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) (Pub. L. 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).

List of Subjects in 40 CFR Part 180

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

Dated: March 21, 2011.

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 180.176 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.176 Mancozeb; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond	0.1
Almond, hulls	4
* * * * *	
Broccoli	7
Cabbage	9
* * * * *	
Lettuce, head	3.5
Lettuce, leaf	18
* * * * *	
Pepper	12
* * * * *	

* * * * *

[FR Doc. 2011–7461 Filed 4–5–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0493; FRL–8863–1]

Ethiprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances (without U.S. registrations) for residues of the insecticide ethiprole [5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(ethyl)-sulfinyl]-1*H*-pyrazole-3-carbonitrile], including its metabolites and degradate, in or on rice and tea. Bayer CropScience LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 6, 2011. Objections and requests for hearings must be received on or before June 6, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0493. 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: Carmen Rodia, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; e-mail address: *rodia.carmen@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 get electronic access to other related information?

You may 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. How 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–2009–0493 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 6, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0493, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 19, 2009 (74 FR 41898) (FRL–8426–7), 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 9E7550) by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709–2014. The petition requested that 40 CFR part 180 be amended by establishing permanent tolerances for residues of the insecticide ethiprole [5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(ethyl)-sulfinyl]-1*H*-pyrazole-3-carbonitrile], expressed as parent equivalent, in or on cattle, fat at 0.1 parts per million (ppm); cattle, liver at 0.1 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.02 ppm; eggs at 0.05 ppm; goat, fat at 0.1 ppm; goat, liver at 0.1 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.02 ppm; hog, fat at 0.1 ppm; hog, liver at 0.1 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.02 ppm; horse, fat at 0.1 ppm; horse, liver at 0.1 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.02 ppm; milk at 0.01 ppm; poultry, fat at 0.1 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.05 ppm; rice, grain at 3.0 ppm; sheep, fat at 0.1 ppm; sheep, liver at 0.1 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts, except liver at 0.02 ppm; and tea, dried at 50 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience LP, the registrant, which is available 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 a number of the petitioned-for tolerances for ethiprole. The reasons for these changes are 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 ethiprole, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethiprole 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.

Ethiprole has a low acute toxicity via the acute oral, dermal, and inhalation routes of exposure, and is not a skin sensitizer nor a skin or eye irritant. In the mammalian toxicology database, the critical effects of ethiprole are hepatoxicity and thyroid toxicity. The rat was the most sensitive species overall after administration of ethiprole. Evidence of hepatoxicity is seen in the 28-day mouse and rat; 90-day rat and dog; chronic/carcinogenicity rat and mouse; 2–generation rat; developmental rat; and subchronic neurotoxicity rat studies, and was manifested as increased liver weight and hepatocellular hypertrophy. Other indicators of hepatotoxicity include:

1. Increased prothrombin time as observed in the 28- and 90-day rat studies; and

2. Changes in clinical chemistry such as increased alanine transaminase activity, increased alkaline phosphates activity, increased cholesterol, increased triglycerides, and increased total protein concentration.

Liver toxicity was also observed within the mice chronic/carcinogenicity study. A statistically significant increased incidence (12%) of hepatocellular adenoma (HCA) was observed in females at the highest dose tested (HDT), when compared to controls (6/50 vs. 0/50). These benign tumors were only observed in high dose females where a reduced survival rate was also observed. Since no treatment-related HCA were reported at the lower dose levels, the dose-dependent effect could not be established. In addition, no hepatocellular carcinoma was noted in either sex. Given the lack of genotoxicity potential, the absence of carcinoma following a prolonged exposure to ethiprole, and the absence of any dose relationship, this increased incidence of HCA in high dose female mice was, therefore, considered to be due to a threshold mechanism with a probable phenobarbital-like action hepatocellular hypertrophy associated

with transient liver cell proliferation followed by a steady state.

Thyroid toxicity was also observed in numerous studies throughout the ethiprole database. These studies include the 28- and 90-day rat; chronic/carcinogenicity rat; 2-generation rat; and subchronic neurotoxicity rat studies. The results/observations of the 3 mechanistic studies conducted in rats suggest that ethiprole exerts effect by inducing hepatic microsomal enzymes (*e.g.,* T4-glucuronyl transferase). This mechanism can lower the circulating levels of thyroid hormones (T4 and T3), resulting in a release from negative feedback inhibition and a compensatory increased secretion of thyroid stimulating hormone (TSH) by the pituitary gland. This negative feedback loop results in increased TSH levels to compensate for the reduced T4 blood levels, since glucuronyl transferase in the liver is conjugating and removing T4 via the bile. The chronic hypersecretion of TSH predisposes the sensitive rodent thyroid gland to develop an increased incidence of focal hyperplasic and neoplasic (adenomas) lesions by a secondary (epigenetic) mechanism. The thyroid toxicity observed in adult rodents was manifested as increased thyroid weight, thyroid follicular hyperthrophy along with higher TSH plasma levels, and reduced T4 (thyroxine) plasma levels. A study that evaluates homeostasis and the developing nervous system in the young is not available.

Based on a battery of mutagenicity studies, ethiprole is not considered to be genotoxic. In accordance with the *EPA's Final Guidelines for Carcinogen Risk Assessment* (March 2005), ethiprole is classified as "Suggestive Evidence of Carcinogenic Potential." This classification is based on benign liver tumors in female mice, and benign thyroid tumors in male rats. While the evidence from animal data is suggestive of carcinogenicity, a cancer risk to humans from dietary exposure to ethiprole is of low concern and the cRfD is deemed protective of any potential cancer risk based on the following weight-of-evidence considerations:

1. The liver tumors in mice were benign with no progression to malignancy;

2. The thyroid tumors in rats were also benign (with no progression to malignancy), and the increase in the tumor incidences at the high dose did not reach statistical significance when compared to controls;

3. In both species (mice and rats), tumors were observed only at the HDT (*i.e.,* there was a lack of evidence of a dose-response relationship);

4. There is no concern for mutagenicity/genotoxicity;

5. The no-observed-adverse-effect-level (NOAEL) of 0.85 milligrams/kilograms/day (mg/kg/day) used for deriving the cRfD is approximately 86-fold lower than the dose (73 mg/kg/day) that induced benign tumors in mice; and

6. The retention of the 10x FQPA SF yields a chronic Population Adjusted Dose (cPAD) that provides even more protection for non-cancer dietary risk (*i.e.,* the cPAD of 0.003 mg/kg/day is approximately 2,400-fold lower than the dose at which tumors were seen).

Thus, for all these reasons, the Agency has determined that the cPAD will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to ethiprole.

More detailed information on the studies received and the nature of the adverse effects caused by ethiprole as well as the NOAEL and the LOAEL from the toxicological studies can be found in the document entitled, "Ethiprole: Human Health Risk Assessment for Proposed Uses on Imported Rice and Tea," dated December 1, 2010, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information on pages 13–20 of 60.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the lowest-observed-adverse-effect-level (LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). 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 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.*

The acute and chronic dietary endpoints were not harmonized with Canada's Pesticide Management Regulatory Agency (PMRA) due to policy differences. For both endpoints, PMRA chose the prenatal developmental toxicity study in rabbits as their POD. PMRA considered this endpoint to be protective of all populations, including pregnant women and their fetuses. EPA did not choose the prenatal developmental toxicity study in rabbits for the acute dietary endpoint as the observed increased incidence of abortions in the dams occurred from days 21 to 28 days of gestation, and was not considered to be a single dose (acute) effect since it did not occur within 1 to 2 days of dosing. In addition, EPA did not rely on the prenatal developmental toxicity in rabbits for the chronic dietary assessment since it is not a long-term study. Instead, EPA relied on the combined chronic/carcinogenicity oral (dietary) toxicity rat study in which thyroid and liver toxicity were observed at 3.21 mg/kg/day with a NOAEL of 0.85 mg/kg/day. This chronic rat study is protective of the effects observed in the rabbit developmental study selected by Canada's PMRA. A summary of the toxicological endpoints for ethiprole used for human health risk assessment is shown in the table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHIPROLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/FQPA safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (All Populations, including Infants, Children, and Females, 13–49 years of age).	NOAEL = 35 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = UF_{DB} = 10x	Acute RfD = 0.35 mg/kg/day .... aPAD = 0.035 mg/kg/day	Acute Neurotoxicity (dietary) in Rats. LOAEL = 250 mg/kg/day, based on increased tremors (females), decreased grooming (both sexes), decreased arousal alert (females), increased number of animals for which no assessment of gait was possible (females), increased eye closure (females), increased standing/sitting hunched (females), deceased activity and rearing counts (females), increased hindlimb and forelimb grip strength (males), decreased forelimb grip strength (day 8) (females), decreased splay (females, day 1), and increased splay (males, day 8).
Chronic Dietary (All Populations).	NOAEL= 0.85 mg/kg/day ..... UF_A = 3x UF_H = 10x FQPA SF = UF_{DB} = 10x	Chronic RfD = 0.03 mg/kg/day cPAD = 0.003 mg/kg/day	Combined Chronic/Carcinogenicity Oral (dietary) Toxicity in Rats. LOAEL = 3.21/4.40 mg/kg/day M/F, based on observed effects in the thyroid and/or liver (histopathologic changes, increased organ weights, and/or altered thyroid hormone or bilirubin levels).
Cancer (Oral, Dermal, Inhalation).	Suggestive Evidence of Carcinogenicity. Quantification of cancer risk using a cancer potency factor is not needed. The cRfD is protective of potential cancer risk.		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic).

More detailed information on the toxicological endpoints for ethiprole can be found in the document entitled, "Ethiprole: Human Health Risk Assessment for Proposed Uses on Imported Rice and Tea," dated December 1, 2010, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information on page 21 of 60.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethiprole, EPA considered exposure under the petitioned-for tolerances. Acute and chronic dietary (food only) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™), Version 2.03. The dietary assessments assumed that 100% of crops with the requested uses of ethiprole were treated and that all treated crops contained residues at tolerance-level residues for acute and chronic dietary exposure. In addition, empirical processing factors were assumed for the requested crop uses. EPA assessed dietary exposures from ethiprole 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. An unrefined, acute dietary exposure assessment using tolerance-level residues, empirical processing factors and assuming 100 percent crop treated (PCT) for the proposed commodities was conducted for the general U.S. population and various population subgroups.

ii. *Chronic exposure.* An unrefined chronic dietary risk analysis was conducted with the DEEM–FCID™ model, assuming tolerance-level residues, empirical processing factors, and 100 PCT.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data is not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has determined that the cPAD will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to ethiprole. No separate exposure assessment pertaining to cancer risk was performed for ethiprole; rather, EPA relied on the chronic exposure assessment described in this Unit for assessing the risk of all chronic effects, including cancer.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue information in the dietary assessment for ethiprole. Tolerance-level residues and 100 PCT were assumed for all proposed food commodities.

More detailed information on the acute and chronic dietary (food only)

exposure and risk assessment for ethiprole can be found in the document entitled, "Ethiprole: Acute and Chronic Dietary (Food Only) Exposure and Risk Assessment for Proposed Imported Tolerances on Rice and Tea," dated December 1, 2010, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information on pages 6–8 of 12.

2. *Dietary exposure from drinking water.* Ethiprole and its degradates were not considered for drinking water assessment because ethiprole is not registered for use in the U.S.; therefore, exposure to drinking water is precluded.

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

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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."

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 ethiprole and any other substances, and ethiprole 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 ethiprole 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 Web site 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 ten-fold (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 safer for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data are available to EPA to support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Although no teratogenic effects were observed in the existing toxicology database, there is uncertainty regarding the potential impact of ethiprole on thyroid hormone homeostasis in the developing organism. Given the observations that thyroid hormones were affected in several studies throughout the ethiprole database and the critical role thyroid hormones play in the development of the nervous system, the Agency is requiring a developmental thyroid toxicity study to assess for more subtle effects that may not be identified in the available core guideline studies.

3. *Conclusion.* Based on the hazard and exposure data, the Agency is retaining the 10x FQPA SF due to the lack of a developmental thyroid toxicity study in rats. As described previously, hormonal changes (decreased T4 plasma levels, increased TSH plasma levels and alteration in thyroid weights) were observed in several studies following oral administration of ethiprole. Therefore, there is concern that perturbation of thyroid homeostasis may lead to hypothyroidism, and possibly result in adverse effects on the developing nervous system. Since the developmental and reproductive studies do not assess the thyroid in the developing animals, EPA has required that a developmental thyroid assay be conducted to evaluate the impact of ethiprole on thyroid hormones, structure and/or thyroid hormone homeostasis during development. EPA's determination on the FQPA SF is based on the following:

i. The toxicological database for ethiprole is complete with the exception of a developmental thyroid toxicity study in juvenile rats, which is needed to address potential prenatal and perinatal thyroid toxicity. Thyroid toxicity was noted throughout the toxicological database; however, the thyroid toxicity was assessed in adult animals only.

ii. In mammals, no neurotoxic effects were observed during the subchronic neurotoxicity study in which adverse effects of increased thyroid and liver weights were observed at 7.2/33 mg/kg/day (LOAEL) in males and females, respectively. The acute neurotoxicity study yielded a LOAEL of 250 mg/kg/day for decreased locomotor activity (both sexes, day 1) and FOB findings in both sexes on the day of treatment (4 hours after dosing). The FOB findings include increased tremors (females), decreased grooming (both sexes), decreased arousal alert (females), increased number of animals for which no assessment of gait was possible (females), increased eye closure (females), increased standing/sitting hunched (females), decreased activity and rearing counts (females), increased hindlimb and forelimb grip strength (males), decreased forelimb grip strength (day 8) (females), decreased splay (females, day 1), and increased splay (males, day 8). The similarity in the NOAELs from the acute neurotoxicity and subchronic neurotoxicity studies are consistent with the metabolism data that suggests that ethiprole is not accumulated in the system.

A developmental neurotoxicity (DNT) study is not required for ethiprole. In view of the fact that thyroid toxicity appears to be the most sensitive endpoint, and thyroid hormones play a critical role in the development of the nervous system, the Agency is requiring the developmental thyroid toxicity study in lieu of the DNT.

iii. There is no evidence that ethiprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies, or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties in the exposure database for ethiprole. Since the dietary exposure estimates were based on several conservative assumptions, the Agency does not believe that the exposure estimates are underestimated.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the

lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists. For this action, there is potential exposure to ethiprole from food only.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for dietary and non-dietary acute exposures, EPA has concluded that acute exposure to ethiprole from food only will utilize 4% of the aPAD for the general U.S. population and 14% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure. There are no residential uses for ethiprole. Based on the explanation in Unit III.C.3., regarding residential use patterns, acute residential exposure to residues of ethiprole is not expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ethiprole from food only will utilize 22% of the cPAD for the general U.S. population and 42% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. There are no residential uses for ethiprole. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of ethiprole is not expected.

3. *Aggregate cancer risk for U.S. population.* Based on the data summarized and referenced in Unit III.A., EPA has concluded that the cRfD/cPAD for ethiprole is protective of the cancer effects. As noted in this Unit, the chronic exposure for the general U.S. population utilizes 22% of the cPAD.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The submitted data are adequate to satisfy residue analytical methods data requirements for tolerance enforcement purposes. The proposed High Performance Liquid Chromatography/Multistage Mass Spectrometer (HPLC/MS–MS) enforcement method, Method 01128, is acceptable for determination of residues of ethiprole and its sulfone metabolite RPA097973 for data collection in plant commodities. The proposed Gas Chromatograph-Electron Capture Device (GC–ECD) method (Report No. B003572) is suitable for determining residues of parent ethiprole and its sulfone metabolite RPA097973 in milk, eggs and tissues. The FDA multiresidue method testing study for ethiprole and its sulfone metabolite RPA097973 is adequate and indicates that PAM multiresidue methods are not suitable for enforcing maximum residue limits (MRLs) due to the thermolability of ethiprole.

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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international MRLs established by the Codex Alimentarius Commission (Codex), as required by section 408(b)(4) of FFDCA. The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level.

There are currently no MRLs established by Codex for ethiprole. The tolerances established in this rule are identical to those being established in Canada.

C. Revisions to Petitioned-for Tolerances

There are currently no U.S. tolerances or MRLs in Canada for ethiprole and no uses for ethiprole are currently being proposed in the U.S. or Canada. As part of PP 9E7550, Bayer CropScience LP proposed harmonized tolerances/MRLs for ethiprole residues to allow for the importation of ethiprole-treated rice (3.0 ppm) and tea (50 ppm) into the U.S. and Canada. In addition, Bayer CropScience LP proposed tolerances for the combined residues of the insecticide ethiprole in or on various livestock commodities.

Adequate residue data are available from the rice field trials conducted in China, India and Thailand reflecting the critical use pattern for ethiprole on imported rice. The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was utilized for determining appropriate tolerance level for ethiprole residues in or on rice, grain. EPA has determined that these residue data indicate that the tolerance in or on rice, grain should be set at 1.7 ppm.

Adequate residue data are available from the tea field trials conducted in China reflecting the critical use pattern for ethiprole on imported tea. These residue data show that the highest average residues on plucked fresh tea leaves will be 11 ppm. Taking into account data from the tea processing study that shows that combined ethiprole residues concentrate by up to 2.53x in dried tea (green and black), EPA determined that a tolerance of 30 ppm for dried tea would be appropriate.

EPA and PMRA are recommending the same tolerance values for rice and tea. In addition, EPA and PMRA are not establishing tolerances on livestock commodities since ethiprole is not registered in the U.S., and feedstuffs derived from rice are unlikely to be imported into the U.S. and Canada and fed to livestock. Further, based upon review of the available residue data supporting PP 9E7550, EPA has determined that the residue of concern in plant commodities (rice and tea) for both tolerance expression and risk assessment is only ethiprole.

V. Conclusion

Therefore, permanent tolerances (without U.S. registrations) are being established for residues of the insecticide ethiprole, including its metabolites and degradate, in or on the imported plant commodities listed in this Unit. Compliance with the tolerance levels specified in this Unit is to be determined by measuring only ethiprole [5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(ethyl)-sulfinyl]-1*H*-pyrazole-3-carbonitrile], in or on the following imported plant commodities: Rice, grain at 1.7 ppm; and tea, dried at 30 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) (Pub. L. 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).

List of Subjects in 40 CFR Part 180

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

Dated: March 25, 2011.

Steven Bradbury,

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 180.652 is added to read as follows:

§ 180.652 Ethiprole; tolerances for residues.

(a) *General.* Tolerances (without U.S. registrations) are established for residues of the insecticide ethiprole, including its metabolites and degradate, in or on the following commodities listed in the table. Compliance with the tolerance levels specified in the table is to be determined by measuring only ethiprole [5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(ethyl)-sulfinyl]-1*H*-pyrazole-3-carbonitrile], in or on the following commodities:

Commodity	Parts per million
Rice, grain [1]	1.7
Tea, dried [1]	30

[1] There are no U.S. registrations for rice and tea.

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

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

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

[FR Doc. 2011–8024 Filed 4–5–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

[EPA–HQ–RCRA–2010–0851; FRL–9290–6]

Land Disposal Restrictions: Nevada and California; Site Specific Treatment Variances for Hazardous Selenium Bearing Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final actions to both issue a site-specific treatment variance to U.S. Ecology Nevada (USEN) in Beatty, Nevada and to withdraw an existing site-specific treatment variance issued to Chemical Waste Management, Inc. (CWM) in Kettleman Hills, California. These actions pertain to the treatment of a hazardous waste generated by the Owens-Brockway Glass Container Company in Vernon, California that is unable to meet the concentration-based treatment standard for selenium established under the Land Disposal Restrictions program. The site-specific treatment variance issued to USEN provides an alternative treatment standard of 59 mg/L for selenium as measured by the Toxicity Characteristic Leaching Procedure. EPA has determined that the treatment performed by USEN provides the best demonstrated treatment available for this waste by reducing the potential amount of selenium released to the environment, while minimizing the total volume of hazardous waste land disposed.

DATES: This direct final rule will be effective June 6, 2011 without further notice, unless EPA receives adverse written comment by May 6, 2011. If EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2010–0851, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: rcra-docket@epa.gov* and *miller.jesse@epa.gov.* Attention Docket ID No. EPA–HQ–RCRA–2010–0851.
- *Fax:* 202–566–9744. Attention Docket ID No. EPA–HQ–RCRA–2010–0851.
- *Mail:* RCRA Docket (28221T), U.S. Environmental Protection Agency, 1200