Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because New Jersey's State Implementation Plans are not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 8, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 12, 2009.

George Pavlou,

Acting Regional Administrator, Region 2.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart FF—New Jersey

■ 2. Section 52.1582 is amended by adding new paragraph (l) to read as follows:

§ 52.1582 Control strategy and regulations: Ozone.

* * * * *

(l) *Attainment determination.* EPA has determined that the Philadelphia-Wilmington-Trenton severe 1-hour ozone nonattainment area attained the 1-hour ozone NAAQS by the applicable attainment date of November 15, 2005. In New Jersey, this area includes the counties of Burlington, Camden, Cumberland, Gloucester, Mercer, and Salem. EPA also has determined that the Philadelphia-Wilmington-Trenton severe 1-hour ozone nonattainment area is not subject to the imposition of the section 185 penalty fees. In addition, the requirements of section 172(c)(9) (contingency measures) do not apply to the area.

[FR Doc. E9–7683 Filed 4–7–09; 8:45 am]

BILLING CODE

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0762; FRL–8408–7]

Bacillus subtilis MBI 600; 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 biofungicide, *Bacillus subtilis* MBI 600, in or on all food commodities, including residues resulting from post-harvest uses, when applied/used in accordance with good agricultural practices. Becker Underwood, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to expand the existing exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* MBI 600 in or on all food commodities.

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0762. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide

for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0762 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 8, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0762, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 14, 2008 (73 FR 67512) (FRL–8388–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7368) by Becker Underwood, Inc., 801 Dayton Ave., P. O. Box 667, Ames, IA 50010. The petition requested that 40 CFR 180.1128 be amended by expanding the existing exemption from the requirement of a tolerance for the biofungicide *Bacillus subtilis* MBI 600 to cover residues in or on all food commodities, including residues resulting from post-harvest uses. The notice included a summary of the petition prepared by the petitioner Becker Underwood, Inc.

Previously, on June 8, 1994 (59 FR 29543) (FRL–4865–8), EPA issued a final rule granting an exemption from the requirement of a tolerance for residues of *Bacillus subtilis* MBI 600 in or on all raw agricultural commodities when applied as a seed treatment on seeds used for growing agricultural crops. In submitting this current petition (i.e., 8F7368), Becker Underwood, Inc. is relying on the data previously submitted by another company, Gustafson, Inc., in support of the existing tolerance exemption for *Bacillus subtilis* MBI 600. These data were previously summarized by EPA in the June 8, 1994, final rule. On July 18, 2002, EPA issued a Tolerance Reassessment Decision in which it found that the existing tolerance exemption for *Bacillus subtilis* MBI 600 continues to meet the FQPA safety standard. This determination in 2002 was based on EPA's review of the data on which Becker Underwood, Inc., is now relying in connection with this action.

There was one comment received in response to the notice of filing. The commenter expressed dissatisfaction with the level of safety EPA provides to Americans. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of *Bacillus subtilis* MBI 600, including a review of studies addressing acute oral, pulmonary and intravenous injection toxicity/pathogenicity; acute dermal toxicity; primary eye irritation: and skin sensitization. EPA review of these studies indicated that the active ingredient is not toxic to test animals when administered via the oral, pulmonary, intravenous or dermal routes of exposure. In addition, the active ingredient was not infective or pathogenic to test animals when administered via the oral, pulmonary or intravenous routes. Moreover, no reports of hypersensitivity have been recorded in personnel working with this organism. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses. Thus, under the standard in FFDCA section 408(c)(2), an exemption from the requirement of a tolerance is appropriate.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, 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, section 408(b)(2)(D) of 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 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.

Toxicological data on the active ingredient were previously submitted to support the existing exemption from the requirement of a tolerance for residues of *Bacillus subtilis* MBI 600 resulting from its use in the treatment of seeds used for growing agricultural crops, and to support various pesticide product registrations held by the petitioner. The previously submitted studies on the active ingredient include the following:

An acceptable acute oral toxicity/pathogenicity study performed in rats (MRID 419074–02) demonstrated the lack of mammalian toxicity at high levels of exposure to *Bacillus subtilis* MBI 600. In this study, *Bacillus subtilis* MBI 600 was not toxic, infective nor pathogenic to rats given an oral dose of 2×10^8 colony forming units (CFU) per animal. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis*.

An acceptable acute pulmonary toxicity/pathogenicity study in rats (MRID 419074–04) demonstrated that *Bacillus subtilis* MBI 600 was neither toxic, pathogenic nor infective to rats dosed intratracheally with 3.4×10^8 CFU of the test material. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis*.

An acceptable acute intravenous injection toxicity/pathogenicity study in rats (MRID 419074–05) demonstrated that *Bacillus subtilis* MBI 600 was neither toxic, pathogenic nor infective to rats dosed intravenously with approximately 4×10^7 CFU of the test material. Although the microbe was detected in every organ tested, the test material displayed a distinct pattern of clearance. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis*.

An acceptable acute dermal toxicity study in rabbits (MRID 419074–03) demonstrated that *Bacillus subtilis* MBI 600 was not toxic to rabbits when a single 5×10^{10} dose was administered dermally. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis*.

An acceptable primary eye irritation study in rabbits (MRID 419074–06) demonstrated that *Bacillus subtilis* MBI 600 produced a slight ocular irritation when a single 0.1 gram ocular dose was administered. Ocular irritation dissipated by day 4. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis*.

A supplemental skin sensitization test resulted in an overall moderate reaction in guinea pigs 24 to 78 hours post-treatment. However, an acceptable dermal sensitization study, conducted with an end use formulation, demonstrated no irritation 2 weeks after sensitization and treatment using 400 milligrams of test material. As a result, the product was determined to not be a dermal sensitizer. Furthermore, in the nearly 15 years since its initial registration as an active ingredient, there have been no hypersensitivity reports associated with *Bacillus subtilis* MBI 600 pesticide products.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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

Bacillus subtilis MBI 600 is ubiquitous in the environment, especially in soils and agricultural environments (indeed, strain MBI 600 of *Bacillus subtilis* is a naturally-occurring isolate of the genus *Bacillus*, originally isolated from faba beans grown at Nottingham University School of Agriculture in the United Kingdom). As a result, dietary exposure to background levels of the naturally occurring microbe likely is already occurring and likely will continue to occur. Because of its ubiquitous presence in the environment, the Agency expects there to be no increase in exposure to *Bacillus subtilis* MBI 600 resulting from the existing and proposed pesticidal uses when compared to existing exposure to background levels of *Bacillus subtilis* MBI 600.

1. *Food*. As discussed above, dietary exposure to the naturally occurring microbe likely is already occurring and likely will continue to occur. Notably, similar *Bacillus subtilis* strains are used internationally in the production of food grade products and in fermented foods in Japan and Thailand. Reports in the literature implicating *Bacillus subtilis* (as distinguished from the specific strain, *Bacillus subtilis* MBI 600, at issue in this action) in food-borne illness do not describe any pathogen or toxin production, but rather simple spoilage from *Bacillus subtilis* growth in dough. Such low-quality dough would not be suitable for bread production by commercial bakeries and so the Agency considers this particular food exposure scenario to be unlikely and the risk to be negligible. The risk posed to adults, infants and children from food-related exposures to *Bacillus subtilis* MBI 600 is minimal due to the demonstrated lack of acute oral toxicity/pathogenicity associated with the microbial pesticide. Based on the evaluation of the submitted data, there are no dietary risks that exceed the Agency's level of concern.

2. *Drinking water exposure*. Because *Bacillus subtilis* MBI 600 is ubiquitous in the environment, exposure to the microbe through drinking water may already be occurring and likely will continue to occur. While the proposed and existing use sites do not include direct application to aquatic environments, the intended use of *Bacillus subtilis* MBI 600 is treatment of growing crops or seed for the control of plant disease. If such uses were to result in pesticide spray drift or runoff that were to reach surface or ground waters, there is the potential for human exposure to *Bacillus subtilis* MBI 600 residues, albeit greatly diluted, in drinking water. Municipal drinking water treatment processes and deep water wells, however, would both further reduce any such residues. More importantly, even if oral exposure to this ubiquitous microbe should occur through drinking water, due to its demonstrated lack of acute oral toxicity/pathogenicity, the Agency concludes that there is a reasonable certainty that no harm will result from such exposure.

B. Other Non-Occupational Exposure

The pesticide uses of *Bacillus subtilis* MBI 600, both those currently allowed and the additional ones being established by this rule, are limited to commercial agricultural and horticultural settings. There are no residential uses. Nonetheless, because *Bacillus subtilis* MBI 600 is naturally occurring and ubiquitous in the environment, the potential for non-dietary, non-occupational exposure to

its residues for the general population, including infants and children, is likely since populations have probably been previously exposed (and likely will continue to be exposed) to background levels of the microbe. However, neither such common human exposures to *Bacillus subtilis* MBI 600 naturally present in soils, waters and plants, nor exposures associated with similar *Bacillus subtilis* strains used internationally in producing food-grade products and fermented foods, have resulted in reports of disease or other effects. Finally, while the literature includes accounts of *Bacillus subtilis* infections in humans (which consistently are reported only in otherwise-compromised individuals), those reports are most notable for their rare and exceptional nature.

EPA's evaluation of the required high-dose Tier I acute toxicity and pathogenicity tests resulted in the assignment of Toxicity Category IV (least toxic), and determinations of not infective and not pathogenic, for all exposure routes. No toxicological end points of concern were identified. There are no dietary endpoints that exceed the Agency's Level of Concern (LOC). Therefore, the Agency has determined that any additional exposure to the microbe resulting from residues attributable to *Bacillus subtilis* MBI 600 pesticide use will not result in additional aggregate non-occupational risk from dermal and inhalation exposures. This conclusion, based solely on non-occupational exposures, is consistent with EPA's determination that no occupational risks exceed the Agency's LOC, meaning that even regular occupational exposures associated with this active ingredient pose negligible risk.

V. Cumulative Effects

No mechanism of toxicity in mammals has been identified for *Bacillus subtilis* MBI 600. Therefore, no cumulative effect with other related organisms is anticipated. Because the available data demonstrate a lack of toxicity/pathogenicity potential for the active ingredient, adverse dietary effects are unlikely.

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

FFDCA section 408(b)(2)(C), as amended by the Food Quality Protection Act (FQPA) of 1996, provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section (b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database, unless EPA determines that a different margin of safety will be safe for infants and children.

Based on the acute toxicity information discussed in Unit III., EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of *Bacillus subtilis* MBI 600. 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* MBI 600 demonstrate a lack of toxicity/pathogenicity potential. Thus, there are no threshold effects of concern and, as a result, the Agency has concluded that the additional tenfold margin of safety for infants and children is unnecessary in this instance. Further, the need to consider consumption patterns, special susceptibility, and cumulative effects does not arise when dealing with pesticides with no demonstrated significant adverse effects.

VII. Other Considerations

A. Endocrine Disruptors

Bacillus subtilis MBI 600 is a ubiquitous organism in the environment that is non-toxic to mammals. To date, there is no evidence to suggest that *Bacillus subtilis* MBI 600 affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Indeed, the submitted toxicity/pathogenicity studies in rodents indicate that, following several routes of exposure, the immune system is intact and able to process and clear the active ingredient. Therefore, it is unlikely that this organism will have estrogenic or endocrine effects.

B. Analytical Method

The Agency is establishing an exemption from the requirement of a tolerance for residues of *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses, for the reasons stated above. Therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for detecting *Bacillus subtilis* MBI 600 residues resulting from its use as a pesticide.

C. Codex Maximum Residue Level

No Codex maximum residue level (MRL) exists for *Bacillus subtilis* MBI 600.

VIII. Conclusions

Based on the toxicity information for *Bacillus subtilis* MBI 600 that was previously submitted and reviewed, 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 *Bacillus subtilis* MBI 600 under reasonably foreseeable circumstances when used as a microbial pesticide in accordance with its label and good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As a result, pursuant to FFDCA sections 408(c) and (d) EPA is establishing an exemption from the requirement of a tolerance for residues of the biofungicide *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as

the 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

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).

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 20, 2009.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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. 321(q), 346a and 371.

■ 2. Section 180.1128 is revised to read as follows:

§ 180.1128 *Bacillus subtilis* MBI 600; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices.

[FR Doc. E9–7172 Filed 4–7–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0167; FRL–8407–8]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite CGA-322704 in or on citrus fruits, citrus pulp, tree nuts, almond hulls, and pistachios. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0167. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8735; e-mail address: *chao.julie@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 those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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