PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart F—[Amended]

■ 2. Section 82.152 is amended by revising the definitions of ''refrigerant'' and ''technician'' to read as follows:

§ 82.152 Definitions.

* * * * *

Refrigerant means, for purposes of this subpart, any substance consisting in part or whole of a class I or class II ozone-depleting substance that is used for heat transfer purposes and provides a cooling effect.

* * * * *

Technician means any person who performs maintenance, service, or repair, that could be reasonably expected to release refrigerants from appliances, except for MVACs, into the atmosphere. Technician also means any person who performs disposal of appliances, except for small appliances, MVACs, and MVAC-like appliances, that could be reasonably expected to release refrigerants from the appliances into the atmosphere. Performing maintenance, service, repair, or disposal could be reasonably expected to release refrigerants only if the activity is reasonably expected to violate the integrity of the refrigerant circuit. Activities reasonably expected to violate the integrity of the refrigerant circuit include activities such as attaching and detaching hoses and gauges to and from the appliance to add or remove refrigerant or to measure pressure and adding refrigerant to and removing refrigerant from the appliance. Activities such as painting the appliance, rewiring an external electrical circuit, replacing insulation on a length of pipe, or tightening nuts and bolts on the appliance are not reasonably expected to violate the integrity of the refrigerant circuit. Performing maintenance, service, repair, or disposal of appliances that have been evacuated pursuant to § 82.156 could not be reasonably expected to release refrigerants from the appliance unless the maintenance, service, or repair consists of adding refrigerant to the appliance. Technician includes but is not limited to installers, contractor employees, in-house service personnel, and in some cases owners and/or operators.

* * * * *

■ 3. Section 82.154 is amended by revising paragraph (a) to read as follows:

§ 82.154 Prohibitions.

(a)(1) Effective June 13, 2005, no person maintaining, servicing, repairing, or disposing of appliances may knowingly vent or otherwise release into the environment any refrigerant or substitute from such appliances, with the exception of the following substitutes in the following end-uses:

(i) Ammonia in commercial or industrial process refrigeration or in absorption units;

(ii) Hydrocarbons in industrial process refrigeration (processing of hydrocarbons);

(iii) Chlorine in industrial process refrigeration (processing of chlorine and chlorine compounds);

(iv) Carbon dioxide in any application;

(v) Nitrogen in any application; or

(vi) Water in any application.

(2) The knowing release of a refrigerant or non-exempt substitute subsequent to its recovery from an appliance shall be considered a violation of this prohibition. De minimis releases associated with good faith attempts to recycle or recover refrigerants or non-exempt substitutes are not subject to this prohibition. Refrigerant releases shall be considered de minimis only if they occur when:

(i) The required practices set forth in § 82.156 are observed, recovery or recycling machines that meet the requirements set forth in § 82.158 are used, and the technician certification provisions set forth in § 82.161 are observed; or

(ii) The requirements set forth in subpart B of this part are observed.

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[FR Doc. 05–7407 Filed 4–12–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0397; FRL–7708–4]

Paecilomyces lilacinus strain 251; 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 fungus *Paecilomyces lilacinus* (*P. lilacinus*) strain 251 in or on food commodities when applied or used in accordance with label directions. Prophyta Biologischer Pflanzenschutz GmbH, Germany 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. Notification that EPA had received the petition was published on November 7, 2003 (68 FR 63088–92) (FRL–7331–7). This regulation eliminates the need to establish a maximum permissible level for residues of *P. lilacinus* strain 251.

DATES: This regulation is effective April 13, 2005. Objections and requests for hearings must be received on or before June 13, 2005.

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–2004–0397. 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, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Mandula, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–7378; e-mail address: *mandula.barbara@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 manufacturing (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 November 7, 2003 (68 FR 63088–92) (FRL–7331–7), 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 3F6737) by (Prophyta Biologischer Pflanzenschutz GmbH, Germany: US Agent: WF Stoneman Co., LLC, PO Box 465, McFarland, WI 53558–0465. This notice included a summary of the petition prepared by the petitioner, Prophyta Biologischer Pflanzenschutz GmbH, Germany. The petition requested that 40 CFR part 180 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of *P. lilacinus* strain 251 in or on food commodities when applied or used in accordance with label directions as a nematicide for the control of plant parasitic nematodes. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

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

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.

P. lilacinus strain 251 is a naturally occurring fungus commonly found in soil. Unlike many other *P. lilacinus* strains, *P. lilacinus* strain 251 does not produce mycotoxins or paecilotoxins. In addition, the results of acute toxicology and pathogenicity studies submitted by the petitioner in support of its petition for an exemption from the requirement of a tolerance for *P. lilacinus* strain 251 indicate negligible to no mammalian toxicity. Moreover, no pathogenicity was observed in any of the tests conducted with *P. lilacinus* strain 251. Accordingly, the toxicology and pathogenicity data generated by Prophyta Biologischer Pflanzenschutz GmbH, Germany support an exemption from the requirements of a tolerance. The data relevant to and in support of this tolerance exemption are presented in more detail below.

1. *Acute toxicity*—i. *acute oral toxicity-rat (OPPTS Guideline 870.1100; MRID 462832–01)*. The test material (2,000 mg/kg body weight) was given to five male and five female rats by gavage in a 10% w/w suspension in water. All animals were necropsied and organ weights were recorded after 14 days. No clinical signs of toxicity were seen. The oral LD_{50} for males, females, and combined was greater than 2,000 mg/kg. Classification: acceptable; Toxicity Category III.

ii. *Acute dermal toxicity-rat (OPPTS Guideline 870.1200; MRID 462832–02)*. The test material (2,000 mg/kg body weight) was applied to the clipped dorsal trunk of five male and five female rats on an area 36 cm^2 for 24 hours. No abnormal clinical signs were seen during 14 days of observation. The acute lethal dose (LD_{50}) is greater than 2,000 mg/kg. Classification: acceptable; Toxicity Category III.

iii. *Acute pulmonary toxicity/pathogenicity-rat (OPPTS Guideline 885.3150; MRID 459418–04)*. Test material was administered by a single intratracheal dose of 0.05 milliliters (mL) containing 2.5×10^8 conidia, to 35 male and 35 female rats. No clinical signs were seen during 15 days of observation. *P. lilacinus* strain 251 was detected in lungs and lung lymph nodes with clearance after 15 days, and in tracheal lymph nodes with clearance after 4 days. Based on this study, the test organism was not toxic, infective, or pathogenic to rats at the applied dose. Classification: acceptable; Toxicity Category III.

iv. *Primary eye irritation-rabbit (OPPTS Guideline 870.2400; MRID 460042–07)*. Test material (100 mg/eye/animal) was applied in the conjunctival sac of one eye, and 0.1 mL distilled water as a control in the other eye of three male rabbits. After 72 hours, no corneal opacity, iritis, or other signs of irritation were seen. Classification: acceptable; Toxicity category IV.

v. *Hypersensitivity study-guinea pig (OPPTS Guideline 870.2600; MRID 459418–07)*. The animals were induced and challenged according to the method of Buehler. Twenty animals were test animals, and 25 animals served as positive and negative controls. Once per week for 3 weeks, approximately 0.5 grams(g) of test material was applied to the shaved skin of test guinea pigs for 6 hours. When challenged with 0.25 g

test material 12 days after the last induction, no signs of sensitization appeared. The test material is not a dermal sensitizer. Classification: acceptable.

vi. *Reporting hypersensitivity incidents (OPPTS Guideline 885.3400).* The registrant has reported no incidents to date. Nonetheless, pursuant to FIFRA section 6(a)(2), the registrant is required to report to the Agency any future incidents of hypersensitivity associated with *P. lilacinus* strain 251.

vii. *Primary dermal irritation-rabbit (OPPTS Guideline 870.2500; MRID 459418–06).* Three female rabbits were each dosed with 0.5 g test material applied on gauze to clipped skin for 4 hours. During the next 72 hours, no clinical signs or irritation were seen. *P. lilacinus* strain 251 was non-irritating at the test dose. Classification: acceptable; Toxicity Category IV.

viii. *Acute intraperitoneal toxicity/pathogenicity-rat (OPPTS Guideline 885.3200; MRID 460042–01).* The testing laboratory reported that the test material was administered to five male and five female rats by a single intraperitoneal dose of 2,000 mg/kg body weight. The laboratory did not confirm the titre of the test substance. No clinical signs of toxicity or pathogenicity were observed in any of the treated or control rats during the 14–day observation period. All rats survived for 14 days. Both control and test animals showed evidence of mycoplasmosis infection on necropsy, but no evidence of abnormalities attributable to the test substance. No test organisms were detected in any of the test animals or in the two control animals examined when the following organs were analyzed: liver, kidney, spleen, lungs, brain, urinary bladder, lymphatic ganglia, or thymus. The digestive tract of one test male and one test female had 270 and 290 cfu/organ respectively, which is attributed to environmental contamination rather than to infectivity. Because the testing laboratory did not analyze the test material for viable conidia before dosing, there is some uncertainty about the viability and dose of the test material. However, 3.89×10^9 cfu/g was found when the registrant analyzed a portion of the test production batch in November 2001, when the lab did its testing. If the test laboratory sample was appropriately shipped and stored, the test sample should have contained a concentration of 3.89×10^9 cfu/g sample, an adequate concentration for testing. Also, while the organ analyses suggest a low level of laboratory environmental contamination with the test organism, the detection of this contamination indicates that the laboratory was capable of detecting the microbe in the various organs if it had been present. While the study is flawed because the test laboratory did not analyze the viability of the test material before dosing, EPA believes that a sufficient concentration of viable microbes was likely used in testing. EPA classifies the study as supplemental because it provides supporting evidence that *P. lilacinus* strain 251 is not toxic or pathogenic to mammals. Classification: supplementary.

ix. *Immune response (OPPTS Guideline 880.3800).* The registrant submitted a waiver request for the immune response study. The waiver was granted, based on results of various rodent studies that showed no evidence of adverse effects to the immune system (MRID 462832–01; 459418–04). Animal behavior and weight gain remained normal, and there was no excess morbidity or mortality in the studies. No organ abnormalities attributed to the test material were seen on necropsy. In a pulmonary pathogenicity study, the fungal titre in various organs decreased during the first 8 days after dosing, and clearance was complete by 14 days. This clearance provides evidence that the immune system was functioning, although a concomitant explanation is that the conidia became non-viable over time because they do not survive more than a few days at temperatures above 36 °C. Taken together, these data indicate that *P. lilacinus* strain 251 does not interfere with immune system function.

2. *Dose response assessment.* No toxicological responses have been identified. Therefore, a dose response assessment could not be performed.

3. *Subchronic and chronic toxicity.* Based on the data generated in accordance with the Tier I toxicology data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III toxicology data requirements also set forth therein were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III toxicology 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 may be exposed dermally and orally to the common soil microbe *P. lilacinus* strain 251 when they get soil on their hands or clothing, or handle pets that have played in soil. Importantly, however, no toxicological endpoints were identified for *P. lilacinus* strain 251 and there is no evidence of adverse effects from oral, dermal, or pulmonary exposure to this microbial agent. The low toxicity and non-pathogenicity/infectivity of *P. lilacinus* strain 251 are demonstrated by the data summarized in Unit III of this preamble.

1. *Food.* While the proposed use pattern may result in dietary exposure with possible residues in or on certain agricultural commodities, negligible, to no risk, is expected for the general population, including infants and children, or animals because *P. lilacinus* strain 251 demonstrated no pathogenicity or oral toxicity at the maximum dose tested, as noted above in Unit III.

2. *Drinking water exposure.* The potential for transfer of *P. lilacinus* strain 251 to surface or ground water during run-off associated with intended use applications is considered minimal, due to its percolation through and resulting capture in soil, and its attachment to plant root nematodes. Accordingly, the use of this microbial pest control agent on terrestrial plants is not anticipated to lower the quality of drinking water. Even if low levels of the microbe were present in drinking water, no risk to the general public would be expected because *P. lilacinus* strain 251 demonstrated no oral pathogenicity or toxicity at the maximum dose tested.

B. Other Non-Occupational Exposures

Based on the proposed use patterns, in which *P. lilacinus* strain 251 is applied directly to soil of agricultural and ornamental crops, the potential for non-dietary, non-occupational exposures to *P. lilacinus* strain 251 pesticide residues by the general population, including infants and children, is low. Moreover, even in the unlikely event of non-dietary, non-occupational exposures to *P. lilacinus* strain 251 pesticide residues, no harm is expected because no toxicity or pathogenicity was found in mammalian studies that included high levels of oral, pulmonary, and dermal exposure.

1. *Dermal exposure.* The potential for dermal exposure to *P. lilacinus* strain 251 pesticide residues for the general population, including infants and

children, is low because there are no residential uses for this pesticide, which will be applied directly to soils used for growing agricultural and ornamental crops. In addition, because *P. lilacinus* strain 251 is a naturally-occurring bacterium in soil, which means there is a great likelihood of prior exposure for most, if not all, individuals, any actual increase in dermal exposure due to the pesticidal use of *P. lilacinus* strain 251 would be negligible. Furthermore, and as demonstrated in Unit III of this preamble, the organism shows low to no dermal toxicity, the acute lethal dose (LD_{50}) is greater than 2000 mg/kg (Toxicity Category III), and *P. lilacinus* strain 251 is essentially non-irritating (Toxicity Category IV). Accordingly, the risks anticipated for this route of exposure, should it occur, are minimal to non-existent.

2. *Inhalation exposure.* Inhalation exposure to *P. lilacinus* strain 251 pesticide residues for the general population, including infants and children, is unlikely because there are no residential use sites and the pesticide is applied directly to soil as a liquid preparation. In addition, because *P. lilacinus* strain 251 is a naturally-occurring bacterium in soil, which means there is a great likelihood of prior exposure for most, if not all, individuals, any actual increase in inhalation exposure due to the pesticidal use of *P. lilacinus* strain 251 would be negligible. Furthermore, and as demonstrated in Unit III of this preamble, the acute pulmonary toxicity/pathogenicity testing performed on the active ingredient did not demonstrate pathogenicity or toxicity of *P. lilacinus* strain 251. (See Unit III of this preamble.) Accordingly, the risks anticipated for this route of exposure, should it occur, are considered minimal.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children. The Agency has considered the potential for cumulative effects of *P. lilacinus* strain 251 and other substances in relation to a common mechanism of toxicity. *P. lilacinus* strain 251 is practically non-toxic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III of this preamble.), no cumulative effects to humans, including infants and children, from the interaction of residues of this product with other related microbial pesticides are anticipated when this product is used as directed on the label and in accordance with good agricultural practices.

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

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 *P. lilacinus* strain 251 due to its use as a nematicide. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, *P. lilacinus* strain 251 is not pathogenic or infective and is practically non-toxic to mammals. (See Unit III of this preamble.) Accordingly, exempting *P. lilacinus* strain 251 from the requirement of a tolerance should be considered safe and pose no significant risk.

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 database 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) are incorporated into EPA risk assessments either by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans, or using a margin of exposure analysis.

Human exposure is expected to be negligible if users follow label directions for this pesticide agent. Moreover, considering the ubiquitous nature of *P. lilacinus* strain 251 in the soil, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase the exposure of the U.S. population, including infants and children, to *P. lilacinus* strain 251. Furthermore, high doses of *P. lilacinus* strain 251, as demonstrated in Unit III of this preamble, show virtually no mammalian toxicity and no pathogenicity when tested by several routes of exposure, including oral and dermal. Hence, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *P. lilacinus* strain 251 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *P. lilacinus* strain 251 residues. Thus, the Agency has determined that the additional margin of safety is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors and Immune System

1. *Endocrine disrupters.* 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 is no 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, *P. lilacinus* strain 251 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. lilacinus* strain 251. As a result, the Agency has determined that there is no impact via endocrine-related effects on the Agency's safety finding set forth in this Final Rule for *P. lilacinus* strain 251.

2. *Immune system.* To date, the Agency has no information to suggest that *P. lilacinus* strain 251 has an adverse effect on the immune system, the physiologic system that protects humans and other organisms from infections and other diseases. As is expected from a non-pathogenic microorganism that is practically non-

toxic to mammals, the submitted toxicity/pathogenicity studies in rodents indicate that following various routes of exposure, the immune system is still intact. For example, lack of morbidity, mortality, weight loss or behavior changes in the test animals provides evidence that the immune system continues to function after dosing.

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 (see Unit III of this preamble), including a lack of mammalian toxicity for *P. lilacinus* strain 251. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *P. lilacinus* strain 251.

C. Codex Maximum Residue Level

There is no Codex Alimentarius Commission Maximum Residue Level (MRL) for *P. lilacinus* strain 251.

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–2004–0397 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 June 13, 2005.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1801 Bell St. S, Arlington, VA. 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 (703) 603–0061.

2. *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–2004–0397, 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 requirement of a tolerance 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: March 29, 2005.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1257 is added to subpart D to read as follows:

§ 180.1257 Paecilomyces lilacinus strain 251; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Paecilomyces lilacinus* strain 251 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 05–7226 Filed 4–12–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0029; FRL–7705–7]

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of acetamiprid in or on tuberous and corm vegetables. Nippon Soda Company c/o Nisso America Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 13, 2005. Objections and requests for hearings must be received on or before June 13, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0029. 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, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Akiva Abramovitch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8328; e-mail address: *abramovitch.akiva@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be