ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300821; FRL–6068–7]

RIN 2070–AB78

Beauveria bassiana (ATCC #74040); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the *Beauveria bassiana* (ATCC #74040) in or on all food commodities when applied or used as ground and aerial foliar sprays for use only on terrestrial crops. TROY Biosciences, Incorporated, 2620 North 37th Drive, Phoenix, Arizona 85009, submitted an amended petition PP 5F4483 to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the exemption from tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Beauveria bassiana* (ATCC #74040) in or on all food commodities.

DATES: This regulation is effective April 28, 1999. Objections and requests for hearings must be received by EPA on or before June 28, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300821], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (''Tolerance Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300821], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300821]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 902W34, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 1998, 63 FR 31771) (FRL–5793–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by TROY Biosciences, Incorporated, 2620 North 37th Drive, Phoenix, Arizona 85009. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the microbial insecticidal agent *Beauveria bassiana* (ATCC #74040) in or on all food commodities.

A comment was received in response to the notice of filing regarding the potential for *Beauveria bassiana* (*B. bassiana*) to colonize corn and infect lungs of wild rodents and nasal passages of humans. The comment also referred to the potentially hazardous effects of beauvericin, a metabolite associated with this microbial pesticide. While *Beauveria bassiana* may infect corn, the acute oral toxicity/pathogenicity studies indicate no undue risk to humans, children and infants from dietary exposure. The data submitted in support of guideline requirements for plants suggest that other plants, including corn, are not likely to be at risk if the pesticide is used as labeled. Also, the acute oral and pulmonary toxicity/pathogenicity studies of the technical grade active ingredient indicate that it is neither toxic nor pathogenic to mammals or humans. The registrant has provided analytical methods and quality assurance procedures to control beauvericin, a potential metabolite, within regulatory levels. The data which were submitted for this petition were evaluated by the Agency and are sufficient to support the exemption from the requirement of a tolerance in or on all food commodities. A summary discussion of the reviews of the data submitted in support of this petition follows.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) 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. Section 408(b)(2)(C) requires EPA 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) 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.''

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

II. Toxicological Profile

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

Results of the following studies support the lack of toxicity/pathogenicity of the Technical Grade Active Ingredient (TGAI), *Beauveria bassiana* (ATCC #74040).

A. Product Chemistry

The data submitted for product identity of the active ingredient, *Beauveria bassiana* (ATCC #74040), and end use product, are sufficient to support the request for the proposed exemption from the requirement of a tolerance. The active ingredient is a naturally-occurring fungus which can be found in the United States and in the environment worldwide.

The registrant proposed sufficient quality assurance methods to control unintentional ingredients and contaminants in the proposed products within regulatory levels. Batches containing human pathogens are to be destroyed. Beauvericin levels in the technical grade active ingredient are not likely to exceed 60 ppm. The registrant has voluntarily withdrawn the registration of an old formulation, which had potential aflatoxin contamination present in an inert ingredient. The proposed new formulation has met the Agency's guideline requirements for microbial pesticides for food use.

B. Toxicology

1. *Acute oral toxicity/pathogenicity in rats, (Technical).* No animal mortality or overt toxic effects were noted in rats dosed orally with 1.9 x 10^8 colony forming units (cfu)/animal of *B. bassiana* (ATCC #74040). Red foci were noted on the lungs of three of the treated animals indicating possible pulmonary toxicity. However, the acute pulmonary toxicity/pathogenicity study confirmed clearance from the lungs as discussed below. Based on these studies, and the nature of the inerts in the sole registered microbial end use product (EP) containing this active ingredient, the EP can be considered a Toxicity Category IV pesticide.

2. *Acute dermal toxicity in rabbits, (Naturalis-L 225). B. bassiana* (ATCC #74040) was not pathogenic, infective or toxic in rabbits dosed dermally at 2 gm per animal containing 4.2 x 10^7 cfu/ml. It was therefore considered Toxicity Category IV for dermal toxicity.

3. *Acute pulmonary toxicity/pathogenicity in rats, (Technical).* No mortality or toxic or pathogenic effects were found in the test animals dosed intratracheally with 2.5 x 10^9 cfu *B. bassiana* (ATCC #74040)/animal. Clearance was complete from the lungs within 15 days of dosing. No significant clinical signs were observed. Brown or tan lesions were noted in the lungs of all treated animals starting on day 4 and an inflammatory response was evident in microscopic examination until day 22. The presence of an inflammatory response is expected as a component of the normal recognition and clearance of microbes by the immune system. No inflammation was evident on tissues examined at the end of the study.

4. *Acute intraperitoneal toxicity/pathogenicity testing in rats, (Technical). B. bassiana* (ATCC #74040) was not pathogenic, infective or toxic in rats when dosed intraperitoneally with 2 x 10^7 cfu/animal. No animals had the test microbe recovered from their blood or had visible lesions on their internal organs at gross necropsy.

5. *Primary eye irritation in rabbits, (Naturalis-L 225).* Rabbits displayed minimal ocular irritation when given a single 0.1 ml ocular dose containing 2 x 10^6 cfu. Based on these data, the pesticide was considered acute Toxicity Category III for eye irritation.

6. *Primary dermal irritation in rabbits, (Naturalis-L 225).* There was no mortality or significant toxic effects in animals singly dosed and exposed for four hours with 5 ml *B. bassiana* (ATCC #74040) containing 5.5 x 10^7 cfu. Based on these data, microbial pesticide was considered Toxicity Category IV for primary dermal irritation effects.

7. *Dermal sensitization.* Data provided to the Agency show that Naturalis-L is a dermal sensitizer. In several animals, the severity of irritation required relocation of test site for inductions 8 and 9. In addition, two animals died during the study - one prior to the challenge phase and one prior to the 48–hour challenge scoring interval. No cause for death was determined. This test was conducted with a test material at 100% concentration rather than at the 50% concentration recommended by the OPPTS harmonized guidelines. The label for this product must state that it is a dermal sensitizer and proper protection equipment should be worn.

8. *Hypersensitivity incidents.* No incidents of hypersensitivity have been reported for this microbial pesticide.

III. Aggregate Exposures and Risk

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure and Risk

Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the exemption from the requirement of a tolerance for this active ingredient.

1. *Food.* The microbial pesticide can be easily removed from foods by washing, peeling, cooking and processing. Even if ingested, the low acute oral toxicity potential indicates minimal risk. Consequently, dietary exposure to the microbial and the risk posed by ingestion of foods treated with the microbial pesticide, are likely to be minimal for adults, infants and children by the oral route.

2. *Drinking water exposure.* The microorganism *Beauveria bassiana* is common in the soil. It is not known as an aquatic microorganism, and therefore is not expected to proliferate in aquatic habitats. Drinking water is not being screened for *Beauveria bassiana* (ATCC #74040) as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *Beauveria bassiana* (ATCC #74040) through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent. However, even if negligible oral exposure should occur through drinking water, the Agency concludes that such exposure would present no risk due to the lack of toxicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

Dermal and inhalation exposure and risk to adults, infants and children via treated lawns or recreational areas are likely if the pesticide is used as labeled. However, the pesticide is a naturally occurring microbe and is ubiquitous in the environment. Based on the low toxicity potential as evidenced by the data submitted, the microbial pesticide active ingredient is likely to pose a minimal to non-existent dermal or inhalation hazard if used as labeled.

IV. Cumulative Effects

There is one other strain of *Beauveria bassiana* registered at this time. While the two strains may produce similar metabolites, the likelihood of adverse dietary effects via a common mechanism of toxicity is likely to be minimal based on the lack of toxicity/pathogenicity potential of the active ingredients.

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when *Beauveria bassiana* (ATCC #74040) is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply.

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to *Beauveria bassiana* (ATCC #74040) from the proposed uses. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

VI. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

The registrant has submitted data in support of the Agency requirements to identify the active ingredient and potential metabolites and contaminants. Analytical methods are available and sufficient to identify metabolites and contaminants within regulatory levels. All batches containing potential human pathogens are to be destroyed.

C. Codex Maximum Residue Level

There are no Codex tolerances or exemption from tolerances for the microbial active ingredient *Beauveria bassiana* ATCC #74040.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d)and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 28, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300821] (including any comments and data submitted electronically). 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 public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia

address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 12, 1999.

Susan B. Hazen,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a), and 371.

2. Section 180.1205 is added to read as follows:

§ 180.1205 Beauveria bassiana ATCC #74040; exemption from the requirements of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the insecticide *Beauveria bassiana* (ATCC #74040) in or on all food commodities when applied or used as ground and aerial foliar sprays for use only on terrestrial crops.

[FR Doc. 99–10093 Filed 4–27–99; 8:45 am]

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