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).

XII. 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: February 19, 2010.

Meredith F. Laws,

Acting Director, Registration Division, 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. In §180.930, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* *	* * *	
1,2,3-Propanetriol, homopolymer diisooctadecanoate (CAS Reg. No. 63705–03–3)		Emulsifier
* *	* * *	

[FR Doc. 2010–3859 Filed 2–24–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0749; FRL–8799–4]

Trichoderma gamsii strain ICC 080; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Trichoderma gamsii* strain ICC 080 on all food/feed commodities when applied preharvest in accordance with good agricultural practices. Isagro, S.p.A. 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 gamsii* strain ICC 080.

DATES: This regulation is effective February 25, 2010. Objections and requests for hearings must be received on or before April 26, 2010, 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–2008–0749. 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: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; e-mail address: *cerrelli.susanne@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 Access Electronic Copies of this Document?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. 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–2008–0749 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 April 26, 2010.

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–2008–0749, 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. Background and Statutory Findings

In the **Federal Register** of November 12, 2008 (73 FR 66897) (FRL–8368–8), 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 8F7327) by Isagro, S.p.A., Via Caldera 21, fabbricato D, la 3, 20153 Milano, Italy. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Trichoderma gamsii* strain ICC 080 (originally classified as *Trichoderma viride).*

The docket (EPA–HQ–OPP–2008–0749) included a summary of the petition prepared by the petitioner Isagro, S.p.A.. An anonymous American citizen commented that only zero residue should be allowed and expressed concern about toxic chemicals found in the bodies of Americans. Pursuant to its authority under Federal Insecticide Fungicide, and Rodenticide Act (FIFRA), the Agency conducted a rigorous assessment of *Trichoderma gamsii* strain ICC 080 and concluded that it is not expected to cause any unreasonable adverse effects to human health or the environment. The Agency is establishing an exemption from the requirement of a tolerance for this active ingredient, as neither toxicity nor pathogenicity were observed for this active ingredient in submitted laboratory studies.

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 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 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 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.

Trichoderma gamsii strain ICC 080 was isolated from a suppressive soil in Sardinia, Italy. *Trichoderma gamsii* strain ICC 080 is used for control of many soil borne fungal plant pathogens [i.e., *Pythium* species (spp.), *Phytophthora* spp., *Sclerotinia* spp., *Sclerotium* spp., *Thielaviopsis basicola*, *Rhizoctonia* spp., *Verticillium* spp]. *Trichoderma gamsii* strain ICC 080 acts as a pathogen antagonist, colonizing in soil and roots to compete with plant pathogenic fungi for space and nutrients. Moreover, *Trichoderma gamsii* strain ICC 080 also attacks the cell walls of pathogens with enzymes.

The Agency has reviewed toxicological data on *Trichoderma gamsii* strain ICC 080 that was submitted by the manufacturer, Isagro, S.p.A. in support of its petition for an exemption from the requirement of a tolerance for residues of *Trichoderma gamsii* strain ICC 080.

EPA review of these studies indicated that the active ingredient was not toxic to test animals when administered via the oral, intraperitoneal or pulmonary routes of exposure. The active ingredient was not infective or pathogenic to test animals when administered via the pulmonary route. This pulmonary clearance is enough evidence to demonstrate no infectivity. No reports of hypersensitivity have been recorded from personnel working with this organism. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of *Trichoderma gamsii* strain ICC 080, including all anticipated dietary exposures and all other exposures for which there is reliable information. Thus, under the standard in FFDCA section 408(c)(2), an exemption from the requirement for a tolerance is appropriate.

Studies on the active ingredient include the following.

An acceptable acute oral toxicity study (MRID #47345801) was performed on rats given a single oral dose of *Trichoderma gamsii* (formerly known as *Trichoderma viride)* strain ICC 080 of (7.5×10^8 CFU/g) in 0.9% NaCl solution at a dose of 2,000 milligrams/kilogram (mg/kg) of body weight in a limit test. The animals were observed for a period

of up to 14 days. The oral LD_{50} for males, females, and the combined test animals were: Males >2,000 mg/kg of body weight, females >2,000 mg/kg of body weight, combined >2,000 mg/kg of body weight. No mortalities occurred during the study. Based on the results of this study, *Trichoderma gamsii* strain ICC 080 was found to be of low acute oral toxicity. There were no treatment related clinical signs, changes in body weight or pathological findings at necropsy.

An acceptable acute intraperitoneal injection toxicity (MRID #47345802) was submitted, in which groups of fasted, 41–48 days old rats (3/sex) were injected with *Trichoderma gamsii* strain ICC 080 (at 7.5 x 10^8 CFU/g) in 0.9% NaCl solution at a dose of 1 x 10^7 CFU/g. Animals were then observed for up to 21 days. Control animals (2/sex) were injected with 0.9% NaCl solution only. *Trichoderma gamsii* strain ICC 080 is not toxic based on the results of this study. There were no treatment - related necropsy findings or changes in body weight. All of the animals treated with the test material experienced slightly reduced mobility, slight ataxia, slightly reduced muscle tone, slight dyspnea, mydriasis, and writhing, observed 60 minutes after administration. All of these clinical signs were completely resolved within 24 hours.

Acceptable acute pulmonary toxicity/pathogenicity studies (MRID #47345803, 47345804) were submitted, in which groups of fasted 43–56 days old rats (31/sex) were exposed by the intratracheal route to *Trichoderma gamsii* strain ICC 080 at a dose of 2.5 x 10^6 CFU/animal. Animals were observed for up to 22 days. Rats in the control group were administered the vehicle, 0.1% solution of Tween 20 in *aqua ad iniectabilia* (water for injection) only. Rats in the reference groups were administered inactivated test item. Samples of feces, lungs, lymph nodes, kidneys, brain, liver, spleen, and blood were taken for microbial enumeration in those tissues. None of the administered *Trichoderma gamsii* conidia from lung tissue of the animals appeared in other organ tissue. Conidia could not be detected in blood samples at any time during the study. Conidia were detected in the feces up to 21 days post administration. Conidia density in the lung tissue decreased to 0 within 21 days post administration. This shows a pattern of clearance and lack of infectivity of *Trichoderma gamsii* strain ICC 080. The recorded pulmonary LD_{50} was greater than 2.5 x 10^6 CFU/animal in males, females and in the combined group of test animals. No mortality occurred. Based upon these results, *Trichoderma gamsii* strain ICC 080 is of low toxicity, and *Trichoderma gamsii* was not infective or pathogenic in the rat. There were no treatment related clinical signs, changes in body weight, or pathological changes observed at necropsy.

IV. Aggregate Exposures

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 the microbial pesticide is likely to occur. However the lack of acute oral toxicity, infectivity, and pathogenicity support the establishment of an exemption from the requirement of a tolerance for *Trichoderma gamsii* strain ICC 080.

1. *Food*. Dietary exposure to the microbe is expected to be minimal. The product is typically applied to soil and sometimes may be applied when the crops are growing in the field, resulting in residues on the crops. The Agency expects residues on food to be minimal because of the typical way in which this pesticide will be applied to soils. Moreover, *Trichoderma* lives in soils and is unlikely to live on the plants because any spores that do end up on the plant due to application will likely decrease over time due to weathering, desiccation and ultraviolet radiation which can kill even quiescent forms of the fungus. In the remote likelihood that the applied fungus can grow on edible portions of the treated crop, there is no hazard present in these residues due to the results of testing which show no toxicity or pathogenicity in treated animals when dosed with the fungus at orders of magnitude above any expected exposure to the microbial pesticide.

2. *Drinking water exposure*. Drinking water exposure is expected to be negligible because this *Trichoderma gamsii* is not applied to water, nor is it expected to proliferate in aquatic environments because *Trichoderma gamsii* lives in soil. Moreover, the Agency believes that *Trichoderma* within the soil will not likely percolate into water because of the large size of the fungal spores and the fact that they adhere to soil particles. Even if oral exposure should occur through drinking water, the Agency concludes that there is a reasonable certainty that no harm will result from the exposure to the residues of *Trichoderma gamsii* in all the anticipated drinking water exposures because of the lack of acute oral toxicity/pathogenicity to mammals as previously described.

B. Other Non-Occupational Exposure

Trichoderma gamsii strain ICC 080 is a naturally occurring microbe and is ubiquitous in the environment. *Trichoderma gamsii* strain ICC 080 will be applied to substrate mixes, ornamental plants, agricultural fields, turf, and various plants grown in greenhouses. Although some applications to turf or ornamental plants may be in residential areas, non-dietary exposure would be expected to be below the Agency's level of concern because of its low toxicity classification, and because the lab results indicate *Trichoderma gamsii* strain ICC 080 is not pathogenic to mammals.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Trichoderma gamsii* strain ICC 080 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. Based on tests in mammalian systems, *Trichoderma gamsii* strain ICC 080 does not appear to be toxic to humans via dietary and pulmonary exposure. Therefore, the requirement to consider cumulative effects does not apply.

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

FFDCA section 408(b)(2)(C) as amended by the FQPA of 1996, 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) also provides that EPA shall apply an additional tenfold 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 unless EPA determines that a different margin of safety will be safe for infants and children.

Based on the acute toxicity information discussed in this Unit, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and

children, to residues of *Trichoderma gamsii* strain ICC 080. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Trichoderma gamsii* strain ICC 080 demonstrate a low toxicity/pathogenicity potential. *Trichoderma gamsii* strain ICC 080 is not a human pathogen and has not been implicated in human disease. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply.

VII. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that *Trichoderma gamsii* strain ICC 080 has an effect on the endocrine system. The submitted acute pulmonary toxicity/pathogenicity study in rodents indicated that following pulmonary exposure, the immune system is still intact and able to process and clear the active ingredient. *Trichoderma gamsii* strain ICC 080 is a ubiquitous organism in the environment and there have been no reports of the organism affecting endocrine systems. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects and it is practically non-toxic to mammals.

B. Analytical Methods

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Because of the lack of toxicity, pathogenicity, and infectivity of this organism and the fact that its use as a pesticide is indistinguishable from what naturally occurs in the environment, the Agency has concluded that an analytical method is not required for enforcement purposes for *Trichoderma gamsii* strain ICC 080.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for *Trichoderma gamsii*.

VIII. Conclusions

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of the *Trichoderma gamsii* strain ICC 080 in or on all food and feed commodities. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed in Unit III., no toxicity or pathogenicity to mammals has been observed in test animals.

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 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 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 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) (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: February 4, 2010.

Steven Bradbury,

Acting Director, Office of Pesticide Program.

■ 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 180.1293 is added to subpart D to read as follows:

§ 180.1293 Trichoderma gamsii strain ICC 080; exemption from the requirement of a tolerance.

Trichoderma gamsii strain ICC 080 is exempted from the requirement of a tolerance in or on all food and feed commodities when applied preharvest and used in accordance with good agricultural practices.

[FR Doc. 2010–3732 Filed 2–24–10; 8:45 am]

BILLING CODE 6560–50–S