VIII. Submission to Congress and the Comptroller General

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 Congress and to the Comptroller General of the United States prior to required information to the U.S. Senate, the United States 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.


Suzan B. Hazen,
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 180.544 is added to read as follows:

§180.544 Methoxyfenozide; tolerances for residues.

(a) General. (1) Tolerances are established for residues of the insecticide methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide in or on the following agricultural commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple pomace, wet</td>
<td>7.0</td>
</tr>
<tr>
<td>Cotton gin byproducts</td>
<td>35</td>
</tr>
<tr>
<td>Cotton, undelinted seed</td>
<td>2.0</td>
</tr>
<tr>
<td>Fat of cattle, goats, hogs, horses and sheep</td>
<td>0.1</td>
</tr>
<tr>
<td>Meat of cattle, goats, hogs, horses and sheep</td>
<td>0.02</td>
</tr>
<tr>
<td>Milk</td>
<td>0.02</td>
</tr>
<tr>
<td>Pome fruits crop group</td>
<td>1.5</td>
</tr>
</tbody>
</table>

(b) Section 18 emergency exemptions. [Reserved]

c) Tolerances with regional registrations. [Reserved]

d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 00–16801 Filed 7–3–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300997; FRL–6555–3]

RIN 2070–AB78

Bacillus subtilis Strain QST 713; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the Bacillus subtilis strain QST 713 in or on all raw agricultural commodities when applied/used according to label instructions. 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 an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Bacillus subtilis strain QST 713.

DATES: This regulation is effective July 5, 2000. Objections and requests for hearings, identified by docket control number [OPP–300997], must be received by EPA, on or before September 5, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the

SUPPLEMENTARY INFORMATION: To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number [OPP–300997] in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Susanne Correlli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8077; and e-mail address: cerrelli.susanne@epa.gov.

SUPPLEMENTARY INFORMATION:
I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

<table>
<thead>
<tr>
<th>Categories</th>
<th>NAICS codes</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>111</td>
<td>Crop production</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>Animal production</td>
</tr>
<tr>
<td></td>
<td>311</td>
<td>Food manufacturing</td>
</tr>
<tr>
<td></td>
<td>32532</td>
<td>Pesticide manufacturing</td>
</tr>
</tbody>
</table>

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “Federal Register—Environmental Documents.” You can also go directly to the Federal Register listings at http://www.epa.gov/fedreg/r/.

2. In person. The Agency has established an official record for this action under docket control number OPP–300997. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents.

The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 365–5805.

II. Background and Statutory Findings

In the Federal Register of April 26, 1999 (64 FR 20295) (FRL–6074–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170) announcing the filing of a pesticide tolerance petition by AgraQuest, Inc., 1530 Drew Ave., Davis California 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 an exemption from the requirement of a tolerance for residues of Bacillus subtilis strain QST 713.

III. Risk Assessment

New 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 tolerance is “safe.” Section 408(c)(2)(A)(ii) 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) 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) 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.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has considered 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.

A battery of tests determined that QST 713 Technical product is not pathogenic and has no significant toxicity. The acute oral toxicity/pathogenicity, acute pulmonary toxicity/pathogenicity and acute intravenous toxicity/pathogenicity studies demonstrated no significant toxicity and a lack of pathogenicity. The dermal toxicity and eye irritation studies resulted in a Toxicity Category III classification. The acute dermal irritation study resulted in a Toxicity Category IV classification. Bacillus subtilis strain QST 713 is a ubiquitous organism in the environment and there have been no reports of the organism affecting the immune system. The submitted toxicity/pathogenicity studies in rodents with Bacillus subtilis strain QST 713 indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. As would be expected for any microbial pesticide, QST 713 did elicit a very mild delayed hypersensitivity response and is considered a potential dermal sensitizer. Further, although it is not known whether strain QST 713 does, the species is known to produce the enzyme subtilisin which has been reported to produce allergic or hypersensitivity reactions to individuals repeatedly exposed to the enzyme in industrial settings. The use of personal protective equipment required for applicators and other handlers mitigates the hypersensitivity risk by minimizing exposure. No hypersensitivity risk is expected for dietary exposure due to the low likelihood that any significant residues will occur on treated food.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to
A low toxicity/pathogenicity potential of Bacillus subtilis has been identified for use in gardens, lawns, or buildings (residential and other indoor uses).

Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the establishment of an exemption from the requirement of a tolerance for Bacillus subtilis strain QST 713.

Food: Dietary exposure to the microbial is expected to be minimal. In addition, standard practices of washing, peeling, cooking, or processing fruits and vegetables will reduce residues of Bacillus subtilis strain QST 713 and further minimize dietary exposure. The risk posed to adults, infants, and children is likely to be minimal, because of the low acute oral toxicity/pathogenicity potential of the microbial pesticide.

Drinking water exposure: Oral exposure, at very low levels, may occur from ingestion of drinking water. Drinking water is not being screened for Bacillus subtilis strain QST 713 as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to the bacterial active ingredient through drinking water. If oral exposure should occur through drinking water, the Agency concludes that such exposure would present minimal risk due to the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

The use sites proposed are for agricultural sites. Dermal and inhalation exposure is expected to be limited to those who apply or handle the pesticide in orchards and farms. Bacillus subtilis presence is ubiquitous in the environment and the use of this product is not expected to increase dermal or inhalation exposure in non-occupational settings.

VI. Cumulative Effects

No mechanism of toxicity in mammals has been identified for Bacillus subtilis strain QST 713. Therefore no cumulative effect with other related organisms is anticipated. Because the data available demonstrate a low toxicity/pathogenicity potential of the active ingredient, the likelihood of adverse dietary effects is expected to be minimal.

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

Based on the acute toxicity/pathogenicity information discussed above, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of Bacillus subtilis strain QST 713. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, the data available on Bacillus subtilis strain QST 713 demonstrate a low toxicity/pathogenicity potential. Bacillus subtilis is not a human pathogen and has not been implicated in human disease, but has been isolated as a rare contaminant from human infections. Risk of increased exposure is likely only to exist for pesticide applicators and manufacturers of the product. The Agency has imposed appropriate risk mitigation measures to protect the workers via the use of protective clothing.

VIII. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that Bacillus subtilis strain QST 713 has an effect on the immune and endocrine systems. No specific tests have been conducted with Bacillus subtilis strain QST 713 to determine such effects. However, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Bacillus subtilis strain QST 713 is a ubiquitous organism in the environment and there have been no reports of the organism affecting endocrine system. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects because it is practically non-toxic to mammals.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore the Agency has concluded that an analytical method is not required for enforcement purposes for Bacillus subtilis strain QST 713.

C. Codex Maximum Residue Level

There are no CODEX values for Bacillus subtilis strain QST 713.
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 to tompsonkis.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. 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.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.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.2. Mail your copies, identified by docket number OPP–300997, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 6.1/6.0 file format or ASCII text file format. 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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). 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 prior consultation as specified by Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or require 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4).

XI. Submission to Congress and the Comptroller General

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 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

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

Dated: June 20, 2000.

Joseph J. Merenda, Jr., Acting Deputy Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-6727-2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; deletion of the Laskin/Poplar Oil Company Superfund Site from the National Priorities List; request for comments.

SUMMARY: EPA Region 5 announces the deletion of the Laskin/Poplar Oil Company Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA is taking this action because it has determined that the responsible parties have implemented all response actions under CERCLA and EPA, in consultation with the State of Ohio, has determined that no further action is appropriate. Moreover, EPA and the State have determined that remedial actions conducted at the Site to date have been protective of public health, welfare, and the environment.

DATES: This “direct final” action will be effective September 5, 2000, unless EPA receives dissenting comments by August 4, 2000. If written dissenting comments are received, EPA will publish a timely withdrawal of the rule in the Federal Register informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Gladys Beard, Associate Remedial Project Manager, Superfund Division, U.S. EPA, Region 5 77 W. Jackson Blvd. (SR-6), Chicago, IL 60604.

Comprehensive information on the site is available at U.S. EPA’s Region 5 office and at the local information repository located at: The Ashtabula Public Library, 355 W. 44th St., Ashtabula, OH 44004. Requests for comprehensive copies of documents should be directed formally to the Region 5 Docket Office. The address and phone number for the Regional Docket Office is Jan Pfundheller (H–7) U.S. EPA, Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–5821.


SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Intended Site Deletion
V. Action

I. Introduction

EPA Region 5 announces the deletion of the Laskin/Poplar Oil Company Site from the National Priorities List (NPL), appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300. U.S. EPA identifies sites that appear to present a significant risk to public health, welfare and the environment, and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial actions that the Hazardous Substance Superfund Response Trust Fund (Fund) finances. Under § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if the conditions at the site warrant such action.

EPA will accept comments on this proposal for thirty (30) days after publication of this document in the Federal Register.

Section II of this action explains the criteria for deleting sites from the NPL. Section III discusses procedures that U.S. EPA is using for this action. Section IV discusses the history of this site and explains how the site meets the deletion criteria. Section V states U.S. EPA’s prospective action of deleting the Site from the NPL unless dissenting comments are received during the comment period.

Deletion of sites from the NPL does not itself create, alter, or revoke any individual’s rights or obligations. Specifically, this deletion does not affect the provisions or requirements of the Consent Decrees entered in United States v. Alvia Laskin, et al Civil Action (84–2035Y N.D. Ohio) and United States v. Anchor Motor Freight Co., et al Civil Action No. (89CV1999 N. D. Ohio).

Furthermore, deletion from the NPL does not in any way alter U.S. EPA’s right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist in Agency Management.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that Sites may be deleted from, or recategorized on, the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required; or

(ii) All appropriate non-time critical Removal Actions or Fund-financed responses under CERCLA have been implemented, and no further response action by responsible parties is appropriate; or

(iii) The Remedial Investigation has shown that the release poses no significant threat to public health or the environment and, therefore, remedial measures are not appropriate. The Laskin/Poplar Oil Site now meets criterion [i]. Criteria (ii) and (iii) are not relevant to this Site.

III. Deletion Procedures

The following procedures were followed before the proposed deletion of this Site from the NPL.

(1) All appropriate response actions, under CERCLA have been implemented and no further EPA action is appropriate; (2) The State of Ohio has