

or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure

“meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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: September 11, 2006.

**James Jones,**

*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 180.621 is added to read as follows:

#### § 180.621 Dithianon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide dithianon, (5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile) in or on the following commodities:

Commodity	Parts per million
Fruit, pome, group 11 <sup>1</sup> .....	5
Hop, dried cones <sup>1</sup> .....	100

<sup>1</sup>No U.S. registration as of September 5, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2006-0613.; FRL-8089-2]

#### Etofenprox; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) in or on rice grain and rice straw. This action is associated with 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 etofenprox in these food commodities. The tolerances expire and are revoked on December 31, 2009.

**DATES:** This regulation is effective September 20, 2006. Objections and requests for hearings must be received on or before November 20, 2006, 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-2006-0613. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday

through Friday, excluding legal holidays. The Docket 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: *Sec-18-Mailbox@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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of the FFDCA, as amended by the FQPA, 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-2006-0613 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 November 20, 2006.

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-2006-0613, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 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 the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the insecticide etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) or on rice grain at 0.01 parts per million (ppm) and rice straw at 0.02 ppm. These tolerances expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the 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 tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the 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 the 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 the 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 the 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 the 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." This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

**III. Emergency Exemption for Etofenprox on Rice and FFDCA Tolerances**

The Applicant asserts that the current emergency situation with respect to weevil management has arisen primarily from the continuing, and probably increasing, practice of cultivating crawfish in ponds in close proximity to rice fields in southern Louisiana. The great majority of crawfish ponds (at least 75%) are close enough to rice fields to be affected by the management practices used in rice. All of the insecticides currently registered for use against the

rice water weevil in Louisiana are toxic to crawfish. The use of etofenprox for weevil control has one significant advantage over currently used liquid products in that it is formulated as a granular and thus there is far less potential for drift. The Applicant states that the estimated economic loss if no effective weevil controls are available is over 8 million dollars.

EPA has authorized under FIFRA section 18 the use of etofenprox on rice for control of rice water weevil (*Lissorhoptrus oryzophilus*) in Louisiana. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of etofenprox in or on rice grain and rice straw. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the 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 lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances expire and are revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in these tolerances remaining in or on rice grain or rice straw after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these 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 etofenprox meets EPA'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 these tolerances serve as a basis for registration of etofenprox by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for etofenprox, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

Consistent with section 408(b)(2)(D) of the FFDCA, 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 etofenprox and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for residues of etofenprox in or on rice grain at 0.01 ppm and rice straw at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

##### **A. Toxicological Endpoints**

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ( $RfD = NOAEL / UF$ ). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) =  $NOAEL / \text{exposure}$ ) is calculated and compared to the LOC.

The linear default risk methodology ( $Q^*$ ) is the primary method currently used by the Agency to quantify carcinogenic risk. The  $Q^*$  approach assumes that any amount of exposure will lead to some degree of cancer risk. A  $Q^*$  is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as  $1 \times 10^6$  or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$ ) is calculated. A summary of the toxicological endpoints for etofenprox used for human risk assessment is shown in the following Table:

## DOSES AND TOXICOLOGICAL ENDPOINTS FOR ETOFENPROX

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies, Intraspecies and any Traditional UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 years of age)	Not selected	NA	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Acute Dietary (General population including infants and children)	Not selected	NA	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Chronic Dietary (All populations)	NOAEL = 3.7 mg/kg/day Chronic RfD = 0.037 mg/kg/day	FQPA SF = 1x cPAD = Chronic RfD/Special FQPA SF = 0.037 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Study in Rat (MRID No. 40449707) LOAEL = 25.5 mg/kg/day based on increased thyroid weights. Related to increased liver weights and histopathology changes in liver and thyroid that occurred at the higher dose.
Incidental Oral Short-Term (1 - 30 days)	NOAEL = 100 mg/kg/day UF = 100	LOC for MOE = 100	Developmental Toxicity in Rabbit (MRID No. 45210602) LOAEL = 300 mg/kg/day based on decreased body weights, body weight gains, and food consumption (maternal toxicity).
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL = 20 mg/kg/day UF = 100	LOC for MOE = 100	Subchronic Oral Toxicity in Rat (MRID No. 40449703) LOAEL = 120 mg/kg/day based on decreased body weight gain, increased liver and thyroid weights with corresponding histopathology, changes in hematology and clinical chemistry.
Dermal (All durations)	NA	NA	No systemic toxicity was identified in the dermal 28-day study; Highest Dose Tested was 1,000 mg/kg/day.
Inhalation (All durations)	NOAEL = 10.6 mg/kg/day UF = 100	LOC for MOE = 100 Residential LOC for MOE = 100 Occupational	13-Week Inhalation Toxicity in Rat (MRID No. 40449705) LOAEL = 52.3 mg/kg/day based on organ weight changes and histopathological changes in liver, adrenals and thyroid.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis."		

UF = uncertainty factor, FQPA SF = Any additional safety factor retained due to concerns unique to the FQPA, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Risk assessments were conducted by EPA to assess dietary exposures from etofenprox in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the

individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The concentration of etofenprox in rice commodities is assumed at tolerance level and 100 percent of rice grown is assumed to be treated.

iii. *Cancer.* Etofenprox has been classified as, "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." In 1989, the EPA classified etofenprox as a "Group C Possible Human Carcinogen" based on thyroid tumors in rats. In 1996 the EPA

evaluated additional information submitted by the registrant, Mitsui Toatsu, regarding the carcinogenic potential of etofenprox. Its objective was to demonstrate a threshold mechanism for the thyroid tumors in rats. In 2005, an additional 4-week dietary investigative study on thyroid function and hepatic microsomal enzyme induction in rats was reviewed by the EPA. In 2005, the Agency considered if the additional study along with the previously submitted data provided sufficient information to support re-evaluation of etofenprox's carcinogenicity status. In consideration of these new data, and in accordance with the EPA Final Guidelines for Carcinogen Risk Assessment, etofenprox was classified as "Not likely to be

carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." This decision was based on the following considerations:

a. Treatment-related thyroid follicular cell tumors were seen in both male and female rats at 4,900 ppm, which was considered to be adequate, and not excessive, to assess carcinogenicity;

b. No treatment-related tumors were seen in male or female mice when tested at a dose that was considered adequate to assess carcinogenicity;

c. There is no mutagenicity concern for etofenprox form *in vivo* or *in vitro* assays;

d. The non-neoplastic toxicological evidence (i.e., thyroid growth and thyroid hormonal changes) indicated that etofenprox was inducing a disruption in the thyroid-pituitary hormonal status; and

e. Rats are substantially more sensitive than humans to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance. The overall weight-of-the-evidence was considered sufficient to indicate that etofenprox induced thyroid follicular tumors through an antithyroid mode of action; The quantification of carcinogenic potential is not applicable. Therefore, no risk quantification is required.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for etofenprox in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of etofenprox. 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 provisional refined rice models (Method A and B) and SCI-GROW models, the estimated environmental concentrations (EECs) of etofenprox for chronic exposures are estimated to be 2.5 parts per billion (ppb) for surface water and 0.002 ppb for ground water.

The estimated drinking water concentrations (EDWCs) for etofenprox were directly entered into the dietary exposure model DEEM-FCID™. For chronic dietary risk assessment, the annual average concentration of 2.5 ppb was used to assess the contribution to 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).

Etofenprox is currently registered for use on the following residential non-dietary sites: Outdoor (yard/patio), spot-on pet treatment, indoor foggers, and crack and crevice/spot treatment to control a variety of crawling and flying insect pests. The residential risk assessment was conducted using the following exposure assumptions: Average food and drinking water exposures are aggregated with exposures to toddlers from inhalation and hand-to-mouth activities following the use of an indoor total-release fogger and hand-to-mouth from contact with a companion cat treated with the etofenprox spot-on product. Aggregate assessment for adults combines average food and water exposures for the total U.S. population with adult handler and post application inhalation exposures from the use of the indoor total-release fogger. These residential uses are believed to be the ones most likely to co-occur (comprehensive flea treatment approach), and also present the most conservative (worst-case) scenario for potential aggregate exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to etofenprox and any other substances and etofenprox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that etofenprox has 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 of the FFDCA 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies.* A prenatal developmental toxicity study in rabbits showed no quantitative/qualitative evidence of increased susceptibility in offspring. In the rabbit study the developmental effects were seen at doses that resulted in maternal deaths at the high dose. Additionally, the rabbit developmental study showed increased abortions, decreased maternal body weights, body weight gains and food consumption. In the rabbit study, the maternal LOAEL (300 milligram/kilogram/day (mg/kg/day)) is equal to the developmental LOAEL. In the 1-generation/developmental study in rats, increased susceptibility in the offspring was not observed. In the rat developmental study, the maternal LOAEL was equal to the developmental LOAEL.

3. *Reproductive toxicity study.* The 2-generation reproduction study in rats did not show evidence of quantitative/qualitative susceptibility in offspring. In this study rats showed decreased pup weights, increased thyroid, liver and kidney weights with corresponding pathological changes in pups, and clinical signs of pups during most of the lactation period which included body tremors, distended abdomen, lethargy, unsteady gait, and abnormal movements. However, except for thyroid weight in female pups, all of these effects occurred at the highest dose tested (HDT). The effects on organ weights carried over to the adults of both the F<sub>1</sub> and F<sub>2</sub> generations with corresponding centrilobular hepatocyte enlargement and increased thyroidal epithelial height in the HDT group of the F<sub>1</sub> generation. At the high dose, parents (F<sub>0</sub>) had similar effects on their organs as the pups: increased liver, thyroid, and kidney weights with pathological changes in the kidney. The parental LOAEL was equal to the offspring LOAEL in the 2-generation reproduction study in rats.

4. *Prenatal and postnatal sensitivity.* There is no indication of increased quantitative/qualitative evidence of susceptibility of the offspring in the developmental rat or rabbit studies or in the 2-gen reproduction study in the rat. Developmental effects were seen at doses that caused maternal toxicity. No developmental effects were seen in the rat 1-generation/developmental study. In the 2-generation reproduction toxicity study, there was no evidence of quantitative and qualitative susceptibility because the presence of toxicity in the offspring occurred at the level of parental toxicity (increased organs weights and associated pathological changes occurred in both the pups and parents). In the developmental neurotoxicity study in rats, the observed eye abnormalities associated with body injuries could not be disassociated from possible altered treatment-related maternal behavior that resulted in injury to the pups.

5. *Conclusion.* The toxicology database for etofenprox is essentially complete. The data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the Food Quality Protection Act (FQPA). Evidence of quantitative and qualitative susceptibility of offspring were not observed, and therefore, the FQPA 10x safety factor was reduced to 1x.

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

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf>.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption

from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk.* An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified. Therefore, acute risk from etofenprox exposure is not expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to etofenprox from food and water will utilize <1% of the cPAD for the U.S. population, and <1% of the cPAD for all infants (<1 year old), the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of etofenprox is not expected. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Etofenprox is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for etofenprox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 960 for adults and 350 for inhalation and 560 for incidental oral for toddlers. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Etofenprox is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for etofenprox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water, and residential exposures

aggregated result in aggregate MOEs of 960 for adults and 130 for toddlers. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water, and residential uses. Therefore, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Etofenprox has been classified as, "not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." Therefore, etofenprox is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to etofenprox residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Team Leader, Emergency Response Team, Risk Integration, Minor Use, Emergency Response Branch (7505P) 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8179; e-mail address: [britten.anthony@epa.gov](mailto:britten.anthony@epa.gov).

### *B. International Residue Limits*

Etofenprox is in the CODEX system with a residue definition of etofenprox (fat soluble), but without an MRL on rice.

## **VI. Conclusion**

Therefore, time-limited tolerances are established for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether), in or on rice, grain at 0.01ppm and rice, straw at 0.02 ppm.

## **VII. Statutory and Executive Order Reviews**

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May

22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the

FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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: September 8, 2006.

**James Jones,**

*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 180.620 is added to read as follows:

#### § 180.620 Etofenprox; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Rice, grain .....	0.01	12/31/09
Rice, straw .....	0.02	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2006-0617; FRL-8091-6]

#### **Pantoea Agglomerans Strain E325; 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 *Pantoea agglomerans* strain E325 on apples and pears when applied/used as a microbial pesticide. Northwest Agricultural Products submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pantoea agglomerans* strain E325.

**DATES:** This regulation is effective September 20, 2006. Objections and requests for hearings must be received on or before November 20, 2006, and must be filed in accordance with the instructions provided in 40 CFR part