not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, determining that the Baltimore Area did not attain the 1997 8-hour ozone NAAQS by its June 15, 2011 attainment date and reclassifying the Baltimore Area by operation of law to be a serious 8-hour ozone nonattainment area for the 1997 8-hour ozone standard, may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: January 24, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

40 CFR part 81 is amended as follows:

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

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

■ 2. In § 81.321 the table entitled ''Maryland—Ozone (8-Hour Standard)'' is amended by revising the entries for Baltimore, MD, revising footnote 4, and adding a new footnote 5 at the end of the table to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
Baltimore, MD:				
Anne Arundel County		Nonattainment	(5)	Subpart 2/Serious.[4]
City of Baltimore		Nonattainment	(5)	Subpart 2/Serious.[4]
Baltimore County		Nonattainment	(5)	Subpart 2/Serious.[4]
Carroll County		Nonattainment	(5)	Subpart 2/Serious.[4]
Harford County		Nonattainment	(5)	Subpart 2/Serious.[4]
Howard County		Nonattainment	(5)	Subpart 2/Serious.[4]
* * *	*	* *	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
* * * * * * *
[4] Attainment date is June 15, 2013.
[5] Effective March 2, 2012.

* * * * *

[FR Doc. 2012–2218 Filed 1–31–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0053; FRL–9333–5]

Trichoderma virens strain G–41; 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 *Trichoderma virens* strain G–41 in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices. BioWorks, Inc., 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 *Trichoderma virens* strain G–41 under the FFDCA.

DATES: This regulation is effective February 1, 2012. Objections and requests for hearings must be received on or before April 2, 2012, 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–2010–0053. 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: Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8920; email address: *kausch.jeannine@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*. 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–2010–0053 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 April 2, 2012. 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–2010–0053, 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 9F7618) by Technology Sciences Group, Inc., on behalf of BioWorks, Inc., 100 Rawson Rd., Suite 205, Victor, NY 14564. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Trichoderma virens* strain G–41. This notice referenced a summary of the petition prepared by the petitioner, BioWorks, Inc., which is available in the docket via *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 Trichoderma virens strain G–41

Trichoderma species are common soil hyphomycetes found in all climate zones ranging from Antarctica to the tropics (Ref. 1). Since 1989, several *Trichoderma* species (*e.g., Trichoderma polysporum, Trichoderma viride,* and *Trichoderma harzianum*) have been used in pesticide products—notably without reported incidents—to control various fungal plant pathogens such as *Pythium* species, *Phytophthora* species, *Heterobasidion annosum,* and *Chondrostereum purpureum*. In conjunction with the registration of some of these pesticide products, EPA established the following exemptions from the requirement of a tolerance:

1. *Gliocladium virens* strain GL–21 (now recognized as *Trichoderma virens* strain GL–21) (40 CFR 180.1100)—see the **Federal Register** of September 20, 1995 (60 FR 48657) (FRL–4974–1) and October 5, 1995 (60 FR 52248) (FRL–4974–1).

2. *Trichoderma harzianum* Rifai strain T–22 (40 CFR 180.1102)—see the **Federal Register** of April 7, 1999 (64 FR 16856) (FRL–6070–3).

3. *Trichoderma harzianum* strain T–39 (40 CFR 180.1201)—see the **Federal Register** of June 22, 2000 (65 FR 38753) (FRL–6383–7).

4. *Trichoderma gamsii* strain ICC 080 (40 CFR 180.1293)—see the **Federal Register** of February 25, 2010 (75 FR 8504) (FRL–8799–4).

5. *Trichoderma asperellum* strain ICC 012 (40 CFR 180.1294)—see the **Federal Register** of March 3, 2010 (75 FR 9527) (FRL–8800–9).

6. *Trichoderma hamatum* isolate 382 (40 CFR 180.1298)—see the **Federal Register** of July 23, 2010 (75 FR 43072) (FRL–8835–6).

Specifically, *Trichoderma virens,* including strain G–41, is a naturally occurring fungus that is native to the United States and is widely distributed throughout the world, inhabiting forest, agricultural, and orchard soils, as well as plant litter (Ref. 2). *Trichoderma virens* strain G–41 was isolated from soil samples taken from *Aphanomyces*-suppressive fields in Livingston County, New York. Much like other *Trichoderma* species, *Trichoderma virens* strain G–41 inhibits or kills certain plant-pathogenic fungi (*e.g., Rhizoctonia* species and *Fusarium* species) through competition for food and space, mycoparasitism, antibiosis, and induction of plant defense responses (Refs. 1, 2, 3, and 4).

B. Microbial Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Trichoderma virens* strain G–41 in or on all food commodities have been fulfilled with data submitted or cited by the petitioner.

The petitioner conducted several acute toxicological tests with *Trichoderma virens* strain G–41 or a substance containing *Trichoderma virens* strain G–41. The acute oral toxicity/pathogenicity test evaluated the potential toxicity and pathogenicity of the active ingredient should dietary exposure occur. The acute dermal toxicity and primary dermal irritation tests evaluated the potential for a substance containing the active ingredient to cause toxicity or irritation should skin exposure occur. The acute inhalation toxicity test evaluated the potential for a substance containing the active ingredient to cause toxicity should inhalation exposure occur. The results of these studies revealed little to no toxicity or irritation attributed to *Trichoderma virens* strain G–41, and all these studies received a Toxicity Category IV classification (see 40 CFR 156.62). Moreover, when the skin was bypassed as a protective barrier during an acute injection toxicity/pathogenicity test, *Trichoderma virens* strain G–41 was not found to be toxic, infective, and/or pathogenic via the intraperitoneal route of exposure. Finally, the petitioner has reported that no hypersensitivity incidents occurred during development and testing of this fungus.

With its petition, BioWorks, Inc., also cited to toxicological data done with a similar, previously registered strain of *Trichoderma virens,* GL–21 (Refs. 1, 3, 4, and 5). Although GL–21 and G–41 are not identical, the two strains share many characteristics typical of *Trichoderma virens* (*e.g.,* particular morphological features, production of certain enzymes involved in mycoparasitism, and weak growth at the temperature of the human body (37°C)), and thus are considered to be functionally similar (Ref. 4). Based on these similarities, EPA concluded that data on *Trichoderma virens* strain GL–21 would be representative of the toxicological nature of *Trichoderma virens* strain G–41 (Ref. 6). These additional data on *Trichoderma virens* strain GL–21 confirmed (*i.e.,* no toxicity observed) and contributed (*i.e.,* no pathogenicity anticipated) to the findings of the acute oral toxicity/pathogenicity study mentioned above and fulfilled the acute pulmonary toxicity/pathogenicity data requirement for *Trichoderma virens* strain G–41.

The overall conclusions from all toxicological information submitted and cited by the petitioner are briefly described below, while more in-depth synopses of some study results can be found in the associated Biopesticides Registration Action Document provided as a reference in Unit IX. (Ref. 5).

1. *Acute oral toxicity/pathogenicity—rat (Harmonized Guideline 885.3050; Master Record Identification Numbers (MRID Nos.) 483438–01 and 407198–04).* The petitioner submitted or cited to data resulting from two separate acute oral toxicity/pathogenicity tests, one conducted with *Trichoderma virens* strain G–41 and the other conducted with *Trichoderma virens* strain GL–21. The results of the first study demonstrated that *Trichoderma virens* strain G–41 was not toxic to rats when administered by oral gavage in a single dose of 1.5×10^8 colony-forming units (cfu)/animal. Although a pattern of clearance was established, the sensitivity of detection indicated low recovery of *Trichoderma virens* strain G–41 from tissues and fluids (*i.e.,* 0.5–9%). Thus, pathogenicity was not unequivocally assessed. The second study demonstrated that *Trichoderma virens* strain GL–21, a strain that is functionally similar to *Trichoderma virens* strain G–41, was not toxic to, infective in, or pathogenic for rats when given a single oral dose of 10^8 cfu/animal and adequately addressed the pathogenicity endpoint that could not be fully assessed in the first study. The weight-of-evidence from the results of these two studies indicates that *Trichoderma virens* strain G–41 is not acutely toxic and/or pathogenic through the oral route of exposure.

2. *Acute pulmonary toxicity/pathogenicity—rat (Harmonized Guideline 885.3150; MRID Nos. 407198–05 and 408640–02).* An acute pulmonary toxicity/pathogenicity study demonstrated that *Trichoderma virens* strain GL–21, a functionally similar strain to *Trichoderma virens* strain G–41, was not toxic to, infective in, or pathogenic for rats when given a single intratracheal dose of 10^8 cfu/animal. Given the functional similarity of these two strains, EPA concludes that *Trichoderma virens* strain G–41 is also not likely to be toxic, infective, and/or pathogenic through the inhalation route. To further support this conclusion, an acceptable acute inhalation toxicity study (MRID No. 478650–04) resulted in no mortalities and only minor signs of toxicity (activity decrease; piloerection) that resolved by day 2 after rats were exposed to a test substance containing *Trichoderma virens* strain G–41 at 5.14 milligrams per liter for 4 hours.

3. *Acute injection toxicity/pathogenicity (intraperitoneal)—rat (Harmonized Guideline 885.3200; MRID Nos. 478651–02 and 482368–01).* An acceptable acute injection toxicity/pathogenicity study demonstrated that *Trichoderma virens* strain G–41 was not toxic to rats when administered intraperitoneally in a single dose of 10^7 cfu/animal. While clearance was not directly assessed in this study, the lack of clinical findings upon necropsy, in combination with the lack of signs of toxicity and mortality in the animals during the observation period, strongly suggests that *Trichoderma virens* strain G–41 is also not pathogenic by intraperitoneal injection.

4. *Hypersensitivity incidents (Harmonized Guideline 885.3400; MRID No. 482526–01).* The petitioner reported that no hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals, occurred during research, development, or testing of *Trichoderma virens* strain G–41.

5. *Acute dermal toxicity—rat (Harmonized Guideline 870.1200; MRID No. 478650–03).* An acceptable acute dermal toxicity study demonstrated that a test substance containing *Trichoderma virens* strain G–41 was not toxic to rats when dosed at 5,050 milligrams per kilogram (mg/kg) for 24 hours. The dermal median lethal dose (LD_{50}), which is a statistically derived single dose that can be expected to cause death in 50% of test animals, was greater than 5,050 mg/kg for male and female rats combined (Toxicity Category IV).

6. *Primary dermal irritation—rabbit (Harmonized Guideline 870.2500; MRID No. 478650–06).* An acceptable primary dermal irritation study demonstrated that a test substance containing *Trichoderma virens* strain G–41 was non-irritating to the skin of rabbits (Toxicity Category IV).

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

1. *Food exposure.* All proposed *Trichoderma virens* strain G–41 applications are soil directed or soil incorporated because of the targeted soilborne pests (*e.g., Rhizoctonia* species and *Fusarium* species). Based on calculations made in EPA's environmental risk assessment for *Trichoderma virens* strain G–41 (Ref. 7), these applications are not expected to significantly increase the populations of this fungus above natural levels in the soil. No reports were available in the literature describing natural concentrations of *Trichoderma virens;* however, *Trichoderma* species have been reported in various types of soils at concentrations of 10^4 to 10^6 colony-forming units per gram (cfu/g) (Refs. 8 and 9). Based on the maximum application rate of the proposed end-use pesticide products containing *Trichoderma virens* strain G–41, the estimated amount of *Trichoderma virens* applied to the soil surface is approximately 6.7×10^3 colony-forming units per square centimeter (cfu/cm^2). Assuming a bulk density of 1 to 2 grams per cubic centimeter (g/cm^3), the maximum application rate will not result in soil concentrations that are substantially greater than concentrations of *Trichoderma virens* naturally found in the soil, and overall increased exposure to *Trichoderma virens* in the terrestrial environment, including on above-ground plant parts such as food commodities, is not expected. Work by Jackson *et al.* (1991) supports this conclusion given that, after *Trichoderma virens* and three other *Trichoderma* isolates were incorporated into soil, fungal numbers either transiently increased, remained stable, or declined (Ref. 10). Should this microbial pesticide be present on food, the acute oral toxicity and pathogenicity data available for *Trichoderma virens* strain G–41 and functionally similar *Trichoderma virens* strain GL–21 demonstrated that no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Trichoderma virens* strain G–41 resulting from application in accordance with good agricultural practices (see additional discussion in Unit III.B.).

2. *Drinking water exposure.* Exposure to residues of *Trichoderma virens* strain G–41 in consumed drinking water is unlikely. The proposed use patterns for *Trichoderma virens* strain G–41 are soil directed and soil incorporated, thereby limiting contact with surface water by drift and runoff. Furthermore, ground water is not expected to have significant exposure to *Trichoderma virens* strain G–41 since, like other *Trichoderma* species, this fungus would likely be filtered out by the particulate nature of many soil types, and be concentrated in upper soil horizons (Refs. 11 and 12) near plant roots (Ref. 13). If *Trichoderma virens* strain G–41 were to be transferred to surface or ground waters (*e.g.,* through spray drift or runoff) that are intended for eventual human consumption and directed to wastewater treatment systems or drinking water facilities, it likely would not survive the conditions water is subjected to in such systems or facilities, including chlorination, pH adjustments, filtration, and occasionally high temperatures (Refs. 14 and 15). For instance, *Trichoderma virens* strain G–41 does not grow well at 37 °C (Refs. 3 and 16), and test data has shown it to be unstable at elevated temperatures; therefore, any heat treatment applied to water containing *Trichoderma virens* strain G–41 would probably render the fungus non-viable. In the remote likelihood that this microbial pesticide is present in drinking water (*e.g.,* water not subject to treatment systems or facilities), the acute oral toxicity and pathogenicity data available for *Trichoderma virens* strain G–41 and functionally similar *Trichoderma virens* strain GL–21 demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Trichoderma virens* strain G–41 resulting from application in accordance with good agricultural practices (see additional discussion in Unit III.B.).

B. Other Non-Occupational Exposure

Given *Trichoderma virens'* natural occurrence in soil (Ref. 2), non-occupational exposure to the fungus is likely already occurring. Even with the proposed pesticide applications of *Trichoderma virens* strain G–41, it is not likely that there will be a significant increase in these exposures due to the relative stability of typical background levels in the soil (see calculations and information presented in the food exposure section above). If significant non-occupational exposures were to occur, such exposures would not exceed EPA's level of concern in light of test results that indicated *Trichoderma virens* strain G–41 is not toxic (acute pulmonary toxicity/pathogenicity, acute dermal toxicity, and acute inhalation toxicity), is non-irritating (primary dermal irritation), and is not pathogenic or infective (acute pulmonary toxicity/pathogenicity) (see additional discussion in Unit III.B.).

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.''

There are several *Trichoderma* species used as active ingredients in registered pesticide products. While these different microbial pest control agents may produce similar metabolites, the likelihood of adverse cumulative effects via a common mechanism of toxicity is not anticipated, based on the lack of toxicity/pathogenicity potential of the active ingredients used on food and/or labeled for residential uses (see Unit III.B., as well as Refs. 17, 18, 19, and 20). 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 Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, 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/information discussed in Unit III.B., as well as use of *Trichoderma* pesticide products since 1989 without reported adverse effects to humans, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Trichoderma virens* strain G–41 is used as labeled in accordance with good agricultural practices. As a result, EPA 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 presented directly above, 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 *Trichoderma virens* strain G–41 when it is used as labeled and in accordance with good agricultural practices as a fungicide. 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 *Trichoderma virens* strain G–41, as well as data available on functionally similar *Trichoderma virens* strain GL–21, 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 for the reasons stated above and because 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 United Nations 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 *Trichoderma virens* strain G–41.

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 *Trichoderma virens* strain G–41. Therefore, an exemption from the requirement of a tolerance is established for residues of *Trichoderma virens* strain G–41 in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

IX. References

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5. U.S. EPA. 2011b. Draft *Trichoderma virens* strain G–41 Biopesticides Registration Action Document dated December 8, 2011 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0057).
6. U.S. EPA and PMRA. 2011b. Data Evaluation Record for Acute Pulmonary Infectivity and Toxicity—Waiver Request. Prepared by L. Heikkila and I. Barsoum, Ph.D. (dated December 6, 2011).
7. U.S. EPA. 2011c. Environmental risk assessment for the FIFRA Section 3 registration of *Trichoderma virens* strain G–41 (PC Code 176604; EPA File Symbols 68539–I, –O, –RN). Memorandum from S. Borges to J. Kausch dated November 14, 2011 (available as ''Supporting & Related Material'' within docket ID number EPA–HQ–OPP–2010–0057).
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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 United States Senate, the United States 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: January 20, 2012.

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 180.1310 is added to subpart D to read as follows:

§ 180.1310 Trichoderma virens strain G–41; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Trichoderma virens* strain G–41, in or on all food commodities, when applied as a fungicide and used in accordance with good agricultural practices.

[FR Doc. 2012–2216 Filed 1–31–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 476

[CMS–1518–CN4]

RIN 0938–AQ24

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of final rule.

SUMMARY: This document corrects technical errors that occurred in the Addendum of the final rule entitled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates'' which appeared in the August 18, 2011 **Federal Register**.

DATES: *Effective Date:* This document is effective January 31, 2012.

Applicability Date: The corrections noted in this document and posted on the CMS Web site are applicable to hospital payments and discharges on or after October 1, 2011.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–4487.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2011–19719 of August 18, 2011 (76 FR 51476), the final rule entitled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2012 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2012 Rates'' (hereinafter referred to as the FY 2012 IPPS/FY 2012 LTCH PPS final rule) there were a number of technical errors in the tables included in the Addendum of the final rule which are, posted on the CMS Web site. In section II. of this correcting document, we describe these errors and note the tables that will include the corrections. We have already made changes to our rates, updated PRICER