

additional costs to State, local, or tribal governments, or to the private sector, result from this action.

#### *H. National Technology Transfer and Advancement Act*

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

EPA believes that VCS are inapplicable to today's action because it does not require the public to perform activities conducive to the use of VCS.

#### *I. Submission to Congress and the Comptroller General*

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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

#### *J. Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 21, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### **List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference,

Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 18, 2001.

**Jane Diamond,**  
*Acting Regional Administrator, Region IX.*

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

#### **PART 52—[AMENDED]**

1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### **Subpart F—California**

2. Section 52.220 is amended by adding paragraphs (c)(285)(i)(B) to read as follows:

##### **§ 52.220 Identification of plan.**

\* \* \* \* \*

- (c) \* \* \*
- (285) \* \* \*
- (i) \* \* \*

(B) San Joaquin Valley Unified Air Pollution Control District.

(1) Rule 4603 adopted on April 11, 1991 and amended on September 21, 2000.

\* \* \* \* \*

[FR Doc. 01-26528 Filed 10-19-01; 8:45 am]

**BILLING CODE 6560-50-P**

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 180**

**[OPP-301056; FRL-6745-6]**

**RIN 2070-AB78**

#### **Pseudomonas Chlororaphis Strain 63-28; 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 *Pseudomonas chlororaphis* Strain 63-28 in or on all food commodities. Agrium US, Inc. 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 *Pseudomonas chlororaphis* Strain 63-28.

**DATES:** This regulation is effective October 22, 2001. Objections and requests for hearings, identified by docket control number OPP-301056, must be received by EPA, on or before December 21, 2001.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301056 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Anne Ball, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8717; and e-mail address: Ball.Anne@epa.gov.

#### **SUPPLEMENTARY INFORMATION:**

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

##### *A. Does this Action Apply to Me?*

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

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml/180/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml/180/Title_40/40cfr180_00.html), a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301056. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the Federal Register of November 20, 1998 (63 FR 64478) (FRL-6042-4), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(d), as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Agrium US, Inc., 4582 S. Ulster St., Suite 1400, Denver, CO 80237. This notice included a summary of the petition prepared by the petitioner Agrium US, Inc. On October 13, 1999 all of Agrium's data were transferred to Eco Soil Systems, Inc. 10740 Thornmint Rd., San Diego, CA 92127 and Eco Soil Systems, Inc. is still interested in seeking this exemption.

There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* Strain 63-28.

## III. Risk Assessment

New 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 tolerance is "safe." Section 408(c)(2)(A)(ii) 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. Section 408(b)(2)(C) requires 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) 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.

## IV. 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.

Acute toxicity studies indicate that AtEze, the end-use product containing *P. chlororaphis* Strain 63-28 is a Toxicity Category IV substance. The acute oral toxicity of *P. chlororaphis*

Strain 63-28 in rats is greater than 5,000 milligrams/kilogram of body weight or Toxicity Category IV. The LD<sub>50</sub> for dermal toxicity of *P. chlororaphis* Strain 63-28 is considered to be > 2g/kg body weight or Toxicity Category IV. In an eye irritation study, six New Zealand White rabbits were treated with the product and all except one showed no ocular irritation with observations continuing for seven days after dosing. (Toxicity Category IV). In a toxicity/pathogenicity study, the product containing *P. chlororaphis* Strain 63-28 was tested following acute intravenous challenge in male and female rats. Intravenous administration of the viable test substance (TS) and killed test substance (KTS) was followed by measuring levels of viable microbes in sampled tissues and observing for signs of toxicity or pathogenicity. A sampling of organs for presence of *P. chlororaphis* showed that cells were present in lungs, spleen, kidneys, and livers of male and female rats, and in the blood, mesenteric lymph nodes and caecum of male rats on day 0 (i.e. the day of treatment with TS). In subsequent sampling, one female rat was found to harbor some viable *P. chlororaphis* in the kidney on day three. All other samples from all animals were negative (i.e., below the detection limit). This lack of detection of the test substance in TS treated rats after day 3 indicates a clearance of the organism from the animals to < 30 cfu/ml or per tissue. No toxic or pathogenic effects were attributable to the intravenous administration of *P. chlororaphis* Strain 63-28 to rats at  $4.3 \times 10^6$  cfu per animal. No effects were noted from application of the killed test substance (KTS).

Tier II and III data as listed in 40 CFR 158.740(c) were not triggered because of *P. chlororaphis* Strain 63-28's ubiquity in nature, favorable toxicological data based on studies submitted, favorable toxicological history because there have been no reports of the organism in the literature as a pathogen of humans or any animals, and inconsequential exposure based on the proposed use. Review of the available toxicology data and literature submitted in support of registration indicates that sufficient information is available for characterization of the risks to humans. Therefore, EPA has concluded that products which contain *P. chlororaphis* Strain 63-28 are not likely to produce adverse effects on humans and the organism is generally considered non-pathogenic to humans.

## V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 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

*P. chlororaphis* Strain 63–28 is a non-toxic, non pathogenic bacterium which is ubiquitous in nature. The Agency has previously registered *Pseudomonas* strains (e.g. *fluorescens*) for use on many crops. These species are closely related but, unlike *P. fluorescens*, there are no reports of any negative pathogenic effects on humans or on other animals by *P. chlororaphis*.

1. *Food.* Review of the available toxicology data submitted in support of registration indicated that sufficient information is available to allow for characterization of the risks to humans. Products which contain *P. chlororaphis* Strain 63–28 are not likely to produce adverse effects on humans via their food since the organism is generally considered as non-toxic and non-pathogenic to humans.

2. *Drinking water exposure.* There is no expected human exposure to the organism in drinking water from pesticidal use. Pesticide application for the only use currently proposed is limited to contained plants in greenhouses as a soil/potting mix drench for ornamental or vegetable crops. The proposed product label directs that for drip or trickle chemigation, the system must contain a functional check valve, vacuum relief valve, and low pressure drain to prevent water source contamination from back flow. Since the organism is non-toxic and non-pathogenic to humans, even if small amounts would seep into the ground water, there would be no adverse effects on humans.

#### B. Other Non-Occupational Exposure

*P. chlororaphis* Strain 63–28 is proposed for use on greenhouse grown vegetables and ornamentals. Exposures resulting from application to ornamentals is anticipated to be negligible because consumers will not be in contact with treated plants until after the foliage is dry when the number of bacteria present is greatly diminished compared to the amount that was applied. Leaf surfaces are nutrient poor and cannot support growth of the bacteria. Also, the bacteria are exposed to ultraviolet light and temperature extremes and are dried out in the greenhouse. Moisture is needed for growth of the bacteria. *P. chlororaphis*

are common on plants and in soil and may be present in the absence of any application, but in relatively small amounts. Increase of the bacteria present through application of the pesticide is expected to be insignificant. No dermal or inhalation exposure is expected.

#### VI. Cumulative Effects

*P. chlororaphis* Strain 63–28 does not share any common mechanisms of toxicity (metabolic mechanisms) with other substances. The use as a microbial pesticide should not significantly increase exposure to naturally occurring sources of *P. chlororaphis* Strain 63–28. Furthermore, the bacteria are not toxic or pathogenic for humans. Therefore, the potential for toxic effects or cumulative effects from the use of this pesticide is not expected.

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

For the U.S. population, including infants and children, aggregate exposure to *P. chlororaphis* Strain 63–28 is expected to be minimal with no known adverse effects. As discussed previously, there is no potential for harm via dietary exposure since the bacteria is considered non-toxic and non-pathogenic to humans. There is a negligible exposure to consumers from other non-occupational sources; however, because the bacterium is non-toxic and non-pathogenic to humans, no risk is foreseen. Moreover no dermal or inhalation exposure is expected. Therefore, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population including infants and children, from aggregate exposure to residues of *P. chlororaphis* Strain 63–28 including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above and throughout this document, no toxicity or pathogenicity to mammals has been observed for *P. chlororaphis* strain 63–28. Thus, a tolerance for *P. chlororaphis* Strain 63–28 is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

#### VIII. Other Considerations

##### A. Endocrine Disruptors

EPA is required under FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a

naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen-and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’S recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and or testing protocols being considered under the Agency’s Endocrine Disruptor Screening Program have been developed, *P. chlororaphis* Strain 63–28 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *P. chlororaphis* Strain 63–28.

##### B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly the Agency has concluded that analytical methods are not needed for enforcement purposes for residues of *P. chlororaphis* Strain 63–28.

##### C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels nor any tolerances or exemptions issued for *P. chlororaphis* Strain 63–28 outside the United States.

#### 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made.

The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-301056 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 December 21, 2001.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please

identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *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 Unit I.B.2. Mail your copies, identified by docket number OPP-301056, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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 file format 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. Regulatory Assessment Requirements**

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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.

#### **XI. Submission to Congress and the Comptroller General**

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: September 28, 2001.

**James Jones,**

*Acting 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), 346(a) and 371.

2. Section 180.1212 is added to subpart D to read as follows:

#### **§ 180.1212 *Pseudomonas chlororaphis* Strain 63–28; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Pseudomonas chlororaphis* Strain 63–28 in or on all food commodities.

[FR Doc. 01–26533 Filed 10–19–01]

**BILLING CODE 6560–50–S**

### **DEPARTMENT OF COMMERCE**

#### **National Oceanic and Atmospheric Administration**

#### **50 CFR Part 635**

**[I.D. 101501B]**

#### **Atlantic Highly Migratory Species Fisheries; Atlantic Bluefin Tuna**

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

**ACTION:** Quota transfers; General category daily retention limit adjustment.

**SUMMARY:** NMFS adjusts the October–December subquota for the General category Atlantic bluefin tuna (BFT) fishery by transferring 50 metric tons (mt) from the Longline South subcategory quota, 10 mt from the

Longline North subquota, and 100 mt from the Angling category (50 mt from the school size class and 50 mt from the large school/small medium size class for the northern area), for a revised coastwide General category subquota of approximately 347.7 mt for October–December, including the addition of underharvest from previous time periods. NMFS also adjusts the Angling South large school/small medium subcategory by transferring 75 mt from the Angling North large school/small medium subcategory. Finally, NMFS adjusts the BFT General category daily retention limit to one fish per vessel. These actions are being taken to allow for maximum utilization of the U.S. landings quota of BFT while maintaining a fair distribution of fishing opportunities, preventing overharvest of the adjusted subquotas for the affected fishing categories, helping to achieve optimum yield in the General category fishery, and allowing the collection of a broad range of data for stock monitoring purposes, consistent with the objectives of the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP).

**DATES:** The quota transfers are effective October 16, 2001, through May 31, 2002. The General category retention limit adjustment is effective October 19, 2001, through December 31, 2001.

**FOR FURTHER INFORMATION CONTACT:** Brad McHale or Pat Scida, 978–281–9260.

#### **SUPPLEMENTARY INFORMATION:**

Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas among the various domestic fishing categories.

#### **Quota Transfers**

Under the implementing regulations at 50 CFR 635.27(a)(8), NMFS has the authority to transfer quotas among categories, or, as appropriate, subcategories, of the fishery, after considering the following factors: (1) The usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock; (2) the catches of the particular category quota to date and the likelihood of closure of that segment of the fishery if no allocation is made; (3) the projected ability of the