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 29, 2009.

Meredith F. Laws,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

■ 2. In §180.910, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
Calcium lactate pentahydrate (CAS Reg. No. 5743–47–5).	.....	Nutrient, stabilizer
* * *	*	*

[FR Doc. E9–10769 Filed 5–12–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0164; FRL–8412–9]

Candida oleophila Strain O; 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 microbial pesticide, *Candida oleophila* Strain O, on apples and pears when applied/used as a post-harvest biofungicide. BioNext sprl (in care of SynTech Global, LLC) 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 *Candida oleophila* Strain O.

DATES: This regulation is effective May 13, 2009. Objections and requests for hearings must be received on or before July 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0164. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8920; e-mail address: kausch.jeannine@*epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0164 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 July 13, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0164, by one of the following methods.

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of March 28, 2008 (73 FR 16673) (FRL–8355–6), 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 7F7310) by BioNext sprl, Passage des deportes, 2, B-5030 Gembloux, Belgium (in care of SynTech Global, LLC, P.O. Box 640, Hockessin, DE 19707). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Candida oleophila* Strain O. This notice included a summary of the petition prepared by the petitioner, BioNext sprl (in care of SynTech Global, LLC). 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 and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... '' Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues '' and ''other substances that have a common mechanism of toxicity.''

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

III. Toxicological Profile

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

Candida oleophila Strain O is a single-celled yeast in the phylum Ascomycota, the class Ascomycetes, and the family Saccharomycetaceae. Found naturally on plant tissues (fruits, flowers, and wood) and in water, it was originally isolated from Golden Delicious apples and is intended for use as an antagonist to control the fungal pathogens, grey mold (*Botrytis cinerea*) and blue mold (*Penicillium expansum*), that cause post-harvest decay on apples and pears. The mode of action for *Candida oleophila* Strain O is primarily through competition for nutrients and pre-colonization of plant wound sites. Submitted data also suggest that production of beta-1,3-glucanases (i.e., hydrolytic enzymes that can degrade fungal phytopathogen cell walls) may contribute to its antagonistic activity. According to reported testing, *Candida oleophila* Strain O does not grow above 33°C, is sensitive to ultraviolet light, and is dependent on a carbon source for growth. Some species of *Candida* are reported as opportunistic pathogens to humans and/or animals. *Candida oleophila*, however, is an environmental microbe unable to grow at mammalian body temperatures and easily distinguished from the *Candida* species reported as clinical isolates. More importantly, no pathogenic effects or infections from *Candida oleophila* Strain O were seen in the submitted infectivity studies discussed below and there have been no clinical reports of *Candida oleophila* infection even though various strains of this species naturally occur on food commodities such as apples, olives, strawberries, fermenting grapes, and tomatoes. Additional information regarding *Candida oleophila* Strain O can be found in the Biopesticides Registration Action Document (BRAD) on the Biopesticides and Pollution Prevention Division (BPPD) website: *http://www.epa.gov/pesticides/biopesticides*.

Studies submitted to the Agency were issued Master Record Identification (MRID) Numbers and reviewed by BPPD scientists. These submissions were considered in light of the microbial pesticides data requirements, which became final on December 26, 2007 (72 FR 61002). The following summaries of the toxicological profile of *Candida oleophila* Strain O are based on an Agency risk assessment memorandum and related data evaluation records dated November 13, 2008.

A. Acute Oral Toxicity and Pathogenicity – Rat (Office of Prevention, Pesticides, and Toxic Substances [OPPTS] Guideline 885.3050; MRID No. 473138-07)

In an acute oral toxicity and pathogenicity study, groups of rats were given a single oral dose of *Candida oleophila* Strain O at a dose of 2.3–3.8 x 10^8 colony-forming units (CFU)/animal. The animals were observed for a period of up to 22 days with interim scheduled sacrifices on days 4, 8, and 15. There were no treatment-related clinical signs, necropsy findings, or changes in body weight. No test organisms were recovered from the gastrointestinal contents, any organs, or blood of any animal or feces from treated animals sacrificed on day 22. Based on the results of this study, *Candida oleophila* Strain O does not appear to be toxic, infective, and/or pathogenic in rats. This study was rated ''ACCEPTABLE'' for risk assessment purposes.

B. Acute Subcutaneous Injection Toxicity and Pathogenicity – Rat (OPPTS Guideline 885.3200; MRID No. 473138-08)

In an acute subcutaneous injection toxicity and pathogenicity study, groups of rats were injected subcutaneously with *Candida oleophila* Strain O with a dose of 1.1–2.0 x 10^7 CFU/animal. The animals were observed for up to 22 days. There were no treatment-related clinical signs, necropsy findings, or changes in body weight. No test

organisms were recovered from the gastrointestinal contents, organs, blood, or the injection site of any animal. Based on the results of this study, *Candida oleophila* Strain O does not appear to be toxic, infective, and/or pathogenic in rats, when dosed at 1.1–2.0 x 10^7 CFU/animal. This study was rated ''ACCEPTABLE'' for risk assessment purposes.

C. Acute Pulmonary Toxicity and Pathogenicity – Rat (OPPTS Guideline 885.3150; MRID No. 473138-09)

In an acute pulmonary toxicity and pathogenicity study, groups of rats were exposed by the intratracheal route to *Candida oleophila* Strain O at a dose of 1.2–5.2 x 10^8 CFU/animal. The animals were observed for up to 22 days. There were no test substance-related clinical signs, necropsy findings, or changes in body weight. Test organisms were recovered in the lungs from the treated males and females sacrificed one hour post dosing with clearance by day 4. No test organisms were recovered from the gastrointestinal contents, organs, or blood of any animal or feces from treated animals sacrificed on day 22. Based on these results, *Candida oleophila* Strain O does not appear to be toxic, infective, and/or pathogenic to rats at 1.2–5.2 x 10^8 CFU/animal. This study was rated ''ACCEPTABLE'' for risk assessment purposes.

D. Hypersensitivity Incidents (OPPTS Guideline 885.3400; MRID No. 473138-12)

During a pilot-plant production trial using fermentation vessels and involving large amounts of *Candida oleophila* Strain O, 3 of 6 workers (all on the same work team) not wearing personal protective equipment (PPE) reported clinical symptoms of a respiratory reaction. No adverse dermal effects have been reported by workers. Respiratory and dermal sensitization to consumers is not anticipated, mainly due to the extremely high exposure to *Candida oleophila* Strain O encountered by workers during the fermentation process as opposed to the very low exposure anticipated on treated fruit intended for human consumption. Any future hypersensitivity reports must be reported per OPPTS Guideline 885.3400.

E. Bacterial Reverse Mutation Test (OPPTS Guideline 870.5100; MRID No. 473138-13) and In Vitro Mammalian Cell Gene Mutation Test (OPPTS Guideline 870.5300; MRID No. 473138-14)

Two mutagenicity tests were submitted, reviewed, and indicated that *Candida oleophila* Strain O did not have mutagenic potential. These studies were rated ''SUPPLEMENTAL'' for the purposes of risk assessment and they are not required studies for this active ingredient.

IV. Aggregate Exposures

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

A. Dietary Exposure

Dietary exposure to *Candida oleophila* Strain O is likely to occur, mainly through food. However, the lack of acute oral toxicity/pathogenicity, based on the toxicology test on rats presented in Unit III., and the ubiquitous nature of the microbe on various food commodities support the establishment of an exemption from the requirement of a tolerance for *Candida oleophila* Strain O. Additionally, under 40 CFR 180.1144, a similar active ingredient, *Candida oleophila* isolate I-182, was assessed previously and granted an exemption from the requirement of a tolerance when used as a post-harvest biological fungicide in or on all raw agricultural commodities.

1. *Food. Candida oleophila* Strain O is naturally present on apples as it was originally isolated in 1991 from the surface of Golden Delicious apples. Based on information submitted to the Agency, population densities of white yeasts are estimated to reach 1.5 x 10^3 CFU/square centimeter (cm^2) on harvested apples, which includes the natural population of *Candida oleophila*. Background levels of *Candida oleophila* Strain O on apples are expected to be below 1.5 x 10^3 CFU/cm^2. Post-harvest treatment with *Candida oleophila* Strain O will probably lead to a temporary increased level of this yeast on apples. The mode of action of *Candida oleophila* Strain O is primarily based on competition for nutrients; therefore, sufficient colonization of apple surfaces has to be reached to ensure efficacy of the active ingredient. The recommended application rate of *Candida oleophila* Strain O leads to an expected residual *Candida oleophila* Strain O population of approximately 4 x 10^4 CFU/cm^2 (10^5 CFU/apple). Standard practices of washing, peeling, cooking, or processing fruits further reduces residues of *Candida oleophila* Strain O and minimizes dietary exposure. Actual dietary exposure is expected to be several orders of magnitude lower than the dose used in the acute oral toxicity/pathogenicity test referenced in Unit III., during which no toxic or pathogenic effects were observed in rats. The Agency concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to the residues of *Candida oleophila* Strain O in food.

2. *Drinking water exposure*. Exposure of humans to residues of *Candida oleophila* Strain O in drinking water is unlikely. The proposed use pattern, use sites, and application methods for *Candida oleophila* Strain O (i.e., dip or drench application to apples and pears after harvest and prior to storage) does not include direct application to aquatic environments. In the unlikely event that *Candida oleophila* Strain O was transferred to surface or ground water intended for eventual human consumption, the microbe would not survive the conditions water is subjected to in a drinking water treatment facility, including flocculation, chlorination, pH adjustments, and/or filtration. Even if oral exposure should occur through drinking water, the Agency concludes that there is a reasonable certainty that no harm will result from the exposure to the residues of *Candida oleophila* Strain O in all the anticipated drinking water exposures because of the lack of acute oral toxicity/pathogenicity to mammals and the ubiquitous nature of the microbe, as previously described.

B. Other Non-Occupational Exposure

Potential non-occupational dermal or inhalation exposure is considered unlikely for this distinctly agricultural use (i.e., post-harvest treatment of the harvested portions—pears and apples—of agricultural plants).

1. *Dermal exposure*. Non-occupational dermal exposure to Candida oleophila Strain O, when used as labeled, is expected to be negligible because it is limited to post-harvest agricultural treatment of apples and pears. However, should non-occupational dermal exposure occur through treated food commodities, the risk posed by this low toxicity microbe is likely to be minimal based on the toxicity and pathogenicity tests described in Unit III. Furthermore, exposure would not be expected to exceed background as similar yeasts and those in the genus and species, Candida oleophila, are commonly associated with particular food commodities.

2. *Inhalation exposure*. Non-occupational inhalation exposure to Candida oleophila Strain O, when used as labeled, is expected to be negligible because of the method of application (i.e., dipping and drenching of apples and pears), which then allows sufficient time for drying prior to distribution to consumers. Furthermore, most of the residual yeast on apples and pears is trapped in the cuticular wax and it is unlikely to be inhaled by consumers.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to *Candida oleophila* Strain O 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. As demonstrated in Unit III., *Candida oleophila* Strain O is not toxic or pathogenic to mammals via several routes of exposure. Additionally, there are no other *Candida oleophila* strains currently registered as pesticides with the Agency. Consequently, since this microbial pesticide has no demonstrated toxicity, there is no reason to anticipate cumulative effects from the residues of this product with other related microbial pesticides.

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) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. 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.

Based on the acute toxicity and pathogenicity data discussed in Unit III., EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to the residues of *Candida oleophila* Strain O. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Candida oleophila* Strain O do not demonstrate toxic, pathogenic, or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required, under Section 408(p) of the FFDCA, 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 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 a scientific basis for including, as part of its program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects on wildlife.

The Agency has no knowledge of *Candida oleophila* Strain O being an endocrine disruptor, nor is this microbe related to any class of known endocrine disruptors. Following several routes of exposure in rodents, the Tier I toxicology data indicated that the immune system was still intact and able to process and clear *Candida oleophila* Strain O from a variety of organs or tissues. Additional data, specifically on the endocrine effects of this microbial pesticide, are not required at this time. Consequently, endocrine-related concerns did not impact the Agency's safety finding for *Candida oleophila* Strain O. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program (EDSP) have been developed and implemented, *Candida oleophila* Strain O may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *Candida oleophila* Strain O.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for *ECandida oleophila* Strain O.

VIII. Conclusions

The results of the studies discussed in Unit III meet the safety requirements of the Food Quality Protection Act (FQPA) of 1996. They support an exemption from the requirement of a tolerance for the residues of the microbial pesticide, *Candida oleophila* Strain O, on apples and pears. In addition, the Agency is of the opinion that, if the microbial active ingredient is used as allowed, aggregate exposure and cumulative effects are not likely to harm the United States population, including infants and children. Therefore, in response to pesticide tolerance petition 7F7310, an exemption from the requirement of a tolerance is established for the residues of the microbial pesticide, *Candida oleophila* Strain O, on apples and pears when applied/used as a post-harvest biofungicide.

IX. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated:May 1, 2009.

Debra Edwards,

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 180.1289 is added to subpart D to read as follows:

§ 180.1289 *Candida oleophila* Strain O; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the microbial pesticide, *Candida oleophila* Strain O, on apples and pears when applied/used as a post-harvest biofungicide.

[FR Doc. E9–10962 Filed 5–12–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0020; FRL–8410–3]

Methoxyfenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the insecticide methoxyfenozide *per se*, in or on sorghum, forage; sorghum, grain; and sorghum, stover. This action is in response to a crisis exemption issued by the Louisiana Department of Agriculture under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorizing use of the pesticide on grain sorghum. This regulation establishes a maximum permissible level for residues of methoxyfenozide in these feed commodities. The time-limited tolerances expire and will be revoked on December 31, 2012.

DATES: This regulation is effective May 13, 2009. Objections and requests for hearings must be received on or before July 13, 2009, 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–2009–0020. All documents in the docket are listed in the docket index available in *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Stacey Groce, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address: *groce.stacey@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**.