Chief Counsel for Advocacy of the Small Business Administration.

X. 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 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 rule in the **Federal Register**. This 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: August 14, 1998.

Arnold E. Layne,

Acting Director, Registration Division, 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. 346a and 371.

2. In § 180.368, in paragraph (b), by alphabetically adding the following commodities to the table to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Grass forage	10	12/31/99
Grass hay	0.2	12/31/99
* * *	* *	* *

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[FR Doc. 98–24471 Filed 9–10–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300701; FRL–6024–2]

RIN 2070–AB78

Bacillus Sphaericus; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the *Bacillus sphaericus* in or on all food commodities when applied/used in or on all food crops. Abbott Laboratories submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus sphaericus*.

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300701], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300701], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300701]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Willie H. Nelson, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)308-8682 e-mail: Nelson.Willie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 22, 1997 (62 FR 44687) (FRL–5737–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by Abbott Laboratories, Sheridan Road, North Chicago, Illinois, 60064. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus sphaericus*.

There were no comments received in response to the notice of filing. the data submitted in the petition and all relevant material have been evaluated.

I. Risk Assessment and Statutory Findings

New section 408(b)(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 tolerance is ''safe.'' Section 408(b)(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...'' 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 us in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of 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.

All available information and data submitted by Abbott Laboratories in support of the pesticide petition (PP 7F4822) have been reviewed, and indicate that there is a reasonable certainty that no harm will result from residues of *Bacillus sphaericus* because of its ubiquitous nature and its low mammalian toxicity. The toxicological data submitted with the petition demonstrate a lack of human health issues and fully supports the exemption from the requirement of a tolerance. The toxicological data submitted in support of the petition were as follows:

1. An acute oral toxicity/pathogenicity study - was conducted with *Bacillus sphaericus* technical material in rats. An oral dose of approximately 1 x 10^8 colony forming units (CFUs) administered to rats resulted in rapid clearance during the 20-day post-treatment observation period. A pattern of clearance during the 49-day post-treatment period was established following an intratracheal installation pf approximately 1 x 10^8 CFUs. Similarly, a pattern of clearance over a 35-day post-treatment period was observed following an intravenous dose of approximately 1 x 10^7 CFUs. There were no mortalities, no evidence of pathogenicity or treatment-related toxicity in rats given either an oral, intratracheal or intravenous dose.

2. An acute oral toxicity study - done on *Bacillus sphaericus* technical material caused no death in rats given a dose of 5,000 milligram/kilograms (mg/kg); therefore, the acute oral LD_{50} was greater than 5,000 mg/kg.

3. Acute dermal LD_{50} - no mortality in rabbits over the 14-day period observation period following a 2,000 mg/kg dermal application for 24 hours; thus, the acute dermal was greater than 2,000 mg/kg.

4. An acute inhalation study - in a 4-hour inhalation toxicity study in rats, the maximum attainable concentration was 0.09 mg/L, with 13.3% of the particles having a mass median aerodynamic diameter of >10 microns. Since there was no mortality or clinical signs during exposure or the 14-day observation period, the 4-day inhalation LC_{50} was greater than 0.09 mg/L.

5. Dermal irritation - described as moderately irritating to rabbits skin at 72 hours. Irritation and iridal effects following a 1,000 mg aliquot of *Bacillus sphaericus* being placed in the eye of rabbits were no longer present at day 10 post-treatment.

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

A. Dietary Exposure

The use patterns for *Bacillus sphaericus* on aquatic crops may result in dietary exposure. However, in the absence of any mammalian toxicological endpoints and the heat used during food processing, risk from the consumption of treated commodities is not expected for neither the general population nor infants and children.

B. Drinking Water Exposure and Risk Characterization

Although the potential exist for *Bacillus sphaericus* to enter drinking water sources, the health risk is expected to be negligible due to: (1) The lack of any mammalian toxicological concerns associated with *Bacillus sphaericus*, (2) lack of any published record of human disease or infection caused by *Bacillus sphaericus*, and (3) the municipal drinking water treatment processes.

C. Other Non-Occupational Exposure

Non-dietary exposure is not anticipated from the use of this microbial pesticide. Occupational exposure will be mitigated through the use of proper personal protective equipment.

IV. Cumulative Effects

Cumulative effects of *Bacillus sphaericus* have been considered. But, *Bacillus sphaericus* does not exhibit a particular mechanism of toxicity common with other agents; therefore, cumulative effects with any other substance are not considered.

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

Based on the information discussed above, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of *Bacillus sphaericus*. This includes anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, the toxicity of *Bacillus sphaericus* to mammals is very low and under reasonably foreseeable circumstances, it does not pose a risk.

FFDCA section 408 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 pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that *Bacillus sphaericus* is practically non-toxic to mammals, including infants and children, and, thus, a margin of exposure (safety) approach is not needed to protect adults or infants and children.

VI. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that *Bacillus sphaericus* will not adversely affect the immune systems. The Agency is not requiring information on the endocrine effects of this microbial pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a

tolerance without any numerical limitations; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *Bacillus sphaericus*.

C. Codex Maximum Residue Level

There are no CODEX tolerances or international tolerance exemptions for *Bacillus sphaericus* at this time.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) 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) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 10, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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). 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). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300701]. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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) (Pub.L. 104-4). Nor does it require prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). In additions, since tolerance 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal

governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. 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 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 the rule in the **Federal Register**. This 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: August 21, 1998.

Stephen L. Johnson,

Deputy 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. 346a and 371.

2. Section 180.1202 is added to subpart D to read as follows:

§ 180.1202 Bacillus sphaericus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticides, *Bacillus sphaericus* when used in or on all food crops.

[FR Doc. 98–24469 Filed 9–10–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300709; FRL 6026–6]

RIN 2070–AB78

Sulfosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes new tolerances to replace recently-expired time-limited tolerances for residues of the herbicide sulfosate (the trimethylsulfonium salt of glyphosate, also known as glyphosate-trimesium) in or on cattle, goats, horses, hogs and sheep, in fat, meat by-products, and meat; in poultry fat, meat-by-products (except liver), meat and liver; in eggs; in milk; in corn stover (field and pop), grain (field and pop), and forage (field); in soybean forage, hay, and seed; and in aspirated grain fractions. Zeneca Ag Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). In addition, this regulation moves existing tolerances for prunes at 0.20 ppm, raisins at 0.20 ppm, and soybean hulls at 7.0 ppm from 40 CFR 185.5375 to 40 CFR 180.489.

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300709, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300709, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300709. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5697; e-mail: tompkins.jim@epamail.epa.gov.