

more flexible staffing may be the most rational option.

**II. Explanation of Changes From Proposed Rule**

The final rule includes the following additional changes to the proposed rule.

Paragraph 241.1(a) has been revised to clarify that the operation or staffing of a Post Office by non-postmaster personnel must be at the direction of the postmaster, and that it may include times when the postmaster is not physically present. While the proposed rule referred to whether a Post Office was “operated or managed” by non-postmaster personnel, the phrase “operated or staffed” better reflects the intended meaning that a postmaster would continue to manage operations at the Post Office, albeit possibly without personally operating or staffing it on a continuous basis.

A sentence is added to paragraph 241.3(a)(1)(ii) (redesignated as 241.3(a)(1)(iii)) to clarify that these regulations will no longer apply to discontinuance actions pending as of December 1, 2011, that pertain to the conversion of a Post Office to another type of USPS-operated facility.

The definition of “consolidation” in paragraph 241.3(a)(2)(iv) is revised to restrict the term’s definition to instances where a Postal Service-operated retail facility is replaced with a contractor-operated retail facility that reports to a Postal Service-operated retail facility. Consistent with the proposed rule, the term no longer encompasses situations where a Post Office is replaced with a Classified Station or Classified Branch.

Paragraph 241.3(b)(4) is revised to indicate the possibility that a consolidated facility’s name, or a similar name, can be used by the succeeding facility, rather than suggesting an expectation that the former name will be maintained, thereby allowing for the range of contract- and service-specific circumstances that can affect such a determination.

The Postal Service hereby adopts the following changes to 39 CFR part 241.

**List of Subjects in 39 CFR Part 241**

Organization and functions (government agencies), Postal Service.

Accordingly, 39 CFR part 241 is amended as follows:

**PART 241—RETAIL ORGANIZATION AND ADMINISTRATION: ESTABLISHMENT, CLASSIFICATION, AND DISCONTINUANCE**

■ 1. The authority citation for 39 CFR part 241 continues to read as follows:

**Authority:** 39 U.S.C. 101, 401, 403, 404, 410, 1001.

■ 2. In § 241.1, paragraph (a) is revised to read as follows:

**§ 241.1 Post offices.**

(a) *Establishment.* Post Offices are established and maintained at locations deemed necessary to ensure that regular and effective postal services are available to all customers within specified geographic boundaries. A Post Office may be operated or staffed by a postmaster or by another type of postal employee at the direction of the postmaster, including when the postmaster is not physically present.

\* \* \* \* \*

■ 3. In § 241.3:

- a. Paragraph (a)(1)(i)(B) is revised;
- b. Paragraph (a)(1)(ii) is redesignated as paragraph (a)(1)(iii), and new paragraph (a)(1)(ii) is added;
- c. Newly redesignated paragraph (a)(1)(iii) is revised;
- d. Paragraph (a)(2)(iv) is revised;
- e. Paragraph (b)(2)(i) is revised;
- f. Paragraph (b)(4) is revised; and
- g. Paragraph (c)(2) is revised.

The revisions and additions read as follows:

**§ 241.3 Discontinuance of USPS-operated retail facilities.**

- (a) \* \* \*
- (1) \* \* \*
- (i) \* \* \*

(B) Combine a USPS-operated Post Office, station, or branch with another USPS-operated retail facility, or

(ii) The conversion of a Post Office into, or the replacement of a Post Office with, another type of USPS-operated retail facility is not a discontinuance action subject to this section. A change in the staffing of a Post Office such that it is staffed only part-time by a postmaster, or not staffed at all by a postmaster, but rather by another type of USPS employee, is not a discontinuance action subject to this section.

(iii) The regulations in this section are mandatory only with respect to discontinuance actions for which initial feasibility studies have been initiated on or after July 14, 2011. Unless otherwise provided by responsible personnel, the rules under § 241.3 as in effect prior to July 14, 2011 shall apply to discontinuance actions for which initial feasibility studies have been initiated prior to July 14, 2011. Discontinuance actions pending as of December 1, 2011, that pertain to the conversion of a Post Office to another type of USPS-operated facility are no longer subject to these regulations.

(2) \* \* \*

(iv) “Consolidation” means an action that converts a Postal Service-operated retail facility into a contractor-operated retail facility. The resulting contractor-operated retail facility reports to a Postal Service-operated retail facility.

\* \* \* \* \*

- (b) \* \* \*
- (2) \* \* \*

(i) In a consolidation, the ZIP Code for the replacement contractor-operated retail facility is the ZIP Code originally assigned to the discontinued facility.

\* \* \* \* \*

(4) *Name of facility established by consolidation.* If a USPS-operated retail facility is consolidated by establishing in its place a contractor-operated facility, the replacement unit can be given the same name of the facility that is replaced, if appropriate in light of the nature of the contract and level of service provided.

(c) \* \* \*

(2) *Consolidation.* The proposed action may include a consolidation of USPS-operated retail facilities. A consolidation arises when a USPS-operated retail facility is replaced with a contractor-operated retail facility.

\* \* \* \* \*

**Stanley F. Mires,**  
*Attorney, Legal Policy and Legislative Advice.*  
[FR Doc. 2011–27641 Filed 10–25–11; 8:45 am]  
**BILLING CODE 7710–12–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2009–0538; FRL–8891–3]

**Bacteriophage of *Clavibacter michiganensis* Subspecies *michiganensis*; 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 of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* in or on tomato when applied as a bactericide in accordance with good agricultural practices. On behalf of OmniLytics, Inc., Interregional Research Project Number 4 (IR–4) 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 lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* under the FFDCA.

**DATES:** This regulation is effective October 26, 2011. Objections and requests for hearings must be received on or before December 27, 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-2009-0538. 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 Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 308-8263; *e-mail address:* [greenway.denise@epa.gov](mailto:greenway.denise@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

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

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/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-2009-0538 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 December 27, 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-HQOPP-2009-0538, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* 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 September 23, 2009 (74 FR 48556) (FRL-8434-7), 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 9E7552) by IR-4, Rutgers University, 500 College Rd. East, Suite 201W, Princeton, NJ 08540 (on behalf of OmniLytics, Inc., 9100 South 500 West, Sandy, UT 84070). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis*. This notice referenced a summary of the petition prepared by the petitioner, IR-4, which is available in the docket via <http://www.regulations.gov>. There were no 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 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 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, section 408(b)(2)(D) of FFDCA 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 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. Bacteriophage Overview

Bacteriophage, the most abundant group of biological entities on the planet, are naturally occurring viruses that are found in soil and water and in association with plants and animals, including humans (Refs. 1 through 8). Bacteriophage are obligate parasites of bacteria, which means they attach to, infect, and reproduce in bacteria, and are host-specific for bacteria, with specific bacteriophage attacking only one bacterial species and most frequently only one strain within a bacterial species (Refs. 9 through 11). As such, bacteriophage do not attack other beneficial bacteria. In addition, there is no evidence for bacteriophage infecting any other life form, including humans, except bacteria (Refs. 7, 12, and 13). Humans and other animals commonly consume bacteriophage as they are abundantly found in water, on plant surfaces, and in foods such as ground beef, pork sausage, chicken, oysters, cheese, mushrooms, and broccoli (Refs. 3, 4, and 14 through 19). In addition, bacteriophage are common commensals of the human gut and likely play an important role in regulating populations of various bacteria in the gastrointestinal tract (Ref. 7). As cited in public literature, bacteriophage 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 (Refs. 7, 20, and 21).

Since 2005, bacteriophage have also been used in a pesticide product (Agriphage; EPA Reg. No. 67986–1), without reported incidents, to control particular bacterial diseases (Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato) of tomato and pepper. In conjunction with registration of the aforementioned pesticide product, EPA established an exemption from the requirement of a tolerance for residues of bacteriophage of Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato in or on tomato and pepper (see the **Federal Register** of December 28, 2005 (70 FR 76704) (FRL–7753–6)). Much like the previously registered bacteriophage, OmniLytics, Inc. is proposing that bacteriophage of Clavibacter michiganensis subspecies michiganensis be applied as a pesticide for a very limited use-to control bacterial canker disease on tomato.

#### B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of bacteriophage of Clavibacter michiganensis subspecies michiganensis in or on tomato have been fulfilled with submission of valid studies from the public literature (Refs. 22 and 23).

As mentioned in Unit III.A., bacteriophage are viruses that only infect specific bacteria, a basic fact supported by both information presented in public literature and the absence of reported adverse effects to humans even with commonplace exposure to bacteriophage. Literature submitted established that bacteriophage have been used historically and through modern times in lieu of or to assist the action of antibiotics. Clinical uses encompass all manner of administration from injection/intravenous and surgical wound applications to topical and ingestible preparations. There have been no reports of adverse effects from such administrations and in other similar cases using controlled scientific studies. Also submitted were literature citations showing that bacteriophage are common and abundant in soils, are in a wide range of plant materials, and are generally present in high numbers in the environment (e.g., up to 1010 plaque-forming units (PFU) per liter may be found in non-polluted waters). Yet again, no adverse effects to humans have been reported with these types of

potential exposure. Moreover, bacteriophage presence reported in foods and feeds ranges from 101 to 105 PFU/100 grams (g) of meat and up to 107 PFU/100 g of cheese without any known harmful effects after consumption of such materials. Finally, the petitioner noted that, during an extensive history of bacteriophage laboratory and pesticidal usage, adverse reports in the literature have not been documented and episodes of hypersensitivity have not occurred.

Because bacteriophage are obligate bacterial parasites and are not known to infect humans, the only human health risk associated with use of bacteriophage of Clavibacter michiganensis subspecies michiganensis as a bactericide is potential for acquisition and production of microbial toxins. This acquisition occurs through lysogeny, which is when bacteriophage integrate into the genome of toxigenic bacterial host strains and pick up and transmit those genetic traits to other bacteria that otherwise would not produce toxic substances. Therefore, bacteriophage of Clavibacter michiganensis subspecies michiganensis that meet the following two conditions do not present this risk issue:

1. Bacteriophage produced in Clavibacter michiganensis subspecies michiganensis, which has been sequenced and determined to be an atoxigenic host bacteria, and
2. Bacteriophage possessing the capability to lyse host bacteria, i.e., completely destroy host cells during the viral production process, which precludes genetic transfer of possible toxins to other bacteria (Ref. 22).

### IV. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

#### A. Dietary Exposure

1. *Food exposure.* Published literature submitted by the petitioner, as well as other publicly available literature, indicate that bacteriophage are commonly associated with food and are therefore regularly consumed by humans. According to Ackermann (1997), these viruses have been found in association with “buds, leaves, root nodules (leguminous plants), roots,

rotting fruit, seeds, stems, and straw; crown gall tumors \* \* \* healthy or diseased alfalfa, barley, beans, broccoli, Brussels sprouts, buckwheat, clover, cotton, cucumber, lucerne, mulberry, oats, peas, peach trees, radish, rutabaga, ryegrass, rye, timothy, tobacco, tomatoes, [and] wheat” (Ref. 14). Moreover, bacteriophage have been isolated from a wide range of food products, including ground beef, pork sausage, chicken, farmed freshwater fish, common carp, marine fish, oil sardines, raw skim milk, and cheese (Refs. 15, 16, and 24 through 27). In fact, several studies have suggested that 100% of the ground beef and chicken meat sold at retail stores contain various levels of bacteriophage. For instance, bacteriophage were recovered from 100% of examined fresh chicken and pork sausage samples and from 33% of delicatessen meat samples analyzed; the levels ranged from  $3.3 \times 10^{10}$  to  $4.4 \times 10^{10}$  PFU/100 g of fresh chicken, up to  $3.5 \times 10^{10}$  PFU/100 g of fresh pork, and up to  $2.7 \times 10^{10}$  PFU/100 g of roast turkey breast samples (Ref 16). Other studies similarly showed the widespread occurrence of bacteriophage in certain foods:

a. 38 bacteriophage-host systems were isolated from 22 of 45 refrigerated products (Ref 27);

b. Bacteriophage infecting fire blight pathogen (*Erwinia amylovora*) were isolated from apple, pear, and raspberry tissues and from soil samples collected at sites displaying fire blight symptoms (Ref 5); and

c. Shellfish, which filter large quantities of seawater, concentrated both bacteria and bacteriophage (Ref 6).

Because lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* are intended to be applied to tomatoes, it is likely that dietary exposure will occur; however, no adverse effects are expected to occur. Despite constant and direct food exposure to bacteriophage (examples provided in the preceding paragraph and in Unit III.), no adverse effects to humans have been reported in publicly available literature. Indeed, no such effects are expected given that bacteriophage, including the one at issue in this action, are not capable of infecting eukaryotic cells and are host specific, attacking only bacteria.

2. *Drinking water exposure.* Published literature submitted by the petitioner, as well as other publicly available literature, indicate that, much like food, bacteriophage are commonly associated with water and are therefore regularly consumed by humans. According to

Demuth *et al.* (1993), “Bacteriophage \* \* \* have been isolated from all types of bacteria and from virtually any aquatic or terrestrial habitat where bacteria can exist. However, only in the last few years has it been recognized that viruses (phage) are extremely abundant in ocean and fresh water and may exceed the concentration of bacteria by up to 100-fold” (Ref. 3). Other studies showed that bacteriophage of *Erwinia carotovora* and *Erwinia ananas* were isolated from certain freshwater lakes in Florida and Texas (Ref. 4) and that coliphage were present in some samples of drinking water (Ref 28).

When lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* are applied to tomato as a bactericide in accordance with good agricultural practices, exposure of humans to residues of these bacteriophage in consumed drinking water may occur. Although lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* are not expected to reach surface water because the proposed use patterns do not include direct application to aquatic sites, it is possible that this microbial pest control agent could make it into ground water. Nonetheless, if oral exposure to lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* occurs through consumed drinking water (*e.g.*, due to surface water contamination by microbial pesticide spray drift or runoff or contact with ground water), for the many reasons enumerated in Unit III. and Unit IV.A.1., EPA concludes there is reasonable certainty that this type of drinking water exposure, or any level of drinking water exposure for that matter, will not result in harm to humans.

#### B. Other Non-Occupational Exposure

Dermal and inhalation non-occupational exposures to lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* are not expected as all proposed pesticide applications will take place in distinct agricultural settings. Even if dermal and inhalation non-occupational exposures were to occur inadvertently (*e.g.*, through spray drift) or due to an eventual expansion of use sites, such exposures would not be

of concern given the information presented in Unit III. and Unit IV.A.

#### 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 exemption, 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 has not found lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* to share a common mechanism of toxicity with any other substances, and lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* do not appear to produce a toxic metabolite against the target pest. For the purposes of this tolerance action, therefore, EPA has assumed that lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* do not have a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) of the FFDCA does not apply. 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 United States (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 (10×) 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 10× or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As previously discussed in Unit III. and Unit IV., humans, including infants and children, have been exposed to bacteriophage through food and water, where they are commonly found, and through decades of therapeutic use with no known or reported adverse effects. Based on this, as well as all the other reasons enumerated repeatedly in this unit, 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 lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis*. 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 public literature available on bacteriophage, including the one at issue in this action, do not demonstrate toxic, pathogenic, and/or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

## VII. Other Considerations

### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above and because EPA 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. In this context, 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 bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis*.

### C. Revisions to Requested Exemption

In its petition, the petitioner requested generally that the Agency issue an exemption from the requirement of a tolerance for residues of bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* in or on tomato. The petitioner's supporting materials indicated that the actual pesticide that would be used would be safe because the bacteriophage were lytic and produced in *Clavibacter michiganensis* subspecies *michiganensis*. The Agency believes both that these two conditions are necessary to make the safety finding and the petitioner was only requesting a narrow exemption; therefore, the Agency is modifying the tolerance exemption regulatory text to include such criteria.

## VIII. Conclusions

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 lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis*. Therefore, an exemption from the requirement of a tolerance is established for residues of lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* in or on tomato when applied as a bactericide in accordance with good agricultural practices.

## IX. References

- Keel C, Ucurum Z, Michaux P, Adrian M, Haas D. 2002. Deleterious impact of a virulent bacteriophage on survival and biocontrol activity of *Pseudomonas fluorescens* strain CHAO in natural soil. *Molecular Plant-Microbe Interactions* 15:567–576.
- Liew KW, Alvarez AM. 1981. Biological and morphological characterization of *Xanthomonas campestris* bacteriophages. *Phytopathology* 71:269–273.
- Demuth J, Neve H, Witzel K–P. 1993. Direct electron microscopy study on the morphological diversity of bacteriophage populations in Lake Plussse. *Applied and Environmental Microbiology* 59:3378–3384.

- Eyre CG, Bartz JA, Concelmo DE. 1995. Bacteriophages of *Erwinia carotovora* and *Erwinia ananas* isolated from freshwater lakes. *Plant Disease* 79:801–804.
- Schnabel EL, Jones AL. 2001. Isolation and characterization of five *Erwinia amylovora* bacteriophages and assessment of phage resistance in strains of *Erwinia amylovora*. *Applied and Environmental Microbiology* 67:59–64.
- Denis FA. 1975. Contamination of shellfish with strains of *Pseudomonas aeruginosa* and specific bacteriophages. *Canadian Journal of Microbiology* 21:1055–1057.
- Merril CR, Scholl D, Adhya SL. 2003. The prospect for bacteriophage therapy in Western medicine. *Nature* 2:489–497.
- Rohwer F. 2003. Global phage diversity. *Cell* 113:1–2.
- Stocker BAD. 1955. Bacteriophage and bacterial classification. *Journal of General Microbiology* 12:375–381.
- Duckworth DH, Gulig PA. 2002. Bacteriophage: potential treatment for bacterial infections. *Biodrugs* 16:57–62.
- Summers WC. 2001. Bacteriophage therapy. *Annual Review of Microbiology* 55:437–451.
- Lorch A. 1999. Bacteriophage: an alternative to antibiotics? *Biotechnology and Development Monitor* 39:14–17.
- Petricciani JC, Hsu TC, Stock AD, Turner JH, Wenger SL, Elisberg BL. 1978. Bacteriophages, vaccines, and people: an assessment of risk. *Proceedings of the Society for Experimental Biology and Medicine*. 58:378–382.
- Ackermann H–W. 1997. Bacteriophage ecology. Pp. 335–339 in: "Progress in Microbial Ecology (Proceedings of Seventh International Symposium on Microbial Ecology)". Martins MT, Sato MIZ, Tiedje JM, Hagler LCN, Döbereiner J, Sanchez PS, eds. Brazilian Society for Microbiology.
- Kennedy JE Jr, Wei CI, Oblinger JL. 1986. Methodology for enumeration of coliphages in foods. *Applied and Environmental Microbiology* 51:956–962.
- Kennedy JE Jr, Oblinger JL, Bitton G. 1984. Recovery of coliphages from chicken, pork sausage and delicatessen meats. *Journal of Food Protection* 47:623–626.
- DePaola A, Motes ML, Chan AM, Suttle CA. 1998. Phages infecting *Vibrio vulnificus* are abundant and diverse in oysters (*Crassostrea virginica*) collected from the Gulf of Mexico. *Applied and Environmental Microbiology* 64:346–351.
- Quiberoni A, Tremblay D, Ackermann H–W, Moineau S, Reinheimer JA. 2006. Diversity of *Streptococcus thermophilus* phages in a large-production cheese factory in Argentina. *Journal of Dairy Science* 89:3791–3799.
- Guillaumes J, Houdeau G, Germain R, Olivier JM. 1988. Improvement of the biocontrol of *Pseudomonas tolaasii* using bacteriophages associated with an antagonistic bacterium. *Bulletin OEPP* 18:77–82.
- Radetsky P. 1996. The good virus. *Discover* 17:50–58.
- Chanishvili N, Chanishvili T, Tediashvili M, Barrow PA. 2001. Phages and their

- application against drug-resistant bacteria. *Journal of Chemical Technology and Biotechnology* 76:689–699.
22. U.S. EPA. 2011. Bacteriophage of *Clavibacter michiganensis* subsp. *michiganensis*—AgriPhage CMM. Memorandum from J.V. Gagliardi, Ph.D. to A. Gross dated June 30, 2011.
  23. U.S. EPA. 2011. Bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* Pesticides Registration Action Document dated August 25, 2011 (available as “Supporting & Related Material” with docket ID number EPA–HQ–OPP2009–0539 at <http://www.regulations.gov>).
  24. Atterbury RJ, Connerton PL, Dodd CER, Rees CED, Connerton IF. 2003. Isolation and characterization of *Campylobacter* bacteriophages from retail poultry. *Applied and Environmental Microbiology* 69:4511–4518.
  25. Gautier M, Rouault A, Sommer P, Briandet R. 1995. Occurrence of *Propionibacterium freudenreichii* bacteriophages in swiss cheese. *Applied and Environmental Microbiology* 61:2572–2576.
  26. Greer GG. 2005. Bacteriophage control of foodborne bacteria. *Journal of Food Protection* 68:1102–1111.
  27. Whitman PA, Marshall RT. 1971. Isolation of psychrophilic bacteriophagehost systems from refrigerated food products. *Applied Microbiology* 22:220–223.
  28. El-Abagy MM, Dutka BJ, Kamel M. 1988. Incidence of coliphage in potable water supplies. *Applied and Environmental Microbiology* 54:1632–1633.

## X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA 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 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 exemption 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. As a result, this action does not 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, 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 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 EPA 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: September 30, 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 180.1307 is added to subpart D to read as follows:

### § 180.1307 Bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis*; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of lytic bacteriophage of *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis* in or on tomato when applied as a bactericide in accordance with good agricultural practices.

[FR Doc. 2011–27042 Filed 10–25–11; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 648

[Docket No. 101119575–1554–02]

RIN 0648–BA46

### Fisheries of the Northeastern United States; Monkfish; Framework Adjustment 7

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements measures that were approved in Framework Adjustment 7 to the Monkfish Fishery Management Plan. The New England Fishery Management Council and Mid-Atlantic Fishery Management Council developed Framework Adjustment 7 to adjust the annual catch target for the Northern Fishery Management Area to be consistent with the most recent