List of Subjects in 40 CFR Part 52
Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.
A. Stanley Meiburg,
Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:
Authority: 42 U.S.C. 7401 et seq.
Subpart S—Kentucky

■ 2. Section 52.936 is added to read as follows:
§ 52.936 Visibility protection.
(a) The requirements of section 169A of the Clean Air Act are not met because the plan does not include approvable measures for meeting the requirements of 40 CFR 51.308 for protection of visibility in mandatory Class I federal areas.
(b) [Reserved]

[Dated: March 13, 2012.]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Bacillus Pumilus Strain GHA 180; 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 Bacillus pumilus strain GHA 180 in or on all food commodities when used in accordance with good agricultural practices. Premier Horticulture submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Bacillus pumilus strain GHA 180.

DATES: This regulation is effective March 30, 2012. Objections and requests for hearings must be received on or before May 29, 2012, 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–2010–0536. All documents in the docket are available at http://www.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), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; email 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 get electronic access to other related information?

C. How can I file an objection or hearing request?
Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2010–0536 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 29, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0536, by one of the following methods:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments.
• Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One
have a common mechanism of toxicity.

residues’ and ‘‘other substances that
information concerning the cumulative
result to infants and children from
reasonable certainty that no harm will
tolerance and to ‘‘ensure that there is a
chemical residue in establishing a
infants and children to the pesticide
toxicity Category IV.

4. Primary Dermal Irritation (OCSPP
Guideline 870.2500; MRID 48005024):
Bacillus pumilus GHA 180 TGAi was
nonirritating to the skin of rabbits
(Toxicity Category IV).

II. Background and Statutory Findings

In the Federal Register of September 30, 2010 (75 FR 60452) (FRL–8637–2),
EPA issued a notice pursuant to FFDCA
section 408(d)(3), 21 U.S.C. 346a(d)(3),
announcing the filing of a pesticide
tolerance petition (PP 07F698) by
Premier Horticulture, 1, Avenue
Premier, Riviere-du-Loup, Quebec,
Canada. The petition requested that 40
CFR part 180 be amended by
establishing an exemption from the
requirement for a tolerance for residues of
Bacillus pumilus GHA 180. This
notice referenced a summary of the
petition prepared by the petitioner,
Premier Horticulture, which is available
in the docket via http://
www.regulations.gov. There were no
comments received in response to the
notice of filing.

Section 408(c)(2)(A)(ii) 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
FFDCA section 408(c)(2)(B), in
establishing or maintaining in effect an
exemption from the requirement of a
tolerance, EPA must take into account
the factors set forth in FFDCA
documentation (Ref. 2). Dried food, such as spices, milk
powder and grains, often contain large
amounts of Bacillus spores (Ref. 3), and
Bacillus pumilus is a natural component of
fermented fish sauce and cocoa bean
fermentations (Ref. 4). Bacillus pumilus
strain GHA 180 is not known to produce
mammalian toxins, and no foodborne
disease outbreaks have been reported.
Based on the results of toxicity studies
conducted with Bacillus pumilus strain
GHA 180 TGAi, no toxicity, infectivity,
pathogenicity or other adverse effects
from dietary exposure to this bacterium
from its pesticide uses are expected (see
Unit III.).

2. Drinking water exposure.
According to the World Health
Organization, Bacillus species are often
detected in drinking water even after
going through disinfection processes at
water treatment facilities (Ref. 5). If
residues of Bacillus pumilus GHA 180
occur in drinking water from its
pesticide uses, no adverse effects are
expected based on the results of toxicity
studies described in Unit III.

B. Other Non-Occupational Exposure

Pesticide products with the active
ingredient Bacillus pumilus strain GHA 180 are only used in greenhouses
and contained nurseries. Non-occupational
exposures may occur in populations
that access residential greenhouses and
apply these pesticide products or
handle soils that have been treated with
Bacillus pumilus. The personal
protective equipment indicated on the
label are expected to be adequate

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 FFDCA section
408(b)(2)(D), 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.

Bacillus pumilus strain GHA 180 is a
bacterium discovered in the root zone of
apple trees in Mexico. It colonizes plant
roots and produces metabolites that
suppress the fungal plant pathogens
Pythium ultimum, Fusarium
oxysporum, Rhizoctonia solani and
Alternaria spp.

Adequate mammalian toxicology data
and information were submitted to
support Bacillus pumilus strain GHA 180
pesticide products. The Draft
Biopesticide Registration Action
Document (BRAD) for Bacillus pumilus
strain GHA 180 provides detailed
information regarding these tests (Ref.
1), which are summarized in this unit.

1. Acute Injection Toxicity/
Pathogenicity (OCSPP
Guideline 885.3200; Master Record Identification
Number (MRID) No. 48005025): Bacillus
pumilus GHA 180 was not toxic and/or
pathogenic to laboratory rats given a
single intravenous dose of 6.8 \times 10^7
colony forming units (CFU).

2. Acute Oral Toxicity (OCSPP
Guideline 870.1100; MRID No.
48005020): Bacillus pumilus GHA 180 was
not toxic to rats given a single oral
dose by gavage [median lethal dose
(LD_{50}>5,000 milligrams/kilograms (mg/
kg) body weight (bw), Toxicity Category IV].

3. Acute Dermal Toxicity (OCSPP
Guideline 870.1200; MRID 48005021):
Bacillus pumilus GHA180 was not toxic
to rats when applied to the skin (LD_{50}
>5050 mg/kg bw, Toxicity Category IV).

4. Acute Inhalation Toxicity (OCSPP
Guideline 870.1300; MRID 48005022):
No signs of toxicity or other adverse
effects occurred in rats exposed nose-
only to an aerosol containing
Bacillus pumilus GHA 180 Technical Grade
of the Active Ingredient (TGAI) (2.18 mg/
L) for 4 hours (LC_{50}>2.18 mg/L, EPA
Toxicity Category IV).

5. Acute Eye Irritation (OCSPP
Guideline 870.2400; MRID 48005023):
Bacillus pumilus GHA 180 was mildly
irritating to the eyes of rabbits (Toxicity
Category III).
to minimize human exposure to those handling pesticide products containing Bacillus pumilus GHA 180. Should human exposure occur, however, no adverse effects are expected based on the lack of toxicity, infectivity and pathogenicity in the studies described in Unit III.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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 has not found Bacillus pumilus strain GHA 180 to share a common mechanism of toxicity with any other substances, and Bacillus pumilus strain GHA 180 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that Bacillus pumilus strain GHA 180 does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

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

FFDCA section 408(b)(2)(C) 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) provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data summarized in Unit III, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of Bacillus pumilus strain GHA180. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on Bacillus pumilus strain GHA 180 does not demonstrate toxic, pathogenic, and/or infective potential to mammals. Because there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for Bacillus pumilus strain GHA 180.

VIII. Conclusions

Therefore, an exemption is established for residues of Bacillus pumilus strain GHA180 in or on all food commodities when used in accordance with good agricultural practices.

IX. References


X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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, entitled “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 FFDCA section 408(d) such as the tolerance 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.

XI. 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.


Marty Monell,
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:


2. Section 180.1313 is added to subpart D to read as follows:

§ 180.1313 Bacillus pumilus strain GHA 180; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus pumilus strain GHA 180 in or on all food commodities when used in accordance with good agricultural practices.


SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in flood-prone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:


§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows: