

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.

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#### 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](mailto: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**.

### *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 cite at <http://www.gpoaccess.gov/ecfr>.

### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (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-2009-0020 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-2009-0020, 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**

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of the insecticide methoxyfenozide *per se* (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) in or on sorghum, forage at 30.0 parts per million (ppm); sorghum, grain at 0.05 ppm; and sorghum, stover at 60.0 ppm. These time-limited tolerances expire and will be revoked on December 31, 2012. EPA will publish a subsequent document in the **Federal Register** to remove the revoked tolerances from the CFR.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(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. Section 408(b)(2)(C) of FFDCA requires 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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## **III. Emergency Exemption for Methoxyfenozide on Various Commodities: Sorghum, forage; Sorghum, grain; and Sorghum, stover and FFDCA Tolerances**

The Louisiana Department of Agriculture requested an emergency exemption for use of methoxyfenozide on grain sorghum to control the southwestern corn borer and sugarcane borer, and issued a crisis exemption for this use pursuant to 40 CFR part 166, subpart C. The Louisiana Department of Agriculture provided information indicating that the southwestern corn borer and sugarcane borer are serious pests that commonly infest grain sorghum. Methoxyfenozide has been authorized under FIFRA section 18 for use on sorghum, forage, sorghum, grain, and sorghum, stover to control southwestern corn borer and sugarcane borer in Louisiana under the crisis provision.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of the insecticide methoxyfenozide *per se* in or on sorghum, forage; sorghum, grain; and sorghum, stover. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire and will be revoked on December 31, 2012, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sorghum, forage; sorghum, grain; and sorghum, stover after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances

earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether methoxyfenozide meets FIFRA's registration requirements for use on sorghum, forage; sorghum, grain; and sorghum, stover or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of methoxyfenozide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for persons in any State other than Louisiana to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for methoxyfenozide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(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. Section 408(b)(2)(C) of FFDCA requires 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. . . ."

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for

residues of the insecticide methoxyfenozide *per se* (benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) in or on sorghum, forage at 30.0 parts per million (ppm); sorghum, grain at 0.05 ppm; and sorghum, stover at 60.0 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

##### A. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment can be found in the document entitled, "Methoxyfenozide. Human Health Risk

Assessment for Proposed Section 18 Use on Grain Sorghum," dated November 20, 2008, by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2009-0020-0002 in that docket. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2009-0020. Double-click on the document to view the referenced information on page 23 of 34.

##### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to methoxyfenozide, EPA considered exposure under the time-limited tolerances established by this action as well as exposures pursuant to existing methoxyfenozide tolerances in (40 CFR 180.544). EPA assessed dietary exposures from methoxyfenozide in food as follows:

i. *Acute exposure.* No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicological studies for methoxyfenozide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of food Intake by Individuals (CSFII). As to residue levels in food, an unrefined chronic dietary analysis for methoxyfenozide was conducted using tolerance levels and 100% crop-treated for all existing and proposed uses. Drinking water was incorporated directly into the dietary assessment using the chronic concentration for surface water generated by the PRZM-EXAMS model at 33.1 ppb. The results of the analysis indicate that chronic risk from the dietary (food and drinking water) exposure to methoxyfenozide will not exceed EPA's level of concern for the general U.S. population and all population subgroups.

iii. *Cancer.* Methoxyfenozide is not likely to be carcinogenic to humans; therefore, a cancer exposure assessment was not conducted. This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment

for methoxyfenozide. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for methoxyfenozide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of methoxyfenozide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of methoxyfenozide for acute dietary exposures are estimated to be 52.2 parts per billion (ppb) for surface water and 7.43 ppb for ground water. The estimated drinking water concentrations (EDWCs) for chronic dietary exposures for non-cancer assessments are estimated to be 33.1 ppb for surface water and 7.43 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. An acute dietary endpoint was not identified; therefore, a quantitative assessment of risk was not conducted for methoxyfenozide. For chronic dietary risk assessment, the water concentration of 33.1 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Methoxyfenozide is not registered for any specific use patterns that would result in residential exposure.

4. *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, 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 has not found methoxyfenozide to share a common mechanism of toxicity with any other substances, and methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of

this tolerance action, therefore, EPA has assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances. 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is not a concern for prenatal and/or postnatal toxicity resulting from exposure to methoxyfenozide. The prenatal and postnatal toxicology database for methoxyfenozide includes rat and rabbit developmental toxicity studies and a 2-generation reproductive study. There was no increased susceptibility in fetuses as compared to maternal animals observed following *in utero* exposures.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for methoxyfenozide is complete for assessment of potential hazard to infants and children.

ii. There is no indication that methoxyfenozide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that methoxyfenozide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or

in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure database. The exposure assessments will not underestimate the potential dietary (food and drinking water) or nondietary exposures for infants and children from use of methoxyfenozide. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to methoxyfenozide in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by methoxyfenozide.

#### D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified, therefore, dietary exposure presents no acute risks of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to methoxyfenozide from food and water will utilize 56% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for methoxyfenozide.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for any use patterns that would result in residential exposure. Therefore, the

short-term aggregate risk is the sum of the risk from exposure to methoxyfenozide through food and water. Thus, the chronic aggregate exposure for the most exposed group is below EPA's level of concern.

#### 4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to methoxyfenozide through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Methoxyfenozide is classified as a "not likely" human carcinogen and thus is not expected to pose a cancer risk to humans. This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to methoxyfenozide residues.

### V. Other Considerations

#### A. Analytical Enforcement Methodology

Adequate enforcement methodology (high pressure liquid chromatography with mass spectrometry (HPLC/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

There are currently no Canadian, Mexican, or Codex maximum residue limits (MRLs) for methoxyfenozide on the commodities for which tolerances are being established.

### VI. Conclusion

Therefore, time-limited tolerances are established for residues of the insecticide methoxyfenozide *per se* (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-

dimethylethyl) hydrazide) in or on sorghum, forage at 30.0 ppm; sorghum, grain at 0.05 ppm; and sorghum, stover at 60.0 ppm. These tolerances expire and will be revoked on December 31, 2012.

### VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) 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 in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances 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).

### VIII. 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, 2009.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.544 is amended by adding paragraph (b) to read as follows:

#### § 180.544 Methoxyfenozide; tolerances for residues.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide methoxyfenozide *per se* (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide), in or on the specified agricultural commodities, resulting from

use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and will be revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Sorghum, forage	30.0	December 31, 2012
Sorghum, grain	0.05	December 31, 2012
Sorghum, stover	60.0	December 31, 2012

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 271

[EPA-R06-RCRA-2008-0755; FRL-8901-1]

#### Texas: Final Authorization of State Hazardous Waste Management Program Revision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Immediate final rule.

**SUMMARY:** The State of Texas has applied to the EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Texas' changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

**DATES:** This final authorization will become effective on July 13, 2009 unless the EPA receives adverse written comment by June 12, 2009. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

**ADDRESSES:** Submit your comments by one of the following methods:

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

2. **E-mail:** [patterson.alima@epa.gov](mailto:patterson.alima@epa.gov).

3. **Mail:** Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

4. **Hand Delivery or Courier:** Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

**Instructions:** Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov), or e-mail. The [regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. You can view and copy Texas' application and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following locations: Texas Commission on Environmental Quality (TCEQ), 12100 Park S. Circle, Austin TX 78753-3087, (512) 239-6079 and EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, phone number (214) 665-8533. Interested persons wanting to

examine these documents should make an appointment with the office at least two weeks in advance.

#### FOR FURTHER INFORMATION CONTACT:

Alima Patterson, Region 6 Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, (214) 665-8533, EPA Region 1445 Ross Avenue, Dallas, Texas 75202-2733, and E-mail address [patterson.alima@epa.gov](mailto:patterson.alima@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask the EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273, and 279.

##### B. What Decisions Have We Made in This Rule?

We conclude that the State of Texas' application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant the State of Texas Final Authorization to operate its hazardous waste program with the changes described in the authorization application. The State of Texas has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that the EPA promulgates