ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0467; FRL–7753–6]

Xanthomonas Campestris pv. Vesicatoria and Pseudomonas Syringae pv. Tomato Specific Bacteriophages; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the bacteriophages that specifically target the bacterial pathogens *Xanthomonas campestris pv. Vesicatoria* and *Pseudomonas syringae pv. tomato* present on tomatoes and peppers when applied/used as bacteriocides on tomatoes and peppers. Omnylytics submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages when applied/used as bacteriocides on tomatoes and peppers.

DATES: This regulation is effective December 28, 2005. Objections and requests for hearings must be received on or before February 27, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0467. All documents in the docket are listed on the www.regulations.gov Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of May 3, 2000 (FR 65 25717) (FRL–6553–2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP OF6111) by OmniLytics, P.O. Box 4296, Logan, Utah 84323–4296. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the bacteriophages that specifically target the bacterial pathogens *Xanthomonas campestris pv. Vesicatoria* and *Pseudomonas syringae pv. tomato* on tomatoes and peppers. This notice included a summary of the petition prepared by the petitioner OmniLytics. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the 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 the 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), 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), 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 the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the 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 that are found in soil, water, and in association with animals, including humans, and plants. The total number of phages worldwide is estimated to be in the range of 1,030 to 1,032. Phages are obligate intracellular parasites of bacteria, which means they attack bacteria, and are not infectious to humans or other animals. Phages are host-specific for bacteria, with specific bacteriophages attacking only one bacterial species and most frequently only one strain of a bacterial specieis. As such, phages do not attack other beneficial soil bacteria. In addition, there is no evidence for non-selective infection. Thus, non-target organisms, such as fish and wildlife, are not affected. Humans and other animals consume phages when they eat food they are commonly found in water, ground beef, pork, sausage, chicken, raw skim milk, oysters, cheese, fresh mushrooms, and lettuce. In addition, phages are common commensals of the human gut and likely play an important role in regulating various bacteria in the gastrointestinal tract. Moreover, phages have been used therapeutically or non-therapeutically in humans for more than 80 years with no ill effects. As cited in public literature, phages have been used as therapeutic agents and are active against bacteria of many human diseases such as anthrax, bronchitis, diarrhea, scarlet fever, typhus, cholera, diphtheria, gonorrhea, paratyphus, bubonic plague, and osteomyelitis. Moreover, hundreds of millions of persons have received live bacteriophage vaccines. These phages have been used in the human population to control polio, measles, mumps and rubella. Recipients of these bacteriophages showed no evidence of adverse reactions to phages. The specific mode of action of the active component of the AgriPhage product is such that these bacteroicides are effective only against the bacterial pathogens which they specifically target, in this case, *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae* pv. tomato bacteria when found on tomatoes and peppers.

In support of this tolerance exemption, data waivers were requested and granted for the required mammalian toxicity studies, including acute toxicity and other toxicological studies used to determine risks to human health. The waiver requests, which were supported by publicly available information submitted by OmniLytics, find their jusitification in the information summarized in the paragraph above, including, more generally, documented lack of toxicity associated with bacteriophages, the fact that bacteriophages only attack specific bacteria, and that they pose little to no risk to humans. Specifically, waivers were granted based on public literature submitted by the applicant for the following studies: Acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, and primary dermal irritation.

1. *Hypersensitivity (OPPTS Harmonized Guideline 870.2600).* The potential for repeated contact of the product with human skin by inhalation or dermal routes is a concern only to applicators of the end-use products (i.e., occupational exposure); however, the risk to applicators from exposure is mitigated as they are required to wear protective chemical-resistant gloves, aprons, footwear and masks. Accordingly, a hypersensitivity study is not required for registration of this product (per 40 CFR 158.690(c)(2)(iii)). In addition, there are no reports of dermal sensitization to low concentrations of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages in the published literature. The registrant also has reported no hypersensitivity incidents to date (OPPTS Harmonized Guideline 885.3400). Nonetheless, pursuant to FIFRA section 6(a)(2), the registrant is required to report to the Agency any future incidents of hypersensitivity associated with *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages.

2. *Immune response (OPPTS Harmonized Guideline 870.7800).* The registrant requested a waiver for this study, and submitted supporting published literature. EPA's review concluded that *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages are common bacteriophages and are found in food consumed by humans (Whitman et. al., 1971). With no known incidences of allergic responses to these or similar phages, there is reasonable certainty that *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages will not induce adverse immune responses in humans. This conclusion is further bolstered by the fact that these bacteriophages are host specific. As a result, the agency approved the waiver request for the Immune Response study.

3. *Acute injection toxicity/ pathogenicity - Rat (OPPTS Harmonized Guideline 885.3200).* The Registrant submitted supporting public literature for this study, and requested a waiver. A waiver was granted based on the fact that *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages and similar bacteriophages are common bacteriophages found in drinking water and food ingested daily by humans and animals. According to published literature no known adverse effects or deaths have occurred in any species as a result of such dietary exposures. Bacteriophages are host specific and attack only the target bacteria. It has been reported in public literature that humans and other animals consume phages when they eat food--they are commonly found in water, ground beef, pork, sausage, chicken, raw skim milk, oysters, cheese, fresh mushrooms, and lettuce. Further, phages have been used in the human population to control polio, measles, mumps and rubella. Recipients of these bacteriophages showed no evidence of adverse reactions to phages.

Based on the published literature and data waivers submitted (and granted) in accordance with the Tier I toxicology data requirements set forth in 40 CFR 158.690(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 the 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 x 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 1 study found *E. 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 *E. coli*, and all 10 contained coliphages. In addition to ground beef, *E. coli* and coliphages were found in fresh 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 a concentration as high as 1.4 x 10^6/gm of swiss cheese. Based on the above and the fact that bacteriophages are host specific, these organisms are not known to pose any human health effects. Throughout the literature cited by the registrant and other publically available literature, there have been no known adverse effects to humans ever reported. Accordingly, the Agency concludes that when *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific Bacteriophages are used according to the manner intended (i.e., to control the bacterial pathogens *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv tomato* on tomatoes and peppers), there is a reasonable certainty that no harm will result to humans from all anticipated dietary exposures (through food) to any residues resulting from such use.

2. *Drinking water exposure*. The *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages 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. Furthermore, in the unlikely event that *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages do reach water consumed by humans, for the many reasons enumerated numerous times above, the Agency concludes that when *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific Bacteriophages are used according to the manner intended (i.e., to control the bacterial pathogens *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv tomato* on tomatoes and peppers), there is a reasonable certainty that no harm will result to humans from all anticipated dietary exposures (through water) to any residues resulting from such use.

B. Other Non-Occupational Exposure

Since *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific Bacteriophages are host specific and inactivated within 24–48 hours after application, 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. Moreover, the general population, including infants and children, are exposed to bacteriophages daily in food and drinking water with no known adverse effects ever being reported. Therefore, the Agency concludes that in the unlikely event there is non-occupational, non-dietary exposure to these specific phages, such exposures would pose no risks to the general population, including infants and children.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the 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.'' These considerations include the possible cumulative effects of such residues on infants and children. *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages are host specific to the *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* bacteria that attack tomatoes and peppers only. Accordingly, under the conditions in which *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages are intended to be used, they will only attack the specific host bacteria causing lysis of that bacteria, and they are only active 24–48 hours after application. Given all of this and the fact that bacteriophages generally are consumed daily in food and drinking water, with no known adverse effects reported, any dietary and non-occupational exposures to *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages, when used according to label directions, are expected to have no cumulative or incremental effects to humans. In addition, due to the unique nature of bacteriophages, as repeatedly noted in this action, the Agency is unaware of any other substances that share a common mechanism of toxicity with the *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages.

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. For all the reasons enumerated repeatedly above, there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

2. *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 infants and 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 this and all the other reasons enumerated repeatedly above, and based on all available information, the Agency concludes that *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages are non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages 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. Endocrine Disruptors

Based on public literature cited by the company, *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages are not known endocrine disruptors nor are other phages related to *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages known endocrine disruptors. Therefore, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this final rule for *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the many reasons repeatedly stated above, including the active ingredient's host specificity, the fact that the human population is exposed to bacteriophages daily, through food, water, and other sources, with no adverse effects, and the fact that bacteriophages have been used therapeutically for more than 80 years with no adverse effects. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific Bacteriophages.

C. Codex Maximum Residue Level

The are no known codex residue levels for this bacteriophage.

VIII. Conclusions

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 *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv.tomato* specific bacteriophages, including all anticipated dietary exposures and all other exposures for which there is reliable information, when used according to label directions, as a microbial pesticide on peppers and tomatoes.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0467 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 27, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0467, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. 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 the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Reference

Whitman, P.A. and R.T. Marshall. *Isolation of psychrophilic bacteriophages-host systems from refrigerated food products.* Applied Microbiology. Vol. 22, No 2, August 1971, pp. 220-223.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 9, 2005.

James Jones,

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 180.1261 is added to subpart D to read as follows:

§ 180.1261 Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato specific Bacteriophages.

An exemption from the requirement of a tolerance is established for residues of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages in or on tomatoes and peppers.

[FR Doc. 05–24540 Filed 12–27–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 22 and 90

[WT Docket No. 02–55; ET Docket No. 00–258; ET Docket No. 95–18; RM–9498; RM–10024; FCC 05–174]

Private Land Mobile Services; 800 MHz Public Safety Interference Proceeding

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission amends the definition of an Enhanced Specialized Mobile Radio (ESMR) system; further delineates the relocation rights of 800 MHz incumbent licensees; narrows the Expansion Band in the Atlanta, Georgia region; reaffirms the Commission's authority to grant Nextel Communications, Inc. (Nextel) spectrum rights to ten megahertz of spectrum in the 1.9 GHz band; permits the Transition Administrator (TA) to follow a calendar year for reporting schedule purposes; permits Nextel to receive credit in the 800 MHz 'true-up' process for the relocation of certain additional BAS incumbent licensees whose licenses were issued prior to November 12, 2004; and clarifies the definitions of ''unacceptable interference'' and ''Critical Infrastructure Industries'' (CII).

DATES: Effective January 27, 2006.

FOR FURTHER INFORMATION CONTACT: *Technical Information:* Brian Marenco, *Brian.Marenco@FCC.gov,* Public Safety