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[FR Doc. 07-2404 Filed 5-15-07; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2005-0121; FRL-7713-1]

### Pythium Oligandrum DV 74; 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 *Pythium oligandrum* DV 74 on food crops. Biopreparaty Co. Ltd. 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 *Pythium oligandrum* DV 74.

**DATES:** This regulation is effective May 16, 2007. Objections and requests for hearings must be received on or before July 16, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-EPA-0121. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only

available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Tessa Milofsky, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0455; e-mail address: [milofsky.tessa@epa.gov](mailto:milofsky.tessa@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 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-EPA-0121 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 July 16, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2005-EPA-0121, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

##### II. Background and Statutory Findings

In the **Federal Register** of May 25, 2005 (70 FR 30105) (FRL-7713-1), 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 4F6877) by Biopreparaty, Co. Ltd. Tylišovska I, Prague 6, Czech Republic. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement *Pythium*

*oligandrum* DV 74. This notice included a summary of the petition prepared by the petitioner Biopreparaty Co. Ltd.

One comment was received from a private citizen opposing the "production or selling" of *Pythium oligandrum* DV 74. The commentor further stated that it was their wish that no exemptions be issued and that no tolerances should be approved. The Agency understands the commentor's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the FFDCA EPA is required to establish pesticide tolerances or exemptions where persons seeking such exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The commentor has not provided the Agency with a specific rationale or additional information pertaining to the legal standards in FFDCA section 408 for opposing the establishment of a tolerance exemption for *Pythium oligandrum* DV 74. In the absence of any additional information of a factual nature, the Agency can not effectively respond to the commentor's disagreement with the Agency's decision.

Another comment was received that supported the registration. The commentator stated that "*Pythium oligandrum* appears to be an unusually effective (in its rapidity of action) and exceptionally safe (in terms of mammalian toxicity) crop protection product."

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.

*A. Acute Oral Toxicity and Pathogenicity (Master Record Identification numbers 464107-02 and 464109-03; Data Request 152-30; OPPTS Harmonize Guideline. 885.3050)*

A guideline acute oral toxicity study was carried out in 2001 using mice. Ten mice (five males, five females) were given a total dose of 5,000 milligrams/kilogram (mg/kg) *Pythium oligandrum* DV 74 and no adverse effects were seen in the mice which were observed for 14 days after dosing. The test substance was rated *Toxicity Category IV*.

*B. Acute Dermal Toxicity (Master Record Identification numbers 464109-04, 464107-02; OPPTS Harmonize Guideline 870.1200)*

A guideline acute dermal toxicity study was conducted using rats. The dermal LD<sub>50</sub> for males, females, and combined was greater than 5,000 mg/kg body wt. *Pythium oligandrum* DV 74 test substance was rated *Toxicity Category IV*.

*C. Acute Inhalation Toxicity (Master Record Identification number 464109-05; OPPTS Harmonize Guideline 870.1300)*

In a four-hour acute inhalation toxicity study using rats, a limit dose (5 mg/L) of *Pythium oligandrum* DV 74 produced no mortality nor adverse effects, and no gross abnormalities were

seen at necropsy 14 days later. Although the MMD was 7.45  $\mu\text{m}$ , approximately 68% of the particles were  $\leq 3.75 \mu\text{m}$ . The acute inhalation LC<sub>50</sub> for males, females, and combined was  $>5 \text{ mg/L}$  for a 4 hour exposure. The test substance is *Toxicity Category IV*.

*D. Acute Pulmonary Toxicity/Pathogenicity-Waiver Granted (Master Record Identification number 464109-10; OPPTS Harmonize Guideline 885.3150)*

In a four-hour acute inhalation toxicity study using rats, a limit dose (5 mg/L) of *Pythium oligandrum* DV 74 produced no mortality or adverse effects, and no gross abnormalities were seen at necropsy 14 days later. Although the MMD was 7.45  $\mu\text{m}$ , approximately 68% of the particles were  $\leq 3.75 \mu\text{m}$ . The acute inhalation LC<sub>50</sub> for males, females, and combined was  $>5 \text{ mg/L}$  for a 4 hour exposure. The test substance is classified as *Toxicity Category IV*. Infectivity testing was waived for this study based on the results of the growth temperature study which showed no growth on plant-based growth media at or above 37° C, and no growth at any temperature on animal tissue-based growth media.

*E. Acute Injection Toxicity/Pathogenicity (Master Record Identification numbers 465823-01, 467542-01, 464109-10, and 469901-01; OPPTS Harmonize Guideline 885.3200)*

An acute injection toxicity/pathogenicity study was conducted using rats. Storage, stability data showed that after Batch No. 150405 was stored for approximately 9 months, of  $1.3 \times 10^6$  oospores/g active ingredient 80.5% were viable after 120 hours incubation, giving  $1.1 \times 10^6$  cfu/g - however, this study lists Batch No. 150405 as containing  $10^7$  granules/g, so viability would then be only 11%. Based on the data submitted, *Pythium oligandrum* DV 74 does not appear toxic nor pathogenic to rats when dosed at  $2.9 \times 10^4$  oospores/animal - although no attempts to isolate viable organisms prior to testing, or from test animals after inoculation, were made. Therefore, infectivity cannot be assessed in the study, initially rated not toxic nor pathogenic. In addition, there were discrepancies with characterization of the test substance. However, infectivity testing was waived for this study, based on the results of the growth temperature study which showed no growth on plant-based growth media at or above 37° C, and no growth at any temperature on animal tissue-based growth media.

*F. Primary Dermal Irritation (Master Record Identification numbers 464605-02 and 464107-02; OPPTS Harmonize Guideline 870.2500)*

An acute dermal irritation study was conducted using rabbits. Very slight erythema was noted on the skin of three rabbits one hour after patch removal, with clearance on two rabbits by 24 hours and on one rabbit by 48 hours. The primary irritation index was 0.3. Technical DV 74 was essentially nonirritating; the test substance was rated *Toxicity Category IV*.

*G. Acute Eye Irritation (Master Record Identification number 464109-06; OPPTS Harmonize Guideline 870.2400)*

An acute eye irritation study was conducted using rabbits. No corneal opacity nor iritis was observed during the study. Positive conjunctival irritation (score 2) was noted on 2 rabbits 1 hour after *Pythium oligandrum* DV 74 instillation with resolution by 48 hours. The maximum average score was 6.7 at 24 hours after test material instillation. The test substance is *Toxicity Category III*.

*H. Skin sensitization-Waiver Granted (Master Record Identification number 464109-10; OPPTS Harmonize Guideline 870.2600)*

A guideline acute dermal toxicity study was conducted using rats. The dermal LD<sub>50</sub> for males, females, and combined was greater than 5,000 mg/kg body wt. *Pythium oligandrum* DV 74 and rated *Toxicity Category IV*. An acute dermal irritation study was conducted using rabbits. Very slight erythema was noted on 3/3 rabbits one hour after patch removal, with clearance on two rabbits by 24 hours and on one rabbit by 48 hours. The primary irritation index was 0.3. Technical DV 74 was essentially nonirritating and rated *Toxicity Category IV*. In addition, *Pythium oligandrum* occurs naturally in a variety of soil types over a wide range of environmental conditions. Although application of *Pythium oligandrum* DV 74 to seeds, foliage, or soil will likely temporarily increase its concentration in the environment, the population is expected to subside to normal levels, because the organism does not thrive in the absence of sufficient nutrients. A search of the public literature found no reports of *Pythium oligandrum* having adverse effects in humans or other mammals. The only known biological effects of *Pythium oligandrum* are parasitic effects on fungal species and stimulation of resistance to parasitic infection in plants. Neither the mechanism of the mycoparasitic action

nor the stimulation of plant resistance is associated with adverse effects in mammals. *Pythium oligandrum* DV 74 is the active ingredient in various over-the-counter products sold in Europe, including a mouthwash, a bath additive and a skin cream. These products have been on the market in parts of the EU since 1999 with no reported adverse effects. The lack of any reported sensitization effects from repeated dermal exposure to the consumer products suggests that *Pythium oligandrum* is not a dermal sensitizer. To reduce exposure to this active ingredient from its pesticide use, the agricultural use label requires that applicators and handlers wear a long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks.

*I. Pathogenicity and Infectivity (Master Record Identification numbers 469901-01 and 02)*

*Pythium oligandrum* DV 74 is primarily a fungal hyperparasite that exhibits limited growth on plant-based media and no growth on animal tissue-based media. In addition, its growth tapers off as temperature approaches normal human body temperature of 37° C and there is no growth at or above this temperature. Therefore, infectivity testing is not possible. This information supports waivers for infectivity testing in the acute oral, acute dermal, acute inhalation, and injection exposure studies.

*J. Subchronic, Chronic Toxicity and Oncogenicity*

Based on the data generated in accordance with Tier I data requirements (40 CFR 158.740(c)), Tier II tests (Guidelines 152B-40 through 152B-49), which include acute oral, acute inhalation, subchronic oral, acute intraperitoneal/intracerebral, primary dermal, primary eye, immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity were not required. Tier III tests (Guidelines 152-50 through 53), which include chronic testing, oncogenicity testing, mutagenicity, and teratogenicity were also not required.

*K. Effects on the Endocrine System*

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) "humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." *Pythium oligandrum* is not a known endocrine disruptor nor is

it related to any class of known endocrine disruptors. Consequently, endocrine-related concerns did not adversely impact the Agency's safety finding for *Pythium oligandrum*.

#### 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

Due to the proposed use of *Pythium oligandrum* on food crops, fungal residues may be present on agricultural commodities. However, negligible to no risk is expected for the general population, including infants and children, because *Pythium oligandrum* demonstrated no pathogenicity nor acute oral toxicity at the maximum doses tested.

1. *Food*. Due to the proposed use of *Pythium oligandrum* on food crops, fungal residues may be present on agricultural commodities. However, negligible to no risk is expected for the general population, including infants and children, because *Pythium oligandrum* demonstrated no pathogenicity or oral toxicity at the maximum doses tested.

2. *Drinking water exposure*. *Pythium oligandrum* does not thrive in aquatic environments and there are no aquatic use sites for the pesticide. Accordingly, application of this pesticide to approved use sites is not expected to increase drinking water exposure to *Pythium oligandrum*. Furthermore, any *Pythium oligandrum* that might be consumed through drinking water would pose negligible to the general population, including infants and children, due to the pesticide's low toxicity classification.

##### B. Other Non-Occupational Exposure

*Pythium oligandrum* will be applied to agricultural fields, turf and professional landscapes, and in home gardens. Although some applications may be made near residential areas, no harm would be expected to result from exposure to *Pythium oligandrum* due to its low toxicity classification.

1. *Dermal exposure*. Dermal exposure is limited by use of the required PPE and REI in occupational settings, and residential users are advised to avoid

skin contact and to wash any exposed skin or clothing.

2. *Inhalation exposure.* The greatest likelihood of inhalation exposure would occur in an occupational setting, among mixers/loaders and applicators. However, as demonstrated in the acute pulmonary toxicity/pathogenicity test, *Pythium oligandrum* is not infective, pathogenic, or toxic to mammals. Despite the benign nature of the active ingredient, the agency requires that all workers exposed to microbial pesticides must wear a dust/mist filtering respirator. As such, the risks anticipated for inhalation exposure are minimal.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Pythium oligandrum* and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. As demonstrated in Unit III.A., *Pythium oligandrum* is not toxic or pathogenic to mammals, and only minimally irritating to eyes. Consequently, 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 *Pythium oligandrum* 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.A., *Pythium oligandrum* is not toxic or pathogenic to mammals, and only minimally irritating in an eye exposure study. Accordingly, exempting *Pythium oligandrum* from the requirement of a tolerance is considered safe and poses 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. 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. Thus, the Agency has determined that an additional margin of safety for infants and children is unnecessary.

#### 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." *Pythium oligandrum* is not a known endocrine disruptor nor is it related to any class of known endocrine disruptors. Consequently, endocrine-related concerns did not adversely impact the Agency's safety finding for *Pythium oligandrum*.

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

The acute oral toxicity and pathogenicity findings discussed in Unit III demonstrate that the active ingredient does not pose a dietary risk. Nevertheless, the Agency has concluded that for the analysis of the pesticide itself, microbiological and biochemical methods exist and are acceptable for the enforcement purposes for product identity of *Pythium oligandrum* DV 74. Other appropriate methods are required for quality control to assure that product characterization, the control of human pathogens, and other unintentional metabolites or ingredients are within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

##### C. Codex Maximum Residue Level

There is no established Codex maximum residue level for residues of *Pythium oligandrum* DV 74.

#### VIII. Conclusions

The results of the studies discussed are sufficient to comply with the requirements of FQPA. They support an exemption from the requirement of tolerance for residues of *Pythium oligandrum* DV 74, on treated food of food commodities. In addition, the Agency is of the opinion that, if the microbial active ingredient is used as allowed, aggregate and cumulative

exposures are not likely to pose any undue hazard to the U.S. population of adult, children, and infant humans. Therefore, an exemption from the requirement of tolerance is granted in response to pesticide petition 4F6877.

#### IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination*

with *Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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).

#### X. Congressional Review Act

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

#### List of Subjects in 40 CFR Part 180

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

Dated: May 4, 2007.

**Debra Edwards,**

*Director, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 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 180.1275 is added to subpart D to read as follows:

#### § 180.1275 *Pythium*; Exception from the requirement of a tolerance.

An exemption from the requirement of tolerance is established on all food/feed commodities, for residues of *pythium oligandrum* DV 74 when the pesticide is used on food crops.

[FR Doc. E7-9298 Filed 5-15-07; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0800; FRL-8128-2]

### Chlorantraniliprole; Time-Limited Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of chlorantraniliprole in or on apple and apple, wet pomace, celery, cucumber, head and leaf lettuce, pear, pepper, spinach, squash, tomato and watermelon commodities. DuPont Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire on May 1, 2010.

**DATES:** This regulation is effective May 16, 2007. Objections and requests for hearings must be received on or before July 16, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0800. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Public Docket, in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

#### FOR FURTHER INFORMATION CONTACT:

Kable Bo Davis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703 306-0415; e-mail address: [kable.davis@epa.gov](mailto:kable.davis@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).

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##### C. Can I File an Objection or Hearing Request?

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