PART 530—EXTRALABEL DRUG USE IN ANIMALS

■ 1. The authority citation for 21 CFR part 530 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

■ 2. In § 530.41, add paragraph (a)(13) to read as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) * * *

(13) Cephalosporins (not including cephapirin) in cattle, swine, chickens, or turkeys:

(i) For disease prevention purposes;

(ii) At unapproved doses, frequencies, durations, or routes of administration; or

(iii) If the drug is not approved for that species and production class.

* * * * *

Dated: November 23, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–35 Filed 1–4–12; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD–2010–OS–0043; RIN 0790–AI62]

32 CFR Part 222

DoD Mandatory Declassification Review (MDR) Program; Correction

AGENCY: Department of Defense.

ACTION: Final rule; correction.

SUMMARY: On December 27, 2011 (76 FR 80744–80747), Department of Defense published a final rule titled DoD Mandatory Declassification Review (MDR) Program, which assigns responsibilities and provides procedures for members of the public to request a declassification review of information classified under the provisions of Executive Order 13526, or predecessor orders. This rule corrects a paragraph identification error in the regulations.

DATES: This correction is effective January 26, 2012.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, (571) 372–0485.

SUPPLEMENTARY INFORMATION: On December 27, 2011, Department of Defense published a final rule titled DoD Mandatory Declassification Review (MDR) Program. Subsequent to the publication of that final rule, Department of Defense discovered that paragraph § 222.5(f) in the third column of page 80746 should have read § 222.5(j).

Correction

In the final rule (FR Doc. 2011–33104) published on December 27, 2011 (76 FR 80744–80747), make the following correction:

§ 222.5 [Corrected]

On page 80746, in § 222.5, in the third column, in the first line of the third paragraph, ''(f) *MDR Appeals.''* should read ''(j) *MDR Appeals.''*.

Dated: December 30, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–33857 Filed 1–5–12; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0547; FRL–9480–1]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD)

Correction

In rule document 2011–33660 appearing on pages 214–217 in the issue of Wednesday, January 4, 2012, make the following corrections:

(1) On page 214, in the second column, in the DATES section, in the second line, ''February 3, 2011'' should read ''February 3, 2012''.

(2) On page 217, in the first column, in the last paragraph, in the fifth line, ''March 7, 2011'' should read ''March 5, 2012''.

[FR Doc. C1–2011–33660 Filed 1–5–12; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0944; FRL–9330–4]

Bacillus Amyloliquefaciens Strain D747; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus amyloliquefaciens* strain D747 (formerly known as *Bacillus subtilis* variant *amyloliquefaciens* strain D747) in or on all food commodities when used in accordance with good agricultural practices. Certis USA LLC 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 amyloliquefaciens* strain D747 (formerly known as *Bacillus subtilis* variant *amyloliquefaciens* strain D747).

DATES: This regulation is effective January 6, 2012. Objections and requests for hearings must be received on or before March 6, 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–2010–0944. 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 the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not made available via 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: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; email address: *cerrelli.susanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural

producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (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 readers 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(g), 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–2010–0944 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 6, 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–2010–0944, 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 Avenue 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 February 4, 2011 (76 FR 6465) (FRL–8858–7), 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 0F7760) by Certis USA LLC, 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 *Bacillus subtilis* variant *amyloliquefaciens* strain D747 (now recognized as *Bacillus amyloliquefaciens* strain D747). This notice referenced a summary of the petition prepared by the petitioner, Certis USA LLC, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

Based upon review of the data supporting the petition, EPA has modified the nomenclature of the active ingredient, which was recently reclassified as *Bacillus amyloliquefaciens* strain D747 (Refs. 1, 2, and 3). The reason for this change is explained in Unit III. A.

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.

A. Overview of Bacillus Amyloliquefaciens Strain D747

Bacillus amyloliquefaciens strain D747 was previously identified as *Bacillus subtilis* variant *amyloliquefaciens* strain D747 in the petition submitted to exempt the bacterium from the requirement of a tolerance when used as a microbial pesticide in or on all food commodities. *Bacillus subtilis* and *Bacillus amyloliquefaciens* were considered subtypes or variants of the same species. Now, however, *Bacillus amyloliquefaciens* is taxonomically designated as a separate species. The

taxonomic designation used in this final rule is correct.

Certis USA, LLC, has proposed to register *Bacillus amyloliquefaciens* strain D747 for control of fungi and bacteria in greenhouses, nurseries, and shadehouses, and on outdoor agricultural crops, ornamentals, and turfgrass. *Bacillus amyloliquefaciens* strain D747 is the active ingredient in the two end-use products (EP) CX–9030 (EPA File Symbol 70051–RNI) and CX–9032 (EPA File Symbol 70051–RNT).

B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the petition to exempt from the requirement of a tolerance residues of *Bacillus amyloliquefaciens strain D747* in or on all food commodities have been fulfilled with acceptable studies. The acute oral, injection and pulmonary toxicity/pathogenicity studies show that *Bacillus amyloliquefaciens strain D747* is not toxic, infective, or pathogenic at the doses tested.

1. *Acute oral toxicity/pathogenicity (Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 885.3050; Master Record Identification Number (MRID) No. 481657–04). Bacillus amyloliquefaciens* strain D747 was administered once orally to 14 rats of both sexes (5-weeks old) at a single dosage of 10^8 colony-forming units (CFU) per animal. No deaths occurred, and no abnormalities (clinical signs, body weight) were observed, during the study or at necropsy. The test microbe was detected at $10^3 - 10^5$ CFU/g in feces 1 day after administration of the test material, but was not detected on day 14. The examination for internal persistence did not detect the test microbe in any organs or tissues, such as the kidney, brain, liver, lung, spleen, stomach, small intestine (duodenum), large intestine (cecum), mesenteric lymph nodes, or blood, throughout the experimental period. Fecal clearance occurred by day 14, and no viable organisms were recovered from blood or other organs or tissues. The results of this acceptable study demonstrated that *Bacillus amyloliquefaciens* strain D747 was not infective, pathogenic, or toxic to rats when orally dosed with 1.0×10^8 CFU/animal.

2. *Acute pulmonary toxicity/pathogenicity (OCSPP Guideline 885.3150; MRID No.481657–06).* Twenty male and female rats were given a single dose of 1.0×10^7 spores *Bacillus amyloliquefaciens* strain D747 via a tracheal route of administration. No mortalities or clinical effects were observed in the test animals throughout the duration of the study. Clearance of the test material was steady, although residual viable cells remained in the lungs and trachea at the end of the 60 day study. This result was typical of spore forming bacteria because bacterial spores take longer to be cleared by healthy immune systems than the vegetative form of bacteria. This acceptable study demonstrated that *Bacillus amyloliquefaciens* strain D747 was not toxic and/or pathogenic to rats when dosed intratracheally at 1.0×10^7 (CFU)/animal.

3. *Acute injection toxicity/pathogenicity (intravenous)—rat (OCSPP Guideline 885.3200; MRID No. 481657–05).* An acceptable acute injection toxicity and pathogenicity study demonstrated that *Bacillus amyloliquefaciens* strain D747 was not toxic, infective, or pathogenic to rats that were injected with approximately 1.0×10^7 CFU/animal.

4. *Bacillus amyloliquefaciens* strain D747 was administered intravenously to groups of 17 male and female rats at a dose of 1.0×10^7 spores per animal. There were no mortalities, no clinical effects from intravenous administration, and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown, it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.

5. *Acute dermal toxicity (OCSPP Guideline 870.1200; MRID No. 481657–08).* An acceptable 14-day acute dermal toxicity study demonstrated that that the CX–9030 product, which contains *Bacillus amyloliquefaciens* strain D747, was not toxic in rats dosed at 5,050 mg/kg. [median lethal dose, (LD_{50}) > 5,050 mg/kg. EPA Toxicity Category IV.]

6. *Acute dermal irritation (OCSPP Guideline 870.2500; MRID No.: 481655–11).* An acceptable dermal irritation study demonstrated that no evidence of irritation occurred from dermal administration of 500 mg of CX–9030 to rabbits during the 4-hour exposure and the 72-hour observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX–9030 was 0.00 (EPA Toxicity Category IV).

7. *Acute dermal irritation (OCSPP Guideline 870.2500; MRID No.: 481655–06).* A second acceptable dermal irritation study also demonstrated that CX–9032 product containing *Bacillus amyloliquefaciens* strain D747 was non-irritating. No evidence of irritation was observed for 72 hours following the 4 hour dermal administration of 0.5 mL undiluted CX–9032 to the shaved skin rabbits. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX–9032 was 0.00 (EPA Toxicity Category IV).

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

Dietary exposure to this microbial pesticide may occur, but the complete absence of any acute oral toxicity, infectivity, and/or pathogenicity effects, as discussed in Unit III.B., supports the conclusion that this active ingredient is not toxic at high exposure levels, and, therefore, establishment of a tolerance exemption for residues of *Bacillus amyloliquefaciens* strain D747 is appropriate.

1. *Food.* Based on the results from the toxicity studies presented in Unit III.B., no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to *Bacillus amyloliquefaciens* strain D747 from the proposed pesticidal uses of *Bacillus amyloliquefaciens* strain D747 are expected. *Bacillus* species, including *Bacillus amyloliquefaciens,* are commonly found in agricultural settings, and occur naturally on fresh produce with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food, such as spices, milk powder, and grains, often contains large amounts of *Bacillus* spores (Ref. 3). *Bacillus amyloliquefaciens* is not known to produce mammalian toxins, and no foodborne illnesses associated with *Bacillus amyloliquefaciens* have been reported.

2. *Drinking water exposure. Bacillus amyloliquefaciens* is naturally present in soils (Ref. 2); therefore, *Bacillus amyloliquefaciens* may occur in surface water and possibly groundwater. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, largely because the spores are resistant to these disinfection

processes (Ref. 4). Should this microbial pesticide be present, no adverse effects are expected from exposure to *Bacillus amyloliquefaciens* through drinking water, based on the results of toxicity studies described in Unit III.B.

B. Other Non-Occupational Exposure

The use sites for these products include residential gardens, as well as agricultural sites. Based on the results of the acute toxicity tests described in Unit III.B., the Agency believes that the potential aggregate, non-occupational risks from exposure to *Bacillus amyloliquefaciens* strain D747, when used as a microbial pesticide, are negligible.

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 the microbial active ingredient to share a common mechanism of toxicity with any other substances, and *Bacillus amyloliquefaciens* strain D747 does not appear to produce any toxic metabolites. For the purposes of this tolerance action, therefore, EPA has assumed that *Bacillus amyloliquefaciens* strain D747 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) 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 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data/information summarized 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 the residues of *Bacillus amyloliquefaciens* strain D747. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because, considered collectively, the data and other information (e.g., lack of toxicity noted for oral, dermal, and inhalation routes of exposure) available on *Bacillus amyloliquefaciens* strain D747 do not demonstrate toxic, pathogenic, and/or infective potential to sensitive populations from exposure to this microbial pest control agent. There are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety is not necessary.

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 amyloliquefaciens* strain D747.

C. Response to Comments

Two comments were submitted. An anonymous comment was submitted expressing opposition to granting an exemption from the requirement of a tolerance to the applicant. (EPA–HQ–OPP–2010–0012–0019). The commenter submitted a number of comments in the same communication that suggested that this and other active ingredients should not be granted exemptions. The commenter expressed concern about toxic chemical residues on produce and on earth, and suggested that the ''Dept. of Health'' should analyze the health effects of toxic chemicals. In the United States, EPA is responsible for regulating pesticides under FIFRA and the FQPA, and has analyzed the toxicity of this microbial active ingredient. As described in Unit III.B., the results of the acute oral, injection and pulmonary toxicity/pathogenicity studies demonstrated that *Bacillus amyloliquefaciens strain D747* is not toxic, infective or pathogenic at the doses tested.

Another commenter also expressed opposition to granting a tolerance or an exemption from the requirement of a tolerance for this and other chemicals that were listed in the same registration notice. (EPA–HQ–OPP–2010–0905–0003). This commenter stated that the food supply must be rigorously tested, that studies must be subjected to independent peer review, and that only long term studies can provide data on the health impact to these chemicals. Consistent with section 408(b)(2)(D) of FFDCA, the testing data that were provided and evaluated by EPA for *Bacillus amyloliquefaciens strain D747,* as described in Unit III.B., support granting this exemption.

VIII. Conclusions

Therefore, an exemption is established for residues of *Bacillus amyloliquefaciens* strain D747.

IX. References

1. Priest, F.G., M. Goodfellow, L.A. Shute, and R.C.W. Berkeley. 1987. *Bacillus amyloliquefaciens* sp. nov., nom. rev. *International Journal of Systematic Bacteriology,* 37: 69–71.
2. Logan, N.A., and P. de Vos. 2009. Genus I. Bacillus, Pp. 21–128 In: P. de Vos, G.M. Garrity, D. Jones, N.R. Krieg, W. Ludwig, F.A. Rainey, K.H. Schleifer, and W. Whitman (Eds.) *Bergey's Manual of Systematic Bacteriology,* Volume 3, 2nd Ed. Springer, New York.

3. Murray, P.R, *et al., Manual of Clinical Microbiology.* Washington, DC: ASM Press; 9th edition, 2007.
4. World Health Organization, Guidelines for Drinking-water Quality. (2011) 4th Ed.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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 180.308 is added to subpart D to read as follows:

§ 180.308 Bacillus amyloliquefaciens strain D747; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide, *Bacillus amyloliquefaciens* strain D747 in or on all food commodities when used in accordance with good agricultural practices.

[FR Doc. 2011–33846 Filed 1–5–12; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 501, 539, and 552

[GSAR Amendment 2011–03; GSAR Case 2011–G503; (Change 52); Docket 2011–0012, Sequence 1]

RIN 3090–AJ15

General Services Administration Acquisition Regulation; Implementation of Information Technology Security Provision

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: GSA has adopted as final, with changes, an interim rule amending the General Services Administration Acquisition Regulation (GSAR) to implement policy and guidelines to strengthen the security requirements for contracts and orders that include information technology (IT) supplies, services and systems.

DATES: *Effective Date:* January 6, 2012.

Applicability Date: This amendment applies to contracts and orders awarded after January 6, 2012 that include information technology (IT) supplies, services and systems with security requirements.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah Lague, Procurement Analyst, at (202) 694–8149, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite GSAR Amendment 2011–03, GSAR Case 2011–G503.

SUPPLEMENTARY INFORMATION:

I. Background

The GSA Office of the Inspector General (OIG) conducted an audit of GSA's information and information technology systems to verify that GSA has met the requirements of the Federal Information Security Management Act of 2002 (FISMA). The OIG made a recommendation to strengthen the security requirements in contracts and orders for information technology supplies, services and systems. GSA agreed with the OIG recommendation and published an interim rule in the **Federal Register** at 76 FR 34886 on June 15, 2011, with a request for comments. As a result, this final rule implements the interim rule with only minor changes.

II. GSAR Changes

The changes to GSAR Parts 539 and 552 will remain as implemented by the interim rule.