

ENVIRONMENTAL PROTECTION AGENCY

[PF-746; FRL-5727-1]

Notice of Filing of Pesticide Petitions**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-746, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under

"SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: James Boland, Regulatory Action Leader, Biopesticides and Pollution Prevention Division, (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5th floor, CS1, 2800 Crystal Drive, Arlington, VA. 22202, (703) 308-8728; e-mail: boland.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows

proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-746] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-746] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 16, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners.

EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Micro Flo Company

PP 7F4801

EPA has received a pesticide petition (PP 7F4801) from Micro Flo Company, P.O. Box 5948, Lakeland FL 33807, c/o SRA International, Inc., 1850 M St., N.W., Washington DC 20036 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirement for a tolerance for residues of plant regulator *Bacillus cereus* BPO1 when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Micro Flo has submitted the following summary of information, data, and arguments in support of its pesticide petition. This summary was prepared by Micro Flo and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusions of the petitioner and not necessarily EPA.

A. Proposed Use Practices

Micro Flo Company's *Bacillus cereus* BPO1 is a foliar-applied plant regulator. When combined with the plant growth regulator, mepiquat chloride, for use on cotton, it allows the grower to manage the cotton plant for short-season production leading to reduced risk of yield and quality loss due to delayed and prolonged harvest. Benefits derived from BPO1 in conjunction with mepiquat chloride include increased early boll retention and/or larger bolls, reduced plant height which provides a more open canopy, less boll rot, improved defoliation, less trash and lower ginning costs, better harvest efficiency and a darker leaf color. Micro Flo is currently exploring potential uses of BPO1 on other major row crops.

BPO1 is applied from early season when the cotton is actively growing and not under stress, through late season on fields that cut out and then regrow or on fields where the cotton does not completely cut out. Application rates,

depending on the cotton variety and its vigor, vary from 0.03 - 0.38 grams BPO1/A.

The maximum application level for BPO1 on cotton is 0.75 gram/acre/year, with an average of 0.2 g/acre/year. For row crops (e.g., corn, soybeans), the maximum application will be less than 2 g/acre/application and less than 20 g/acre/year. This tolerance exemption petition is for use of *Bacillus cereus* BPO1 up to 20 g/acre/year. There is a 30-day pre-harvest interval (PHI). Livestock should not be fed or permitted to graze on BPO1-treated cotton forage.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The ATCC classification of Micro Flo's *Bacillus cereus* BPO1 is 55675. Only residues of BPO1 would be present, and these residues are indistinguishable from naturally-occurring *Bacillus cereus* without using specific genetic testing procedures for differentiating them.

2. *Magnitude of the residue anticipated at the time of harvest and the method used to determine the residue.* No magnitude of residue (MOR) studies have been conducted on BPO1 as total application rates are exceedingly low (Cotton: average, 0.2 g BPO1/acre/year; maximum, 0.75 g/acre/year; Other major row crops [e.g., soybeans, corn]: <20 g BPO1/acre/year) and it is toxicologically innocuous. The Pre-Harvest Interval (PHI) is currently 30 days. *Bacillus cereus* is indigenous and widespread throughout the United States and the rest of the world.

3. *Statement regarding the lack of need for an analytical method for detecting and measuring the levels of the pesticide residue.* As indicated above, the naturally-occurring population of *B. cereus* may make it impossible to distinguish between natural and introduced microbial populations without utilizing genetic differentiation techniques and therefore to establish and enforce tolerances for BPO1. In addition, the PHI is currently 30 days.

C. Mammalian Toxicity Profile

Acute mammalian toxicity studies via oral, dermal, inhalation, eye, intratracheal and intravenous routes were conducted with *Bacillus cereus* BPO1. No pathogenicity was observed. BPO1 was also tested for enterotoxin production; none was detected.

In a blood agar hemolysis assay conducted with BPO1, weak alpha hemolysis was observed. Based on the results of the above studies, subchronic, reproductive, teratology, chronic and

mutagenicity studies were not deemed necessary.

D. Aggregate Exposure

1. *Dietary exposure—*a. *Food.* *Bacillus cereus* BPO1 is currently pending registration for use on cotton at rates up to 0.75 g/A/year. Micro Flo Co. will, however, be evaluating BPO1 for future registration for use on other row crops (e.g., soybeans, corn) at rates less than 20 g/A/year. Considering the extremely low application rates, ubiquitous nature and natural occurrence of *Bacillus cereus*, the potential dietary exposure to BPO1 is minuscule.

b. *Drinking water.* *Bacillus cereus* BPO1 is prohibited on the label from direct application to water, although possible spray drift may contact drinking water. Again, considering the extremely low application rates, non-toxic mode of action, ubiquitous nature and natural occurrence of *Bacillus cereus*, the potential drinking water exposure to BPO1 is minuscule.

2. *Non-dietary exposure.* There is no anticipated non-dietary exposure to *Bacillus cereus* BPO1. Contact with naturally-occurring populations of *B. cereus* is common throughout the world. Residue exposure through contact with cotton seeds/oil and clothing produced from BPO1-treated cotton has been theoretically considered; residues are unlikely to be present after the delinting/cleaning process.

E. Cumulative Effects

Although there are other currently registered *Bacillus* products, some of which hold tolerance exemptions, their modes of action are unlike BPO1. Specifically, the other products typically produce enterotoxin which, when the bacteria producing it is consumed by insect pests, causes the pest to die. BPO1 does not produce enterotoxin, but instead appears to enable the target plant to more readily and efficiently uptake and utilize growth nutrients. BPO1 is a true growth regulator and to our knowledge does not have classic pesticidal activity. Maximum anticipated application rates are 0.75 g/A/year (cotton) and <20 g/A/year (major row crops including soybeans and corn). Based on the above, it is therefore felt that BPO1 should not be considered similar to existing *Bacillus* products.

F. Safety Determination

1. *U. S. population.* Since: (a) the maximum currently sought use rate is 0.75 g BPO1/A/year for use on cotton (and 20 g/A/year on other row crops for which registration applications have not been submitted), (b) the associated

anticipated minute residue levels are extremely unlikely to add appreciably to the natural, indigenous background levels of *Bacillus cereus*, (c) BPO1 does not produce enterotoxin, and (d) the toxicity/pathogenicity/infectivity studies show virtually no negative effects, BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

2. *Infants and children.* As previously discussed, based on the minuscule quantities of BPO1 used, its lack of toxicity and pathogenicity, and its mode of action, it is exceedingly improbable that infants or children would be at greater risk to BPO1 exposure than would adults. BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

3. *Endocrine effects.* There is no evidence that BPO1 has endocrine disrupter effects individually or in combination with any other chemical. It is unlikely to be an endocrine disrupter or to have a synergistic endocrine effect in combination with other chemicals.

G. Existing Tolerances

1. *Existing U.S. tolerances or exemptions from the requirement of a tolerance.* There are no current tolerances or tolerance exemptions for *Bacillus cereus* strain BPO1.

2. *International tolerances or exemptions from the requirement of a tolerance.* There are no Codex Maximum Residue Levels or tolerance exemptions for *Bacillus cereus* strain BPO1.

[FR Doc. 97-16358 Filed 6-24-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-737; FRL-5719-7]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-737, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Public Information and