Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/adopted date	EPA approval date and citation [3]	Explanations
* *	*	* *	*	*
XX. Wyoming State Implementation Plan for Regional Haze for 309.	Statewide	Submitted: 1/12/2011	12/12/2012 [Insert **Federal Register** page number where the document begins].	

[3] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

[FR Doc. 2012–29985 Filed 12–11–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0669; FRL–9369–3]

Bacillus subtilis Strain QST 713 Variant Soil; Amendment to an Exemption From the Requirement of a Tolerance for Bacillus subtilis Strain QST 713 To Include Residues of Bacillus subtilis Strain QST 713 Variant Soil

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* strain QST 713 in or on all food commodities by including residues of *Bacillus subtilis* strain QST 713 variant soil. Agraquest, Inc. submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing exemption from the requirement of a tolerance for *Bacillus subtilis* strain QST 713 to include residues of products containing *Bacillus subtilis* strain QST 713 variant soil in or on all agricultural commodities. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* strain QST 713 variant soil under the FFDCA.

DATES: This regulation is effective December 12, 2012. Objections and requests for hearings must be received on or before February 11, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0669, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Glikes, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–6231; email address: *glikes.michael@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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, please 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 the EPA, you must identify docket ID number EPA–HQ–OPP–2011–0669 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 February 11, 2013. 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 (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0669, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please

follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of September 7, 2011 (76 FR 55329) (FRL–8886–7), the 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 1F7896) by Agraquest, Inc., 1540 Drew Ave., Davis, CA 95618. The petition requested that 40 CFR part 180.1209 be amended by including residues of *Bacillus subtilis* strain QST 713 variant soil. This notice referenced a summary of the petition prepared by the petitioner, Agraquest, Inc., which is available in the docket, *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 the 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 the 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.''

The EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, the EPA determines the toxicity of pesticides. Second, the 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), the 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. The EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bacillus subtilis is a rod-shaped, gram-positive, aerobic flagellar bacterium that is ubiquitous in nature and has been recovered from water, soil, air, and decomposing plant residues (Ref 1.). The bacterium produces an endospore that allows it to endure extreme conditions of heat and desiccation in the environment (Ref. 1). *Bacillus subtilis* is not considered toxic or pathogenic to humans, animals, or plants (Ref. 2). Several strains of *Bacillus subtilis* are used predominantly as fungicidal active ingredients in various pesticides registered with the EPA.

In 2000, the EPA first registered *Bacillus subtilis* strain QST 713 as a pesticide active ingredient. EPA described the nature and toxicological profile of *Bacillus subtilis* strain QST 713 in the **Federal Register** of July 5, 2000 (65 FR 41365) (FRL–6555–3) as the basis for establishing the tolerance exemption for *Bacillus subtilis* strain QST 713 in or on all food commodities at 40 CFR 180.1209. A battery of tests, as described in that **Federal Register** citation, determined that *Bacillus subtilis* strain QST 713 is not pathogenic and has no significant toxicity. The petitioner is now requesting that this tolerance be amended to include residues of *Bacillus subtilis* strain QST 713 variant soil. *Bacillus subtilis* strain QST 713 variant soil is a naturally occurring variant of *Bacillus subtilis* strain QST 713 and is present in products containing the active ingredient *Bacillus subtilis* strain QST 713, although at low levels (Ref. 3). The variant strain is distinguished from the parent strain by the presence of the swrA gene, which is an essential gene for *Bacillus* to move over solid substances, and by a phenotype associated with enhanced biofilm formation, growth promotion and disease protection (Ref. 3). Based on its review of the variant and studies submitted by the petitioner, EPA concludes that the variant and the parent strain are substantially similar for the purposes of assessing toxicity, pathogenicity and infectivity (Ref. 3).

The applicant, Agraquest, Inc., cited or submitted adequate mammalian toxicology data and information to support the exemption from the requirement of a tolerance for residues of *Bacillus subtilis* strain QST 713 variant soil in or on all raw agricultural commodities. These data are cited and described in the EPA's March 2012 Bacillus subtilis Final Registration Review Decision (Ref. 1). In addition, Agraquest submitted an acute injection toxicity/pathogenicity study *(OCSPP Guideline 885.3200; MRID 48530909)* that showed that *Bacillus subtilis* strain QST 713 variant soil TGAI was not toxic, infective, or pathogenic to rats when injected intravenously at a dose of 6.6×10^8 colony forming units.

The applicant reported that no hypersensitivity incidents occurred during research, development, or testing of *Bacillus subtilis* strain QST 713 variant soil. Acceptable Tier I mammalian toxicology data and information support registration of the proposed end-use product, Serenade Soil DPZ. In light of the results of the acute toxicity/pathogenicity data and the absence of hypersensitivity incidents, the EPA did not require testing at higher tiers (i.e., Tiers II and III).

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 exposure.* Due to the ubiquitous nature of the *Bacillus subtilis* and the concentrations of *Bacillus subtilis* and other closely related *Bacillus* species that already exist in the environment, the EPA expects human exposure to *Bacillus subtilis* strain QST 713 variant soil resulting from the proposed pesticidal uses will be no greater than existing human exposure to background levels of *Bacillus subtilis.* The EPA in its registration review decision (Ref. 1) concluded ''the risk posed to adults, infants, and children is likely to be minimal because of the low acute oral toxicity/pathogenicity

potential of *Bacillus subtilis s*train QST 713.'' Based on the EPA's evaluation of the *Bacillus subtilis s*train QST 713 data and the EPA's conclusion that *Bacillus subtilis s*train QST 713 and *Bacillus subtilis s*train QST 713 variant soil are substantially similar for the purposes of assessing toxicity, pathogenicity, and infectivity (Ref. 3), no adverse effects from dietary exposure to *Bacillus subtilis* strain QST 713 variant soil from its pesticidal uses are expected (see Unit III.).

2. *Drinking water exposure.* Because *Bacillus subtilis* is ubiquitous in the environment, exposure to the microbe through drinking water may already be occurring and likely will continue (Ref. 3). EPA expects exposures to *Bacillus subtilis* strain QST 713 variant soil to be not much greater than background levels because the proposed use patterns are soil directed and/or soil incorporated, thereby limiting contact with surface water by drift and runoff. Furthermore, ground water is not expected to have significant exposure to *Bacillus subtilis* strain QST 713 variant soil since, like other microorganisms, this microbial pesticide would likely be filtered out by the particulate nature of many soil types. If residues of *Bacillus subtilis* strain QST 713 variant soil were to be transferred to surface or ground waters that are intended for eventual human consumption (e.g., through spray drift or runoff) and directed to wastewater treatment systems or drinking water facilities, *Bacillus subtilis* strain QST 713 variant soil likely would not survive the conditions water is subjected to in such systems or facilities, including chlorination, pH adjustments, filtration, and/or occasional high temperatures. As discussed in the EPA's *Bacillus subtilis* Case 6012, Final Registration Review Decision (Ref. 1), intake of low levels of ubiquitous *Bacillus subtilis* in drinking water may occur, but exposure would represent a minimal risk due to the low toxicity of the strain. Similarly, exposure to other strains of *Bacillus subtilis* would not represent a greater risk. It is reasonable to conclude, based on the similarity in product composition and production, measured physical/chemical, and pathogenicity/infectivity toxicity data, that the risk from any potential exposure to *Bacillus subtilis* strain QST 713 variant soil resulting from the proposed pesticidal use would be minimal and equivalent to the risk from exposure to *Bacillus subtilis* strain QST 713.

B. Other Non-occupational Exposures

The use sites proposed for products containing *Bacillus subtilis* strain QST 713 variant soil include both agricultural and residential garden sites, so the EPA expects there to be some non-occupational exposure as a result of the application of this pesticide. Given *Bacillus subtilis* strain QST 713 variant soil's natural occurrence in soil, the EPA determined that non-occupational exposure to the bacterium likely is already occurring (Ref. 3). Additional exposure to the microorganism, due to pesticidal applications, is likely to occur but is not expected to exceed EPA's level of concern, particularly in light of available data that demonstrate *Bacillus subtilis* strain QST 713 is not toxic (acute dermal toxicity and acute pulmonary toxicity/pathogenicity), non-irritating (primary dermal irritation), and not pathogenic (acute pulmonary toxicity/pathogenicity) and the EPA's conclusion that *Bacillus subtilis s*train QST 713 and *Bacillus subtilis s*train QST 713 variant soil are substantially similar for the purposes of assessing toxicity, pathogenicity, and infectivity (Ref. 3). Based on the toxicity information submitted to the EPA, aggregate exposure to *Bacillus subtilis* strain QST 713 variant soil would be below the levels in the safety testing conducted on *Bacillus subtilis* strain QST 713 and would not represent an undue risk due to the lack of residues of toxicological concern and the low toxicity of the active ingredient. The EPA concluded that non-dietary exposures to the general population, including infants and children, would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

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.''

Bacillus subtilis strain QST 713 variant soil does not operate via a toxic mode of action and thus does not share a common mechanism of toxicity with any other substances. Therefore, section 408(b)(2)(D)(v) does not apply.

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

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, 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 exposure (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 exposure (safety) will be safe for infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act 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 information discussed in Unit III.B., EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Bacillus subtilis* strain QST 713 variant soil is used as labeled in accordance with good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Moreover, based on the same data and EPA analysis as presented directly above, the Agency is able to conclude 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 subtilis* strain QST 713 variant soil when it is used as labeled and in accordance with good agricultural practices. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm from this bacterium in its use as an antifungal agent via dietary exposure since the microorganism is non-toxic, non-pathogenic, and not infective. This conclusion is supported by the data on the substantially similar strain *Bacillus subtilis* strain QST 713, public literature and EPA's *Bacillus subtilis* Case 6012, Final Registration Review Decision (Ref. 1). EPA concludes that there is a reasonable certainty of no harm to infants and children from aggregate exposure to *Bacillus subtilis* strain QST 713 variant soil.

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, the EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. The 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. The 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 subtilis* strain QST 713 variant soil.

VIII. Conclusions

The 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 residues of *Bacillus subtilis* strain QST 713 variant soil. Therefore, the EPA is amending the tolerance exemption for *Bacillus subtilis* strain QST 713 to include residues of *Bacillus subtilis* strain QST 713 variant soil in or on all food commodities when used in accordance with good agricultural practices.

IX. References

1. U.S. EPA. 2010. *Bacillus subtilis* Final Registration Review Decision. Case 6012. March 2010.

2. U.S. EPA. 1997. *Bacillus subtilis* Final Risk Assessment.

3. U.S. EPA. July 11, 2012. Memorandum from Dr. Ibrahim S. Barsoum and Dr. John L. Kough to Michael Glikes: Review of Product Chemistry and Acute Toxicity Studies for Section 3 Registration of a new TGAI, *Bacillus subtilis* strain QST variant soil, and a new EP, Serenade soil DPZ (EPA Reg. No. 69592–EI).

X. Statutory and Executive Order Reviews

This final rule amends an exiting tolerance under FFDCA section 408(d) 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 exemption from 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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: November 26, 2012.

Steven Bradbury,

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. Revise § 180.1209 to read as follows:

§ 180.1209 Bacillus subtilisstrain QST 713 and strain QST 713 variant soil; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticides *Bacillus subtilis* strain QST 713 and strain QST 713 variant soil when used in or on all food commodities.

[FR Doc. 2012–29903 Filed 12–11–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0326; FRL–9371–5]

Spirodiclofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.