persons and vessels must comply with the instructions of the Captain of the Port or his designated representative.

(c) *Effective period.* This section becomes effective at 7 a.m. p.d.t. on May 28, 2004, and terminates at 11:59 p.m. p.d.t on June 4, 2004. If the need for this security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zone and will announce that fact via Broadcast Notice to Mariners.

Dated: May 25, 2004.

Steven J. Boyle,

Commander, U.S. Coast Guard, Acting Captain of the Port, San Francisco Bay, California.

[FR Doc. 04–12537 Filed 6–2–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0041; FRL–7361–3]

Streptomyces lydicus WYEC 108; 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 microbial pesticide *Streptomyces lydicus* WYEC 108 on all agricultural commodities when applied/used in accordance with label directions. Natural Industries, 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 *Streptomyces lydicus* WYEC 108.

DATES: This regulation is effective June 3, 2004. Objections and requests for hearings must be received on or before August 2, 2004.

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 ID number OPP–2004–0041. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* 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, 1921 Jefferson Davis Hwy., 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: Alan Reynolds, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0515; e-mail address: *reynolds.alan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production/agriculture (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturer (NAICS 311)
- Pesticide manufacturing (NAICS 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. 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 August 1, 2000 (65 FR 46912) (FRL –6595–4), 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 0F6163) by Natural Industries, Inc., 6223 Theall Road, Houston, TX 77066. This notice included a summary of the petition prepared by the petitioner Natural Industries, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of the microbial pesticide *Streptomyces lydicus* WYEC 108.

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.

Streptomyces lydicus WYEC 108 is a common, well-characterized, naturally-occurring soil bacterium. It has been researched extensively in both the laboratory and under field conditions and has been described in scientific literature for over 45 years. The results of the acute toxicology and pathogenicity studies required of the petitioner under FFDCA section 408(d)(2)(A) in support of the petition for an exemption from the requirement of a tolerance for *Streptomyces lydicus* WYEC 108 indicate that the bacterium is non-toxic, non-irritating, and non-pathogenic.

Tests performed by Natural Industries, Inc. cited in support of this Food Tolerance Exemption Petition are summarized below.

1. *Acute oral toxicity* - Rat (OPPTS Harmonized Guideline 870.1100) MRID 451117–01.

Test Material: Actinovate Soluble.

Test Dose: 5,050 mg/per/kg, CFU not measured.

Result: No mortality, LD_{50} > 5,050 mg/per/kg; no observable abnormalities on necropsy, and minor clinical signs (piloerection in all 3 males at 24 hours, diarrhea in 1 female each at 1 and 2 hours and soft feces in 1 male at 4 hours) with complete symptom clearance by day 2. (J. Gagliardi/J. Kough memorandum to A. Reynolds, 1/14/04 (hereafter referred to as BPPD Review - 1/14/04)).

2 *Acute pulmonary toxicity/pathogenicity* - Rat (OPPTS Harmonize Guideline 885.3150) MRID 451117–02.

Test Material: *Streptomyces lydicus* WYEC 108 (TGAI).

Test Dose: 9.1 x 10^8 CFU per animal, plus an inactivated control.

Result: No mortality, LD_{50} > 9.1 x 10^8 CFU per animal; inactivated control produced slight piloerection in all animals; *Streptomyces lydicus* WYEC 108 produced piloerection plus crust on eyes, walking on tiptoe, and one female with raspy breathing. Necropsy showed no abnormalities and WYEC 108 cleared from all tissues by 28 days (BPPD Review - 1/14/04).

3. *Acute injection toxicity/pathogenicity* - Rat (OPPTS Harmonize Guideline 885.3200) MRID 451117–03.

Test Material: *Streptomyces lydicus* WYEC 108 (TGAI).

Test Dose: 9.33 x 10^8 CFU per animal, plus an inactivated control.

Result: No mortality, LD_{50} >9.33 x 10^8 CFU per animal; inactivated control and *Streptomyces lydicus* WYEC 108 produced no clinical symptomology with no observable abnormalities on necropsy, though one control male had an enlarged/hardened abdomen and also one control male had an enlarged and mottled spleen and liver(BPPD Review - 1/14/04).

4. *Hypersensitivity incidents (OPPTS Harmonize Guideline.* 885.3400). The registrant reported (April 24, 2000) no incidents to date. Nonetheless, the registrant is required to report to the Agency any future incidents of hypersensitivity associated with *Streptomyces lydicus* WYEC 108 pursuant to FIFRA section 6(a)(2).

5. *Data Waivers:* In addition to the data summarized above, the following required studies were waived for *Streptomyces lydicus*.

i. *Acute oral toxicity/pathogenicity (OPPTS 885.3050).* An acceptable acute oral toxicity study (870.1100) was submitted by the registrant (discussed above). This study showed no mortality or abnormalities among the orally-dosed rats (Toxicity Category IV). In addition, toxicity/pathogenicity studies were conducted on the most likely route of human exposure, pulmonary, and the most sensitive route of exposure, intravenous injection, to determine whether or not the material is toxic, pathogenic, or infective to mammals. Both of those studies were acceptable and demonstrated a lack of toxicity and pathogenicity from *Streptomyces lydicus* WYEC 108 to the test animals. Therefore, the data waiver request for acute oral toxicity/pathogenicity testing was granted (J. Gagliardi/J. Kough memorandum to A. Reynolds, 5/21/03 (hereafter referred to as BPPD Review - 5/21/03).

ii. *Acute dermal toxicity/pathogenicity (OPPTS 885.3100).* The registrant has submitted acceptable acute oral toxicity, acute pulmonary toxicity/pathogenicity, acute injection toxicity/pathogenicity, primary eye irritation, and primary dermal irritation studies that demonstrate the lack of toxicity, pathogenicity, infectivity, and irritation for the active ingredient, *Streptomyces lydicus* WYEC 108 (see discussions above). As such, the data waiver request for acute dermal toxicity/pathogenicity testing was granted (J. Gagliardi/J. Kough memorandum to A. Reynolds, 2/11/04).

iii. *Acute inhalation toxicity (OPPTS 870.1300).* The registrant submitted an acceptable acute pulmonary toxicity/pathogenicity study (see discussion above) that demonstrated no toxicity, pathogenicity, or infectivity associated with the active ingredient, *Streptomyces lydicus* WYEC 108. The inert ingredients in the end-use product are not expected to increase the pathogenicity or toxicity of the TGAI. As such, the data waiver request for acute inhalation toxicity testing was granted (BPPD Review - 5/21/03).

iv. *Hypersensitivity study (OPPTS 870.2600).* The registrant has reported that there have been no hypersensitivity incidents during production and testing of *Streptomyces lydicus* WYEC 108 (TGAI or end use product). In addition, the submitted toxicity and irritation studies (as discussed above) have shown minimal toxicity and/or irritation potential for *Streptomyces lydicus* WYEC 108. The registrant is required to also report any adverse incidents to the Agency under FIFRA section 6(a)(2). Therefore, the data waiver request for the hypersensitivity study was granted (BPPD Review - 5/21/03).

v. *Immune response (OPPTS 885.3800).* The submitted acute injection toxicity/pathogenicity study (as discussed above) demonstrated that *Streptomyces lydicus* WYEC 108 is cleared by the immune system from the bodies of the test animals. Therefore, the data waiver request for immune response testing was granted (BPPD Review - 5/21/03).

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

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

Humans and animals are commonly exposed to *Streptomyces lydicus*, a common and naturally-occurring soil-inhabiting bacterium. No toxicological endpoints were identified for *Streptomyces lydicus* WYEC 108. The low toxicity and non-pathogenicity of *Streptomyces lydicus* WYEC 108 is demonstrated by the data summarized in Unit III above.

1. *Food*. The method of application for *Streptomyces lydicus* WYEC 108 is a soil mix/drench to potted plants and turf grass or as a foliar application to greenhouse crops. As such, there may be plant residues of *Streptomyces lydicus* WYEC 108 and dietary exposure on agricultural commodities. However, negligible to no risk is expected for the general population, including infants and children, because *Streptomyces lydicus* WYEC 108 demonstrated no pathogenicity or oral toxicity at the maximum doses tested (as noted in Unit III above).

2. *Drinking water exposure*. *Streptomyces lydicus* WYEC 108 is found naturally in soil, but does not thrive in aquatic environments. There are also no aquatic use sites for the pesticide, so exposure in drinking water is not expected. In addition, there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent (see Unit III above). Accordingly, the use of *Streptomyces lydicus* WYEC 108 on terrestrial plants is not expected to negatively impact the quality of drinking water.

B. Other Non-Occupational Exposure

Based on the proposed agricultural and horticultural use patterns, the potential for non-dietary exposure to *Streptomyces lydicus* WYEC 108 residues for general population, including infants and children, is unlikely. In addition, adults are required to wear personal protective equipment during application to mitigate any exposure. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Streptomyces lydicus* WYEC 108, should fall well below the currently tested microbial safety standards.

The potential for dermal or inhalation exposure to *Streptomyces lydicus* WYEC 108 pesticide residues for the general population, including infants and children, is unlikely because the potential use sites are agricultural and horticultural. However, since *Streptomyces lydicus* is a common, naturally-occurring soil bacterium, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed microbial pesticide would be negligible. Furthermore, as demonstrated in Unit III above, the organism is essentially non-irritating (Toxicity Category IV) and the acute pulmonary toxicity/pathogenicity testing performed on *Streptomyces lydicus* WYEC 108 demonstrated no pathogenicity or toxicity. As such, the risks anticipated for these routes of exposure are considered minimal.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to 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. The Agency has considered the potential for cumulative effects of*Streptomyces lydicus* WYEC 108 and other substances in relation to a common mechanism of toxicity. As demonstrated above, *Streptomyces lydicus* WYEC 108 is non-toxic and non-pathogenic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III above), no cumulative effects from the residues of this product with other related microbial pesticides are anticipated.

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

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *Streptomyces lydicus* WYEC 108 due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed in Unit III above, *Streptomyces lydicus* WYEC 108 is not pathogenic or infective and is non-toxic to mammals. Accordingly, exempting *Streptomyces lydicus* WYEC 108 from the requirement of a tolerance should be considered safe and pose no significant risks.

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) 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 margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety), which often are referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk. Because *Streptomyces lydicus* WYEC 108 is a common, naturally-occurring bacterium, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase exposure to the U.S. population, including infants and children. In addition, actual exposures to adults and children through diet are expected to be several orders of magnitude less than the doses used in the toxicity and pathogenicity tests referenced in Unit III above. Thus, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the 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 scientific basis for including, as part of the screening 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 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 EDSP have been developed, *Streptomyces lydicus* WYEC 108 may be subjected to additional

screening and/or testing to better characterize effects related to endocrine disruption.

The submitted toxicity/pathogenicity studies indicated that following several routes of exposure, the immune systems of the tested animals were not compromised and that they were able to clear the active ingredient (see Unit III above). Based on the available data, there is no current evidence that *Streptomyces lydicus* WYEC 108 acts as a hormone or endocrine disruptor, or that it produces toxins or secondary metabolites that would cause mammalian toxicity, pathogenicity, or irritation. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this Final Rule for *Streptomyces lydicus* WYEC 108.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Streptomyces lydicus* WYEC 108's lack of mammalian toxicity. *Streptomyces lydicus* WYEC 108 is a common and naturally-occurring soil-inhabiting bacterium. There is a great likelihood of prior exposure for most, if not all individuals and the increase in exposure due to this proposed microbial pesticide would be negligible. For these reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for *Streptomyces lydicus* WYEC 108.

C. Codex Maximum Residue Level

There is no Codex Alimentarium Commission Maximum Residue Level for *Streptomyces lydicus* WYEC 108.

VIII. 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 OPP–2004–0041 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 August 2, 2004.

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. *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*, 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 20460–0001.

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 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.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 OPP–2004–0041, 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).

IX. 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. 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: May 24, 2004.

Jim 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 180.1253 is added to subpart D to read as follows:

§ 180.1253 Streptomyces lydicus WYEC 108; Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Streptomyces lydicus* WYEC 108 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 04–12558 Filed 6–2–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket Nos. 02–34 and 02–54, FCC 03–102]

Satellite Licensing Procedures

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document corrects errors in the rule changes published in the **Federal Register** of August 27, 2003, regarding reform of space station licensing procedures.

DATES: Effective June 3, 2004.

FOR FURTHER INFORMATION CONTACT: Stephen Duall, Attorney Advisor, Satellite Division, International Bureau, telephone (202) 418–1103 or via the Internet at *Stephen.Duall@fcc.gov.*

SUPPLEMENTARY INFORMATION:

Background

This document corrects errors in § 25.146 of the Commission's rules. The Commission published a document in the **Federal Register** of August 27, 2003,