EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approval date	Explanation
* *	* *	*	*	*
Non-Interference Demonstration and Maintenance Plan Revision for Federal Low-Reid Vapor Pressure Requirement in the Atlanta Area.	Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Paulding, and Rockdale counties.	8/15/2018	4/23/2019, [Insert **Federal Register** citation].	

[FR Doc. 2019–08062 Filed 4–22–19; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0593; FRL–9991–86]

Bacteriophage Active Against Xylella fastidiosa; 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 lytic bacteriophage active against *Xylella fastidiosa* in or on all food commodities when the bacteriophage are sequenced and have sequences free of toxins and lysogenic genes and are used in accordance with label directions and good agricultural practices. Otsuka Pharmaceutical Co., Ltd. (c/o Technology Sciences Group 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 bacteriophage active against *Xylella fastidiosa* in or on all food commodities under FFDCA.

DATES: This regulation is effective April 23, 2019. Objections and requests for hearings must be received on or before June 24, 2019, 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–2017–0593, 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*.

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 Publishing Office's e-CFR site at *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(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–2017–0593 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 June 24, 2019. 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–2017–0593, 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

In the **Federal Register** of March 6, 2018 (83 FR 9471) (FRL–9973–27), 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 7F8562) by Otsuka Pharmaceutical Co., Ltd. (Otsuka), 2–9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, 101–8535, Japan (c/o Technology Sciences Group Inc., 712 Fifth St., Suite A, Davis, CA 95616). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the bactericide bacteriophages active against *Xylella fastidiosa* in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner Otsuka (c/o Technology Sciences Group Inc.) and available in the docket via *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit III.C.

Based upon review of data and other information supporting the petition, EPA is granting a tolerance exemption that differs slightly from what the petition requested. The reason for this difference is explained in Unit III.D.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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 infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicity and exposure data on bacteriophage active against *Xylella fastidiosa* and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Bacteriophage Active Against *Xylella fastidiosa*'' (Safety Determination). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data demonstrated that, with regard to humans, bacteriophage active against *Xylella fastidiosa* are not anticipated to be toxic, pathogenic, or infective via any route of exposure. Furthermore, humans, including infants and children, have been exposed to bacteriophage through food and water, where they are commonly found, with no known adverse effects. Although there may be some exposure to residues when bacteriophage active against *Xylella fastidiosa* is used on food commodities in accordance with label directions and good agricultural practices (only grape for now), there is a lack of concern due to the lack of potential for adverse effects. EPA also determined in the Safety Determination that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for bacteriophage active against *Xylella fastidiosa*.

Based upon its evaluation in the Safety Determination, 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 bacteriophage active against *Xylella fastidiosa*. Therefore, an exemption from the requirement of a tolerance is established for residues of lytic bacteriophage active against *Xylella fastidiosa* in or on all food commodities when the bacteriophage are sequenced and have sequences free of toxins and lysogenic genes and are used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Response to Comments

Nine comments were received in response to the notice of filing. EPA reviewed the comments and determined that they are irrelevant to the tolerance exemption in this action.

D. Differences Between Petition and Tolerance Exemption Rule

In its petition, the petitioner requested generally that EPA issue an exemption from the requirement of a tolerance for residues of bacteriophage active against *Xylella fastidiosa* in or on all food commodities. The petitioner's supporting materials indicated that the actual pesticide that would be used would be safe because the bacteriophage were lytic and were sequenced and have sequences free of toxins and lysogenic genes. EPA believes that only bacteriophage that have these same characteristics as the organism tested would be safe and should be exempt from the requirement of a tolerance. Therefore, EPA is issuing a tolerance exemption that differs slightly from the petition by limiting the exemption to residues of the bacteriophage that possess the same characteristics as the bacteriophage that were tested to support this exemption.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 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 FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (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: April 12, 2019.

Richard P. Keigwin, Jr.,

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. Add § 180.1365 to subpart D to read as follows:

§ 180.1365 Bacteriophage active against *Xylella fastidiosa;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of lytic bacteriophage active against *Xylella fastidiosa* in or on all food commodities when the bacteriophage are sequenced and have sequences free of toxins and lysogenic genes and are used in accordance with label directions and good agricultural practices.

[FR Doc. 2019–08111 Filed 4–22–19; 8:45 am]

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NATIONAL SCIENCE FOUNDATION

45 CFR Part 670

RIN 3145–AA59

Conservation of Antarctic Animals and Plants

AGENCY: National Science Foundation.

ACTION: Direct final rule.

SUMMARY: Pursuant to the Antarctic Conservation Act of 1978, as amended, the National Science Foundation (NSF) is amending its regulations to reflect changes to designated Antarctic specially protected areas (ASPA), Antarctic specially managed areas (ASMA) and historic sites or monuments (HSM). These changes reflect decisions already adopted by the Antarctic Treaty Parties at recent Antarctic Treaty Consultative Meetings (ATCM). The United States Department of State heads the United States delegation to these annual Antarctic Treaty meetings.

DATES: Effective April 23, 2019.

FOR FURTHER INFORMATION CONTACT: Bijan Gilanshah, Assistant General Counsel, Office of the General Counsel, at 703–292–8060, National Science Foundation, 2415 Eisenhower Avenue, Suite W 18200, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION: The Antarctic Conservation Act of 1978, as amended (''ACA'') (16 U.S.C. 2401, *et seq.*) implements the Protocol on Environmental Protection to the Antarctic Treaty (''the Protocol''). Annex V contains provisions for the protection of specially designated areas specially managed areas and historic sites and monuments. Section 2405 of title 16 of the ACA directs the Director of the National Science Foundation to issue such regulations as are necessary and appropriate to implement Annex V to the Protocol.

The Antarctic Treaty Parties, which includes the United States, periodically adopt measures to establish, consolidate or revoke specially protected areas, specially managed areas and historical sites or monuments in Antarctica. This rule is being revised to reflect five added Antarctic specially protected areas (ASPAs 171–175) and six historical sites and monuments in Antarctica (HSM 87–92). The rule is also being revised to reflect the revocation, of three Antarctic specially protected areas (ASPAs 114, 118 and 130) and one Antarctic specially managed area (ASMA 3) primarily due to consolidation.

Public Participation

The changes to these areas and sites reflect decisions already made by the Antarctic Treaty Parties at recent international ATOM meetings. Because these amendments directly involve a foreign affairs function, the provisions of Executive Order 12866, Executive Order 13771 and the Administrative Procedure Act (5 U.S.C. 553), requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Further, because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601 and 612) does not apply.

Environmental Impact

This final rule makes technical conforming changes to the National Science Foundation's regulations to reflect the substantive outcomes of recent Antarctic Treaty Consultative Meetings. The actions taken by the Antarctic Treaty Parties to manage and protect these new Antarctic areas and historic resources will result in added protection of the Antarctic environment and its historic resources.

Reducing Regulation and Controlling Regulatory Costs

In implementing these international ATOM agreed to changes, this direct final rule relates to a foreign affairs