Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 28, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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 may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon Monoxide, Hydrocarbons, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

Dated: September 19, 2005.

Lawrence E. Starfield,

Acting Regional Administrator, Region 6.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart SS—Texas

■ 2. The table in § 52.2270(c) entitled ''EPA Approved Regulations in the Texas SIP'' is amended under chapter 106, subchapter A, by removing the entry for section 106.5, ''Public Notice.''

[FR Doc. 05–19358 Filed 9–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0244; FRL–773-5]

Muscodor albus QST 20799 and the Volatiles Produced on Rehydration; 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 *Muscodor albus* (*M. albus*) QST 20799 and the volatiles produced on its rehydration on all food commodities when applied or used for all agricultural applications, including seed, propagule and post harvest treatments. This action is in response to a pesticide petition submitted to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *M. albus* QST 20799 and the volatiles produced on its rehydration.

DATES: This regulation is effective September 28, 2005. Objections and requests for hearings must be received on or before November 28, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0244. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–8097; e-mail address: *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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of April 7, 2004 (69 FR 18370–18375) (FRL–734-4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6745) by AgraQuest, Inc. (EPA Company No. 69592), 1530 Drew Avenue, Davis, CA 95616. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *M. albus* QST 20799. This notice included a summary of the petition prepared by the petitioner AgraQuest, Inc. There were no comments received in response to the notice of filing.

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

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

III. Toxicological Profile

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

M. albus QST 20799, a fungus, was originally isolated from the bark of a cinnamon tree in Honduras. It was imported into the United States with appropriate permits issued by the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS). It grows as a white sterile mycelium and does not produce asexual or sexual spores or other reproductive structures such as chlamydospores or sclerotia. When hydrated, *M. albus* QST 20799 produces a number of volatiles, mainly alcohols, acids, and esters, that are claimed to inhibit and kill plant pathogenic organisms that cause diseases such as root rot, damping off, and wilt.

The registrant is seeking to register a microbial pesticide in which the Manufacturing Use Product (MP) contains *M. albus* QST 20799 as the active ingredient. End-use Products (EPs) will be formulated from the MP by addition of inerts. The EPs, which will be registered concurrently with the MP, will be shipped as dried products. The EPs are proposed for use as a seed and propagule or soil treatment to control root diseases in greenhouse and field crops, as well as for control of post-harvest decay in fresh fruits and vegetables and cut flowers.

1. *Acute oral toxicity - rats (OPPTS 870.1100).* Three female and three male rats were dosed with a single dose of *M. albus* QST 20799 in distilled water at 5 grams/kilogram body weight (g/kg bw). The rodents were observed for 14 days (Master Record Identification Number (MRID) 46106401). No mortality was observed, all animals gained weight, and there were no clinical signs, or abnormal findings at necropsy. The oral LD_{50} for males, females, and combined was greater than 5,000 milligram/kilogram (mg/kg) (Biopesticides and Pollution Prevention Division (BPPD) Data Evaluation Record (DER) dated April 28, 2004, hereinafter referred to as ''BPPD DER 04/28/04'').

M. albus QST 20799 produces volatiles when it is rehydrated. Generally, an acute oral test is not required when the test material is volatile. Nevertheless, the Agency considered the patterns of use, and the nature of the volatiles produced under these conditions. *M. albus* QST 20799 and its volatiles are not expected to be present in or on treated food commodities as a result of these proposed uses. The pesticide is incorporated into soil prior to planting, is not viable in soil once its food source is exhausted, and is not in direct contact with treated seed and propagule, or food or feed commodities treated post harvest. It is not a systemic pesticide and, thus, will not be translocated in seed and propagule, or other treated food and feed commodities. The volatiles are well-known fragrances and flavors of food and beverages, are short-lived, and are not expected to remain on treated food or feed commodities. Thus, acute oral tests, as conducted with the test material, *M. albus* QST 20799, are sufficient to evaluate in support of the petition of an exemption from tolerance.

2. *Acute oral toxicity/pathogenicity - rat study (Guideline 152–30; OPPTS 885.3050).* Twenty-two male and 22 female rats were treated by oral gavage for 22 days with a white aqueous suspension of *M. albus* QST 20799 (mean dry weight percentage: 1.82%) (MRID 46039404). Clinical signs were observed and body weights recorded

twice per day. The sacrificed rats were subjected to necropsy. No mortality was observed, all animals gained weight, and there were no clinical signs, or abnormal findings at necropsy. *M. albus* QST 20799 was not detected in kidney, brain, liver, heart, lungs, spleen, mesenteric lymph nodes, blood samples, or intestinal contents. *M. albus* QST 20799 does not appear to be toxic, infective, and/or pathogenic to rats, when dosed at 10^8 cfu (0.1 g total dry weight)/animal. The study results were considered acceptable and the active ingredient is considered in Toxicity Category IV for acute oral effects (BPPD DER 04/28/04).

3. *Acute pulmonary toxicity/ pathogenicity - rat (OPPTS 885.3150).* Twenty-nine female and 29 male rats received, by intratracheal instillation, a dose of 3 milliliters (ml) (1.9×10^3 to 2.4×10^3 cfu) of an aqueous suspension of *M. albus* QST 20799. They were observed for 22 days post treatment (MRID 46039406). However, two rats died early in the experiment likely due to the dosing procedure. Another rat was sacrificed at 4 days due to the severity of the clinical signs. Surviving rats were sacrificed, then subjected to necropsy. Recovery of viable test organism from blood, organs, intestinal contents, and feces was determined. No clinical signs related to the test organism or macroscopic abnormalities were noted in the rats. No test organisms were detected in any tissue sample tested. In general, *M. albus* QST 20799 does not appear to be toxic, infective, and/or pathogenic to rats at this dose. This study was considered acceptable (BPPD DER 04/28/04).

4. *Acute dermal toxicity - rabbits (Guideline 152–31; OPPTS 870–2500/ 885–3100).* To investigate dermal toxicity of *M. albus* QST 20799, five male and five female New Zealand white rabbits were treated with an aqueous suspension of *M. albus* QST 20799. The fur representing approximately 10% of the total body surface was clipped on the dorso-lumbar region of each rabbit. The test substance (2 ml/kg equivalent to 2 g/kg body weight) was applied on the skin site on each rabbit, then covered (MRID #46106402). After the dressings were removed in 24 hours, the rabbits were observed at least twice daily for survival and were checked for clinical signs hourly post treatment and twice on subsequent days for 14 days. Body weight was recorded on days 1, 8, and 15. The Draize method was utilized to rate skin irritation after test substance removal. The rabbits were euthanized and gross necropsied on day 15. No rabbits died and no clinical signs of toxicity were observed throughout the study. No dermal irritation was noted on any animal. One female lost weight during the first week and four males and one female lost weight during the second week. Overall, all animals gained weight. No treatment-related abnormal findings were noted. The test organism was not toxic to rabbits. The acute lethal dose (LD_{50}) was greater than 2 mg/kg. The study is acceptable, and the pesticide is considered Toxicity Category IV for dermal effects (BPPD DER 04/28/04).

5. *Primary eye irritation (OPPTS Guideline 870.2400).* Three female young adult New Zealand White rabbits were treated with *M. albus* QST 20799. A solution of 0.1 ml/eye/animal was applied into the conjunctival sac of one eye, and the eye held closed for approximately 1 second. The contralateral eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours after test material instillation (MRID 46039407). No corneal opacity, iritis, or positive conjunctival irritation was noted on any rabbit during the study. *M. albus* QST 20799 was practically non-irritating to the eyes of the rabbits. This study was considered acceptable and the pesticide placed in Toxicity Category IV for primary eye irritation (BPPD DER 04/28/ 04).

6. *Data waiver requests: MP and EP.* Requests were made to waive data for the following requirements for the TGAI/MP and EP:

- Acute Inhalation (Guideline 152–32; OPPTS 870.1300);
- Acute Intravenous (IV), Intracerebral (IC), Intraperitoneal (IP) injection Toxicity/Pathogenicity (Guideline 152–33; OPPTS 885.3200);
- Cell Culture (Guideline 152.39; OPPTS 885.3500);
- Immune Response (Guideline 152–38; OPPTS 885.3800);
- Hypersensitivity Study (Guideline 152–36);
- Hypersensitivity Incidents (Guideline 152–37; OPPTS 870.3400).

i. *Acute inhalation toxicity/ pathogenicity.* The registrant cited the acute pulmonary toxicity/pathogenicity study (see Unit III.3, above) to justify waiving the acute inhalation study. In that study the active ingredient cleared tissues and was not toxic, infective, or pathogenic to rats when instilled intratracheally. In addition, the registrant's argument that the exposure during formulations of the granular EPs from the MP justifies granting this request to waive acute inhalation data requirements for the MP.

However, the Agency did consider that exposure to all the volatiles produced during rehydration of the pesticide was not fully addressed. For product characterization and to establish that pesticide residues do not accumulate on treated commodities, the registrant provided data to the Agency about potential volatiles produced during rehydration of the active ingredient. These volatiles occur naturally in food products, and are used as fragrances, flavoring agents or as solvents. In submitted chromatograms, seven peaks (pks) were identified as pks 1, 2, 3, 4, 6, 10 and 11, as discussed below (BPPD DER 06/ /05).

- (Pk 1) Ethyl propionate in wine, white grapes and, cocoa;
- (Pk 2) Isobutyl alcohol in food and beverages;
- (Pk 3) 2-Methylbutyl acetate in apples;
- (Pk 4) Isoamyl isobutyrate in honey, hop oil and whiskey;
- (Pk 6) 2-Methyl-1-butanol in wine, kiwi, apples and alcoholic beverages. It is a volatile component of blue cheese aroma, concord grape juice essence, nectarines, apples, papaya fruit, oranges, tomatoes and is released in the volatile emissions from poultry manure.
- (Pk 10) Isobutyric acid in cheese, fruits, vinegar and alcoholic beverages;

(Pk 11) Phenethyl alcohol in foods such as olive oil, grapes, tea, apple juice, coffee, and alcoholic beverages (BPPD DER 06/ /05).

At room temperature a 10 gram sample of the EP, Arabesque, rehydrated 1:1 with water, produced low concentrations of the volatiles ranging from 0.15 parts per billion (ppb) for 2-Methylbutyl acetate and Isoamyl isobutyrate to 20.5 ppb for Isobutyric acid. The inhalation LC_{50} was reported from published literature for most of the volatiles and found to be within acceptable threshold levels. Volatiles dissipating from the rehydrated pesticide are well below those reported inhalation LC_{50} values. All the volatiles are reported as naturally occurring in foods as fragrances and flavors, and they dissipate shortly after rehydration, without compromising efficacy in the time required for storage or other treatments related to proposed agricultural practices. However, the inhalation LC_{50} was not reported for Ethyl propionate, 2-Methylbutyl acetate, and Isoamyl isobutyrate. The Agency is of the opinion that the exposure to these substances may not pose a dietary risk via inhalation, because they are short-lived, well-characterized flavors and fragrances, which occur naturally in consumed food and feed commodities. This data requirement is satisfied for the purposes of the exemption from tolerance.

ii. *Acute IV/IP/IC study.* In an acute oral toxicity/pathogenicity study (see Unit III.1 and 2 above) with the technical grade active ingredient (TGAI), no clinical signs of toxicity were observed in rats and no viable *M. albus* QST 20799 was recovered from blood, organs, or intestinal contents. Data from the registrant's in-house study show that *M. albus* is not viable at temperatures of 34 °C and above, and, therefore, would not be expected to survive at mammalian body temperatures. Based on the low toxicity potential indicated by these observations, the request to waive the acute IP study was granted.

iii. *Cell culture.* This study is required for a virus and is not required for a fungal active ingredient such as *M. albus* QST 20799. The request to waive this data requirement is granted.

iv. *Immune response.* The lack of pathogenicity seen in the acute oral toxicity/pathogenicity study with the TGAI indicates the immune system was not adversely affected by *M. albus* QST 20799. Based on these considerations, the justifications to support the request to waive data requirements for the immune response studies for the TGAI/MP are acceptable.

v. *Hypersensitivity study.* No incidents of hypersensitivity have occurred during the research, development, or testing of *M. albus* QST 20799 or the Arabesque™ end product. A hypersensitivity study is not required at this time, but may be required in the future if there are reports of hypersensitivity incidents associated with this active ingredient used in pesticides.

vi. *Hypersensitivity incidents (Guideline 152–37; OPPTS 870.3400).* The registrant requested to waive reports of hypersensitivity incidents, because no incidents of hypersensitivity associated with the TGAI or proposed components of the EP have been reported to date. However, the registrant agreed to report hypersensitivity incidents, should they occur in the future. This guideline requirement is satisfied at this time. In order to comply with FIFRA requirements under Section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency. This data requirement is not waived.

7. *Subchronic, chronic toxicity and oncogenicity, and residue data.* Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

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

A. Dietary Exposure

Use of *M. albus* QST 20799 and its EPs is not likely to cause any harm via consumption of food or feed treated with the microbe, which is not applied directly to food as discussed below.

1. *Food.* Residues of *M. albus* QST 20799 and its volatiles are not expected on treated food commodities from the proposed use patterns. After pesticides containing *M. albus* QST 20799 are incorporated into soil prior to planting, the fungal active ingredient survives poorly in the soil once the food supply is depleted. Even though the fungal active ingredient itself, does not survive in soil, the volatiles produced by the microbe appear to control the target soil pests. Thus, neither the fungus nor its volatiles are in direct contact with, or expected to remain on, treated food commodities.

Similarly, treatment using pesticides containing *M. albus* Strain QST 20799 after food is harvested (i.e., post harvest) does not involve contact with the treated commodities. Post-harvest treatment involves exposure of the food to the pesticide in warehouses or in shipping containers. Here, the rehydrated pesticides containing the fungal active ingredient are in sachets or containers, and are not in direct contact with the food or feed. During the period of treatment, volatiles released from the microbe inhibit the growth of organisms, which cause disease on food commodities, when they are being stored after harvest.

Furthermore, the active ingredient is not a systemic pesticide. Thus, detectable residues of *M. albus* QST 20799, the microbe, are not expected on treated seed and propagules or food or feed commodities. The volatiles do occur naturally as flavors and fragrances in food and feed commodities. Hence, they are not expected to be present on treated seed and propagules, food or feed, solely as a result of treatment with this pesticide.

As previously discussed in Unit III, data submitted to the Agency indicate that some of the volatiles produced by the fungus are Ethyl propionate, Isobutyl alcohol, 2-Methylbutyl acetate, Isoamyl isobutyrate, 2-Methyl-1-butanol, Isobutyric acid, Phenethyl alcohol. Many of these compounds are found in fruit aromas, fresh leaves, wine and rum aromas, blue cheese aroma, natural essential oils and olive and vegetable oil. Data submissions to the Agency indicate that residues of the volatiles do not appear to adhere to the treated commodities, nor leave any detectable residues on treated apples. Based on the nature of the volatiles, and their natural occurrence in some food commodities, they are not expected to be detectable residues solely as a result of treatment with *M. albus* QST 20799.

From the above discussion it is clear that during any of the proposed uses, residues of the microbe or its volatiles are not expected on treated commodities. Normal washing, peeling, cooking, or processing of treated fruits and vegetables would further reduce any possible residues of *M. albus* QST 20799 or its volatiles. Finally, as discussed in Unit III, the acute oral tests demonstrate low toxicity potential via dietary exposure to this Toxicity Category IV pesticide. Hence, even if the pesticide was present in or on food commodities, exposure via the dietary route is not expected to cause any harm.

Therefore, the Agency has decided that dietary exposure from the proposed uses of *M. albus* QST 20799 and its volatiles is not likely to adversely affect the U.S. adult population, infants and children.

2. *Drinking water exposure.* Exposure to *M. albus* QST 20799 in drinking water is not likely to adversely affect U.S. adult population, infants and children, if the pesticide is used as labeled. The active ingredient belongs to the group referred to as ''mycelia sterilia'' which do not produce spores. This feature of the microbe allows for a short life cycle of *M. albus* QST 20799. Since *M. albus* Strain QST 20799 occurs as a sterile mycelium and has no spores or resting structure, it is unlikely to be capable of substantial growth in soil after its food base in the product has been exhausted. Thus, transfer of *M. albus* Strain QST 20799 from soil to groundwater is unlikely. Even if such a transfer were to occur, the fungus would not tolerate the conditions drinking water treatment would provide, e.g., chlorination, pH adjustments, high temperatures, and/or processing conditions.

The proposed uses of pesticides containing this active ingredient, suggest that neither the parent fungus, nor its volatiles are likely to persist or

accumulate in drinking water when the active ingredient is used as labeled. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this active ingredient is not likely to adversely affect the U.S. population of adult humans, infants and children.

B. Other Non-Occupational Exposure

Non-occupational dermal and inhalation exposure is unlikely, since the use sites are commercial and agricultural. Pesticide drift is expected to be minimal, since the EP is incorporated into the soil for pre-planting treatment, or is used in enclosed containers for post-harvest treatment. Soil survivability of *M. albus* Strain QST 20799 is poor, and it has no spores or resting structure. The volatile compounds produced by *M. albus* Strain QST 20799 dissipate rapidly in the environment. The acute pulmonary toxicity study demonstrated no treatment-related adverse effects when the active ingredient was instilled into rats intratracheally. No hypersensitivity incidents have been reported for either the TGAI/MP or EPs.

1. *Dermal exposure.* The low toxicity potential observed in the acute dermal studies discussed above (Unit III), the low exposure potential based on low application rates, and the lack of persistence of the active ingredient, leads EPA to conclude that this pesticide poses minimal risk to human populations via non-occupational dermal exposure. The volatiles produced by the active ingredient dissipate rapidly, and are thus not likely to adhere to, or penetrate, clothing, or adhere to the skin of the non-occupationally exposed population.

Moreover, potential non-occupational dermal exposure to *M. albus* Strain QST 20799 is unlikely because the use sites are commercial and agricultural. The pesticide is granular in nature and the methods of application minimize pesticide drift. As previously discussed in Units III and IV, a lack of hypersensitivity incidents and the poor survivability of the fungus in soil indicate *M. albus* Strain QST 20799 poses minimal risk to populations via non-occupational dermal exposure.

Thus, the Agency does not expect pesticides containing *M. albus* QST 20799 to pose a non-occupational dermal exposure hazard.

2. *Inhalation exposure.* Non-occupational inhalation exposure to the active ingredient itself is not likely to cause an inhalation hazard. No treatment-related effects associated with the active ingredient were observed in the pulmonary tests reported above. The volatiles are produced on rehydration and are expected to dissipate during storage and shipment of treated commodities. They are also not likely to persist in the environment after application, as discussed above. Furthermore, these volatiles are known as fragrances or flavors associated with food. Based on the low potential for non-occupational inhalation exposure, the Agency does not expect these pesticides containing *M. albus* QST 20799 and its volatiles to pose an inhalation hazard.

In summary, the potential aggregate exposure via treatment of soil, seed and propagules, fruits and vegetables, and cut flowers with *M. albus* Strain QST 20799 is not likely to pose a hazard via aggregate exposure. This includes hazards derived from (a) dietary exposure from the treated food/feed commodities, (b) drinking water potentially exposed secondary to treatment of sites with this pesticide; and (c) dermal and inhalation non-occupational and occupational exposure of populations exposed to *M. albus* Strain QST 20799.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *M. albus* QST 20799 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, *M. albus* QST 20799 and its volatiles do not appear to be toxic or pathogenic to humans. No other registered pesticide contains *M. albus* QST 20799 as an active ingredient. The pesticide is proposed to be used in a manner which will not directly contact treated food or feed commodities. It will not be translocated in seed and propagule because it is not systemic. One of the proposed uses, as a methyl bromide replacement, is a soil treatment.

The volatiles, which are produced by the rehydrated fungus, appear to dissipate and are not absorbed by treated food commodities, thus leaving no detectable residues. The volatiles are also well-known components of fragrance and flavor associated with food, and are only produced for short periods when the fungus is rehydrated. Based on the low toxicity potential of *M. albus* QST 20799 and its volatiles (see Unit III above), and the low exposure scenario when the proposed pesticides are used as labeled, no cumulative or incremental effect is expected from its use.

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

There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposures to residues of *M. albus* QST 20799, as a result of its proposed uses. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent on treated food commodities via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral, pulmonary, and dermal effects with no toxicity or infectivity at the doses tested (see Unit III. above). Moreover, potential non-occupational inhalation or dermal exposure is not expected to pose any adverse effects to exposed populations via aggregate and cumulative exposure (see Units IV. and V.)

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessment either directly, or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk. In this instance, based on all the available information (as discussed in detail above), the Agency concludes that the fungus, *M. albus* QST 20799, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *M. albus* QST 20799 is used as labeled, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *M. albus* QST 20799.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

At this time, the Agency is not requiring information on the endocrine effects of this active ingredient, *M. albus* QST 20799. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an ''endocrine disruptor'' produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral, pulmonary and dermal routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed labeled uses of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this Final Rule for *M. albus* QST 20799.

B. Analytical Method(s)

The acute oral studies discussed above demonstrate that neither the active ingredient nor the volatiles produced by the rehydrated fungus pose a dietary risk. In addition, the active ingredient is not likely to come into contact with the treated food commodities. The volatiles from the rehydrated fungal active ingredient dissipate quickly. They do not appear to leave any detectable residues on treated food commodities, when used as labeled. Furthermore, the low application rate and non-persistence on food during soil applications suggests very low exposure potential via the dietary route. Since residues are not expected on treated commodities, the Agency has concluded that an analytical method to detect residues of this pesticide on treated food commodities for enforcement purposes is not needed.

Nevertheless, the Agency has concluded that for analysis of the pesticide itself, microbiological and biochemical methods exist and are acceptable for enforcement purposes for product identity of *M. albus* QST 20799, and the volatiles produced by the rehydrated fungus. Other appropriate methods are required for quality control to assure that product characterization, the control of human pathogens and other unintentional metabolites or ingredients are within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *M. albus* QST 20799.

VIII. Conclusions

The results of the studies discussed above are sufficient to comply with the requirements of the FQPA. They support an exemption from the requirement of a tolerance for residues of *M. albus* QST 20799, on treated food or feed commodities. In addition, the Agency is of the opinion that, if the microbial active ingredient is used as labeled, aggregate and cumulative exposures are not likely to pose any undue hazard. The volatiles produced when the fungus is rehydrated also do not pose an incremental dietary and non-dietary risk to the adult human U.S. population, children and infants. Therefore, an exemption from tolerance is granted in response to pesticide petition 3F6745.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0244 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 November 28, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0244, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 20, 2005.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1260 is added to subpart D to read as follows:

§ 180.1260 Muscodor albus QST 20799 and the volatiles produced on rehydration; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established on all food/feed commodities, for residues of *Muscodor albus* QST 20799, and the volatiles produced on its rehydration, when the pesticide is used for all agricultural applications, including seed, propagule and post harvest treatments.

[FR Doc. 05–19259 Filed 9–27–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 310

[SFUND–2005–0009; FRL–7976–2]

RIN 2050–AE36

Reimbursement to Local Governments for Emergency Responses to Hazardous Substances Releases

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of February 18, 1998, to streamline procedures used to reimburse local governments for emergency response costs. Local governments may be reimbursed for certain costs they incur in taking temporary emergency measures related to releases of hazardous substances, pollutants and contaminants. This document is being issued to correct the address to mail the completed application and supporting data provided and the telephone numbers listed in Appendix II to the regulations.

DATES: This technical correction is effective on September 28, 2005.

ADDRESSES: *Docket:* All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Superfund Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Superfund Docket is (202) 566–0276.

FOR FURTHER INFORMATION CONTACT: Lynn Beasley, Regulation and Policy Development Division, Office of Emergency Management, Office of Solid Waste and Emergency Response (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–1965; fax number: (202) 564–2625; e-mail address: *beasley.lynn@epa.gov.* For further information regarding specific aspects of the final rule for reimbursement to local governments, contact: Lisa Boynton, Local Governments Reimbursement Project Officer, Program Operations and Coordination Division, Office of Emergency Management, Office of Solid Waste and Emergency Response (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–2487; fax number: (202) 564–8211; e-mail address: *boynton.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Type of entity	Examples of affected entities
Local or Tribal Governments.	Governing bodies of county, parish, municipality, city, town, township, federally recognized Indian tribe or general purpose unit of local government.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Access Electronic Copies of This Document and Other Related Information?

The instructions provided under the **Federal Register** document of February 18, 1998, 63 FR 8284, are no longer current. The current information is as follows:

- Docket ID No. SFUND–2005–0009.
- Federal eRulemaking Portal: *http://www.regulations.gov.*
- Agency Web site: *http://www.epa.gov/edocket.* EDOCKET, EPA's electronic public docket and comment system.
- E-mail: *superfund.docket@epa.gov.*
- Fax: (202) 566–0224.

Mail: Superfund Docket, Environmental Protection Agency, Mailcode: 5202T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In addition to using EDOCKET at *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

II. What Does This Correction Do?

On February 18, 1998, (63 FR 8284) EPA published streamlined procedures for use by local governments seeking reimbursement for emergency response costs. Local governments may be reimbursed for certain costs they incur in taking temporary emergency measures related to releases of hazardous substances pollutants and contaminants. Those procedures are found in 40 CFR part 310. Section 310.15(d) gives the address to mail the completed application and supporting data for reimbursement. Appendix II to 40 CFR part 310 provides EPA Regions and NRC Telephone Lines. The mailing address and some of the telephone numbers are now incorrect. This technical correction provides the corrected address to mail the completed application and supporting data and the EPA Regions and NRC phone numbers.

III. Why Is This Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely correcting information that