

*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).

**VII. 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: April 1, 2011.

**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. Section 180.593 is amended by:
  - i. Revising the introductory text in paragraph (a);
  - ii. Removing the commodities “Cucumber,” “Grape” and “Strawberry” from the table in paragraph (a);
  - iii. Revising the entry “Vegetable, cucurbit subgroup 9A” to read “Melon subgroup 9A” in the table; and
  - iv. Alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.593 Etoxazole; tolerances for residues.**

(a) *General.* Tolerances are established for residues of etoxazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only etoxazole (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole) in or on the commodity.

Commodity	Parts per million
* * * * *	*
Avocado .....	0.20
Berry, low growing, subgroup 13-07G .....	0.50
Caneberry subgroup 13-07A .....	1.5
Canistel .....	0.20
* * * * *	*
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F .....	0.50

Commodity	Parts per million
* * * * *	*
Mango .....	0.20
Melon subgroup 9A .....	0.20
* * * * *	*
Papaya .....	0.20
Pepper/eggplant subgroup 8-10B .....	0.20
* * * * *	*
Sapodilla .....	0.20
Sapote, black .....	0.20
Sapote, mamey .....	0.20
* * * * *	*
Squash/cucumber subgroup 9B .....	0.02
Star apple .....	0.20
* * * * *	*
Tea, dried * .....	15
* * * * *	*

\* There are currently no U.S. registrations for tea as of April 13, 2011.

\* \* \* \* \*  
[FR Doc. 2011-8550 Filed 4-12-11; 8:45 am]  
**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0274; FRL-8868-4]

***Escherichia coli* O157:H7 Specific Bacteriophages; Temporary Exemption From the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria when applied/used on food contact surfaces in food processing plants in accordance with the terms of Experimental Use Permit (EUP) No. 74234-EUP-2. Intralytix, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria. The temporary tolerance exemption expires on April 1, 2013.

**DATES:** This regulation is effective April 13, 2011. Objections and requests for hearings must be received on or before June 13, 2011, 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-2010-0274. 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:** Tracy Lantz, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6415; e-mail address: [lantz.tracy@epa.gov](mailto:lantz.tracy@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://www.gpoaccess.gov/ecfr>.

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

Under FFDC 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-2010-0274 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 13, 2011. 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-2010-0274, 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 May 5, 2010 (75 FR 24692) (FRL-8820-7), EPA issued a notice pursuant to section 408(d)(3) of FFDC, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9G7585) by Intralytix, Inc., 701 East Pratt Street, Baltimore, MD 21202. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Escherichia coli* O157:H7 Specific Bacteriophages. This notice referenced a summary of the petition prepared by the petitioner Intralytix, Inc., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDC 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 FFDC 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 FFDC, 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 FFDC, 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 FFDC 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.

Phages are naturally occurring viruses infecting bacteria. They are found in soil and water and in association with plants and animals, including humans. Bacteriophages are obligate parasites of bacteria, which means they attach to, infect, and reproduce in bacteria. Phages are host-specific for bacteria, with specific bacteriophages attacking only one bacterial species and most frequently only one strain within a bacterial species. As such, phages do not attack other beneficial bacteria. In addition, there is no evidence for bacteriophages infecting any other life form, including humans, except bacteria. Thus, non-target organisms, such as mammals, birds, fish, plants, and other wildlife, are not affected by exposure to bacteriophages. Humans and other animals commonly consume bacteriophages as they are abundantly found in water, on plant surfaces, and in foods such as ground beef, pork sausage, chicken, oysters, cheese, fresh mushrooms, and lettuce. In addition, phages are common commensals of the human gut and likely play an important role in regulating populations of various bacteria in the gastrointestinal tract. As cited in public literature, phages have been used for more than 80 years as therapeutic agents with no ill effects and are active against bacteria that cause many infections and human diseases.

Since bacteriophage do not infect humans, there is not a human health risk concern from the bacteriophages themselves. The potential concerns for human health risk from bacteriophages relate to their interaction with the bacteria they infect. If bacteriophage do not lyse (*i.e.*, break open) the bacterial cell they infect, there is a possibility the cell will survive the infection and incorporate any DNA carried by the bacteriophage in its genome (*i.e.* lysogenize). If genes for shigatoxins I and II, often associated with pathogenic strains of *Escherichia coli* O157:H7, are carried by a lysogenized bacteriophage into an atoxigenic *Escherichia coli*, there is a possibility, in theory, to

convert a commensal and harmless bacterium into a pathogen. This theoretical risk is handled in three ways for this tolerance exemption: (1) Only lytic bacteriophage are used; (2) bacteriophage covered by this tolerance exemption are DNA sequenced to ensure they do not have the ability to convey shigatoxins I and II; and (3) host bacteria used to grow bacteriophage also are atoxigenic in that they do not carry DNA sequences capable of shigatoxin production.

To address the infectivity and toxicity endpoints for oral, pulmonary, and injection exposures, the petitioner provided publicly available information documenting a lack of mammalian toxicity or infectivity associated with bacteriophages due to the specificity of bacteriophages attachment and attack to a narrow range of bacterial strains. As a result, the public literature demonstrates that phages pose little to no risk to humans even with the known wide exposure in food and the environment.

Based on the published literature and information submitted in accordance with the Tier I toxicology data requirements set forth in 40 CFR 158.2140(c), the Tier II and Tier III toxicology data requirements also set forth therein were not triggered and, therefore, not required in connection with this action.

### 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

1. *Food.* All phages, including those at issue in this action, are similar in nature in that they are host-specific, attacking only bacteria. Published literature submitted by the registrant, and other publically available literature, indicate that humans are exposed to phages daily, and these phages are commonly found in humans, having no known adverse effects. Indeed, humans and other animals routinely consume phages when they eat food such as raw produce and cheese. For example, it is reported that 1,000 ( $10^3$ ) to  $5 \times 10^5$  phages can be isolated routinely per gram (g) of high quality cheese. Pathogenic microorganisms are often found in foods; therefore, it is not surprising that

one study found *Escherichia coli* and coliphages in 11 of 12 foods purchased at retail markets. In this study, 10 purchases of each of the 12 foods were made. All 10 of the fresh ground beef purchases were contaminated with *Escherichia coli*, and all 10 contained coliphages. In addition to ground beef, *Escherichia coli* and coliphages were found in chicken, fresh pork, fresh oyster, fresh mushrooms, lettuce, chicken pot pie, biscuit dough, deli loaf, deli roasted turkey, and package roasted chicken. Another example of phages in food has been *Propionibacterium freundenreichii* phage found in concentrations as high as  $1.4 \times 10^6$ /gm of swiss cheese.

The use of the bacteriophages covered by this tolerance in food processing plants on food contact surfaces could result in some residues of these bacteriophages on food. The Agency anticipates that food coming into contact with these surfaces could get residues of the phages on them and foods with *Escherichia coli* O157:H7 may end up with more phages on them as the bacteriophages covered by this tolerance exemption infect the bacteria and produce progeny.

2. *Drinking water exposure.* The *Escherichia coli* bacteriophages covered by this tolerance exemption are not intended for use in drinking water, nor are the approved uses likely to result in these bacteriophages reaching surface water or ground water that might be used as drinking water. Use sites are only for food processing facilities.

#### B. Other Non-Occupational Exposure

Since *Escherichia coli* bacteriophages subject to this tolerance exemption are only intended to be applied to food contact surfaces in food processing plants, the potential for non-occupational, non-dietary exposures (*i.e.*, dermal and inhalation exposures) to these phages by the general population, including infants and children, is highly unlikely.

### 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 lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria to

share a common mechanism of toxicity with any other substances. Moreover, bacteriophage that meet these conditions do not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this action, EPA has assumed that lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria do 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

### A. U.S. Population

Based on the fact that bacteriophages are host-specific and do not cause harm to human health, except in theoretical instances that the Agency is avoiding through its conditions on this exemption, there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

### B. Infants and Children

FFDCA section 408 (b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (MOE) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different MOE will be safe for children. MOEs, which are often referred to as uncertainty (safety) factors, are incorporated into EPA risk assessments either directly, or through the use of a MOE analysis or by using uncertainty factors in calculating a dose level that poses no appreciable risk. As previously mentioned in the toxicological profile, humans, including infants and children, have been exposed to phages generally through food and water, where they are commonly found, and through decades of therapeutic use, with no known or reported adverse effects. Based on all available information, the Agency concludes that

lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria are non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria are used as labeled, the Agency concludes that the additional MOE is not necessary to protect infants and children and that not adding any additional MOE will be safe for infants and children.

## 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 lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria.

### C. Revisions to Petitioned-for Tolerances

In its petition PP 9G7585, Intralytix requested that the Agency establish a tolerance exemption for residues of *Escherichia coli* O157:H7 specific bacteriophages. The Agency is narrowing the scope of the tolerance exemption to residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria because that is the category of

bacteriophages for which the Agency can make a safety finding.

## VIII. Conclusion

The Agency 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 lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria, including all anticipated dietary exposures and all other exposures for which there is reliable information, when used according to label directions, as a microbial on food contact surfaces in food processing plants. Therefore, a temporary exemption is established for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria.

## IX. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes,

nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCFA. 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).

#### X. Congressional Review Act

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

#### List of Subjects in 40 CFR Part 180

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

Dated: April 5, 2011.

**Steven Bradbury**,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 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 § 180.1301 to subpart D to read as follows:

**§ 180.1301 *Escherichia coli* O157:H7 specific bacteriophages; temporary exemption from the requirement of a tolerance.**

A temporary exemption from the requirement of a tolerance is established for residues of lytic bacteriophages that are specific to *Escherichia coli* O157:H7, sequence negative for shiga toxins I and II, and grown on atoxigenic host bacteria when used/applied on food contact surfaces in food processing plants in accordance with the terms of Experimental Use Permit (EUP) No. 74234-EUP-2. This temporary exemption expires on April 1, 2013.

[FR Doc. 2011-8712 Filed 4-12-11; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 300

[EPA-HQ-SFUND-1983-0002; FRL-9291-6]

**National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List: Deletion of the Spiegelberg Landfill Superfund Site**

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

**ACTION:** Direct final rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the Spiegelberg Landfill Superfund Site (Site), located in Green Oak Township, Michigan from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Michigan through the Michigan Department of Environmental Quality (MDEQ), because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** This direct final deletion is effective June 13, 2011 unless EPA

receives adverse comments by May 13, 2011. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA-HQ-SFUND-1983-0002, by one of the following methods:

- <http://www.regulations.gov>: Follow on-line instructions for submitting comments.

- *E-mail:* Howard Caine, Remedial Project Manager, at [caine.howard@epa.gov](mailto:caine.howard@epa.gov) or Cheryl Allen, Community Involvement Coordinator, at [allen.cheryl@epa.gov](mailto:allen.cheryl@epa.gov).

- *Fax:* Gladys Beard, Deletion Process Manager, at (312) 697-2077.

- *Mail:* Howard Caine, Remedial Project Manager, U.S. Environmental Protection Agency (SR-6J), 77 W. Jackson Boulevard, Chicago, IL 60604, (312) 353-9685; or Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI-7J), 77 W. Jackson Boulevard, Chicago, IL 60604, (312) 353-6196 or (800) 621-8431.

- *Hand delivery:* Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI-7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

**Instructions:** Direct your comments to Docket ID no. EPA-HQ-SFUND-1983-0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment