that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on July 5, 2011. This will incorporate these rules into the federally enforceable SIP.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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 July 5, 2011. Filing a petition for reconsideration by the Administrator of this final rule does 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 31, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(385) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(385) New and amended regulations for the following APCDs were submitted on February 28, 2011.

(i) Incorporation by Reference.

(A) Mendocino County Air Quality Management District.

(*1*) Rule 130, "Definitions," amended February 15, 2011.

(B) Northern Sonoma County Air Pollution Control District.

(*1*) Rule 130, "Definitions," amended December 14, 2010.

[FR Doc. 2011–11038 Filed 5–4–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0194; FRL–8872–3]

Metarhizium anisopliae Strain F52; 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 *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices. Novozymes Biologicals, 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 *Metarhizium anisopliae* strain F52 under the FFDCA.

DATES: This regulation is effective May 6, 2011. Objections and requests for hearings must be received on or before July 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0194. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–8097; *e-mail address: bacchus.shanaz@epa.gov.*

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://www.gpoaccess.gov/ecfr.* 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–2009–0194 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 July 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0194, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online 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 April 8, 2009 (74 FR 15969) (FRL–8407–6), 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 8F7508) by Novozymes Biologicals, Inc., 5400 Corporate Circle, Salem, VA 24153. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52. This notice referenced a summary of the petition prepared by the petitioner, Novozymes Biologicals, 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 has 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 Metarhizium Anisopliae Strain F52

Metarhizium anisopliae strain F52 (called MetF52), a deuteromycetous and entomopathogenic fungus that is found worldwide, infects numerous insect (primarily Coleoptera of the families Elateridae and Curculionidae), mite, and tick species that are contacted by it. Once spores of *Metarhizium anisopliae* strain F52 attach to the surface of the target pest, they germinate, grow, penetrate the target pest's exoskeleton, continue to grow in the target pest, and eventually cause death. Susceptible insects, mites, or ticks that come into contact with other insects, mites, or ticks that have been infected with *Metarhizium anisopliae* strain F52 also become infected with the fungus, thus continuing this microbe's pesticidal effect.

Given this distinct capability and efficiency in controlling various insects, mites, and ticks, *Metarhizium anisopliae* strain F52 is currently recognized as the active ingredient in several microbial pesticide products, which were conditionally registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in June 2003 to Earth BioSciences, Inc. Since the registration of these pesticide products in 2003, they have been labeled specifically for non-food applications in urban and suburban (residential) areas to control various insects (e.g., thrips and root weevils), mites, and ticks. In 2006, the *Metarhizium anisopliae* strain F52-containing registrations were transferred from Earth BioSciences, Inc. to Novozymes Biologicals, Inc. (TAE–001 Technical Bioinsecticide, EPA Reg. No. 70127–7; Taenure Granular Bioinsecticide, EPA Reg. No. 70127–8; Tick-EX G, EPA Reg. No. 70127–9; Tick-EX EC, EPA Reg. No. 70127–10).

After maintaining the registrations with non-food uses for several years, Novozymes Biologicals, Inc. has now petitioned EPA to establish an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities. Accordingly, EPA has reevaluated an assessment of the mammalian toxicology data that were submitted prior to 2003 to support the initial applications for *Metarhizium anisopliae* strain F52 pesticide products. The overall conclusions from these data are described in Unit III.B., while more in-depth synopses of the study results can be found in a 2001 risk assessment, the 2003 *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document (BRAD), and the 2011 Addendum to the *Metarhizium anisopliae* strain F52 BRAD provided as references in Unit IX. (Refs. 1, 2, and 3).

B. Microbial Pesticide Toxicology Data Requirements

All mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities have been fulfilled with acceptable studies.

1. *Acute oral toxicity and pathogenicity—rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 448447–09).* An acceptable acute oral toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed at approximately 1.04×10^8 colony-forming units (cfu)/animal.

2. *Acute dermal toxicity—rabbit (Harmonized Guideline 885.3100; MRID No. 448447–10).* An acceptable acute dermal toxicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic to rabbits when dosed at 3.63–4.42×10^{10} cfu/animal (median lethal dose (LD_{50}) > 2,000 milligrams per kilogram (mg/kg); Toxicity Category III).

3. *Acute pulmonary toxicity and pathogenicity—rat (Harmonized Guideline 885.3150; MRID No. 448447–11).* An acceptable acute pulmonary toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed intratracheally at approximately 1.17×10^8 cfu/animal.

4. *Acute injection toxicity and pathogenicity—rat (Harmonized Guideline 885.3200; MRID No. 448447–12).* An acceptable acute injection toxicity and pathogenicity study demonstrated that *Metarhizium anisopliae* strain F52 was not toxic and/or pathogenic to rats when dosed intraperitoneally at approximately 1×10^7 cfu/animal.

5. *Acute eye irritation—rabbit (Harmonized Guideline 870.2400; MRID No. 448447–13).* An acceptable acute eye irritation study demonstrated that *Metarhizium anisopliae* strain F52 was moderately irritating (i.e., the test substance caused corneal opacity, iritis, and conjunctival irritation with resolution by day 4) to rabbits when dosed at 6.3×10^8 cfu/eye/animal (Toxicity Category III).

6. *Dermal sensitization—guinea pig (Harmonized Guideline 870.2600; MRID No. 448447–15).* An acceptable dermal sensitization study demonstrated that *Metarhizium anisopliae* strain F52 was not a dermal sensitizer to guinea pigs when induced and challenged at 2.37×10^9 cfu.

7. *Hypersensitivity incidents (Harmonized Guideline 885.3400; MRID No. 448447–14).* No hypersensitivity incidents involving *Metarhizium anisopliae* strain F52 and occurring during fermentation, processing, formulation, research, or application have been reported to EPA.

IV. Aggregate Exposure

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

A. Dietary Exposure

Dietary exposure to this microbial pesticide may occur (more likely through food than drinking water), but the lack of acute oral toxicity, infectivity, and/or pathogenicity, as exhibited in a toxicology test on rats presented in Unit III.B., supports the establishment of a tolerance exemption for residues of *Metarhizium anisopliae* strain F52.

1. *Food.* Exposure to this microbial active ingredient through food is expected to be minimal. When applied in accordance with good agricultural practices, *Metarhizium anisopliae* strain F52, a known pathogen of various insects, mites, and ticks, is unlikely to persist on plants. Any spores on plants due to pesticide application would presumably decrease over time, similar to other fungal entomopathogens and microbial pest control agents, because of environmental factors such as rainfall, ultraviolet radiation, and temperature (Refs. 4 and 5). For example, several studies, designed to evaluate the susceptibility of *Metarhizium* spores to sunlight, showed that ultraviolet radiation (UV–A and UV–B) quickly causes inactivation of these spores, both with and without the use of substances intended to act as sunscreens (Ref. 6). In the unlikely event that the applied fungus grew on the edible portions of treated crops, the results of the toxicology testing demonstrated that no toxicity, infectivity, and/or pathogenicity in treated animals occurred, even when dosed with high levels of *Metarhizium anisopliae* strain F52 by the oral route of exposure (see additional discussion in Unit III.B.). In conclusion, there are no concerns for *Metarhizium anisopliae* strain F52 exposure through food.

2. *Drinking water exposure.* Much like dietary exposure, drinking water exposure is expected to be negligible, albeit for slightly different reasons. Given the terrestrial use sites, the application methods with reduced chance for offsite movement of *Metarhizium anisopliae* strain F52 (e.g., soil incorporation), and low application rates, it is not likely that use of *Metarhizium anisopliae* strain F52 products, when good agricultural practices are followed, will result in significant increase in fungal spore exposure in drinking water. With regard to percolation through the soil, Zimmerman (2007) suggests that *Metarhizium anisopliae* is a typical soil-borne fungus as it has mostly been isolated from the upper soil layer. Further, Zimmerman (2007) also goes on to describe field tests in which many sprayed *Metarhizium anisopliae* spores were found in upper layers of loamy soil and humus, thereby supporting the soil adhesion theory and the absence of significant spore percolation down to ground water. In the unlikely event of exposure to *Metarhizium anisopliae* strain F52 spores through drinking water, the results of the oral toxicology testing, as described in Unit III.B., demonstrated that no toxicity, infectivity, and/or pathogenicity in treated animals occurred. As was concluded for food exposure, there are no concerns for *Metarhizium anisopliae* strain F52 exposure through drinking water.

B. Other Non-Occupational Exposure

Deuteromycetous fungi, such as *Metarhizium anisopliae* strain F52, are naturally occurring and found worldwide. As a pesticidal active ingredient, *Metarhizium anisopliae* strain F52 has historically been applied in residential areas. Because of the use patterns and low application rates, there will not likely be a significant increase in exposure over the background levels of *Metarhizium anisopliae* strain F52 in these residential areas. Furthermore, there is no evidence of any concern for inhalation or dermal toxicity at exposure levels several orders of magnitude higher than would be expected to be encountered by a typical residential end user (see Unit III.B.). Finally, given that this deuteromycetous fungi affects only certain species of insects, mites, and ticks, and that no recognized relationships exist between the *Metarhizium* genus and any pathogen of humans and animals, no adverse effects to humans from inhalation or dermal exposure to this widespread fungus have been reported or are anticipated.

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, 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 has not found *Metarhizium anisopliae* strain F52 to share a common mechanism of toxicity with any other substances, and *Metarhizium anisopliae* strain F52 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Metarhizium anisopliae* strain F52 does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Metarhizium anisopliae* strain F52 that need to be considered. 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 U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold 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. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments, 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.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., as well as use of *Metarhizium anisopliae* strain F52 as a microbial pesticide for approximately eight years without reported adverse effects to humans, 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 the residues of *Metarhizium anisopliae* strain F52. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on *Metarhizium anisopliae* strain F52 do not demonstrate toxic, pathogenic, and/or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever

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

The Codex has not established a MRL for *Metarhizium anisopliae* strain F52.

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 *Metarhizium anisopliae* strain F52. Therefore, an exemption is established for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices.

IX. References

1. U.S. EPA. 2011. Addendum to *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document dated March 2011 (available as "Supporting & Related Materials" within docket ID number EPA–HQ–OPP–2010–0081 at *http://www.regulations.gov*).
2. U.S. EPA. 2003. *Metarhizium anisopliae* strain F52 Biopesticides Registration Action Document.
3. U.S. EPA. 2001. Review of Toxicology Data for *Metarhizium anisopliae* F52 in Support of a Section Three Registration for *Metarhizium anisopliae* F52 from Taensa, Inc., Fairfield, CT. Memorandum from C.A. Wozniak, PhD and J.L. Kough, PhD to L. Cole dated December 11, 2001 (available as "Supporting & Related Materials" within docket ID number EPA–HQ–OPP–2010–0081 at *http://www.regulations.gov*).
4. Jaronski ST. 2010. Ecological factors in the inundative use of fungal entomopathogens. *Biocontrol* 55:159–185.
5. U.S. EPA. 1996. Microbial Pesticide Test Guidelines—Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from: *http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm.*
6. Zimmermann G. 2007. Review of safety of the entomopathogenic fungus *Metarhizium anisopliae. Biocontrol Sci Techn* 17(9):879–920.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

XI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 28, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.1303 is added to subpart D to read as follows:

§ 180.1303 Metarhizium anisopliae strain F52; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Metarhizium anisopliae* strain F52 in or on all food commodities when applied as an insecticide, miticide, or ixodicide and used in accordance with good agricultural practices.

[FR Doc. 2011–11030 Filed 5–5–11; 8:45 am]

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