ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0567; FRL–8390–9]

Etofenprox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of etofenprox (2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether) in or on rice, grain. Mitsui Chemical, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 12, 2008. Objections and requests for hearings must be received on or before February 10, 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–2008–0567. 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: Kevin Sweeney, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5063; e-mail address: *sweeney.kevin@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 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2008–0567. 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 as required by 40 CFR part 178 on or before February 10, 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 this copy, identified by docket ID number EPA–HQ–OPP–2008–0567, 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. Petition for Tolerance

In the **Federal Register** of August 13, 2008 (73 FR 47185) (FRL– 8376–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7215) by Mitsui Chemicals, Inc., Shiodome City Center, 1–5–2, Higashi-Shimbashi, Minato-ku, Tokyo, Japan 105–7117 c/o Landis International, Inc. P.O. Box 5126, 3185 Madison Highway, Valdosta, GA 31603–5126 USA. The petition requested that 40 CFR 180.620 be amended by establishing tolerances for combined residues or residues of the insecticide etofenprox and the metabolite 2-(4-ethyoxyphenyl)-2-methylpropyl 3-phenoxybenzoate, in or on rice, grain at 0.01 parts per million (ppm) and rice, straw at 0.06 ppm. That notice referenced a summary of the petition prepared by Mitsui Chemicals, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the tolerance expression to include only residues of etofenprox *per se* in or on rice grain of 0.01 ppm. EPA has also concluded that a etofenprox tolerance for rice straw is unnecessary. The reason for these changes is explained in Unit IV.C.

III. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of 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 and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of etofenprox in or on rice, grain at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Etofenprox has low acute toxicity from the oral, dermal, and inhalation routes of exposure. It is not an acute eye or skin irritant and is not a dermal sensitizer; however, etofenprox does cause skin irritation after repeated exposure. The major target organs of etofenprox are the liver, thyroid, kidney, and hematopoietic system.

Etofenprox was assessed in a complete battery of subchronic, chronic, carcinogenicity, developmental and reproductive studies as well as acute, subchronic, and developmental neurotoxicity studies. Etofenprox is classified as a synthetic pyrethroid ether insecticide and has an excitatory neurotoxic mode of action. Neurotoxicity studies, including a developmental neurotoxicity study in the rat, did show some evidence of neurotoxic effects as is expected of a neurotoxicant but these effects were unremarkable.

The most sensitive target organs in the toxicology database are the thyroid and liver. The kidney is also a common target organ of toxicity. There is no evidence of carcinogenicity and etofenprox is classified as ''Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis'' and, therefore, no quantitative cancer risk assessment is required. There is no indication of increased quantitative or qualitative susceptibility of the developing offspring in toxicology database for etofenprox. Developmental effects were seen at doses that caused maternal toxicity. There was no evidence of reproductive effects in the 2–generation reproduction study in rats. Etofenprox was negative for mutagenic/genotoxic potential based on the results of mutagenicity studies. There is no evidence of immunotoxicity in the database. Immunotoxicity studies are a new data requirement and are required as a condition of registration. The toxicology database for etofenprox is sufficient to assess human health hazards and the Point of Departure (POD) selected for deriving the chronic reference dose will adequately account for all chronic effects determined to result from exposure to etofenprox in chronic animal studies, including potential immunotoxicity effects.

Specific information on the studies received and the nature of the adverse effects caused by etofenprox, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, can be found at *http://www.regulations.gov* in document *Etofenprox: Human Health Risk Assessment for Proposed Section 3 Uses on Rice and as ULV Mosquito Adulticide*, at pages 14–29 in docket ID number EPA–HQ–OPP–2008–0567.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological POD is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, 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 etofenprox used for human risk assessment can be found at *http://www.regulations.gov* in document *Etofenprox: Human Health Risk Assessment for Proposed Section 3 Uses on Rice and as ULV Mosquito Adulticide*, at pages 30–31 in docket ID number EPA–HQ–OPP–2008–0567.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. EPA assessed dietary exposure to etofenprox, the EPA considered exposure under the petitioned for tolerance on rice, grain; the first food use of etofenprox. EPA assessed dietary exposures from etofenprox in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and 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 1–day or single exposure.

No such effects were identified in the toxicological studies for etofenprox; 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, 1998 CSFII. As to residue levels in food, EPA assumed that all rice grain contained tolerance level residues of etofenprox

and that 100 percent of the rice crop was treated with etofenprox.

iii. *Cancer*. EPA classified etofenprox as ''Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.'' An increased incidence of thyroid follicular adenomas and/or carcinomas was seen in males and females administered etofenprox in their diet at 4,900 ppm, a dose that was considered adequate to assess potential for carcinogenicity. No treatment-related tumors were seen in male or female mice when tested at a dose that was considered adequate to assess carcinogenicity. The non-neoplastic toxicological evidence (i.e. thyroid growth, thyroid hormonal changes) indicated that etofenprox was inducing a disruption in the thyroid-pituitary hormonal status. Rats are substantially more sensitive to humans to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance. There was no mutagenicity concern for etofenprox from *in vivo* or *in vitro* assays. The overall weight-of-evidence was considered sufficient to indicate that etofenprox induces thyroid follicular tumors through an anti-thyroid mode of action. The Agency has determined that quantification of human cancer risk is not appropriate because the chronic reference dose is protective against the chronic effects determined to result from exposure to etofenprox, including potential cancer effects.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for etofenprox. 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 etofenprox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 Tier I Rice Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of etofenprox for chronic exposure were calculated based on a maximum application rate of 0.27 pound (lb) active ingredient (ai)/acre(A)/year. The estimated drinking water concentrations (EDWCs) of etofenprox for chronic exposures for non-cancer assessments are estimated to be 0.88 (parts per billion (ppb) for surface water and 1.55 x 10–^{3} ppb for ground water. Acute exposure (single dose or 1–day exposure) effects were not identified in the toxicological studies for etofenprox; therefore, a quantitative acute drinking water assessment is unnecessary.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.88 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 the following uses that could result in residential exposures: Indoor and outdoor (yard patio) use as an insect fogger, indoor/outdoor crack and crevice/spot treatment; as a cat and dog spot-on treatment; and outdoors as a wide-area mosquito adulticide. EPA assessed residential exposure using the following assumptions: Adults are potentially exposed to etofenprox residues during residential application of etofenprox. Both adults and children are potentially exposed to etofenprox residues after application (post-application) of etofenprox products in residential settings. Exposure estimates were generated for residential handlers and individuals with potential post-application contact with lawn, soil, treated indoor surfaces, and treated pets using the EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment, and dissipation or transfer data from a turf transferable residue (TTR) study and a pet transferrable residue study. Short-term and intermediate-term inhalation exposures for adults, and short-term and intermediate-term incidental oral and inhalation exposures for children are anticipated. These estimates are considered conservative, but appropriate, since the study data were generated at maximum application rates.

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.''

Etofenprox is classified as a synthetic pyrethroid ether insecticide and is a member of the pyrethroid class of pesticides. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data show that there are multiple types of sodium channels and it is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect. Nor do we have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When available, the Agency will evaluate results of this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. 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 safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database includes a developmental toxicity studies in rabbits and rats; a 2–generation reproduction studies in the

rat; and a developmental (DNT) neurotoxicity study in the rat. There was no evidence of increased quantitative or qualitative susceptibility following *in-utero* and/or postnatal exposure in the development toxicity studies in rats or rabbits, or in the 2–generation rat reproduction study.

3. *Conclusion*. EPA has determined that reliable data show 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 etofenprox is complete, except for immunotoxicity testing. Immunotoxicity studies are a new data requirement and EPA has determined that an additional uncertainty factor is not required to account for potential immunotoxicity. The reasons for this determination are explained as follows:

EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted, these studies are not yet available for etofenprox. Due to the lack of evidence of immunotoxicity for etofenprox, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 3.7 milligram/kilogram/day (mg/kg/day), which is already established as the cRfD point of departure for etofenprox. An additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity.

ii. There is no evidence that etofenprox 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.

iii. There are no residual uncertainties identified in the exposure databases for the following reasons:

- The chronic dietary food exposure assessment utilizes proposed tolerance level residues and 100 PCT information for all commodities. By using these screening level assessments, actual exposures/risk will not be underestimated;
- EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to etofenprox in drinking water.
- EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by etofenprox.

E. 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 and no acute dietary endpoint was selected. Therefore, etofenprox is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to etofenprox from food and water will utilize < 1% of the cPAD for the general U.S. population and all population subgroups. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of etofenprox is not expected.

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

Etofenprox is currently registered for uses that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to etofenprox. Since the doses and endpoints selected for etofenprox to assess short-term and intermediate-term exposure are identical, the short-term and intermediate-term risk estimates for etofenprox are the same.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term and intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 1,200 for adults and 170 for toddlers. For adults, the short-term/ intermediate-term aggregate risks combined food and drinking water exposure with short-term/intermediate term inhalation exposure. For toddler short-term and intermediate-term aggregate risks, the average food and drinking water exposure was combined with toddler incidental oral exposures following pet treatments and indoor fogger applications, and inhalation exposure following indoor fogger applications.

4. *Aggregate cancer risk for U.S. population*. The Agency has classified etofenprox as ''Not likely to be carcinogenic to humans at doses that do not alter thyroid hormone homeostasis.'' The chronic reference dose will is protective of chronic effects determined to result from exposure to etofenprox, including potential cancer effects.

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 etofenprox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Liquid Chromatographic Mass Spectrometric (LC/MS/MS) method) 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*.

B. International Residue Limits

The Codex Alimentarius Commission (CODEX) has established maximum residue levels (MRLs) for the residue of etofenprox *per se* in or on pome fruits at 1 mg/kg and potato at 0.01 mg/kg. Currently, there are no CODEX MRLs for rice commodities. Etofenprox is scheduled for periodic re-evaluation by CODEX in 2012. As discussed in this unit, EPA has adopted a tolerance expression for etofenprox which should make the rice tolerances compatible with proposed CODEX MRLs for rice commodities.

C. Revisions to Petitioned-For Tolerances

The petitioner proposed tolerances for combined residues or residues of the insecticide etofenprox and the metabolite 2-(4-ethyoxyphenyl)-2-

methylpropyl 3-phenoxybenzoate, in or on rice, grain at 0.01 ppm and rice, straw at 0.06 ppm. Although EPA has included the metabolite 2-(4-ethyoxyphenyl)-2-methylpropyl 3-phenoxybenzoate in its assessment of exposure and risk for etofenprox, EPA has decided to exclude the metabolite from the tolerance expression because the metabolism and residue studies show that the parent compound will serve as a better indicator of potential misuse. Limiting the tolerance expression to the parent only also allows for harmonization with the proposed Codex MRLs. EPA has determined that rice, straw is not a significant feedstuff; therefore, a tolerance for residues of etofenprox *per se* in/on rice straw is not needed. The tolerance has been revised to reflect the correct commodity definition, ''rice, grain'' and the proposed tolerance expression has been revised to residues of etofenprox *per se* in or on rice, grain of 0.01 ppm.

V. Conclusion

Therefore, a tolerance is established for residues of etofenprox, (2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether), in or on rice, grain at 0.01 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. 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).

40 CFR Part 180

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

Dated: December 4, 2008.

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 180.620 is amended by revising pargraph (a) to read as follows:

§ 180.620 Etofenprox; tolerance for residues.

(a) *General.* A tolerance is established for residues of the insecticide etofenprox [2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether] in or on the following raw agricultural commodity:

Commodity	Parts per million
Rice, grain	0.01

* * * * *

[FR Doc. E8–29346 Filed 12–11–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0217; FRL–8393–1]

Isoxaflutole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the pesticide tolerance for isoxaflutole by removing isoxaflutole's benzoic acid metabolite (RPA 203328) from the established tolerance expression and revising downward tolerance levels for isoxaflutole in or on field corn. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 12, 2008. Objections and requests for hearings must be received on or before February 10, 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–2008–0217. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some