

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 FFDCFA. 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, or otherwise have any unique impacts or local governments. 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).

Although this action does not 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

#### 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 rule in the **Federal Register**. This 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: February 24, 2009.

**Lois Rossi,**

*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. In §180.960, the table is amended by adding alphabetically the following polymer to read:

#### § 180.960 Polymers; exemptions from the requirement of a tolerance.

\* \* \* \* \*

Polymer	CAS No.
* * *	* *
Castor oil, ethoxylated, oleate, minimum number average molecular weight (in amu) 2,000.	220037-02-5
* * *	* *

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2008-0845; FRL-8401-5]

#### Dinotefuran; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of dinotefuran, [ *N*-methyl-*N*'-nitro-*N*'-((tetrahydro-3-furyl)methyl)guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on rice, grain. This action is in response to EPA's granting

of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on rice. This regulation establishes a maximum permissible level for residues of dinotefuran in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2009.

**DATES:** This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 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-2008-0845. 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:

Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9364; e-mail address: [pemberton.libby@epa.gov](mailto:pemberton.libby@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–2008–0845 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 May 26, 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–2008–0845, 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 combined residues of dinotefuran. This time-limited tolerance expires and is revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances for the combined residues of the insecticide, dinotefuran, [N-methyl- N’-nitro- N’’-(tetrahydro-3-furanyl)methyl]guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran 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 and the new safety standard 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 Dinotefuran on Rice and FFDCA Tolerances

Texas declared a crisis exemption under FIFRA section 18 for the use of dinotefuran on rice for control of rice stink bug (*Oebalus pugnax* (F.)).

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by the combined residues of dinotefuran, [N-methyl- N’-nitro- N’’-(tetrahydro-3-furanyl)methyl]guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on rice, grain. 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 are revoked on December 31, 2009, 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 rice, grain 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 dinotefuran meets FIFRA's registration requirements for use on rice or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of dinotefuran by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Texas to use this pesticide on these crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for dinotefuran, 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 combined residues of the insecticide, dinotefuran, [ *N*-methyl- *N'*-nitro- *N''*-(tetrahydro-3-furyl)methyl)guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran. 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 dinotefuran used for human risk assessment can be found at <http://www.regulations.gov> in document *Section 18 Emergency Exemptions for the Use of Dinotefuran on Rice in Texas to Control Stink Bugs*, on page number 6 in docket ID number EPA-HQ-OPP-2008-0845.

##### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dinotefuran, EPA considered exposure under the time-limited tolerance established by this action as well as all existing dinotefuran tolerances in 40 CFR 180.603. EPA assessed dietary exposures from dinotefuran in food as follows:

i. *Acute exposure.* In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100% crop treated (PCT) and tolerance level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA insert 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed 100 PCT and tolerance level residues.

iii. *Cancer.* Dinotefuran is classified as not likely to be a carcinogen, so no dietary assessment was performed for cancer.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for dinotefuran. 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 dinotefuran in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dinotefuran. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppfed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of dinotefuran for surface water, the acute and chronic total EDWCs (parent + metabolites) are 281 parts per billion

(ppb) for acute and 139 ppb for chronic, respectively. The acute and chronic ground water total EDWC (parent + metabolites) is 4.9 ppb.

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).

Dinotefuran is currently registered for uses that could result in residential exposures during the application of products containing dinotefuran and from entering areas previously treated with dinotefuran, such as lawns where children might play, or golf courses and home gardens that could lead to exposures for adults. The Agency combines risks resulting from exposures to individual chemicals when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. For this assessment, the Agency has added together risk values for adults applying dinotefuran to residential lawns and then being exposed to the treated lawn. For children, dermal and incidental oral exposures from activities on treated lawn were combined. These are considered to represent worst case scenarios for co-occurring residential exposures. The proposed section 18 uses of dinotefuran do not add any additional residential exposures or risks.

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 dinotefuran to share a common mechanism of toxicity with any other substances, and dinotefuran does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dinotefuran 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.* EPA evaluated the potential for increased susceptibility of infants and children from exposure to dinotefuran. EPA concluded that the toxicology database for dinotefuran is adequate for FQPA assessment. Available studies include developmental toxicity studies in rats and rabbits, a reproductive toxicity study in rats, and acute and subchronic neurotoxicity studies in rats. EPA concluded that there is low concern for prenatal and/or postnatal toxicity resulting from exposure to dinotefuran. However, there is a concern for neurotoxicity and developmental neurotoxicity resulting from exposure to dinotefuran, and also a concern for immunotoxicity following exposure to dinotefuran during the period of organogenesis.

3. *Conclusion.* Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for dinotefuran, the EPA characterized the degree of concern for the effects observed in the rat reproduction study as low, noting these effects occurred in the presence of parental toxicity and only at the highest dose tested. For all toxicity endpoints established for dinotefuran, a NOAEL lower than this offspring NOAEL is used. No residual uncertainties were identified.

The absence of a NOAEL for the chronic dog study and the need for a developmental immunotoxicity (DIT) study generate some uncertainty regarding the protectiveness of the chronic regulatory endpoint and long-term LOC. Accordingly, EPA does not have reliable data supporting adoption of a safety factor other than the default additional 10x factor as specified in FFDCA section 408(b)(2)(C). The chronic endpoint and long-term LOC have therefore been generated using an

overall safety/uncertainty factor of 1,000 (representing 100x for inter-species extrapolation and intra-species variation, and an additional 10x pursuant to FFDCA section 408(b)(2)(C), i.e., use of a LOAEL). However, the Agency does not have similar concerns regarding acute, short-term, and intermediate-term risk assessments, since the absence of a NOAEL only occurred in a chronic study.

EPA concluded that there is concern for developmental neurotoxicity following exposure to dinotefuran, and recommended that a developmental neurotoxicity (DNT) study in rats be conducted. However, EPA determined that a database uncertainty factor (UFDB) is not needed to account for the lack of the DNT study. The Agency believes there are reliable data showing that the regulatory endpoints are protective of children despite the need for a developmental neurotoxicity study. Developmental neurotoxicity data received and reviewed for other compounds in this chemical class (i.e., neonicotinoids) including thiacloprid, clothianidin, and imidacloprid, indicate that the results of the required DNT study will not likely impact the regulatory doses selected for dinotefuran.

EPA also concluded that there is a concern for immunotoxicity following exposure to dinotefuran during the period of organogenesis. This concern was based on the decreases in absolute and adjusted thymus and spleen weights observed in several species in various studies. In addition, the available data indicate that the juvenile rats appeared to be more sensitive/susceptible to these effects than adults in the 2-generation reproduction study. Therefore, EPA recommended that testing be conducted to assess immune system function in adults and young animals following exposure during the period of organogenesis. A protocol for this testing was developed by the registrant and these studies are now ongoing.

### 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.* The aggregate acute risk estimates include exposure to residues of dinotefuran in food and drinking water. Since the acute dietary exposure assessment already includes the highest acute exposure from the drinking water modeling data, no further calculations are necessary. The acute risk estimate for all populations, resulting from aggregate exposure to dinotefuran in food and drinking water is below EPA's LOC. The food and drinking water exposure estimates for the most highly exposed subgroup, children 1–2 yrs old, is 4.4% of the aPAD.

2. *Chronic risk.* The aggregate chronic risk estimates include exposure to residues of dinotefuran in food and drinking water. Since the chronic dietary exposure assessment already includes the highest chronic exposure from the drinking water modeling data, no further calculations are necessary. The EPA concluded that dinotefuran exposure from food consumption will utilize 42% of the cPAD for the general U. S. population and 86% for children 1–2 years old, the most sensitive subgroup. Dinotefuran is not expected to pose a chronic dietary risk for the general population (including children and infants). The chronic risk estimate for all populations, resulting from aggregate exposure to dinotefuran in food and drinking water is below EPA's LOC.

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). Because there are existing residential uses of dinotefuran, short-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes were considered. However, the toxicological effects for oral and inhalation routes of exposure are different (i.e., neurotoxicity for oral and decrease in body weight for inhalation); and therefore, these exposure scenarios have not been combined. Also, because no systemic toxicity was seen at the limit dose in a 28-day dermal toxicity study, no quantification of short-term dermal risk is required. Therefore, a short-term aggregate risk assessment was not performed. An intermediate-term aggregate risk assessment was performed as a screening level assessment, which will apply to short-term aggregate risk.

4. *Intermediate-term risk.* An intermediate-term aggregate risk assessment was performed as a screening level assessment. Intermediate-term aggregate risk assessments were performed for adults and children. For children, the subgroup with the highest estimated chronic dietary exposure (children 1–2 years old) was aggregated with residential exposures to children playing on treated lawns (dermal and oral hand-to-mouth exposures) in order to calculate the worst case intermediate-term aggregate risk to children. The reciprocal MOE method was used to conduct the intermediate-term aggregate risk assessment for children, since the LOCs are identical for all MOEs in the calculation. For adults, the aggregate risk index (ARI) method was used, since LOC are not identical for all types of exposure in the calculation. For children, the aggregate MOE is 400 which is greater than 100, and therefore does not exceed EPA's LOC. For adults, the total aggregate ARI is 5.5 which is greater than 1, and therefore does not exceed EPA's LOC.

5. *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 dinotefuran residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology (for plant commodities (High Performance Liquid Chromatography (HPLC)/Mass Spectrometry (MS); HPLC/Ultraviolet (UV); and HPLC/MS/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 established Codex, Canadian, or Mexican maximum residue limits for residues of dinotefuran in/on plant or livestock commodities.

## VI. Conclusion

Therefore, time-limited tolerances are established for combined residues of the insecticide, dinotefuran, [ *N*-methyl- *N*'-nitro- *N*''-(tetrahydro-3-furyl)methyl]guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-

methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran, in or on rice, grain at 2.8 parts per million (ppm). These tolerances expire and are revoked on December 31, 2011.

## 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: February 24, 2009.

**Lois Rossi,**

*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 180.603 is amended by revising paragraph (b) to read as follows:

**§ 180.603 Dinotefuran; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of Dinotefuran, [ *N*-methyl- *N'*-nitro- *N''*-(tetrahydro-3-furanyl)methyl]guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Rice, grain .....	2.8	12/31/09

\* \* \* \* \*

[FR Doc. E9-6253 Filed 3-24-09; 8:45 am]  
BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0875; FRL-8400-8]

**Fenpropathrin; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fenpropathrin in or on almond, hulls at 4.5 parts per million (ppm); cherry, sweet, at 5.0 ppm; cherry, tart at 5.0 ppm; fruit, stone, crop group 12 (except cherry) at 1.4 ppm; nuts, tree, crop group 14 at 0.10 ppm; pistachio at 0.10 ppm, PP 4E6867; avocado at 1.0 ppm; black sapote at 1.0 ppm; canistel at 1.0 ppm; maney sapote at 1.0 ppm; mango at 1.0 ppm; papaya at 1.0 ppm; sapodilla at 1.0 ppm; star apple at 1.0 ppm, PP 6E7066; caneberry, subgroup 13-07A at 12 ppm; and olive at 5.0 ppm, PP 7E7298. In addition, the Agency is deleting a time-limited tolerance on currant at 15 ppm which had an expiration date of 12/31/

2008. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 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-2006-0875. 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:** Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of