



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0536; FRL-9343-1]

***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 [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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 listed in the docket index 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?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, go to: <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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 [*insert date 60 days after date of publication in the Federal Register*]. 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 non-CBI 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.
- *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 Facility'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 September 30, 2010 (75 FR 60452) (FRL-8837-2), 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 0F7698) 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 of 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)(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 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 section 408(b)(2)(C), 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, FFDCA 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.

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 6.8×10^7 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 (LD₅₀) >5,000 milligrams/kilograms (mg/kg) body weight (bw), Toxicity Category IV].

3. *Acute Dermal Toxicity (OCSP 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 (OCSP 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 (OCSP Guideline 870.2400; MRID 48005023):*

Bacillus pumilus GHA 180 was mildly irritating to the eyes of rabbits (Toxicity Category III).

6. *Primary Dermal Irritation (OCSP Guideline 870.2500; MRID 48005024):*

Bacillus pumilus GHA 180 TGAI was nonirritating to the skin of rabbits (Toxicity Category IV).

IV. Aggregate Exposures

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 ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* *Bacillus* species, including *Bacillus pumilus*, are common in soils (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 food borne 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* GHA 180. The personal protective equipment indicated on the label are expected to be adequate 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 website 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

1. U.S. EPA. February 2012. Draft Biopesticides Registration Action Document of *Bacillus pumilus* strain GHA 180.
2. Logan, N.A., and P. de Vos. 2009. Genus I. *Bacillus*, pp. 21-128 In: P. de Vos, G.M. Garrity, D. Jones, N.R. Krieg, W. Ludwig, F.A. Rainey, K.H. Schleifer, and W. Whitman (Eds.) *Bergey's Manual of Systematic Bacteriology*, Volume 3, 2nd Ed. Springer, New York.
3. Murray, P.R, et al., *Manual of Clinical Microbiology*. Washington, D. C.: ASM Press; 9th edition, 2007.
4. Doyle, M.P., L.R. Beuchat and T.J. Montville. 1997. *Food Microbiology: Fundamentals and Frontiers*. American Society for Microbiology, Washington, D.C.
5. World Health Organization, *Guidelines for Drinking-water Quality*.(2011) Fourth Edition.

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.

Dated: March 15, 2012.

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:

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

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.

[FR Doc. 2012-7490 Filed 03/29/2012 at 8:45 am; Publication Date: 03/30/2012]