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

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
standards.

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).

The 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
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
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.

(A) Mendocino County Air Quality
Management District.

(i) Rule 130, “Definitions,” amended
February 15, 2011.

(ii) Rule 133, “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

[80–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
Biologics, 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?


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:


- 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 9F7508) 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 deuteromycete 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 C, EPA Reg. No. 70127–9; Tick-EX EC, EPA Reg. No. 70127–10).

After maintaining the registrations without 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 × 10^6 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 × 10^6 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 × 10^6 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 × 10^6 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 × 10^6 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 × 10^6 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 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 fungus 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)(I)(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.
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


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 26355, 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(c)(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:


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.