Commodity	Parts per million
* * * * *	*
Corn, field, forage	6.0
* * * * *	*
Grain, aspirated fractions	100.0
* * * * *	*

* * * * *

[FR Doc. 03–15128 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0113; FRL–7301–1]

Bacillus Pumilus Strain QST2808; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Bacillus pumilus* strain QST2808 in or on all agricultural commodities when applied/used in accordance with label directions. AgraQuest, Inc. 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 the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* strain QST2808. The temporary tolerance exemption will expire on June 30, 2006.

DATES: This regulation is effective June 18, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0113, must be received by EPA on or before August 18, 2003.

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

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511C), 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/Agriculture (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0113. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 3, 2001 (66 FR 22225) (FRL–6773–9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1G6240), submitted by AgraQuest, Inc., 1530 Drew Avenue, Davis, CA 95616. This notice included a summary of the petition prepared by the petitioner AgraQuest, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain QST2808. Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA

determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bacillus pumilus is a ubiquitous and naturally occurring bacteria found in soil. The results of the acute toxicology and pathogenicity studies required of the petitioner under section 408(d)(2)(A) of the FFDCA in support of its petition for a temporary exemption from the requirement of a tolerance for *Bacillus pumilus* strain QST2808 indicate negligible to no mammalian toxicity. In addition, no pathogenicity was observed in any of the tests conducted with the *Bacillus pumilus* strain QST2808 Technical product.

The toxicology and pathogenicity data generated by AgraQuest, Inc in support of this temporary exemption from the requirement of a tolerance are summarized below.

1. *Acute oral toxicity and pathogenicity rats (OPPTS Harmonized Guideline 885.3050; Master Record Identification Number (MRID) 451366–04).* Fifteen male and fifteen female rats each were administered 4.1 x 10^9 cfu of *Bacillus pumilus* strain QST2808 Technical and observed for 14 days. Based on the data, *Bacillus pumilus* strain QST2808 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed at 4.1 x 10^9 cfu/animal. Classification: Acceptable; Toxicity Category IV. (C. Etsitty's Memorandum to John L. Kough, dated 1/7/02 (hereinafter referred to as ''BPPD Review - 1/7/02'')).

2. *Acute dermal toxicity (OPPTS Harmonized Guideline 885.3100; MRID 451366–05).* Five male and five female rabbits were dermally treated with 2g/kg body weight *Bacillus pumilus* strain QST2808 Technical for 24 hours and observed for the following 14 days. The acute lethal dose (LD_{50}) is greater than 2,000 mg/kg. Classification: Acceptable; Toxicity Category III. (BPPD Review - 1/7/02).

3. *Primary eye irritation (OPPTS Harmonized Guideline 870.2400; MRID 452679–01).* Three male rabbits each were administered 0.1 mL of QST2808 Technical in the everted lower lid of one eye and then observed for 72 hours. Based on the data, QST2808 Technical showed minimal effects to the eye. Classification: Acceptable; Toxicity Category IV. (BPPD Review - 1/7/02).

4. *Acute injection toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3200; MRID 451366–07).* Eighteen male and eighteen female rats each were dosed at 1.6 x 10^8 cfu *Bacillus pumilus* strain QST2808 Technical intravenously and monitored over a period of 28 days. A gross necropsy was performed on all rats. Based on the data, the test organism was not toxic, infective, or pathogenic to rats. Classification: Acceptable. (BPPD Review - 1/7/02).

5. *Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 451366–06).* Eighteen male and eighteen female rats each were administered 1.6 x 10^8 cfu *Bacillus pumilus* strain QST2808 Technical by a single intratracheal dosage and monitored over a period of 35 days for clinical signs of toxicity. Necropsy studies showed no significant signs of abnormalities due to the test organism. Based on the data, *Bacillus pumilus* strain QST2808 was not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. Classification: Acceptable. (BPPD Review - 1/7/02).

6. *Acute Inhalation toxicity (OPPTS Harmonized Guideline 870.1300).* Results of the acute pulmonary toxicity/pathogenicity (MRID 451366–06) performed with *Bacillus pumilus* strain QST2808 Technical indicate that it is not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. For the purposes of this specific action, the Agency has determined that the acute pulmonary toxicity/pathogenicity data are adequate to support and/or fulfill this particular data requirement.

7. *Primary dermal irritation (OPPTS Harmonized Guideline 870.2500; MRID 452679–02).* Each of three male adult rabbits were treated dermally with 0.5 mL QST2808 Technical for 4 hours and observed for the following 72 hours. Based on the data, no abnormal clinical signs were noted. Approximately 60 minutes after patch removal, very slight erythema was noted on one of the three rabbits with resolution by 24 hours. When dosed with QST2808 Technical at 0.5 mL/animal, QST2808 Technical was essentially non-irritating. Classification: Acceptable; Toxicity Category IV. (BPPD Review - 1/7/02).

8. *Hypersensitivity incidents (OPPTS Harmonized Guideline 885.3400).* The registrant reported (November 1, 2000) no incidents to date.

9. *Immune response.* There is no information to suggest that *Bacillus pumilus* strain QST2808 has an effect on the immune system. The submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient (MRID 451366–04; 451366–06, and 451366–07).

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

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or

buildings (residential and other indoor uses).

A. Dietary Exposure

Humans and animals are commonly exposed to *Bacillus pumilus*, a ubiquitous microorganism that inhabits soil. No toxicological endpoints were identified for *Bacillus pumilus* strain QST2808. The low toxicity and non-pathogenicity/infectivity of *Bacillus pumilus* strain QST2808 is demonstrated by the data summarized in Unit III of this action.

1. *Food*. While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, negligible to no risk is expected for the general population, including infants and children, or animals because *Bacillus pumilus* strain QST2808 technical demonstrated no pathogenicity or oral toxicity at the maximum doses tested, as noted above in (Unit III).

2. *Drinking water exposure*. Most importantly, there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See ''Unit III. Toxicological Profile'' above.) In addition, the potential for transfer of *Bacillus pumilus* strain QST2808 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due in part to its percolation through and resulting capture in soil. Accordingly, the use of this microbial pest control agent on terrestrial plants is not anticipated to negatively impact the quality of drinking water.

B. Other Non-Occupational Exposure

Based on the proposed use patterns, the potential of non-dietary exposures to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Bacillus pumilus* strain QST2808, should fall well below the currently tested microbial safety levels.

1. *Dermal exposure*. The potential for dermal exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* strain QST2808 is a naturally occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the organism is of low dermal toxicity, the acute lethal dose (LD_{50}) is greater than 2,000 mg/kg, and the QST2808 Technical was essentially non-irritating (Toxicity Category IV). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure*. The potential for inhalation exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* is a natural occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the acute pulmonary toxicity/pathogenicity testing performed on the technical formulation did not demonstrate pathogenicity or toxicity of *Bacillus pumilus* strain QST2808. (See Unit III above.) Accordingly, the risks anticipated for this route of exposure are considered minimal.

V. Cumulative Effects

The Agency has considered the potential for cumulative effects of *Bacillus pumilus* strain QST2808 and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Bacillus pumilus* strain QST2808 is practically non-toxic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III above), no cumulative effects from the residues of this product with other related microbial pesticides is anticipated.

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

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *Bacillus pumilus* strain QST2808 due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, *Bacillus pumilus* strain QST2808 is not pathogenic or infective and is practically non-toxic to mammals. (See Unit III above.) Accordingly, exempting *Bacillus pumilus* strain QST 2808 from the requirement of a tolerance should be considered safe and pose no significant risk.

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either directly through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Due to the ubiquitous nature of *Bacillus pumilus*, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase exposure to the U.S. population, including infants and children. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus pumilus* strain QST2808 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus pumilus* strain QST2808 residues.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone

systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus pumilus* strain QST2808 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

To date, the Agency has no information to suggest that *Bacillus pumilus* strain QST2808 has an effect on the endocrine systems. Moreover, as is expected from a non-pathogenic microorganism that is practically non-toxic to mammals, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. (BPPD Review - 1/7/02).

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Bacillus pumilus* strain QST2808's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus pumilus* strain QST2808.

C. Codex Maximum Residue Level

There is no Codex Alimentarius Commission Maximum Residue Level for *Bacillus pumilus* strain QST2808.

VIII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0113 in the subject line on the first page of your submission. All objections and requests for hearings must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 18, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0113, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes a temporary exemption from the tolerance requirement for *Bacillus pumilus* strain QST2808 under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule '' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

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

■ 2. Section 180.1226 is added to subpart D to read as follows:

§ 180.1226 Bacillus pumilus strain QST2808; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 03–15129 Filed 6–17 –03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0196; FRL–7311–2]

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin, methyl (E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝(methoxymethylene)-benzeneacetate, in or on artichoke, globe; asparagus; brassica, head and stem, subgroup 5A; herb subgroup 19A, (dried) except chive; and herb subgroup 19A, (fresh) except chive. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).