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[FR Doc. 2011–21362 Filed 8–23–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0087; FRL–8884–6]

Pseudomonas fluorescens Strain CL145A; 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 *Pseudomonas fluorescens* strain CL145A in or on all food commodities when applied as a molluscicide. Marrone Bio Innovations, Inc. (formerly Marrone Organic Innovations, Inc.) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pseudomonas fluorescens* strain CL145A under the FFDCA.

DATES: This regulation is effective August 24, 2011. Objections and requests for hearings must be received on or before October 24, 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–2009–0087. 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: Ann Sibold, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address: *sibold.ann@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, pesticide manufacturer, hydroelectric power facility operator or water supply system operator. 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).
- Hydroelectric power generation (NAICS code 221111).
- Water supply and irrigation systems (NAICS code 221310).

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.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2009–0087 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 October 24, 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–2009–0087, 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 March 16, 2009 (74 FR 11100) (FRL–8405–1), 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 9F7511) by Marrone Bio Innovations, Inc. (formerly Marrone Organic Innovations, Inc.), 2121 Second Street, Suite B–107, Davis, CA 95618. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas fluorescens* strain CL145A in or on all food commodities when applied as a molluscicide. This notice referenced a summary of the petition prepared by the petitioner,

Marrone Bio Innovations, Inc. (formerly Marrone Organic Innovations, Inc.), which is available in the docket via *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit VII.C.

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 the 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. Overview of Pseudomonas fluorescens and Pseudomonas fluorescens Strain CL145A

Pseudomonas fluorescens is ubiquitous in soil and water and is commonly associated with plants, including those food plants consumed raw. The Manual of Clinical Microbiology (8th edition) states the following: ''*Pseudomonas* spp. have a worldwide distribution with a predilection for moist environments. They are found in water and soil and on plants, including fruits and vegetables'' (Ref. 1). Although *Pseudomonas fluorescens* is of low virulence and usually not clinically significant, it has been associated with opportunistic infections in compromised patients when *Pseudomonas fluorescens*-contaminated blood product was used for transfusions.

In the past, EPA has registered several pesticide products, each containing a different isolate of *Pseudomonas fluorescens* as an active ingredient:

1. *Pseudomonas fluorescens* strain NCIB 12089—used as a mushroom blotch control agent and exempted from the requirement of a tolerance (40 CFR 180.1129) in the **Federal Register** of August 24, 1994 (59 FR 43490) (FRL–4899–5);

2. *Pseudomonas fluorescens* A506 and *Pseudomonas fluorescens* 1629RS—used for reduction of frost and frost damage on various food crops and exempted from the requirement of a tolerance (40 CFR 180.1114) in the **Federal Register** of September 16, 1992 (57 FR 42700) (FRL–4161–1); and

3. *Pseudomonas fluorescens* EG–1053—used for control of the *Pythium-Rhizoctonia* seedling disease complex of cotton and exempted from the requirement of a tolerance (40 CFR 180.1088) in the **Federal Register** of March 10, 1988 (53 FR 7740) (FRL–3339–2).

Out of these isolates, only *Pseudomonas fluorescens* A506 is still contained in an actively registered pesticide product.

Pseudomonas fluorescens strain CL145A is a naturally occurring bacterial species that was isolated from a river mud sample in the northeastern United States. This isolate is being registered as a biocontrol agent for zebra mussels (*Dreissena polymorpha*) and quagga mussels (*Dreissena bugensis*) that infest enclosed and other confined static or flowing water infrastructures (e.g., water storage chambers and tanks, pipes, general plumbing and equipment, and other water conveyance structures associated with civil infrastructure). When a zebra or quagga mussel ingests artificially high densities of *Pseudomonas fluorescens* strain CL145A, a toxin within this bacterium's cells destroys the digestive system of the mussel.

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 *Pseudomonas fluorescens* strain CL145A in or on all food commodities have been fulfilled with data submitted by the petitioner or data waiver requests that have been granted by EPA. Acceptable (i.e., data that are scientifically sound and useful for risk assessment) acute oral toxicity, acute inhalation toxicity, and acute pulmonary toxicity/pathogenicity data, which addressed potential routes of exposure to the active ingredient and which tested doses significantly higher than or comparable to the labeled application rates, were classified in Toxicity Categories IV or III (toxicity studies) (see 40 CFR 156.62) or indicated that *Pseudomonas fluorescens* CL145A was not toxic, infective and/or pathogenic (toxicity/pathogenicity study). The overall conclusions from all toxicological information submitted by the petitioner is described below, while more in-depth synopses of the study results can be found in the associated Biopesticides Registration Action Document provided as a reference in Unit IX. (Ref. 2).

1. *Acute oral toxicity—rat (Harmonized Guideline 870.1100; Master Record Identification Number (MRID No.) 476402–02).* An acceptable acute oral toxicity study demonstrated that *Pseudomonas fluorescens* strain CL145A was not toxic to rats when dosed at 5,000 milligrams per kilogram (mg/kg) (or 2.35×10^{10} colony-forming units per kilogram (CFU/kg)). The no observed adverse effect level (NOAEL) and median lethal dose (LD_{50}) (i.e., a statistically derived single dose that can be expected to cause death in 50% of test animals) were greater than 5,000 mg/kg (or greater than 2.35×10^{10} CFU/kg) (Toxicity Category IV).

2. *Acute oral toxicity/pathogenicity (Harmonized Guideline 885.3050; MRID No). 477494–03).* The rationale provided in support of a data waiver request for acute oral toxicity/pathogenicity stated that *Pseudomonas fluorescens* is considered an ubiquitous inhabitant of soil and water and is found on the surface and roots of a variety of plant types, including food plants consumed raw. Pseudomonads and, in particular, *Pseudomonas fluorescens* are considered a benign part of the regular

human diet commonly occurring on the surface of leafy green vegetables and other food stuffs (Refs. 1, 3, and 4). Additionally, an acute oral toxicity study conducted on rats (MRID No. 476402–02) found the NOAEL and LD_{50} were greater than 5,000 mg/kg, corresponding to greater than 2.35×10^{10} CFU/kg (Toxicity Category IV). Based on this rationale, oral infectivity, clearance, and pathogenicity testing for *Pseudomonas fluorescens* strain CL145A was waived. It should be noted that this is a different data requirement from the acute oral toxicity test (Harmonized Guideline 870.1100; MRID No. 476402–02), which only evaluated toxicity, but not pathogenicity and infectivity potential, of the microbial pest control agent.

3. *Acute inhalation toxicity—rat (Harmonized Guideline 870.1300; MRID No. 476402–04).* An acceptable acute inhalation toxicity study demonstrated that *Pseudomonas fluorescens* strain CL145A was not toxic to rats when exposed to approximately 0.225 milligrams per liter (mg/L) (or 1.1×10^6 colony-forming units per liter (CFU/L)). The NOAEL and median lethal concentration (LC_{50}) were greater than 0.225 mg/L (or greater than 1.1×10^6 CFU/L) (Toxicity Category II but upgraded to Toxicity Category III with the results of MRID No. 482767–02. The dose used in the acute pulmonary toxicity/pathogenicity study (MRID No. 482767–02), which looked at the same route of exposure and did not show any toxicity, pathogenicity, and/or infectivity, was greater than the dose used in the study described in this unit. Thus, this allowed the Toxicity Category, as initially established in this study, to be upgraded from II to III.).

4. *Acute pulmonary toxicity/pathogenicity—rat (Harmonized Guideline 885.3150; MRID No. 482767–02).* An acceptable acute pulmonary toxicity and pathogenicity study demonstrated that *Pseudomonas fluorescens* strain CL145A was not toxic, infective, and/or pathogenic to rats when dosed intratrachaelly at 3.4×10^8 colony-forming units (CFU)/rat. As detailed in the acute inhalation toxicity study summary in this unit, this study upgraded the Toxicity Category for MRID No. 476402–04 from II to III.

5. *Acute dermal toxicity—rat (Harmonized Guideline 870.1200; MRID No. 476402–03).* An acceptable acute dermal toxicity study demonstrated that *Pseudomonas fluorescens* strain CL145A was not toxic to rats when dosed at 5,050 mg/kg (or 2.38×10^{10} CFU/kg). The LD_{50} was greater than 5,050 mg/kg (or greater than 2.38×10^{10} CFU/kg) (Toxicity Category IV).

6. *Acute eye irritation—rabbit (Harmonized Guideline 870.2400; MRID No. 476402–05).* An acceptable acute eye irritation study demonstrated that *Pseudomonas fluorescens* strain CL145A was practically non-irritating to rabbits (irritation symptoms cleared by 48 hours; Toxicity Category IV).

7. *Primary dermal irritation—rabbit (Harmonized Guideline 870.2500; MRID No. 476402–06).* An acceptable primary dermal irritation study demonstrated that *Pseudomonas fluorescens* strain CL145A was practically non-irritating to rabbits (irritation symptoms cleared by 24 hours; Toxicity Category IV).

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

Pseudomonas fluorescens strain CL145A end-use products are not labeled for direct application to food crops. Any potential food exposures would be as a result of its presence in water. Thus, minimal dietary exposure to this microbial pesticide may occur through irrigation water, wash water or drinking water (see discussions of food and drinking water exposures in this unit); however, the lack of acute oral toxicity, as exhibited in a toxicology test on rats, and the rationales justifying the waiver of acute oral toxicity/pathogenicity testing (see Unit III.B.) support the establishment of a tolerance exemption for residues of *Pseudomonas fluorescens* strain CL145A.

1. *Food.* Exposure to this microbial active ingredient through food is expected to be minimal. *Pseudomonas fluorescens* strain CL145A end-use products are not labeled for direct application to food crops. Rather, *Pseudomonas fluorescens* strain CL145A will be applied to water in enclosed and other confined static or flowing water infrastructures to control zebra and quagga mussels. The treatment areas are limited to completely enclosed pipe or water conveyance systems or concrete chambers with defined inlets or outlets. Nevertheless, water drawn downstream from points of application (e.g., pump stations and irrigation systems) and used to irrigate or wash food crops may contain *Pseudomonas fluorescens* strain CL145A. Concentrations of *Pseudomonas fluorescens* will be diluted as water flows past points of application and thus will rapidly decrease. Also, natural degradation (e.g., environmental factors such as ultraviolet light, nutrient depletion and bacterial grazing/predation by protists and others) and manmade filtering operations are expected to greatly lower the overall level of the pesticide after application (Refs. 5 and 6). Furthermore, *Pseudomonas fluorescens* is considered ubiquitous in soil and water and is commonly associated with plants, including food plants consumed raw; thus, this microorganism is already part of the normal human diet (Refs. 1, 3, and 4). Exposure to *Pseudomonas fluorescens* strain CL145A through food that has come into contact with treated irrigation or wash waters is not expected to exceed background levels of similar Pseudomonads already present in the human diet (Refs. 1, 3, and 4). Nonetheless, in the unlikely event that this microbial pesticide is present on food, the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity and/or pathogenicity is likely to occur with any exposure level of *Pseudomonas fluorescens* strain CL145A (see additional discussion in Unit III.B.).

2. *Drinking water exposure.* Much like food exposure, drinking water exposure is expected to be negligible for similar reasons:

i. Concentrations of *Pseudomonas fluorescens* strain CL145A will be diluted as water flows past points of application;

ii. Natural degradation (e.g., environmental factors such as ultraviolet light, nutrient depletion and bacterial grazing/predation by protists and others) of the microbial active ingredient will occur; and

iii. Flocculation and filtering at water treatment plants will further inactivate and decrease levels of *Pseudomonas fluorescens* strain CL145A (Refs. 5 and 6). Additionally, *Pseudomonas fluorescens* is already present naturally in soil, in water, and on plants, thereby making it a part of the normal human diet (Refs. 1, 3, and 4). Exposure to *Pseudomonas fluorescens* strain CL145A through drinking water is not expected to exceed background levels of similar Pseudomonads already present in the human diet (Refs. 1, 3, and 4). Nonetheless, in the unlikely event that this microbial pesticide is present in drinking water, the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity and/or pathogenicity is likely to occur

with any exposure level of *Pseudomonas fluorescens* strain CL145A (see additional discussion in Unit III.B.).

B. Other Non-Occupational Exposure

Dermal and inhalation non-occupational exposure to *Pseudomonas fluorescens* strain CL145A is expected to be minimal to non-existent. *Pseudomonas fluorescens* strain CL145A end-use products are labeled for application to use sites—enclosed and other confined static or flowing water infrastructures infested with zebra and/or quagga mussels—that are not considered residential areas.

1. *Dermal exposure.* Although dermal exposure to *Pseudomonas fluorescens* strain CL145A may occur when water from a treated dam or industrial facility is discharged to surface water and is subsequently used by a community water system in a residential area, such exposure is expected to be minimal due to dilution, natural degradation, and filtering at water treatment plants (Refs. 5 and 6). Moreover, acute dermal toxicity and primary dermal irritation tests demonstrated that *Pseudomonas fluorescens* strain CL145A is not toxic and is practically non-irritating via the dermal route of exposure (see additional discussion in Unit III.B.).

2. *Inhalation exposure.* Inhalation exposure to *Pseudomonas fluorescens* strain CL145A is not anticipated with the labeled (i.e., water-based) molluscicide use. If inhalation exposure to *Pseudomonas fluorescens* strain CL145A were to occur in gardens, lawns, or buildings (i.e., residential areas), such exposure would not exceed EPA's level of concern given the acute inhalation toxicity and acute pulmonary toxicity/pathogenicity tests that demonstrated *Pseudomonas fluorescens* strain CL145A's lack of toxicity, pathogenicity and/or infectivity (see additional discussion in Unit III.B.).

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 *Pseudomonas fluorescens* strain CL145A to share a common mechanism of toxicity with any other substances. *Pseudomonas fluorescens* strain CL145A affects gut function in the target molluscs and does not produce a similar toxic response in the other species tested. For the purposes of this tolerance action, therefore, EPA has assumed that *Pseudomonas fluorescens* strain CL145A does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Pseudomonas fluorescens* strain CL145A that need to be considered. 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 website at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for 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 (10X) 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 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data/information discussed in Unit III.B., 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 *Pseudomonas fluorescens* strain CL145A. 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 data (e.g., lack of toxicity noted for oral, dermal, and inhalation routes of exposure) available on *Pseudomonas fluorescens* strain CL145A do not demonstrate toxic, pathogenic, and/or infective potential to sensitive populations from exposure to this microbial pest control agent. 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 since 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 *Pseudomonas fluorescens* strain CL145A.

C. Response to Comments

In response to the Notice of Filing, EPA received one comment, protesting the presence of this product in food, the proposed exemption from the requirement of a tolerance, and the toxicity of the product. In response, EPA again emphasizes that *Pseudomonas fluorescens* strain CL145A is present naturally in soil and water (Refs. 1, 3, and 4), is not toxic, pathogenic, and/or infective for dietary considerations (see additional discussion in Unit III.B.), and, in any event, is expected to degrade quickly in the environment (Ref. 6). Biological materials from dead cells would be consumed by degradative microflora in treatment areas, and the few live cells diluted in treated waters would likely not approach the levels of *Pseudomonas fluorescens* already present in water, in soil, and on foods (Refs. 1, 3, 4, and 6). EPA has concluded 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 *Pseudomonas fluorescens* strain CL145A in or on all food commodities (see Unit VIII.). Thus, under the

standard in FFDCA section 408(c)(2), a tolerance exemption is appropriate.

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 *Pseudomonas fluorescens* strain CL145A. Therefore, an exemption from the requirement of a tolerance is established for residues of *Pseudomonas fluorescens* strain CL145A in or on all food commodities when applied as a molluscicide.

IX. References

1. Murray PR, Baron E, Jorgensen JH, Pfaller MA, Yolken RH, editors. 2003. Manual of Clinical Biology. 8th ed. Washington (DC): ASM Press.
2. U.S. EPA. 2011. *Pseudomonas fluorescens* strain CL145A Biopesticides Registration Action Document dated July 2011 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2011–0568 at *http://www.regulations.gov*).
3. Garrity GM, Bell JA, Lilburn T, editors. 2005. ''Pseudomonadales'' *in* Bergey's Manual of Systematic Bacteriology. 2nd ed. New York (NY): Springer.
4. Organisation for Economic Co-operation and Development. 1997. Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Pseudomonas*. Available from *http://www.rebeca-net.de/downloads/OECD%20Consensus%20document%20pseudomonas.pdf*.
5. U.S. EPA. 2004. Primer for Municipal Wastewater Treatment Systems. EPA 832–R–04–001.
6. U.S. EPA. 1996. Microbial Pesticide Test Guidelines—Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from *http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm*.

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: July 29, 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 180.1304 is added to subpart D to read as follows:

§ 180.1304 Pseudomonas fluorescens strain CL145A; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudomonas fluorescens* strain CL145A in or on all food commodities when applied as a molluscicide.

[FR Doc. 2011–21249 Filed 8–23–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0430; FRL–8881–5]

2-Propenoic Acid, Polymer With Ethenylbenzene and (1-methylethenyl) Benzene, Sodium Salt; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, sodium salt when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This