Commodity	Parts per million
* * * * *	
Avocado	1.2
* * * * *	
Canistel	1.2
* * * * *	
Cattle, meat byproducts	0.02
Citrus, dried pulp	8.0
Citrus, oil	340
* * * * *	
Goat, meat byproducts	0.02
* * * * *	
Horse, meat byproducts	0.02
* * * * *	
Kiwifruit	1.8
* * * * *	
Lemon	0.60
Lime	0.60
* * * * *	
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
* * * * *	
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Sheep, meat byproducts	0.02
* * * * *	
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
* * * * *	
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugarbeet, subgroup 1B	0.75
* * * * *	

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[FR Doc. E8–19747 Filed 8–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1020; FRL–8378–5]

Bacillus subtilis GB03; 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 microbial pesticide *Bacillus subtilis* GB03 in or on all raw agricultural commodities when applied in accordance with good agricultural practices. Growth Products Ltd. 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 amendment of the existing exemption from the requirement of a tolerance to cover use in or on all agricultural commodities and remove the regulatory text specifying ''when applied as a seed treatment.'' This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* GB03 in or on all raw agricultural commodities.

DATES: This regulation is effective August 27, 2008. Objections and requests for hearings must be received on or before October 27, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1020. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket identification (ID) number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; e-mail address: *cerrelli.susanne@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this ''**Federal Register**'' document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–1020 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 27, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–1020, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 2, 2007 (72 FR 62237) (FRL–8153–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7236) by Growth Products Ltd., P.O. Box 1259, White Plains, NY 10602. 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* GB03. This notice included a summary of the petition prepared by the petitioner Growth Products Ltd. One comment was received in response to this notice expressing opposition to expanding the number of toxic poisons and expressing dissatisfaction with the level of safety EPA provides Americans. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of *Bacillus subtilis* GB03, including a review of an acute oral toxicity/pathogenicity study in the rat, an acute dermal toxicity study in the rabbit, an acute pulmonary toxicity/pathogenicity study in the rat, an acute intravenous toxicity/pathogenicity study in the rat and a primary eye irritation study in the rabbit. EPA review of these studies indicated that the active ingredient was not toxic to test animals when administered via the oral, dermal, intravenous or pulmonary routes of exposure. The active ingredient was not infective or pathogenic to test animals when administered via the oral, pulmonary and intravenous routes. No reports of hypersensitivity have been recorded from personnel working with this organism. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of *Bacillus subtilis* GB03 in or on food and feed. Thus, under the standard in FFDCA section 408(c)2, an exemption from the requirement for a tolerance is appropriate.

Section 408(c)(2)(A)(i) of 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 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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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 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 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.

Toxicological data on the active ingredient has been previously accepted to support the current exemption from the requirement of a tolerance for residues (for seed treatment of agricultural commodities) and various registrations by the manufacturer Bayer CropScience (formerly Gustafson LLC). Studies on the active ingredient include the following:

An acceptable acute oral toxicity/pathogenicity study performed on rats (MRID 41812302) demonstrated the lack of mammalian toxicity at high levels of exposure to *Bacillus subtilis* GB03. In this study *Bacillus subtilis* GB03 was neither toxic nor infective to rats given an oral dose of 1.9×10^8 CFU/animal.

An acceptable acute dermal toxicity/pathogenicity study on rabbits (MRID 41812303) showed no abnormalities in body weight gain during the study. Desquamation, erythema and edema were observed in the majority of treated rabbits by day 2, with all signs diminishing by day 15. No abnormalities were noted in the rabbits at necropsy. *Bacillus subtilis* GB03 was not considered toxic when a single 2g (3.6×10^9 CFU)/animal dose was administered dermally. The dermal toxicity study resulted in a classification of toxicity category III.

An acceptable acute injection toxicity/pathogenicity study on rats (MRID 41812305) demonstrated that *Bacillus subtilis* GB03 was not infective, pathogenic or toxic for rats when dosed intravenously with approximately 1.8×10^7 CFU of the test material. Although the organism was detected in every organ tested, a distinct clearance pattern was demonstrated. No abnormalities were noted during necropsy. Based on the submitted data, the test material was not infectious, pathogenic or toxic to rats.

An acceptable primary eye irritation in rabbits study (MRID 41812306) demonstrated that *Bacillus subtilis* GB03 produced a slight to severe ocular irritation when a single 0.1 g ocular dose was administered. Ocular irritation dissipated 7 days post dosing. The primary eye irritation study resulted in a classification of toxicity category III for this strain of *B. subtilis*.

An acceptable acute pulmonary toxicity/pathogenicity in rats study (MRID 41812304) demonstrated that *Bacillus subtilis* GB03 was neither toxic, pathogenic nor infective to rats when dosed intratracheally with approximately 2.84×10^8 CFU of the test material.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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

Dietary exposure to the microbial pesticide is likely to occur. However the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe support the establishment of an exemption from the requirement of a tolerance for *Bacillus subtilis* GB03.

1. *Food*. Dietary exposure to the microbe is expected to be minimal. The risk posed to adults, infants and children is minimal because of the low acute oral toxicity/pathogenicity potential of the microbial pesticide. In addition, standard practices of washing, peeling, cooking or processing fruits and vegetables reduces residues of *Bacillus subtilis* GB03 and further minimizes dietary exposure.

2. *Drinking water exposure*. Exposure to humans from residues of *Bacillus subtilis* GB03 in consumed drinking water would be unlikely. The proposed and existing use sites of *Bacillus subtilis* do not include direct application to aquatic environments. Potential exposure to surface water would be negligible. The intended use of *Bacillus subtilis* GB03 is treatment of growing plants and crops for the purposes of disease control. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally, the bacteria would not tolerate the conditions water is subjected to in a drinking water treatment facility (including: chlorination, pH adjustments, and/or filtration). If oral exposure should occur through drinking water, the Agency concludes that such exposure would present insignificant risk due to the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

The use sites for these products include residential garden sites, as well as agricultural sites. *Bacillus subtilis* is ubiquitous in the environment. Based on evaluations of the Tier I acute toxicity tests, the Agency believes that the potential aggregate non-occupational risk derived from dermal and inhalation exposure through the application of *Bacillus subtilis* GB03 is well below the currently tested microbial safety levels.

V. Cumulative Effects

No mechanism of toxicity in mammals has been identified for *Bacillus subtilis* GB03. Therefore, no cumulative effect with other related organisms is anticipated. Because the available data demonstrate a low toxicity/pathogenicity potential of the active ingredient, adverse dietary effects are unlikely.

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

FFDCA section 408(b)(2)(C) as amended by the Food Quality Protection Act (FQPA) of 1996, provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children.

Based on the acute toxicity information discussed in Unit III, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of *Bacillus subtilis* GB03. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Bacillus subtilis* GB03 demonstrate a low toxicity/pathogenicity potential. *Bacillus subtilis* is not a human pathogen and has not been implicated in human disease, but

has been isolated as a rare contaminant from human infections. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

VII. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that *Bacillus subtilis* GB03 has an effect on the endocrine system. No specific tests have been conducted with *Bacillus subtilis* GB03 to determine such effects. However, 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. *Bacillus subtilis* GB03 is a ubiquitous organism in the environment and there have been no reports of the organism affecting endocrine systems. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects and it is practically non-toxic to mammals.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *Bacillus subtilis* GB03.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for *Bacillus subtilis* GB03.

VIII. Conclusions

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of the *Bacillus subtilis* GB03 in or on all food and feed commodities. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity or pathogenicity to mammals has been observed in test animals.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: August 14, 2008

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, 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), 346a and 371.

■ 2. Section 180.1111 is revised to read as follows:

§ 180.1111 Bacillus subtilis GB03; exemption from the requirement of a tolerance.

The biofungicide *Bacillus subtilis* GB03 is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used in accordance with good agricultural practices.

[FR Doc. E8–19860 Filed 8–26–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0987; FRL–8376–4]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of the fungicide fenbuconazole, alpha–[2–(4–