

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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 3, 2015.

**Robert McNally**,

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. Revise § 180.1128 to read as follows:

#### § 180.1128 *Bacillus amyloliquefaciens* MBI600; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Bacillus amyloliquefaciens* MBI600 (antecedent *Bacillus subtilis* MBI600) in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2015-0766; FRL-9939-95]

#### Extension of Pesticide Residue Tolerances for Emergency Exemptions (Multiple Chemicals)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends existing time-limited tolerances for residues of the pesticides bifenthrin in or on apple, peach and nectarine; dinotefuran in or on pome fruit and stone fruit; imidacloprid in or on sugarcane, cane and sugarcane molasses; and streptomycin in or on grapefruit and grapefruit, dried pulp. These actions are in response to EPA's

granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

**DATES:** This regulation is effective December 16, 2015. Objections and requests for hearings must be received on or before February 16, 2016, 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0766, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

- Pesticide manufacturing (NAICS code 32532).

##### 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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

##### 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-2015-0766 in the subject line on the first page of your submission. All requests must be in writing, and must be received by the Hearing Clerk on or before February 16, 2016. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0766 by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Background and Statutory Findings

EPA published final rules in the **Federal Register** for each chemical listed. The initial issuance of these final rules announced that EPA, on its own initiative, under FFDCA section 408, 21 U.S.C. 346a, was establishing time-limited tolerances for residues of a pesticide in or on one or more food commodities.

EPA established the tolerances because FFDCA section 408(l)(6) requires EPA to establish a time-limited tolerance, or exemption from the requirement for a tolerance, for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or time for public comment.

EPA received requests to extend the emergency use of these chemicals for this year's growing season. After having reviewed these submissions, EPA concurs that emergency conditions continue to exist. EPA assessed the potential risks presented by residues for each chemical. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

The data and other relevant material have been evaluated and discussed in the final rules originally published to support these uses. Based on that data and information considered, the Agency reaffirms that extension of these time-limited tolerances will continue to meet the requirements of FFDCA section 408(l)(6). Therefore, each of the time-limited tolerances is extended until the date listed, when they will expire and become revoked. EPA intends to publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on the dates listed, under FFDCA section 408(l)(5), residues of a pesticide not in excess of the amount specified in the tolerance remaining in or on a commodity after that date will not be unlawful, provided the residues are present as a result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, a tolerance was in place at the time of the application, and the residues do not exceed the level that was authorized by the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other

relevant information on these pesticides indicates that the residues are not safe.

Tolerances for the use of the following pesticide chemicals on specific commodities are being extended:

**Bifenthrin.** EPA has authorized under FIFRA section 18 the use of bifenthrin on apple, peach, and nectarine for control of the brown marmorated stinkbug in multiple states. This regulation extends existing time-limited tolerances for residues of the insecticide bifenthrin, including its metabolites and degradates, in or on apple, peach, and nectarine at 0.5 part per million (ppm) for an additional 3-year period. These tolerances will expire and are revoked on December 31, 2018. The time-limited tolerances were originally published in the **Federal Register** of September 14, 2012 (77 FR 56782) (FRL-9361-6).

**Dinotefuran.** EPA has authorized under FIFRA section 18 the use of dinotefuran on pome fruit and stone fruit for control of the brown marmorated stinkbug in multiple states. This regulation extends existing time-limited tolerances for residues of the insecticide dinotefuran, including its metabolites and degradates, in or on fruit, pome, group 11 and fruit, stone, group 12 at 2.0 ppm for an additional three-year period. These tolerances will expire and are revoked on December 31, 2018. The time-limited tolerances were originally published in the **Federal Register** of November 9, 2012 (77 FR 67282) (FRL-9366-3), and revised in the **Federal Register** of January 22, 2014 (79 FR 3508) (FRL-9402-8).

**Imidacloprid.** EPA has authorized under FIFRA section 18 the use of imidacloprid on sugarcane for control of the West Indian cane fly in Louisiana. This regulation extends existing time-limited tolerances for residues of the insecticide imidacloprid, including its metabolites and degradates, in or on sugarcane, cane at 6.0 ppm and sugarcane, molasses at 50 ppm for an additional 3-year period. These tolerances will expire and are revoked on December 31, 2018. The time-limited tolerances were originally published in the **Federal Register** of June 5, 2013 (78 FR 33736) (FRL-9387-9).

**Streptomycin.** EPA has authorized under FIFRA section 18 the use of streptomycin on grapefruit for control of citrus canker in Florida. This regulation extends existing time-limited tolerances for residues of the pesticide streptomycin, including its metabolites and degradates, in or on grapefruit at 0.15 ppm and grapefruit, dried pulp at 0.40 ppm for an additional 3-year period. These tolerances will expire and are revoked on December 31, 2018. The time-limited tolerances were originally

published in the **Federal Register** of May 17, 2013 (78 FR 29049) (FRL-9385-3).

## III. 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 United Nations 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 MRLs for bifenthrin in/on apple, peach, or nectarine; dinotefuran in/on pome fruit or stone fruit; imidacloprid in/on sugarcane, cane or sugarcane molasses; nor streptomycin in/on grapefruit or grapefruit, dried pulp.

## IV. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 under FFDCA sections 408(e) and 408(l)(6), such as the tolerances 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

**V. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

**Register.** This action 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 8, 2015.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. In § 180.245, revise the table in paragraph (b) to read as follows:

**§ 180.245 Streptomycin; tolerances for residues.**

\* \* \* \* \*  
(b) \* \* \*

Commodity	Parts per million	Expiration/ revocation date
Grapefruit .....	0.15	12/31/2018
Grapefruit, dried pulp .....	0.40	12/31/2018

\* \* \* \* \*  
■ 3. In § 180.442, revise the table in paragraph (b) to read as follows:

**§ 180.442 Bifenthrin; tolerances for residues.**  
\* \* \* \* \*

Commodity	Parts per million	Expiration/ revocation date
Apple .....	0.5	12/31/2018
Nectarine .....	0.5	12/31/2018
Peach .....	0.5	12/31/2018

\* \* \* \* \*  
■ 4. In § 180.472, revise the table in paragraph (b) to read as follows:

**§ 180.472 Imidacloprid; tolerances for residues.**  
\* \* \* \* \*

Commodity	Parts per million	Expiration/ revocation date
Sugarcane, cane .....	6.0	12/31/2018
Sugarcane, molasses .....	50	12/31/2018

\* \* \* \* \*  
■ 5. In § 180.603, revise the table in paragraph (b) to read as follows:

**§ 180.603 Dinotefuran; tolerances for residues.**  
\* \* \* \* \*

Commodity	Parts per million	Expiration/ revocation date
Fruit, pome, Group 11 .....	2.0	12/31/2018
Fruit, stone, Group 12 .....	2.0	12/31/2018

\* \* \* \* \*  
 [FR Doc. 2015-31518 Filed 12-15-15; 8:45 am]  
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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2015-0023; FRL-9935-81]

### Choline Chloride; 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 Choline Chloride (Acetyl Choline) in or on all food commodities when applied/used pre-harvest and used in accordance with label directions and good agricultural practices. CP Bio, Inc., 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 Choline Chloride.

**DATES:** This regulation is effective December 16, 2015. Objections and requests for hearings must be received on or before February 16, 2016, 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0023, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone

number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this action apply to me?

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- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
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##### II. Background and Statutory Findings

In the **Federal Register** of March 4, 2015 (80 FR 11611) (FRL-9922-68), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F8287) by CP Bio, Inc., 4802 Murrieta Street, Chino, CA 91710. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Choline Chloride in or on all food commodities (when applied pre-harvest). That document referenced a summary of the petition prepared by the petitioner CP Bio, Inc., which is available in the docket, <http://www.regulations.gov>. There were no substantive comments received in response to the notice of filing.

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 FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of