

Dated: July 17, 2003.

Authority: 42 U.S.C. 7401 *et seq.*

Subchapter E, by adding a new individual entry for section 117.524 and revising the entry for section 117.570.

Lawrence Starfield,

Acting Regional Administrator, Region 6.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

Subpart SS—Texas

2. In § 52.2270 the table in paragraph (c) is amended under Chapter 117, Subchapter B, by adding a new entry heading as “Division 4—Cement Kilns”, adding new individual entries for sections “117.260, 117.261, 117.265, 117.273, 117.279, and 117.283”;

§ 52.2270 Identification of plan.

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(c) * * *

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/submittal date	EPA approval date	Explanation
* * *	* * *	* * *	* * *	* * *
Chapter 117 (Reg 7)—Control of Air Pollution From Nitrogen Compounds				
* * *	* * *	* * *	* * *	* * *
Section 117.223	Source Cap	04/19/00	03/16/01, 66 FR 15200	(b)(1) Requires EPA's approval.
Subchapter B—Division 4—Cement Kilns				
Section 117.260	Cement Kiln Definitions	04/30/00, 04/02/03	July 30, 2003 and [FR page number].	
Section 117.261	Applicability	04/30/00	July 30, 2003 and [FR page number].	Also finalizes 65 FR 64914.
Section 117.265	Emission Specifications	04/30/00, 04/02/03	July 30, 2003 and [FR page number].	
Section 117.273	Continuous Demonstration of Compliance.	04/30/00	July 30, 2003 and [FR page number].	Also finalizes 65 FR 64914
Section 117.279	Notification, Record-keeping, and Reporting Requirements.	04/30/00, 04/02/03	July 30, 2003 and [FR page number].	
Section 117.283	Source Cap	04/30/00, 04/02/03	July 30, 2003 and [FR page number].	
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Subchapter E—Administrative Provisions				
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Section 117.524	Compliance Schedule for Cement Kilns.	04/30/00, 04/02/03	July 30, 2003 and [FR page number].	
Section 117.570	Use of Emissions Credits for Compliance.	04/02/03	July 30, 2003 and [FR page number].	
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[FR Doc. 03-19279 Filed 7-29-03; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0059; FRL-7309-8]

Bacillus subtilis var. amyloliquefaciens strain FZB24; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 on all agricultural commodities when applied/used in accordance with good agricultural use practices for plant strengthening, growth enhancement, and plant disease suppression. Earth BioSciences submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from

the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

DATES: This regulation is effective July 30, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0059, must be received on or before September 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Robyn Rose, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9581; e-mail address: rose.robyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)
- Antimicrobial pesticides (NAICS 32561)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0059. The official public docket is intended to serve as a repository for materials (i.e., documents

and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of October 22, 2002 (67 FR 32231) (FRL-7275-7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(d), as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 2F06453) by Earth BioSciences, 451 Orange St, New Haven, CT 06511. This notice included a summary of the petition prepared by the petitioner Earth BioSciences. There were no comments received in response to the Notice of Filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

Section 408(c)(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 exemption is "safe." Section 408(c)(2)(A)(ii) of the 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. Section 408(b)(2)(C) of the FFDCA 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) of the 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."

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.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed 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.

Earth BioSciences, formerly Taensa, Inc., conducted the toxicology studies required under section 408(d)(2)(A) of the FFDCA to support its petition for an exemption from the requirement of tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. As illustrated below, the studies conducted indicate a low mammalian toxicity for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. In addition, no pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. All toxicology data generated by Earth

BioSciences have been reviewed by the Biopesticides and Pollution Prevention Division ("BPPD").

Toxicology data in support of the exemption from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 included studies with spores (technical) and with the formulated product (water dispersible powder) as follows:

1. *Acute toxicity and/or*

pathogenicity—i. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 Spores (Technical):

- *Acute oral toxicity/pathogenicity in rats*. "... does not appear to be toxic and/or pathogenic in rats when dosed at 1.3×10^8 cfu." BPPD Review of Product Chemistry and Toxicity/Pathogenicity Data Submitted by Taensa, Inc., for the Registration of TAE-022 and TAE-022 WDG, which contains *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 (Submission No.: S559221; DP Barcode: 254584; Master Record Identification (MRID) No's.: 447581-01 through 447581-20) (hereinafter referred to as "BPPD Review - December 20, 1999").

- *Acute dermal toxicity/pathogenicity in rabbits*. "The severity of irritation persisted 72 hours, and slight irritation persisted for 10 days, and all resolved by day 11. No deaths observed. The acute lethal dose (LD_{50}) is greater than 2,000 mg/kg. . . Dermal Toxicity = Toxicity III." (BPPD Review - December 20, 1999).

- *Acute inhalation toxicity in rats*. "The inhalation LC_{50} for males, females, and combined was > 0.93 mg/L. Toxicity Category III." (Submission No.: S616797; DP Barcode: 283473; MRID No's.: 456725-01 and 456725-02) (hereinafter referred to as "BPPD Review - April 25, 2002")

- *Acute pulmonary toxicity/pathogenicity in rats*. "... does not appear to be toxic and/or pathogenic in rats, when dosed at 1.3×10^8 cfu/animal. No total clearance is seen from the lungs of treated test animals. . . showed a distinct pattern of clearance from kidney, liver, and spleen." (BPPD Review - December 20, 1999).

- *Acute intravenous toxicity/pathogenicity in rats*. "... does not appear to be toxic and/or pathogenic in rats, when dosed at 1.7×10^8 cfu/animal." (BPPD Review - December 20, 1999).

- *Primary eye irritation*. "... showed no signs of persistent irritation into day 21, when dosed at 4.7×10^{10} cfu/right eye/animal." (BPPD Review - December 20, 1999.) The December 20, 1999 BPPD review indicated Toxicity Category I, but was amended in a March 7, 2000 review to Toxicity Category II based on a comparison of test animals showing

similar recovery trends and leading to reversibility within 21 days. Addendum to Toxicity Category for TAE-022, which contains *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 (Submission No.: S559221; DP Barcode: 254584; MRID No.: 447581-14).

- *Primary dermal irritation*. "... severity of irritations persisted >72 hours, but resolved by day 11. Dermal irritation = Toxicity II." (BPPD Review - December 20, 1999).

- *Hypersensitivity testing*. "Based on the submitted data. . . does not appear to be a sensitizer when dosed at 3.6×10^{10} cfu." (BPPD Review - December 20, 1999).

- *Hypersensitivity incident reporting*. "No recorded or reported hypersensitivity reaction. . . based on handling MCPA in lab control setting, equating to 55 person years. . ." (BPPD Review - December 20, 1999).

- *Immune response*. "There is no information to suggest that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 has an effect on the immune system. The submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient." (BPPD Review - December 20, 1999).

- *Potential health effects*. "Based on information given, there are no apparent negative effects. . . Cited literature on *B. subtilis* indicate and/or support the development as a biological control. . ." (BPPD Review - December 20, 1999).

- *Growth parameters*. "... is shown to grow at all tested temperatures (e.g., 30, 34, 37, and 50 °C). The enumeration shows a low 4.2×10^{11} cfu/g at 37 °C to a high 6.0×10^{11} cfu/g at 34 °C." (BPPD Review - December 20, 1999).

- ii. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 WDG (Formulation):

- *Acute oral LD_{50} toxicity in rats*. "Toxic/limit dose. . . is greater than 2.8 g/kg body weight (6.7×10^{10} cfu/kg). . . Toxicity Category III." (BPPD Review - December 20, 1999).

- *Acute dermal LD_{50} toxicity in rats*. "The severity of irritation persisted >72 hours, but resolved by day 11. No deaths observed. The acute dose (LD_{50}) is greater than 2,000 mg/kg. . . Dermal irritation = Toxicity Category II; Dermal Toxicity = Toxicity Category III." (BPPD Review - December 20, 1999).

- *Acute inhalation lethal concentration (LC_{50}) toxicity in rats (Formulation)*. "... an acute inhalation medium (LC_{50}) in male and female rats is greater than 0.93 mg/L. . . Toxicity Category III." (BPPD Review - April 25, 2002)

- *Primary eye irritation*. "No corneal opacity, and no signs of irritation by day 7, when dosed. . . at 3.6×10^{10} cfu/right eye/animal. . . Toxicity Category III." (BPPD Review - December 20, 1999).

- *Hypersensitivity*. "Not a sensitizer when dosed at 3.6×10^{10} cfu. No hypersensitivity incidents have been reported." (BPPD Review - December 20, 1999).

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action.

IV. Aggregate Exposures

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

A. Dietary Exposure

Bacillus subtilis var. *amyloliquefaciens* strain FZB24 is a naturally-occurring microorganism and widespread in the environment. The low toxicity and non-pathogenicity/infectivity of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is demonstrated by the data summarized in this action. The end-use (formulated) product will be applied to all agricultural commodities as a seed treatment and via incorporation, drenching, spraying, dipping, chemigation and hydroponics.

1. *Food*. While the proposed use pattern may result in dietary exposure with possible residues on all agricultural commodities, negligible risk is expected for the general population, as well as for infants and children. Submitted acute toxicology tests (MRID Numbers 447581-08, 447581-09, 447581-10, 447581-11, 447581-12, 447581-13, 447581-14, 447581-16, and 456725-02) demonstrate that based upon the use sites, use patterns, application method, use rates, low exposure, and minimal risk of toxicity, the potential risks from dietary exposure for both the general population and infants and children are considered low.

2. *Drinking water exposure*. Although *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 spores may be found naturally in water, it is not known as an aquatic bacterium, and therefore is not expected to proliferate in aquatic

habitats. (Earth BioSciences petition from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, dated May 3, 2002.) In addition, the potential for transfer of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due in part to its percolation through and resulting capture in soil. Most importantly, though, the risk from consumption of drinking water containing *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is considered minimal as there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See Unit III.) Accordingly, it is not considered to be a risk to drinking water.

B. Other Non-Occupational Exposure

Based on the proposed use patterns, the potential of non-dietary exposures to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 pesticide residues for the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, should fall well below the currently tested microbial safety levels. (MRID Numbers 447581-10, 447581-11, 447581-12, and 456725-02).

1. *Dermal exposure.* Dermal exposure via the skin is a potential route of exposure resulting from applications of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. Unbroken skin is a natural barrier to microbial invasion of the human body. Dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. Acute dermal toxicity/pathogenicity data resulted in irritation that persisted 72 hours, and slight irritation persisted for 10 days, and all resolved by day 11. No deaths were observed. The acute lethal dose (LD₅₀) is greater than 2,000 mg/kg. (BPPD Review - December 20, 1999). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure.* Inhalation would be an additional potential route of exposure resulting from applications of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. However, because the pulmonary study showed no adverse effects (MRID Numbers 447581-12 and 456725-02)

the risks anticipated for this route of exposure are considered minimal.

V. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, the Agency is confident that there will not be cumulative effects from the residues of this product on all agricultural commodities. (See Unit III.)

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

1. *U.S. population.* *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism and *Bacillus subtilis* var. *amyloliquefaciens* is widespread in the environment. Based on the very low levels of mammalian toxicity associated with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, which is demonstrated by the data summarized above, and the history of safe use of *B. subtilis*, the Agency has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Accordingly, exempting *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 from the requirement of a tolerance should be considered safe and pose no significant risk.

2. *Infants and children.* FFDCA section 408(b)(2)(C) 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either directly 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 to humans. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of

Bacillus subtilis var. *amyloliquefaciens* strain FZB24 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 residues. Also, for food use of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is appropriate and adequate to protect human health, including that of infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. It is a naturally occurring bacteria that is widespread in the environment. To date, there is no evidence to suggest that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24

affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

C. Codex Maximum Residue Level

There are no Codex maximum residue levels established for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your written objections and hearing requests with the Hearing Clerk in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0059 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 29, 2003.

1. *Filing the request.* Your objections must specify the specific provisions in the regulation that you object to, and the

grounds for the objections (40 CFR 178.25). 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). 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

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 the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0059, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May

22, 2001). 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) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCFA, such as the exemption from the tolerance requirement 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of section 408(n)(4) of the FFDCFA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

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 to 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 this final rule in the **Federal Register**. This final 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: June 20, 2003.

James Jones,

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 180.1243 is added to subpart D to read as follows:

§ 180.1243 *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 03-19134 Filed 7-29-03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0246; FRL-7319-6]

Boscalid; 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on certain commodities and establishes a tolerance for the combined residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and its metabolites 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide and the glucuronic acid conjugate of 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide in or on certain commodities. BASF Corporation requested tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 30, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0246, must be received on or before September 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration