.6302)	Clear to very faint yellow-brown or cloudy at 24°C (5 batches)	Not applicable	474267-06
Physical State (830.6303)	Liquid at 20°C	Not applicable	474267-06
Odor (830.6304)	No odor	Not applicable	474267-06
Stability to Normal and Elevated Temperatures, Metals, and Metal Ions (830.6313)	Stable after exposure to 54°C for 14 days.	Not applicable	474267-07
Storage Stability (830.6317)	Preliminary results indicated that after 1 month of storage at 4°C, the TGAI/MP had a 5% loss of attachment and a 15% loss of infectivity. **Pasteuria Bioscience, Incorporated was required to submit the final storage stability study to the Agency on or before June 1, 2010. This information has been provided to the Agency (MRID No. 479672-01) and is being reviewed for acceptability.**		474267-08
Miscibility (830.6319)	Not applicable	Not required because *Pasteuria usgae* – BL1 is not an emulsifiable form of microbial pesticide (refer to test note #2 of 40 CFR § 158.2120(d)).	Not applicable
Corrosion Characteristics (830.6320)	Not applicable	Waived because *Pasteuria usgae* – BL1 will be packaged for very short time periods in plastic as it moves from the manufacturing facility to the formulation facility for end-use products. There will be no long-term exposure to the packaging. **Classification: Acceptable**	474350-01
pH (830.7000)	6.80–6.96 (5 batches)* 6–7.3**	Not applicable	474267-06* CSF**

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	MP	
Viscosity (830.7100)	Not applicable	Waived because *Pasteuria usgae* – BL1 is not viscous and will not be applied as a product. There will be no environmental exposure. **Classification: Acceptable**	474350-01
Density/Relative Density/Bulk Density (Specific Gravity) (830.7300)	Specific gravity = 1.006–1.008 gram/cubic centimeter (g/cm^3) (5 batches)* Specific gravity = 1.0 g/cm^3**	Not applicable	474267-06* CSF**

TABLE 2. Product Analysis Data Requirements for the End-Use Products, Econem™ and *Pasteuria usgae* – Liquid Formulation (40 CFR § 158.2120)

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	*Pasteuria usgae* – Liquid Formulation**	
Product Chemistry and Composition			
Product Identity (885.1100)	Econem™ is an end-use product and a natural biological control for use on turf against sting nematodes. It contains 0.0020% *Pasteuria usgae* (at least 1 x 10^4 spores per gram or 4.5 x 10^6 spores per pound). **Classification: Acceptable**	*Pasteuria usgae* – Liquid Formulation is proposed as an end-use product, which will be used to control sting nematodes in turf and strawberry. It contains 0.0033% *Pasteuria usgae* (at least 1.3 x 10^7 spores per gram or 5.8 x 10^9 spores per pound). Currently, *Pasteuria usgae* has an exemption from the requirement of a tolerance for all food commodities (40 CFR § 180.1290), while all inert ingredients in this formulation are cleared for food use under 40 CFR part 180, subpart D ("Exemptions from Tolerances"). **Classification: Acceptable**	475218-01* 475963-01**
Manufacturing Process (885.1200)	Submitted data satisfied the requirement of manufacturing process for this end-use product. **Classification: Acceptable**	Submitted data satisfied the requirement of manufacturing process for this end-use product. **Classification: Acceptable**	475218-01* 475963-01**
Deposition of a Sample in a Nationally Recognized Culture Collection (Not applicable)	Not applicable		Not applicable

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	*Pasteuria usgae* – Liquid Formulation**	
Discussion of Formation of Unintentional Ingredients (885.1300)	Submitted data satisfied the requirement of discussion of formation of unintentional ingredients for this end-use product. **Classification: Acceptable**	Submitted data satisfied the requirement of discussion of formation of unintentional ingredients for this end-use product. **Classification: Acceptable**	475218-02* 475963-01**
Analysis and Certified Limits			
Analysis of Samples (885.1400)	Submitted data satisfied the requirement of analysis of samples for this end-use product for the purposes of a conditional, time-limited FIFRA section 3(c)(7)(A) registration only. **Classification: Supplemental: Upgradeable. A new five-batch analysis, with all batches from production level, must be submitted to the Agency on or before August 1, 2011.**	Submitted data satisfied the requirement of analysis of samples for this end-use product. **Classification: Acceptable**	475375-01* 475963-03**
Certification of Limits (885.1500)	The certified limits for the active and inert ingredients fell within the OCSPP Guideline 830.1750 specified ranges. **Classification: Acceptable**	The certified limits for the active and inert ingredients fell within the OCSPP Guideline 830.1750 specified ranges. **Classification: Acceptable**	475218-04* 475963-04**
Physical and Chemical Characteristics			
Color (830.6302)	Not applicable		Not applicable
Physical State (830.6303)	Not applicable		Not applicable
Odor (830.6304)	Not applicable		Not applicable
Stability to Normal and Elevated Temperatures, Metals, and Metal Ions (830.6313)	Not applicable		Not applicable
Storage Stability (830.6317)	**Pasteuria Bioscience, Incorporated was required to submit the final storage stability study to the Agency on or before September 1, 2010. This information has been provided to the Agency (MRID No. 480262-01) and is being reviewed for acceptability.**	**A twelve-month storage stability study is ongoing, and results must be submitted to the Agency upon completion (on or before June 18, 2011).**	475218-05* 476504-03**

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	***Pasteuria usgae* – Liquid Formulation****	
Miscibility (830.6319)	Not required because Econem™ is not an emulsifiable form of microbial pesticide (refer to test note #2 of 40 CFR § 158.2120(d)).	Not required because *Pasteuria usgae* – Liquid Formulation is not an emulsifiable form of microbial pesticide (refer to test note #2 of 40 CFR § 158.2120(d)).	Not applicable
Corrosion Characteristics (830.6320)	The test material was stored at 20ºC. Evaluation of the container pieces, regarding evidence of corrosion or other changes, occurred at months 0, 3, 6, 9, and 12. **Pasteuria Bioscience, Incorporated was required to submit the final corrosion characteristics study on or before September 1, 2010. This information has been provided to the Agency (MRID No. 480262-02) and is being reviewed for acceptability.**	**A twelve-month corrosion characteristics study is ongoing, and results must be submitted to the Agency upon completion (on or before June 18, 2011).**	475218-06* 476504-04**
pH (830.7000)	Not applicable		Not applicable
Viscosity (830.7100)	Not required because Econem™ is not a liquid form of microbial pesticide (refer to test note #4 of 40 CFR § 158.2120(d)).	15239.66 CentiStokes (cSt) at 20ºC and 2591.34 cSt at 40ºC	476504-02**
Density/Relative Density/Bulk Density (Specific Gravity) (830.7300)	Not applicable		Not applicable

TABLE 3. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/ Manufacturing-Use Product (MP), *Pasteuria usgae* – BL1 (40 CFR § 158.2140)

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	**MP**	
Tier I			
Acute Oral Toxicity/Pathogenicity (885.3050)	Not toxic and/or pathogenic to rats by oral dose of 1 x 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. **Classification: Acceptable TOXICITY CATEGORY IV**	Not applicable	474267-09

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	MP	
Acute Dermal Toxicity (885.3100)	Not toxic to rats when treated with 2,000 mg/kg at 10^8 spores/mL. The acute dermal LD_{50} was greater than 2,000 mg/kg for 10^8 spores/mL. **Classification: Acceptable TOXICITY CATEGORY IV**	Not applicable	474267-12
Acute Pulmonary Toxicity/Pathogenicity (885.3150)	Not toxic and/or pathogenic to rats by pulmonary dose of 1–3 x 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. **Classification: Acceptable TOXICITY CATEGORY IV**	Not applicable	474267-10
Acute Injection Toxicity/Pathogenicity (885.3200)	Not toxic and/or pathogenic to rats by intravenous dose of 1x 10^8 spores/animal. Since microbial enumeration was not performed because the test material would not grow on agar media, the infectivity was uncertain. However, because the spores are highly specific to the sting nematode, infectivity is unlikely to be a concern. **Classification: Acceptable**	Not applicable	474267-11
Hypersensitivity Incidents (885.3400)	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals occurring during the testing or production of the TGAI/MP, were observed by the registrant. Any future hypersensitivity incidents must be reported to the Agency.		474350-02
Cell Culture (885.3500)	Not required because *Pasteuria usgae* is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).	Not applicable	Not applicable
Acute Oral Toxicity (870.1100)	Not applicable	Waived based on the results of MRID Number 474267-09 and because the MP is equivalent to the TGAI. **Classification: Acceptable TOXICITY CATEGORY IV**	474979-01

Data Requirement (OCSPP Guideline)	Results		MRID Number
	TGAI	MP	
Acute Dermal Toxicity (870.1200)	Not applicable	Waived based on the results of MRID Number 474267-12 and because the MP is equivalent to the TGAI. **Classification: Acceptable TOXICITY CATEGORY IV**	474979-01
Acute Inhalation Toxicity (870.1300)	Not applicable	Waived based on the results of MRID Number 474267-10 and because the MP is equivalent to the TGAI. **Classification: Acceptable TOXICITY CATEGORY IV**	474979-01
Acute Eye Irritation (870.2400)	Not applicable	Waived based on *Pasteuria usgae*'s lack of toxicity in the other toxicology studies and precautionary statements that mitigate potential for worker exposure. **Classification: Acceptable TOXICITY CATEGORY III**	474350-03
Primary Dermal Irritation (870.2500)	Not applicable	Waived based on the results of MRID Number 474267-12 and precautionary statements/personal protective equipment that mitigate potential for worker exposure. **Classification: Acceptable TOXICITY CATEGORY III**	474350-03
Tiers II and III			
Not required for *Pasteuria usgae* based on the lack of acute toxicity/pathogenicity in the Tier I studies.			

TABLE 4. Toxicology Data Requirements for the End-Use Products, Econem™ and *Pasteuria usgae* – Liquid Formulation (40 CFR § 158.2140)

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	***Pasteuria usgae* – Liquid Formulation****	
Tier I			
Acute Oral Toxicity/Pathogenicity (885.3050)	Not applicable		Not applicable
Acute Dermal Toxicity (885.3100)	Not applicable		Not applicable
Acute Pulmonary Toxicity/Pathogenicity (885.3150)	Not applicable		Not applicable
Acute Injection Toxicity/Pathogenicity (885.3200)	Not applicable		Not applicable

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	***Pasteuria usgae* – Liquid Formulation****	
Hypersensitivity Incidents (885.3400)	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals occurring during the testing or production of these end-use products, were observed by the registrant. Any future hypersensitivity incidents must be reported to the Agency.		475218-07* 475963-06**
Cell Culture (885.3500)	Not applicable		Not applicable
Acute Oral Toxicity (870.1100)	Waived based on the results of MRID Number 474267-09 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY IV**	Waived based on the results of MRID Number 474267-09 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY IV**	475218-10* 475963-07**
Acute Dermal Toxicity (870.1200)	Waived based on the results of MRID Number 474267-12 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	Waived based on the results of MRID Number 474267-12 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	475218-10* 475963-07**
Acute Inhalation Toxicity (870.1300)	Waived based on the results of MRID Number 474267-10 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	Waived based on the results of MRID Number 474267-10 and because this formulation contains inert ingredients, which are not of toxicological concern and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	475218-10* 475963-07**
Acute Eye Irritation (870.2400)	Econem™ was moderately irritating to the eye based on the highest maximum mean total score of 37.0, recorded 1 hour after test material instillation. **Classification: Acceptable TOXICITY CATEGORY III**	*Pasteuria usgae* – Liquid Formulation was not irritating to the eye based on the highest maximum mean total score of 0.0. **Classification: Acceptable TOXICITY CATEGORY IV**	475218-08* 476504-05**
Primary Dermal Irritation (870.2500)	Econem™ was slightly irritating to the skin. The Primary Irritation Index was 0.1. **Classification: Acceptable TOXICITY CATEGORY IV**	*Pasteuria usgae* – Liquid Formulation was not a dermal irritant. The Primary Irritation Index was 0.0. **Classification: Acceptable TOXICITY CATEGORY IV**	475218-09* 476504-06**

Data Requirement (OCSPP Guideline)	Results		MRID Number
	Econem™*	***Pasteuria usgae* – Liquid Formulation****	
Tiers II and III			
Not required for *Pasteuria usgae* based on the lack of acute toxicity/pathogenicity in the Tier I studies.			
Additional Studies			
Subcutaneous Injection Toxicity (Not applicable)	Not applicable	None of the five lots of *Pasteuria usgae* – Liquid Formulation induced mortality or clinical signs of toxicity in mice when injected subcutaneously at a concentration of 1.0×10^6 spores per animal. **Classification: Acceptable**	476504-01**

TABLE 5. Nontarget Organism and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Pasteuria usgae* (40 CFR § 158.2150)

Data Requirement (OCSPP Guideline)	Results	Toxicity Category/Description	MRID Number
Tier I			
Avian Oral Toxicity (885.4050)	Data waiver rationale provided sufficient information to determine that toxicity/pathogenicity to avian wildlife is not expected. **Classification: Acceptable**	Not applicable	474267-13
Avian Inhalation Toxicity/Pathogenicity (885.4100)	Not required as the nature of the microbial pesticide does not indicate potential pathogenicity to birds or relatedness to any known bird pathogens (refer to test note #3 of 40 CFR § 158.2150(e)).	Not applicable	Not applicable
Wild Mammal Toxicity/Pathogenicity (885.4150)	Tests required by 40 CFR § 158.2140 were adequate and appropriate for assessment of hazards to wild mammals (refer to test note #4 of 40 CFR § 158.2150(e)). **Classification: Acceptable for wild mammal risk assessment**	Testing indicated no adverse effects to laboratory rats at 1×10^8 spores/mL when dosed orally.	474267-09
Freshwater Fish Toxicity/Pathogenicity (885.4200)	*Pasteuria usgae* will not be applied directly to water and is not expected to enter freshwater environments in amounts that are significantly higher than naturally occurring concentrations. Data waiver rationale provided sufficient information to determine that toxicity/pathogenicity or substantial exposure to freshwater fish is not expected. **Classification: Acceptable**	Not applicable	474267-13

Data Requirement (OCSPP Guideline)	Results	Toxicity Category/Description	MRID Number
Freshwater Invertebrate Toxicity/Pathogenicity (885.4240)	*Pasteuria usgae* will not be applied directly to water and is not expected to enter freshwater environments in amounts that are significantly higher than naturally occurring concentrations. Data waiver rationale provided sufficient information to determine that toxicity/pathogenicity or substantial exposure to freshwater invertebrates is not expected. **Classification: Acceptable**	Not applicable	474267-13
Estuarine/Marine Fish and Invertebrate Testing (885.4280)	Not required because *Pasteuria usgae* will not be applied to water and is not expected to enter marine/estuarine environments in amounts that are significantly higher than naturally occurring concentrations (refer to test note #6 of 40 CFR § 158.2150(e)).	Not applicable	Not applicable
Nontarget Plant Testing (885.4300)	Not required because *Pasteuria usgae* is not related to known plant pathogens, and adverse effects to plants are not expected (refer to test note #7 of 40 CFR § 158.2150(e)).	Not applicable	Not applicable
Nontarget Insect Testing (885.4340)	Data waiver rationale provided sufficient information to determine that toxicity/pathogenicity to nontarget insects is not expected. **Classification: Acceptable**	Not applicable	474267-13
Honey Bee Testing (885.4380)	Data waiver rationale provided sufficient information to determine that toxicity/pathogenicity to honey bees is not expected. **Classification: Acceptable**	Not applicable	474267-13
Tiers II, III, and IV			
Not required for *Pasteuria usgae* based on the acceptability of the waiver rationales provided for Tier I.			

APPENDIX B – *PASTEURIA USGAE* MANUFACTURING-USE AND END-USE PRODUCTS

EPA Registration Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate	Target Pest
85004-1	*Pasteuria usgae* – BL1	0.01%	Technical	N/A	N/A	N/A	N/A
85004-2	Econem™	0.0020%	End Use – Granular	Turf	Standard ground application equipment (e.g., drop spreader)	2–10 pounds of product per 1,000 square feet of turf	Sting nematode
85004-3	*Pasteuria usgae* – Liquid Formulation	0.0033%	End Use – Liquid	Turf and Strawberry	Standard ground spray application equipment or chemigation	0.1–5 gallons of product per 100 square feet of turf or strawberry bed	Sting nematode