



Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

November 1, 2008

Re: This Experimental Use Permit application and Petition for a Temporary Exemption from the Requirement of a Tolerance for *Pasteuria usgae* – Clay granule (EP) and *Pasteuria usgae* – Liquid formulation (EP)

Pasteuria Bioscience Inc. (PBI, Establishment No. 85004) respectfully submits this Experimental Use Permit (EUP) request linked with a Petition for a Temporary Exemption from the Requirement of a Tolerance pursuant to §5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with respect to two formulations of the bio-nematicide *Pasteuria usgae*, a Clay Granule and Liquid Formulation, both of which are end products (EP). The purpose of this EUP is to evaluate the active ingredient, *Pasteuria usgae*, using two different formulations on strawberries and turf. The Petition for a Temporary Exemption from the Requirement of a Tolerance is focused on strawberries for both end products.

The experimental research program will focus primarily on efficacy of the sting nematode (*Belonolaimus longicaudatus*) and agronomic performance evaluations of the respective crops – turf grasses and strawberries. A temporary exemption from the requirement of a tolerance is also sought in relation to the use on strawberries so that the *Pasteuria usgae* treated strawberries may enter the commerce. This EUP and temporary exemption from the requirement of a tolerance are natural steps to a full Section 3 registration and permanent exemption from the requirement of a tolerance of these end products.

In May, a registration application (85004-R) was submitted and is currently under EPA review for *Pasteuria usgae* – Liquid Suspension (TGAI/MP). And in August, a second registration application (85004-E) was submitted and is currently under EPA review for *Pasteuria usgae* – Clay Granule (EP). Early in 2009, it is anticipated that a third registration for a liquid formulation *Pasteuria usgae* will be submitted, the same formulation in this experimental research program under the requested EUP.

Plant-parasitic nematodes attack a wide range of crops causing billions of dollars of losses to growers each year. Since nematodes are microscopic and attack the plant root system, the direct feeding damage is hidden but the impact on the plant is dramatic, causing crop yield reduction and/or cosmetic effects that lower the value of the plant products. The market for turf nematode

control in the US today is about \$5M and expected to grow to \$10-15M per annum. The market for strawberries is even larger since this is a high value food crop. This market is primarily for sting nematode control and currently is dominated by 1,3-dichloropropene, chloropicrin, phenamiphos, and methyl bromide chemistries, all of which have handling and reentry restrictions due to their toxicology profiles.

Bacteria of the genus *Pasteuria* have long been recognized as promising biological control agents for plant-parasitic nematodes. Recently, PBI has developed a proprietary *in vitro* production method of this bacterium that has been successfully scaled-up to a commercially viable methodology. *Pasteuria* spp. are ubiquitous in nature and have been reported to infect more than 300 different nematode species from nearly every country where investigations were conducted. Despite extensive testing with a wide range of nematode species, *Pasteuria usgae* [AF254387] has an extremely narrow host range, specific to a single nematode species, sting nematodes (*Belonolaimus longicaudatus*).

In this EUP request, the required EPA forms are included (i.e. 8570-17, 8570-4, 8570-34 and 8570-35), with a copy of each product label, and a listing of the contents and result summary. A temporary exemption from the requirement of a tolerance is included in Volume 10 of 10.

PBI is seeking this EUP request that is tentatively categorized as B610, "Food use; EUP application; establish temporary tolerance exemption" with an associated registration fee of \$11,025. Since PBI is a small start up bio-nematicide firm, a fee waiver reduction has been granted. Taking into account the 75% reduction in the registration fee, \$2,756.25 was paid on the pay.gov website on October 30, 2008. A pay.gov acknowledgement of payment is included in the volume, Annex 2.

Please let me know if you have any questions or need further clarification for the information included herein.

Sincerely,



Susan MacIntosh

President

On behalf of *Pasteuria* Bioscience, Inc.™

MacIntosh & Associates, Inc.

1203 Hartford Ave

Saint Paul, MN 55116-1622

Tel. +1.651.340.1262

Cell +1.612.720.926

Email: macintosh-associates@comcast.net

Cc: David N. Duncan, Ph.D., President & CEO, *Pasteuria* Bioscience, Inc.
Kelly Smith, Ph.D., Chief Technical Officer, *Pasteuria* Bioscience, Inc.

Pasteuria Bioscience, Inc.

November 1, 2008

Annex 1. Data Matrix
Pasteuria usgae – Liquid Formulation

Volume	Guideline Study	Title	MRID #
1	Not applicable	Administrative Materials	Admin.
2	885.1100 885.1200	Product identity and Manufacturing process	47596301
3	885.1300	Discussion of formulation of unintended ingredients	47605401
4	885.1400	Analysis of samples	47596303
5	885.1500	Certification of limits	47596304
6	830.6317 830.6320 830.7100	Request for waivers from the requirement to conduct Storage Stability – 830.6317, Corrosion Characteristics – 830.6320 and Viscosity – 830.7100 for <i>Pasteuria usgae</i> – Liquid Formulation (EP)	47596305
7	885.3400	Hypersensitivity incidents	47596306
8	870.1100 870.1200 870.1300	Request for waivers from the requirement to conduct Toxicology guideline studies: Acute Oral Toxicity – 870.1100, Acute Dermal Toxicity – 870.1200 and Acute Inhalation Toxicity – 870.1300 for <i>Pasteuria usgae</i> – Liquid Formulation (EP)	47596307
9	870.2400 870.2500	Request for waivers from the requirement to conduct Toxicology guideline studies: Acute eye irritation study – 870.2400 and Primary dermal irritation study – 870.2500 for <i>Pasteuria usgae</i> – Liquid Formulation (EP)	47596308
10	Not Applicable	Petition Request for a Temporary Exemption from the Requirement of a Tolerance to <i>Pasteuria usgae</i> – Clay Granule and <i>Pasteuria usgae</i> – Liquid Formulation	Admin.

Submitter: Susan MacIntosh, B.A.
 MacIntosh & Associates, Inc.
 Regulatory Consultant on behalf of Pasteuria Bioscience, Inc.