

**Subpart P—Indiana**

■ 2. In § 52.770 the table in paragraph (c) is amended by revising the entries

for “2–2–1” and “2–2–4” to read as follows:

**§ 52.770 Identification of plan.**

\* \* \* \* \*  
(c) \* \* \*

**EPA-APPROVED INDIANA REGULATIONS**

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
2–2–1	Definitions	03/16/2011	9/28/2011, [Insert page number where the document begins].	
2–2–4	Air quality analysis; requirements	03/16/2011	9/28/2011, [Insert page number where the document begins].	

\* \* \* \* \*

■ 3. In § 52.773, paragraph (k) is removed.  
[FR Doc. 2011–24790 Filed 9–27–11; 8:45 am]  
**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2010–0087; FRL–8889–8]

**Isaria fumosorosea Apopka Strain 97; 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 *Isaria fumosorosea* (formerly known as *Paecilomyces fumosoroseus*) Apopka strain 97 in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices. Certis USA, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Isaria fumosorosea* Apopka strain 97 under the FFDCA.

**DATES:** This regulation is effective September 28, 2011. Objections and requests for hearings must be received on or before November 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0087. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

**B. How can I get electronic access to other related information?**

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

**C. How can I file an objection or hearing request?**

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation

in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0087 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0087, by one of the following methods:

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

## II. Background and Statutory Findings

In the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL-8810-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7665) by Certis USA, LLC, 9145 Guilford Rd., Suite 175, Columbia, MD 21046. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Paecilomyces fumosoroseus* (now recognized as *Isaria fumosorosea*) Apopka strain 97. This notice referenced a summary of the petition prepared by the petitioner, Certis USA, LLC, which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the nomenclature of the active ingredient, which was recently reclassified as *Isaria fumosorosea* (Refs. 1, 2, and 3). The reason for this change is explained in Unit VII.C. Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. \* \* \*" Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] \* \* \* residues and other substances that have a common mechanism of toxicity."

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

## III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

### A. Overview of *Isaria fumosorosea* Apopka Strain 97

In 1986, *Paecilomyces fumosoroseus* Apopka strain 97, an entomopathogenic fungus, was isolated from a mealy bug in a greenhouse in Apopka, Florida. It was recently reclassified, however, as *Isaria fumosorosea* Apopka strain 97 (Refs. 1, 2, and 3). Because of this history, in this and other EPA documents it is variously referred to as *Isaria fumosorosea* Apopka strain 97, *Paecilomyces fumosoroseus* Apopka strain 97, or PFR-97. The pure culture was identified in 1988 and deposited at the American Type Culture Collection (ATCC # 20874) in Manassas, Virginia. Conidia of the fungus attach to, and penetrate, the cuticle of the host insect or mite where they germinate and grow. This leads to pathogenesis and eventual death of the diseased insect or mite host.

*Isaria fumosorosea* Apopka strain 97 is the active ingredient in two microbial pesticide products, which were registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) on April 22, 1998 to Thermo Trilogy:

1. PFR-97™ MUP (EPA Reg. No. 70051-17); and
2. PFR-97™ 20% WDG (EPA Reg. No. 70051-19).

Later, Thermo Trilogy changed its name to Certis USA, LLC; Certis USA, LLC is both the petitioner and the current registrant of the aforementioned products. Since the registration of these pesticide products in 1998, they have been labeled specifically for non-food applications in greenhouses and nurseries to control various insects and mites (e.g., whiteflies, aphids, thrips and spider mites).

After maintaining the registrations with non-food uses for 13 years, Certis USA, LLC has now petitioned EPA to establish an exemption from the requirement of a tolerance for residues of *Isaria fumosorosea* Apopka strain 97 in or on all food commodities. Accordingly, EPA has reassessed the mammalian toxicology data that were submitted prior to 1998 to support the initial applications for *Isaria fumosorosea* Apopka strain 97 pesticide products. The overall conclusions from these data, along with Toxicity Category classifications (as appropriate), are described in Unit III.B., while more in-depth synopses of the study results can be found in the 2011 *Isaria fumosorosea* (formerly *Paecilomyces fumosoroseus*) Apopka strain 97 Biopesticides Registration Action Document (BRAD) and a 2011 data evaluation record provided as references in Unit IX. (Refs.

3 and 4). To learn more about the Toxicity Categories, please see 40 CFR 156.62.

#### B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Isaria fumosorosea* Apopka strain 97 in or on all food commodities have been fulfilled with studies evaluated by EPA as acceptable (*i.e.*, data that are scientifically sound and useful for risk assessment) or supplemental (*i.e.*, data that provide some information useful for risk assessment).

1. *Acute oral toxicity/pathogenicity—rat* (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 431639-01). An acceptable acute oral toxicity/pathogenicity study demonstrated that *Isaria fumosorosea* Apopka strain 97 was not toxic, pathogenic, or infectious to test rodents. An oral dose of  $1.7 \times 10^6$  colony-forming units (cfu)/animal in a conidia spore suspension did not produce mortality or abnormal clinical effects. No signs of fungal contamination were reported for the brain, mesenteric lymph nodes, blood, kidney, spleen, liver, lung or cecum, and no infectivity or pathogenicity was recorded (Toxicity Category IV).

2. *Acute dermal toxicity—rabbit* (Harmonized Guideline 885.3100; MRID No. 432255-01). An acceptable acute dermal toxicity test demonstrated that *Isaria fumosorosea* Apopka strain 97 was not toxic to rabbits when applied dermally. Two grams of test substance applied to the skin of rabbits produced a mild irritation at 72 hours post dosing, but dermal irritation was completely reversed by day 7. There were no deaths and no evidence of systemic toxicity. The acute dermal median lethal dose ( $LD_{50}$ ) (*i.e.*, a statistically derived single dose that can be expected to cause death in 50% of test animals) was greater than 2,000 milligrams per kilogram (mg/kg) (Toxicity Category III).

3. *Acute pulmonary toxicity/pathogenicity—rat* (Harmonized Guideline 885.3150; MRID No. 431398-02). An acceptable acute pulmonary toxicity/pathogenicity study demonstrated that *Isaria fumosorosea* Apopka strain 97 was not toxic, pathogenic, or infectious when a single dose ( $10^6$  conidia spores/animal) was intratracheally administered to rats. No deaths, signs of toxicity or infection, or colonization of the lungs were observed. Total clearance of the fungus was attained by day eight after treatment (Toxicity Category IV).

4. *Acute injection toxicity/pathogenicity (intraperitoneal)—rat* (Harmonized Guideline 885.3200; MRID No. 431398-03). An acceptable acute injection toxicity/pathogenicity study demonstrated that single intraperitoneal doses of *Isaria fumosorosea* Apopka strain 97 suspensions, containing  $1.6 \times 10^7$  conidia spores per animal, had no toxic or pathogenic effects. Moreover, the spores were cleared from the body within two days (Toxicity Category IV).

5. *Acute eye irritation—rabbit* (Harmonized Guideline 870.2400; MRID No. 431462-01). An acceptable acute eye irritation study demonstrated that *Isaria fumosorosea* Apopka strain 97 produced slight eye irritation in rabbits. A dose of 0.1 milliliter of diluted test substance, containing  $\geq 10^7$  cfu, was instilled in the eye, which was examined 1 hour, 24 hours, 48 hours, 72 hours, 4 days, and 7 days after treatment (irritation symptoms reversed by day 4; Toxicity Category IV).

6. *Primary dermal irritation—rabbit* (Harmonized Guideline 870.2500; MRID No. 431462-02). An acceptable primary dermal irritation study demonstrated that *Isaria fumosorosea* Apopka strain 97 was slightly irritating to the skin of rabbits (irritation symptoms reversed by 48 hours; Toxicity Category IV).

7. *Dermal sensitization—guinea pig* (Harmonized Guideline 870.2600; MRID No. 431462-03). A supplemental dermal sensitization study demonstrated that *Isaria fumosorosea* Apopka strain 97 was not a dermal sensitizer to guinea pigs when induced and challenged at  $3.0 \times 10^7 - 5.3 \times 10^9$  cfu.

8. *Hypersensitivity incidents* (Harmonized Guideline 885.3400). No hypersensitivity incidents involving *Isaria fumosorosea* Apopka strain 97 have been reported to EPA over the last 13 years, during which time the associated pesticide products have been both manufactured and used for non-food uses.

#### IV. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### A. Dietary Exposure

Dietary exposure to this microbial pesticide may occur (more likely through food than drinking water), but the lack of acute oral toxicity,

infectivity, and/or pathogenicity, as exhibited in a toxicology test on rats presented in Unit III.B., supports the establishment of a tolerance exemption for residues of *Isaria fumosorosea* Apopka strain 97 in or on all food commodities when used in accordance with good agricultural practices.

1. *Food exposure*. For several reasons described in this unit, exposure to this microbial active ingredient through food is expected to be minimal. When applied in accordance with good agricultural practices, *Isaria fumosorosea* Apopka strain 97, a well-recognized pathogen of various insects and mites, is unlikely to persist on plants (Refs. 3 and 4). Any spores on plants due to pesticide application would presumably decrease over time, similar to other fungal entomopathogens and microbial pest control agents, because of constantly fluctuating environmental factors such as rainfall, ultraviolet radiation, and temperature (Refs. 2, 3, 4, 5, and 6). For instance, using artificial sunlight, Fargues *et al.* (1997) investigated the effects of solar radiation on *Paecilomyces fumosoroseus* Apopka strain 97 conidia and found that both ultraviolet-B (280–320 nm) and ultraviolet-A (320–400 nm) light were most detrimental to the germinability, survival, and infectivity of the conidia (Ref. 6). In addition to certain environmental factors, washing, peeling, and/or other processing of food treated with *Isaria fumosorosea* Apopka strain 97 should further remove, dilute, and/or inactivate pesticidal residues on food (to the extent they exist), particularly in light of the inability of this microbe to survive in water or at temperatures higher than 25°C (Refs. 3, 4, and 5). In the remote likelihood that this microbial pesticide is present in or on food, the acute oral toxicity and pathogenicity data demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any such exposure to *Isaria fumosorosea* Apopka strain 97 (see additional discussion in Unit III.B.).

2. *Drinking water exposure*. The potential for significant transfer of *Isaria fumosorosea* Apopka strain 97 to drinking water is minimal to non-existent, specifically given the three bases elaborated upon in this unit. First, there are no aquatic use sites permitted for pesticide products containing *Isaria fumosoroseus* Apopka strain 97, so exposure to surface water is not anticipated. Second, *Isaria fumosorosea* Apopka strain 97 is not known as an aquatic microorganism; therefore, even if *Isaria fumosorosea* Apopka strain 97 were to inadvertently come into contact with surface or ground waters, it is

unlikely to proliferate in water (Refs. 3 and 4). Finally, if *Isaria fumosorosea* Apopka strain 97 were to be transferred to surface water intended for eventual human consumption (e.g., through spray drift or runoff) and also managed to persist, it would not survive the conditions water is subjected to in wastewater treatment systems or drinking water facilities, including high temperatures, chlorination, pH adjustments and/or filtration (Refs. 7 and 8). In the remote likelihood that this microbial pesticide is present in drinking water, the acute oral toxicity and pathogenicity data demonstrated no toxicity, infectivity and/or pathogenicity is likely to occur with any such exposure to *Isaria fumosorosea* Apopka strain 97 (see additional discussion in Unit III.B.).

#### B. Other Non-Occupational Exposure

Non-occupational dermal and inhalation exposure to *Isaria fumosorosea* Apopka strain 97 is expected to be minimal to non-existent, primarily because it will be applied to agricultural sites not in the proximity of residential areas where facilities with sensitive subpopulations (e.g., schools, nursing homes, and daycares) are most often situated. Even if non-occupational dermal and inhalation exposure were to occur inadvertently (e.g., through spray drift) or due to an eventual expansion of use sites, such exposure would not be of concern since testing indicates that *Isaria fumosorosea* Apopka strain 97 is not toxic, pathogenic, and/or infective (acute dermal toxicity and acute pulmonary toxicity/pathogenicity); is only slightly irritating (primary dermal irritation); and is not a sensitizer (dermal sensitization) (see additional discussion in Unit III.B.). In addition, this active ingredient has been in use for approximately 13 years without reported incidents.

#### V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] \* \* \* residues and other substances that have a common mechanism of toxicity.” These considerations include the possible cumulative effects of such residues on infants and children. EPA has not found *Isaria fumosorosea* Apopka strain 97 to share a common mechanism of toxicity to mammals with any other substances, and *Isaria fumosorosea* Apopka strain 97 does not appear to produce a toxic

metabolite produced by other substances that may be of toxicological concern to human health. For the purposes of this tolerance action, therefore, EPA has assumed that *Isaria fumosorosea* Apopka strain 97 does not have a common mechanism of toxicity with other substances. Following from this, EPA concludes that no cumulative or incremental effects to humans, including infants and children, are anticipated in connection with the use of *Isaria fumosorosea* Apopka strain 97 when it is used in accordance with its label directions and good agricultural practices. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

#### VI. Determination of Safety for United States (U.S.) Population, Infants and Children

In considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., as well as use of *Isaria fumosorosea* Apopka strain 97 as a microbial pesticide for approximately 13 years without reported adverse effects to humans, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Isaria fumosorosea* Apopka strain 97 is used as labeled in accordance with good agricultural practices. As a result, the Agency concludes that no additional

margin of exposure (safety) is necessary to protect infants and children, and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Moreover, based on the same data and EPA analysis as previewed in this unit, the Agency is able to conclude that there is a reasonable certainty that no harm will result to the U. S. population, including infants and children, from aggregate exposure to the residues of *Isaria fumosorosea* Apopka strain 97 when it is used—as labeled and in accordance with good agricultural practices—as an insecticide or miticide. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because, considered collectively, the data and information available on *Isaria fumosorosea* Apopka strain 97 do not demonstrate toxic, pathogenic, and/or infective potential to mammals, including infants and children.

#### VII. Other Considerations

##### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Isaria fumosorosea* Apopka strain 97.

##### C. Revisions to Petitioned-for Tolerance Exemption

In the **Federal Register** of March 10, 2010, EPA announced Certis USA, LLC’s filing of a pesticide petition that

proposed establishing an exemption from the requirement of a tolerance for residues of *Paecilomyces fumosoroseus* Apopka strain 97. Data submitted to EPA, as well as a review of current literature, demonstrate that the taxonomy of the microorganism has changed. *Paecilomyces fumosoroseus* Apopka strain 97 is now classified as *Isaria fumosorosea* Apopka strain 97 (Refs. 1, 2, and 3).

### VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Isaria fumosorosea* Apopka strain 97. Therefore, an exemption from the requirement of a tolerance is established for residues of *Isaria fumosorosea* (formerly *Paecilomyces fumosoroseus*) Apopka strain 97 in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices.

### IX. References

1. Agricultural Research Service Collection of Entomopathogenic Fungal (ARSEF) Cultures. January 24, 2011. *Isaria*, plus *Paecilomyces* and *Evlachovea* USDA-ARS Biological Integrated Pest Management Research, Robert W. Holley Center for Agriculture and Health. 538 Tower Road, Ithaca, New York 14853-2901.
2. Zimmermann G. 2008. The entomopathogenic fungi *Isaria farinosa* (formerly *Paecilomyces farinosus*) and the *Isaria fumosorosea* species complex (formerly *Paecilomyces fumosoroseus*): biology, ecology and use in biological control. *Biocontrol Science and Technology* 18:865-901.
3. U.S. EPA. 2011. *Isaria fumosorosea* (formerly *Paecilomyces fumosoroseus*) Apopka strain 97 Draft Biopesticides Registration Action Document (BRAD) dated August 10, 2011 (available as "Supporting & Related Material" within docket ID number EPA-HQ-OPP-2010-0088 at <http://www.regulations.gov>).
4. U.S. EPA. 2011. Request for Exemption from the Requirement of a Tolerance. Data evaluation record prepared by I. Barsoum, Ph.D. (available as "Supporting & Related Material" within docket ID number EPA-HQ-OPP-2010-0088 at <http://www.regulations.gov>).
5. U.S. EPA. 1996. Microbial Pesticide Test Guidelines—Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from [http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series885.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm).
6. Fargues J, Rougier M, Goujet R, Smits N, Coustere C, Itier B. 1997. Inactivation of Conidia of *Paecilomyces fumosoroseus* by Near-Ultraviolet (UVB and UVA) and Visible Radiation. *Journal of Invertebrate Pathology* 69:70-78.
7. U.S. EPA. 2004. Primer for Municipal Wastewater Treatment Systems. EPA 832-R-04-001. Available from <http://www.epa.gov/npdes/pubs/primer.pdf>.
8. Centers for Disease Control and Prevention. 2009. Drinking Water—Water Treatment. Available from [http://www.cdc.gov/healthywater/drinking/public/water\\_treatment.html](http://www.cdc.gov/healthywater/drinking/public/water_treatment.html).

### X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

### XI. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

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

Dated: September 20, 2011.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

### PART 180—[AMENDED]

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

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

■ 2. Section 180.1306 is added to subpart D to read as follows:

**§ 180.1306 *Isaria fumosorosea* (formerly *Paecilomyces fumosoroseus*) Apopka strain 97; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Isaria fumosorosea* (formerly *Paecilomyces fumosoroseus*) Apopka strain 97 in or on all food commodities

when applied as an insecticide or miticide and used in accordance with good agricultural practices.

[FR Doc. 2011-24990 Filed 9-27-11; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-0849; FRL-8889-1]

#### Fluazifop-P-butyl; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes and increases tolerances for residues of fluazifop-P-butyl in or on cotton, gin byproducts; cotton, refined oil; and cotton, undelinted seed. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 28, 2011. Objections and requests for hearings must be received on or before November 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0849. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone*

*number:* (703) 305-1243; *e-mail address:* [montague.kathryn@epa.gov](mailto:montague.kathryn@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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

###### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0849 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk

as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0849, 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 Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### **II. Summary of Petitioned-for Tolerance**

In the **Federal Register** of December 15, 2010 (75 FR 78240) (FRL-8853-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7768) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on cotton, undelinted seed at 0.9 ppm; and cotton, gin byproducts at 0.8 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition EPA has made changes to the requested tolerances. First, EPA is raising the proposed cotton, gin byproducts tolerance from 0.8 ppm to 1.5 ppm; second, raising the established cotton, refined oil tolerance from 0.2 ppm to 1.3 ppm; and finally,