small entities. The term ''small entity'' is defined to have the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction,'' as defined in the RFA.

As authorized by 5 U.S.C. 553(d)(3), the Department finds that good cause exists for dispensing with the 30-day delay in the effective date of this rule. These regulations exempt certain investigative records maintained by the Department from notification, access, and amendment of a record. In order to protect the confidentiality of such investigatory records the Department finds that it is in the public interest to make these regulations effective upon publication.

List of Subjects in 31 CFR Part 1

Privacy.

Part 1, Subpart C of title 31 of the Code of Federal Regulations is amended as follows:

PART 1—[AMENDED]

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

Authority: 5 U.S.C. 301 and 31 U.S.C. 321. Subpart A also issued under 5 U.S.C. 552 as amended. Subpart C also issued under 5 U.S.C. 552a.

■ 2. In § 1.36, redesignate paragraphs (g)(1)(i) through (xiii) as (g)(1)(ii) through (xiv), respectively, and add new paragraph (g)(1)(i) to read as follows:

§ 1.36 Systems exempt in whole or in part from provisions of 5 U.S.C. 552a and this part.

* * * * *

(g) * * *

(1) * * *

(i) Treasury:

Number	System name
Treasury .013.	Department of the Treasury Civil Rights Complaints and Compliance Review Files.

* * * * *

Dated: December 22, 2011.

Melissa Hartman,

Deputy Assistant Secretary for Privacy, Transparency, and Records.

[FR Doc. 2012–338 Filed 1–10–12; 8:45 am]

BILLING CODE 4810–25–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0104; FRL–9330–9]

Bacillus Subtilis Strain CX–9060; 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 microbial pesticide *Bacillus subtilis* strain CX–9060 in or on all food commodities when applied/used in accordance with good agricultural practices. Certis U.S.A., L.L.C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), 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 CX–9060.

DATES: This regulation is effective January 11, 2012. Objections and requests for hearings must be received on or before March 12, 2012, 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–2010–0104. 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), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; email 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 get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0104 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be

received by the Hearing Clerk on or before March 12, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b). In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0104, 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 March 10, 2010 (75 FR 11171) (FRL–8810–8), 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 9F7643) by Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Bacillus subtilis* strain CX–9060. This notice referenced a summary of the petition prepared by the petitioner, Certis U.S.A., L.L.C., which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Although the Certis U.S.A., L.L.C. pesticide tolerance petition (PP 9F7643) specified that the requested exemption include residues resulting from post-harvest uses, the removal on December 8, 2010 of 40 CFR 180.1(h) (75 FR 76284, FRL–8853–8) eliminates the option for the expression of tolerances or exemptions from the requirement of a tolerance to include any reference to post-harvest use patterns. Therefore, the exemption established today by this rule does not specify post-harvest applications. Incidentally, there currently are no post-harvest uses proposed for the product containing *Bacillus subtilis* strain CX–9060. The addition of such uses to a *Bacillus subtilis* strain CX–9060 product label should be sought by amendment of the pesticide product under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

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

A new strain, *Bacillus subtilis* strain CX–9060, proposed as a microbial pesticide by Certis U.S.A., L.L.C., is the subject of this final rule. *Bacillus subtilis* strain CX–9060 was isolated from a peat medium containing a naturally occurring strain of the *Bacillus subtilis* bacterium. The progenitor strain, *Bacillus subtilis* MBI 600, is a currently registered pesticide. Data and information, submitted by Certis U.S.A., L.L.C. and reviewed by the Agency, indicate that both *Bacillus subtilis* strain CX–9060 and *Bacillus subtilis* MBI 600 are in the *B. subtilis/amyloliquifaciens* group, and are closely related. The established level of equivalency is such that citation of existing data on the progenitor strain supports the *Bacillus subtilis* strain CX–9060 petition for an exemption from the requirement of a tolerance.

The toxicological data on *Bacillus subtilis* MBI 600 cited by Certis U.S.A., L.L.C. were previously submitted to support an exemption from the requirement of a tolerance for residues of that active ingredient in or on all raw agricultural commodities resulting from its use in the treatment of seeds used for growing agricultural crops (June 8, 1994; 59 FR 29543; FRL–4865–8), and later to support an amendment that established a broader exemption for use of *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 (April 8, 2009; 74 FR 15865; FRL–8408–7). The previously submitted studies on *Bacillus subtilis* MBI 600 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 from all organs. The study resulted in a classification of Toxicity Category IV for this strain of *Bacillus subtilis.*

New studies submitted by Certis U.S.A., L.L.C., and conducted with a formulation containing 25.0% *Bacillus subtilis* strain CX–9060 (at a concentration of 5×10^{10} spores per gram), include the following:

• An acceptable acute eye irritation study in rabbits (MRID 478203–05) demonstrated that the undiluted test article was mildly irritating when a single 0.1 mL ocular dose was administered. At one hour post-treatment, one animal showed signs of corneal opacity, which cleared by 24 hours. Chemosis exhibited by one animal at 1 and 24 hours post-treatment cleared at 48 hours. The study resulted in a classification of Toxicity Category III.

• An acceptable primary dermal irritation study in rabbits (MRID 478203–04) resulted in an observation of slight erythema in a single animal at 24 hours, which resolved by 48 hours. The study resulted in a classification of Toxicity Category IV.

Consistent with test note five, 40 CFR 158.2140, waiver of the acute oral, acute dermal, and acute inhalation toxicity tests, which provide data on the end-use pesticide product, was requested by the petitioner. The justification supporting a waiver of these tests (MRID 478203–06) was adequate as the petitioner demonstrated that the combination of inert ingredients is not likely to pose any significant human health risks. Furthermore, the Agency has assigned Toxicity Category IV for all three routes of exposure: Acute oral toxicity (based upon the results of the cited acute oral toxicity/pathogenicity study (MRID 419074–02)); acute dermal toxicity (based upon the low toxicity of the inert ingredients and observed slight dermal irritation (MRID 478203–04)); and acute inhalation toxicity (based upon the results of the cited acute pulmonary toxicity/pathogenicity study (MRID 419074–04)).

There have been no reports of hypersensitivity in over 15 years of registered uses of the progenitor strain, nor have incidents associated with the testing or production of *Bacillus subtilis* strain CX–9060 been reported. Any future hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.

Consistent with test note four, 40 CFR 158.2140, no cell culture OCSPP Guideline 885.3500) data submission is required because *Bacillus subtilis* strain CX–9060 is not a virus.

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

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).

1. *Food. Bacillus subtilis* is ubiquitous in the environment (Ref. 1), especially in soils (Ref. 3) and agricultural environments (Ref. 4). Strain CX–9060 of *Bacillus subtilis* is derived from a naturally occurring isolate of the genus *Bacillus,* which was originally isolated from faba bean plants grown at the Nottingham University School of Agriculture in the United Kingdom. As a result, human dietary exposure to background levels of the microbe is likely occurring and will likely continue. Due to the ubiquitous presence of *Bacillus subtilis* in the environment, the Agency expects human exposure to *Bacillus subtilis* strain CX–9060 resulting from the proposed pesticidal uses will be no greater than existing human exposure to background levels of *Bacillus subtilis.*

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* strain CX–9060, at issue in this action) in food-borne illness, do not describe any pathogen or toxin production, only simple food spoilage from *Bacillus subtilis* growth in dough. This, in combination with test results (stated above) showing a lack of acute oral toxicity/pathogenicity, indicates the risk posed to adults, infants, and children from food-related exposures to *Bacillus subtilis* strain CX–9060 is expected to be minimal. Based on the Agency's evaluation of the submitted and cited data, there are no dietary risks that exceed the Agency's Level of Concern (LOC).

2. *Drinking water exposure.* Because *Bacillus subtilis* is ubiquitous in the environment, exposure to the microbe through drinking water may already be occurring and likely will continue. The proposed use sites do not include direct application to aquatic environments: the intended use of *Bacillus subtilis* strain CX–9060 is to treat growing crops (including roots and cuttings) for the control of plant disease. If the uses resulted in pesticide residues in spray drift or runoff that were to reach surface or ground waters, there is the potential for human exposure to *Bacillus subtilis* strain CX–9060 residues in drinking water, albeit likely greatly diluted. Municipal drinking water treatment processes and deep water wells, however, should further reduce any such residues. More importantly, even if oral exposure to this ubiquitous microbe should occur through drinking water, due to its expected 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* strain CX–9060 are limited to commercial agricultural and horticultural settings. There are no residential uses; it is not intended to be used in and around the home, or in schools, day care facilities or other such settings. Nonetheless, residential and other non-occupational exposure may

occur since *Bacillus subtilis* is ubiquitous in the environment. The potential for non-dietary, non-occupational exposure to *Bacillus subtilis* strain CX–9060 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 *Bacillus subtilis.* Neither such common human exposures to similar *Bacillus subtilis* strains naturally present in soils, waters and plants, nor exposures associated with those *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 bacteremias associated with immunosuppression, surgical intervention, neoplastic disease, and trauma), 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, which were cited in support of this petition, resulted in the assignment of Toxicity Category IV (least toxic), as well as 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 LOC. Therefore, the Agency has determined that any additional exposure to the microbe resulting from residues attributable to *Bacillus subtilis* strain CX–9060 pesticide use will not result in additional aggregate non-occupational risk from dermal and inhalation exposures. Because even regular occupational exposures associated with this active ingredient pose negligible risk, no risk is expected from non-occupation exposures.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found *Bacillus subtilis* strain CX–9060 to share a common mechanism of toxicity with any other substances, and *Bacillus subtilis* strain CX–9060 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Bacillus subtilis* strain CX–9060 does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

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 U.S. population, including infants and children, from aggregate exposure to residues of *Bacillus subtilis* strain CX–9060. 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 CX–9060 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. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Bacillus subtilis* strain CX–9060.

VIII. Conclusions

Therefore, an exemption is established for residues of *Bacillus subtilis* strain CX–9060 in or on all food commodities.

IX. References

1. U.S. EPA. 2010. *Bacillus subtilis* Final Registration Review Decision. Case 6012. March 2010.
2. U.S. EPA. 1997. *Bacillus subtilis* Final Risk Assessment. Available from *http://www.epa.gov/oppt/biotech/pubs/fra/fra009.htm.*
3. Bergey. 2009. Bergey's Manual of Systematic Bacteriology, Volume 3; 2nd Ed. Springer. New York.
4. U.S. EPA. 2008. Memorandum (J. V. Gagliardi to D. Greenway). December 23, 2008. *Bacillus subtilis* MBI 600.

X. 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) (Pub. L. 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).

XI. 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: December 15, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.1309 is added to subpart D to read as follows:

§ 180.1309 Bacillus subtilis strain CX–9060; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus subtilis* strain CX–9060, in or on all food commodities, when applied or used in accordance with good agricultural practices.

[FR Doc. 2012–228 Filed 1–10–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 20 and 54

[WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208; FCC 11–189]

Connect America Fund; Developing an Unified Intercarrier Compensation Regime; Lifeline and Link Up

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission amends rules regarding the attributes of ''voice telephony service'' to be supported by the Federal universal service support mechanisms. This action is necessary to reflect the evolution of the marketplace and to limit supported services. The Commission also waives certain effective dates so that intercarrier compensation for non-access traffic exchanged between Local Exchange Carriers (LEC) and Commercial Mobile Radio Service (CMRS) providers pursuant to an interconnection agreement in effect as of December 23, 2011, will be subject to a default bill-and-keep methodology on July 1, 2012, rather than on December 29, 2011. This action is necessary to limit marketplace disruption by delaying bill-and-keep until carriers are eligible to receive recovery as part of the transitional revenue recovery mechanism for this type of traffic.

DATES: Effective January 11, 2012.

FOR FURTHER INFORMATION CONTACT: Amy Bender, Wireline Competition Bureau, (202) 418–1469, or Victoria Goldberg, Wireline Competition Bureau, (202) 418–7353, or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration (Order) in WC Docket Nos. 10–90, 07–135, 05–337, 03–109, GN Docket No. 09–51, CC Docket Nos. 01–92, 96–45, WT Docket No. 10–208, FCC 11–189, released on December 23, 2011. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554.

1. In this Order, the Commission modifies on its own motion two aspects of the *USF/ICC Transformation Order,* 76 FR 73830, November 18, 2011.

2. In the *USF/ICC Transformation Order,* the Commission eliminated its former list of nine supported services and amended § 54.101 of the Commission's rules to specify that ''voice telephony service'' is supported by federal universal service support mechanisms. The Commission found this to be a more technologically neutral approach that focuses on the functionality offered instead of the technologies used, while allowing services to be provided over any platform. This approach also recognizes that many of the services enumerated in the previous rule are universal today and that the importance of operator services and directory assistance, in particular, has declined with changes in the marketplace. A number of parties have raised questions about how the amended rule should be understood to affect Lifeline-only ETCs and their compliance with section 214(e)(1)(A) of the Act, which requires a carrier to provide supported services using its own facilities, in whole or in part, in order to be eligible to receive support. Several parties have urged the Commission to take action to ensure that there is no disruption to the services currently being provided to