

**EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION
COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN
THE FEDERAL REGISTER (7/1/2006)**

EPA Biopesticides and Pollution Prevention Division contact: Shanaz Bacchus: (703) 308-8097

**Applicant: AgroGreen, Biological Division of Minrav Infrastructures (1993) Ltd.
("AgroGreen")**

6F7111

EPA has received a pesticide petition (6F7111) from AgroGreen, 3 Habossem str., P.O. Box 153, Ashdod, 77101 Israel (submitted by RegWest Company, LLC; 30856 Rocky Road; Greeley, CO 80631-9375) proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.

To establish an exemption from the requirement of a tolerance for
Microbial pesticide *Bacillus firmus* isolate I-1582

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, AgroGreen has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by AgroGreen and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. AgroGreen Petition Summary
6F7111

A. Product Name and Proposed Use Practices

Product Name:

Chancellor.

Proposed Use Practices:

Registration of Chancellor is being proposed as a liquid formulation for the stimulation and protection of plant roots and the suppression of plant pathogenic nematodes on fruits, vegetables, field crops, turf and ornamentals. Chancellor suppresses nematode populations. Chancellor is applied for soil incorporation by drenching, placement in furrow or by drip irrigation; it is also suitable for application by foliar spray or fertigation on turf and may be applied with a pressure or hose-end spray or drenched when treating home lawns and gardens. Application rates: soil application: from 1 to 12 pints per acre; turf: 1 oz/gal water; ornamentals: 1 to 6 ounces per gallon water; seed treatment: 1 to 12 oz per 100 pounds; soil treatment/compost: 8 to 24 oz per 50 pounds; residential lawn and garden: ½ to 2 oz per gallon of water applied at the rate of 1 gallon solution per 10 square feet.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues.

The active ingredient in Chancellor is *Bacillus firmus* strain I-1582. *Bacillus firmus* is a Gram-positive, nonpathogenic and harmless bacterium. *Bacillus firmus* is ubiquitous in nature and may be isolated from the air, streams, soils, oil wells, oceans and a variety of plant root surfaces.

A summary of the *Bacillus firmus* strain I-1582 product identity is as follows:

Trade Name: Chancellor

Scientific Name: *Bacillus firmus* strain I-1582

Morphology: The isolate has been described as having rods with a length of 3.2 to 5.0 micrometers and a width of 1.0 to 1.3 micrometers. The spores are ellipsoid and there is no swelling of the sporangium. The maximum temperature for growth is 40° to 45°C and the minimum temperature is 5° to 10°C. Pigments have been noted for growth on certain mediums; growth on CASO appears yellow while growth on FP appears cream-colored. There is no anaerobic growth.

2. Magnitude of residues at the time of harvest and method used to determine the residue.

No residues of *Bacillus firmus* strain I-1582 are anticipated in treated crops at harvest. OPPTS Guideline 885.2000 states that "If Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data (with the general exception of a monitoring method) would be indicated and thus a recommendation for an exemption from the requirements of a tolerance can be made." Studies with *Bacillus firmus* strain I-1582 demonstrate low mammalian toxicity. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus firmus* strain I-1582. Because it is naturally occurring, pesticide residues cannot be distinguished from those that exist in the environment.

3. A statement of why an analytical method of detecting and measuring the levels of the pesticide residue are not needed.

OPPTS Guideline 885.2000 states that "If Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data (with the general exception of a monitoring method) would be indicated and thus a recommendation for an exemption from the requirements of a tolerance can be made." Studies with *Bacillus firmus* strain I-1582 demonstrate low mammalian toxicity. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus firmus* strain I-1582. Further, *Bacillus firmus* strain I-1582 is a naturally-occurring microorganism and *Bacillus firmus* is widespread in the environment. Also, because of the low toxicity potential and its natural occurrence, even if residues occur on treated agricultural food/feed items, they would not harm U.S. human adult, children and infant populations.

C. Mammalian Toxicological Profile

AgroGreen conducted the required toxicology studies to support its petition for an exemption from the requirement of a tolerance and associated registration. The studies conducted show low mammalian toxicity for *Bacillus firmus* strain I-1582. No

pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus firmus* strain I-1582. *Bacillus firmus* strain I-1582 does not produce toxins.

Toxicology data in support of the exemption from the requirement of a tolerance for *Bacillus firmus* strain I-1582 included studies with the cell mass (technical) and with the formulated product as follows:

Acute Toxicity and/or Pathogenicity

Guideline 885.3050: Acute oral toxicity/pathogenicity (spores – tan powder [technical]): The acute oral toxicity/pathogenicity for *B. firmus* spores is greater than 10^8 CFU/animal (rat). There was no mortality during the study. Total clearance of the live organism from the blood occurred by Day 7 and clearance from the remaining test organs occurred by Day 14.

Guideline 885.3100: Acute dermal toxicity/pathogenicity (formulated product): The estimated LD₅₀ was determined to be > 5050 mg/kg (rabbit). No mortality occurred during the study. There were no clinical signs of toxicity at any time throughout the study. The gross necropsy conducted at termination of the study revealed no observable abnormalities.

Guideline 885.3150: Acute pulmonary toxicology/pathogenicity (spores – tan powder [technical]): The test substance produced no toxicity or indications of pathogenicity when administered by pulmonary instillation to albino rats at a dose of > 10^8 CFU/animal. There was no mortality during the study. Clearance of the live organism from all tissues analyzed was complete by Day 14.

Guideline 885.3200: Acute injection toxicology/pathogenicity (I.V) (spores – tan powder [technical]): The test substance produced no toxicity or indications of pathogenicity when administered intravenously to albino rats at a dose of 10^7 CFU/animal. There was no mortality during the study. Clearance of the live organism from all tissues analyzed was complete by Day 21.

D. Aggregate Exposure

1. Dietary exposure.

Bacillus firmus is naturally-occurring and widespread in the environment. The low toxicity and nonpathogenicity/infectivity of *Bacillus firmus* strain I-1582 is demonstrated by the data summarized above. The product will be applied by incorporation into soil and/or by drenching.

i. Food.

It is not anticipated that residues of *Bacillus firmus* strain I-1582 will occur in treated raw agricultural commodities. Also, because of the low toxicity potential and its natural occurrence, even if residues occur on treated agricultural food/feed items, they would not harm U.S. human adult, children and infant populations. The product will be applied by incorporation into soil and/or by drenching. Because *Bacillus firmus* strain I-1582 is

naturally occurring, pesticide residues cannot be distinguished from those that exist in the environment.

ii. Drinking Water.

It is not anticipated that residues of *Bacillus firmus* strain I-1582 will occur in drinking water. *Bacillus firmus* strain I-1582 is ubiquitous in nature and may be isolated from the air, water (seas, streams, oceans, rivers), soils and a variety of plant root surfaces. Because *Bacillus firmus* strain I-1582 is naturally occurring in the environment, pesticide residues in drinking water cannot be distinguished from those that exist in the environment.

2. Non-dietary exposure.

The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant. *Bacillus firmus* strain I-1582 is ubiquitous in nature and may be isolated from the air, water (seas, streams, oceans, rivers), soils and a variety of plant root surfaces. Because *Bacillus firmus* strain I-1582 is naturally occurring in the environment, pesticide residues cannot be distinguished from those that exist in the environment.

E. Cumulative Effects

There is no anticipated potential for cumulative effects of *Bacillus firmus* strain I-1582 and other substances that have a common mechanism of toxicity. In the rat acute oral study, total clearance of the live organism from the blood occurred by Day 7 and clearance from the remaining test organs by Day 14. The rat acute pulmonary study showed total clearance of the live organisms from the blood, kidneys and liver by Day 7 and clearance from the remaining test organs by Day 14. The acute injection study showed clearance of the live organism from the cecum contents and liver by Day 14 and clearance from the remaining test organs by Day 21. Toxic effects produced by *Bacillus firmus* strain I-1582 should not be cumulative with those of any other chemical compounds.

F. Safety Determination

1. U.S. population.

Bacillus firmus is a naturally-occurring microorganism which is widespread and ubiquitous in the environment. The low toxicity of *Bacillus firmus* strain I-1582 is demonstrated by the data summarized above. Based on this information, the aggregate exposure to *Bacillus firmus* strain I-1582 over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to *Bacillus firmus* strain I-1582 residues. Exempting *Bacillus firmus* strain I-1582 from the requirement of a tolerance should be considered safe and pose insignificant risk.

2. Infants and children.

The toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus firmus* strain I-1582. There is a reasonable certainty that no harm will result to infants and

children from aggregate exposure to *Bacillus firmus* strain I-1582 residues.

G. Effects on the Immune and Endocrine Systems

No specific tests have been conducted with *Bacillus firmus* strain I-1582 to determine whether it may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen or other endocrine effects. However, it is not likely that *Bacillus firmus* strain I-1582 would have estrogen or endocrine effects because:

- It is a naturally-occurring microorganism which is widespread and ubiquitous in the environment.
- It has demonstrated low mammalian toxicity
- No pathogenicity, infectivity or systemic effects were observed in any of the tests conducted with *Bacillus firmus* strain I-1582 (except very slight to slight erythema on Day 1 of the acute dermal study):
 - When administered orally to rats the total clearance of the live organism from the blood occurred by Day 7 and clearance from the remaining test organs occurred by Day 14.
 - When administered by pulmonary instillation to rats, clearance of the live organism from all tissues analyzed was complete by Day 14.
 - When administered intravenously to rats clearance of the live organism from all tissues analyzed was complete by Day 21.
- An exhaustive literature search of the AGRICOLA, TOXLINE, BIOLOGICAL ABSTRACTS, Life Sciences 1990-1998, PubMed (indexed for MEDLINE) and OCLC databases for all years of available publications was conducted. There were no reports of pathogenic or systemic effects.
- *Bacillus firmus* strain I-1582 does not secrete any toxins or antibiotics.

H. Existing Tolerances

The applicant is not aware of any tolerances or exemptions from the requirement of a tolerance that may have been established or applied for domestically, other than this petition.

I. International Tolerances

The applicant is not aware of any tolerances or exemptions from the requirement of a tolerance that may have been established or applied for internationally, other than this petition.