the Federal Government and Indian tribes. Thus, EPA 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 EPA 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).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 29, 2012.

Keith A. Matthews,

Director, Biopesticides and Pollution Prevention 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 180.1206 is amended by revising paragraph (b) to read as follows:

§ 180.1206 Aspergillus flavus AF36; exemption from the requirement of a tolerance.

* * * * *

(b) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36 in or on pistachio when applied as an antifungal agent and used in accordance with good agricultural practices.

* * * * *

[FR Doc. 2012–5769 Filed 3–8–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0349; FRL–9335–7]

Penthiopyrad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of penthiopyrad in or on multiple commodities which are identified and discussed later in this document. Mitsui Chemical Agro, Inc. c/o Landis International Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 9, 2012. Objections and requests for hearings must be received on or before May 8, 2012, 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–2010–0349. 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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8050; email address: *maignan.tawanda@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2010–0349 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 May 8, 2012. 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–2010–0349, 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 Tolerances

In the **Federal Register** of October 27, 2010 (75 FR 66092) (FRL–8848–3), 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 9F7661) by Mitsui Chemical Agro, Inc. c/o Landis International Inc., P.O. Box 5126 Valdosta, GA 31603–5126. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide penthiopyrad, (RS)-*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, in or on fruit, pome, group 11 at 0.4 parts per million (ppm); apple, wet pomace at 1.0 ppm; fruit, stone, group 12 at 4.0 ppm; low growing berry, subgroup 13–07G at 3.0 ppm; vegetable, bulb, group 3 at 4.0 ppm; vegetable, brassica head and stem, subgroup 5A at 8.0 ppm; vegetable, brassica leafy, subgroup 5B at 45 ppm; vegetable, fruiting, group 8 at 2.5 ppm; tomato, paste at 5.0 ppm; vegetable, cucurbit, group 9 at 1.0 ppm; vegetable, leafy, except brassica, group 4 at 20 ppm; vegetable, root, subgroup 1A at 2.5 ppm; vegetable, tuberous and corm, subgroup 1C at 0.06 ppm; vegetables, leaves of root and tuber, group 2 at 55 ppm; vegetable, edible-podded legume, subgroup 6A at 2.5 ppm; vegetable, succulent, shelled peas and beans, subgroup 6B at 0.4 ppm; vegetable, pea and bean, dried shelled, except soybean, subgroup 6C at 0.3 ppm; soybean, seed at 0.3 ppm; soybean, hulls at 1.0 ppm; peanut, nutmeat at 0.04 ppm; grain, cereal (except corn, millet, sorghum) at 0.2 ppm; corn, field, sweet, pop at 0.01 ppm; corn, refined oil at 0.03 ppm; cereal grain, millet at 0.9 ppm; cereal grain, sorghum at 0.9 ppm; nut, tree, group 14 (including pistachios) at 0.05 ppm; almond, hulls at 6.0 ppm; canola at 1.0 ppm; sunflower at 0.8 ppm; cotton, seed at 0.35 ppm; cotton, gin byproducts at 10 ppm; alfalfa, forage at 10 ppm; alfalfa, hay at 25 ppm; foliage of legume vegetables, group 7, hay at 80 ppm; foliage of legume vegetables, group 7, vines/forage at 30 ppm; peanut, hay at 50 ppm; grain, cereal, group 16, hay at 90 ppm; grain, cereal, group 16, forage at 25 ppm; grain, cereal, group 16, straw at 2 ppm; grain, cereal, stover at 11 ppm and establishing tolerances for residues of penthiopyrad, (RS)-*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-pyrazole-4-carboxamide and its major metabolite PAM (1-methyl-3-trifluoromethyl-1*H*-pyrazole-4-carboxamide) in animal commodities hog, meat at 0.01 ppm; hog, fat at 0.01 ppm; hog, liver at 0.01 ppm; hog, kidney at 0.01 ppm; hog, meat byproducts at 0.01 ppm; cattle, meat at 0.05 ppm; cattle, fat at 0.05 ppm; cattle, liver at 0.2 ppm; cattle, kidney at 0.1 ppm; cattle, meat byproducts at 0.2 ppm; sheep, meat at 0.01 ppm; sheep, fat at 0.02 ppm; sheep, liver at 0.05 ppm; sheep, kidney at 0.02 ppm; sheep, meat byproducts at 0.05 ppm; milk at 0.05 ppm; milk, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, liver at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; poultry, eggs at 0.01 ppm. That notice referenced a summary of the petition prepared by Mitsui Chemical Agro, Inc. c/o Landis International, 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 revised several of the proposed tolerance levels. 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 penthiopyrad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with penthiopyrad 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.

For penthiopyrad, the liver and thyroid are the target organs. In toxicity studies, short-term oral exposure resulted in liver alterations in rats and mice at similar doses, and in dogs at higher doses. Short-term exposure also resulted in thyroid changes in mice and rats. Other effects observed were body weight changes and hematological alterations in rats and dogs, along with gallbladder effects in dogs. Short-term dermal exposure did not result in dermal irritation or systemic effects up to the limit dose tested.

Long-term exposure in rats resulted in liver effects; adrenal, ovarian, and

thyroid hypertrophy; and thyroid tumors. In mice, chronic exposure led to liver and thyroid effects and liver tumors. In dogs, effects noted (liver, gallbladder, and adrenal glands) were similar to those seen in subchronic dog studies, with the addition of more progressive gallbladder effects.

No evidence of increased quantitative or qualitative susceptibility was observed in developmental toxicity studies in rats or rabbits or in a reproduction toxicity study in rats. However, increased quantitative susceptibility was seen in a developmental neurotoxicity (DNT) study in rats. In the DNT, decreased body weight, increased motor activity, and tremors were seen in offspring animals in the absence of maternal toxicity.

Clinical signs (hunched posture, unsteady gait, reduced body temperature, and increased landing foots play) were observed in the acute neurotoxicity study in rats. However, no clinical signs were observed in the subchronic neurotoxicity study in rats. In the immunotoxicity study in mice, decreased plaque forming ability was observed at the limit dose. However, in the immunotoxicity study in rats, no evidence of immunotoxicity was observed up to the highest dose tested. Penthiopyrad has been classified as having ''suggestive evidence of carcinogenicity.'' Although liver tumors were seen in a cancer study in the mouse, the tumors were only observed at high doses and only noted in one sex and one species. The no-observed-adverse-effect-level (NOAEL) (27 milligrams/kilogram/day (mg/kg)) used for establishing the chronic reference dose is approximately 10-fold lower than the lowest dose (200 mg/kg/day) that induced liver tumors in mice. Based on these factors, including the fact that the only tumors seen were liver tumors in mice, the Agency has determined that the quantification of risk using a non-linear approach will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to penthiopyrad. The EPA received a number of studies for penthiopyrad metabolites, including subchronic oral, mutagenicity studies, etc.; however, none of these studies indicated that metabolites were more toxic than the parent.

Specific information on the studies received and the nature of the adverse effects caused by penthiopyrad as well as the NOAEL and can be found at *http://www.regulations.gov* in the document ''Penthiopyrad. Human Health Risk Assessment for the Section 3 Registration Action on Numerous Agricultural Crops, Turfgrass, and Ornamentals,'' starting on page 23 in docket ID number EPA–HQ–OPP–2010–0349.

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 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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the 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.*

A summary of the toxicological endpoints for penthiopyrad used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PENTHIOPYRAD FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	NOAEL = 125 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day .... aPAD = 1.25 mg/kg/day	Acute Neurotoxicity in Rats LOAEL = 500 mg/kg/day based on transient functional alterations (e.g., hunched posture, unsteady gait, reduced body temperature, and increased landing foot splay) and decreased motor activity at the estimated time-to-peak-effect (4 hours) on the day of administration.
Chronic dietary (All populations)	NOAEL = 27 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.27 mg/kg/day cPAD = 0.27 mg/kg/day	*Co-critical studies.* Chronic Toxicity/Carcinogenicity in Rats LOAEL = 83 mg/kg/day, based on decreased body weight gain and adrenal effects in females and hepatic periportal fatty degeneration in males. Chronic Toxicity in Rats LOAEL = 100 mg/kg/day, based on altered plasma chemistry profile, increased liver weight and alterations in the adrenal and thyroid glands.
Incidental Oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 27 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	28–Day Oral Toxicity in Dogs LOAEL = 80 mg/kg/day, based on mucosal edema in the gall bladder.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PENTHIOPYRAD FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Children's Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 100 mg/kg/day (dermal absorption factor = 40%. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	Postnatal Developmental Neurotoxicity in Rats LOAEL = 250 mg/kg/day, based on decreased body weight (8%) in offspring animals seen in the absence of maternal toxicity.
Adult Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 75 mg/kg/day (dermal absorption factor = 40%. UF_A = 10x UF_H = 10x	Residential LOC for MOE = 100.	Developmental in Rabbits LOAEL = 225 mg/kg/day, based on abortion.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Inhalation (or oral) study ..... NOAEL = 27 mg/kg/day (inhalation absorption factor = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28–Day Oral Toxicity in Dogs LOAEL = 80 mg/kg/day, based on mucosal edema in the gall bladder.
Cancer (Oral, dermal, inhalation).	Classification: ''Suggestive Evidence of Carcinogenicity'' based on liver tumors in male mice. The dose and non-cancer endpoint selected for chronic dietary exposure (cRfD) are protective of potential cancer effects.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. milligrams/kilograms/day = mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to penthiopyrad, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from penthiopyrad 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.

Such effects were identified for penthiopyrad. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, 100% crop treated assumptions for all commodities, and both default and empirical processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, 100% crop treated assumptions for all commodities, and both default and empirical processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has determined that quantification using a linear low dose approach was not required, and the chronic dose and endpoint are considered to be protective of cancer effects. Thus, no separate exposure assessment was performed in assessing cancer risk.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for penthiopyrad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of penthiopyrad. 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 First Index Reservoir Screening Tool (FIRST), provisional Tier 1 Cranberry and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of penthiopyrad for acute exposures are estimated to be 289 parts per billion (ppb) for surface water and ≤98 ppb for groundwater. For chronic exposures are estimated to be 222 ppb for surface water and ≤98 ppb for groundwater. The surface water estimates were used for both the acute and chronic (non-cancer/cancer) assessments because they were higher than the groundwater estimates. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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).

Penthiopyrad is currently registered for the following use that could result in residential exposures: Turfgrass. EPA assessed residential exposure using the following assumptions:

No chemical-specific unit exposure data were provided in support of this submission; therefore, the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (June 2011) and the Outdoor Residential Exposure Task Force (OREFT) study unit exposures were used to estimate handler exposures. These unit exposures were based on residential handlers wearing short pants, short-sleeved shirt, and no gloves.

Postapplication scenarios include children (1 to 3 years old) playing on treated turf, adults performing yard work on treated turf, and adults playing golf on treated turf. The postapplication scenarios resulting from commercial and residential applications were assessed using default assumptions and transfer coefficients from the EPA Draft SOPs for Residential Exposure Assessments, 2000. As the short- and intermediate-term dermal endpoints are the same for each route of exposure, only short-term dermal exposures were assessed for adults and children. EPA estimates short-term dermal postapplication exposure based on day-0 residues, that is, the residue

present on the day of application. Using day-0 residues to assess intermediate-term exposure does not take into account dissipation of residues over time and, thus, results in a conservative estimate. Therefore, the short-term dermal postapplication exposure assessment represents the worst case scenario and is protective of intermediate-term dermal exposure. Additionally, oral non-dietary ingestion exposures were assessed for children (i.e., soil ingestion, and hand-/object-to-mouth). 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.''

EPA has not found penthiopyrad to share a common mechanism of toxicity with any other substances, and penthiopyrad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that penthiopyrad does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see 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 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.* There is no evidence of increased quantitative or qualitative susceptibility in developmental toxicity studies on rats/rabbits or in a reproduction toxicity study on rats. However, there is evidence of increased susceptibility following prenatal/or postnatal exposure in preliminary and definitive DNT studies on rats. Effects include decreased body weight, increased motor activity, and tremors (definitive), as well as mortality (preliminary).

Although increased susceptibility was seen in the DNT studies, the EPA concluded that there is a low concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of penthiopyrad because:

- The pup body weight changes noted in the definitive and preliminary DNT studies were observed in other developmental/reproduction studies at similar doses. Additionally, the body weight changes in these studies occurred in the presence of significant maternal toxicity and there was no evidence of increased susceptibility. Although clinical signs (tremors and increased motor activity) were noted in offspring animals in the DNT study, the neurotoxic potential of penthiopyrad has been adequately characterized in the available neurotoxicity studies. In the preliminary DNT study, mortality was observed in the offspring animals at the limit dose. However, this finding is attributed to the poor condition (body weight loss, under activity, pallor) of the offspring animals in this dose group.
- Clear NOAELs have been identified for all offspring effects and the risk assessments are based on the most sensitive endpoints. Therefore, the NOAELs selected for risk assessment are protective of potential developmental and offspring effects.

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 penthiopyrad is complete.

ii. There is no concern for neurotoxicity after exposure to penthiopyrad. A complete neurotoxicity battery is available for penthiopyrad. This includes acute neurotoxicity, subchronic neurotoxicity, and DNT studies in rats. As a result, the neurotoxic potential of penthiopyrad is well characterized and no additional data are needed

iii. There is no residual concern regarding increased quantitative or qualitative prenatal and/or postnatal susceptibility for the reasons explained in Unit III.D.2.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to penthiopyrad in drinking water. EPA used similarly conservative assumptions to assess residential exposures, including those of adults applying penthiopyrad and postapplication exposures of adults and children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by penthiopyrad.

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 acute PAD (aPAD) and chronic PAD (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.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to penthiopyrad will occupy 7% of the aPAD for the general U.S. population and 11% of the aPAD for children 1 to 2 years old (the population group receiving the greatest exposure). Since acute aggregate risk results from exposure to residues in food and water alone, the acute aggregate risks are not of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to penthiopyrad from food and water will utilize 11% of the cPAD for the general U.S. population and 19% of the cPAD for children 1 to 2 years old (the population group receiving the greatest exposure). Since there are no residential scenarios that result in long-term exposure to penthiopyrad, the chronic aggregate risks are equivalent to the chronic dietary risks and are not of concern.

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

intermediate-term toxicological endpoints for penthiopyrad are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are protective of intermediate-term exposure and risk. Penthiopyrad is proposed for registration for uses that could result in short-/intermediate-term residential exposures, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short -term residential exposures to penthiopyrad.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in adult aggregate estimated MOEs of 580 for males and females. Furthermore, although there is the potential for exposure to children resulting from two different routes (i.e. dermal and oral exposure), the toxicological effects from the dermal and oral routes of exposure are different. As a result, a combined residential exposure assessment was not conducted for children. The short-term aggregate risk assessment for children resulted in estimated MOEs of 500 for dermal and 410 for oral exposure. Because EPA's level of concern for penthiopyrad is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the relevant cancer studies EPA has concluded that the pesticide poses no greater than a negligible cancer risk and the chronic dietary risk assessment is protective of cancer effects and, therefore, cancer risk resulting from exposure to penthiopyrad is not of concern.

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 penthiopyrad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate liquid chromatography methods with tandem mass spectrometry (LC/MS/MS) are available to enforce the tolerance expressions for penthiopyrad in plant (Method CEMR 3727 also known as Method CEM 3399–001) and livestock (Methods LDA0082 and LDA0083) matrices.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email 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 maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for the new active ingredient penthiopyrad.

C. Revisions to Petitioned-For Tolerances

The EPA has revised several of the proposed tolerance levels. The major reason for the modifications is that the petitioner determined the proposed tolerances using the tolerance calculation procedure utilized by countries in the North American Free Trade Agreement but EPA conducted a joint review of this chemical with the United Kingdom and utilized a similar, but slightly different tolerance calculation procedure followed by the Organization for Economic Co-operation and Development.

V. Conclusion

Therefore, tolerances are established for residues of penthiopyrad, *N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, in or on plant and livestock commodities as indicated below.

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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination With Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: February 24, 2012.

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. Add § 180.658 to subpart C to read as follows:

§ 180.658 Penthiopyrad; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of penthiopyrad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only penthiopyrad (*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide).

Commodity	Parts per million
Alfalfa, forage	7.0
Alfalfa, hay	20
Almond, hulls	6.0
Apple, wet pomace	1.5
Barley, grain	0.15
Barley, hay	80
Barley, milled byproducts	0.90
Barley, straw	1.0
Beet, sugar, dried pulp	1.5
Beet, sugar, roots	0.5
Berry, low growing, subgroup 13–07G	3.0
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	50
Buckwheat, grain	0.15
Canola	1.5
Corn, field, forage	40
Corn, field, grain	0.01
Corn, field, refined oil	0.05
Corn, field, stover	15
Corn, pop, grain	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Cotton, seed	1.5
Cotton, gin byproducts	15
Fruit, pome, group 11–10	0.50
Fruit, stone, group 12	4.0
Grain, aspirated fractions	30
Millet, *spp.*	0.80
Nut, tree, group 14	0.06
Oat, forage	40
Oat, grain	0.15
Oat, hay	80
Oat, straw	1.0
Pea and bean, dried shelled, except soybean, subgroup 6C	0.40
Peanut	0.04
Peanut, hay	30
Peanut, refined oil	0.06
Pistachio	0.06
Potato, processed potato waste	0.20
Rye, forage	40
Rye, grain	0.15
Rye, straw	1.0
Sorghum, forage	40
Sorghum, grain, grain	0.80
Sorghum, stover	15
Soybean, seed	0.40
Sunflower, seed	1.5
Teosinte, grain	0.15
Tomato, paste	3.5
Triticale, forage	40
Triticale, grain	0.15
Triticale, hay	80
Triticale, straw	1.0
Vegetable, bulb, group 3–07	3.0
Vegetable, cucurbit, group 9	0.60
Vegetable, foliage of legume, group 7, hay	200
Vegetable, foliage of legume, group 7, vines/forage	50
Vegetable, fruiting, group 8–10	3.0
Vegetable, leafy, except brassica, group 4	30
Vegetable, leaves of root and tuber, group 2	50
Vegetable, legume, edible podded, subgroup 6A	4.0
Vegetable, legume, succulent shelled, subgroup 6B	0.40
Vegetable, root, subgroup 1B, except sugar beet	3.0
Vegetable, tuber and corm, subgroup 1C	0.06
Wheat, forage	40
Wheat, grain	0.15
Wheat, hay	80
Wheat, milled byproducts	0.30
Wheat, straw	1.0

(2) Tolerances are established for residues of penthiopyrad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of penthiopyrad (*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide) and its metabolite (1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide), calculated as the stoichiometric equivalent of penthiopyrad, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts	0.09
Goat, fat	0.03
Goat, meat	0.03
Goat, meat byproducts	0.09
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts	0.09
Milk	0.02
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts	0.09

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

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

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

[FR Doc. 2012–5650 Filed 3–8–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51 and 54

[WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208; DA 12–147]

Connect America Fund; a National Broadband Plan for Our Future; Establishing Just and Reasonable Rates for Local Exchange Carriers; High-Cost Universal Service Support

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission clarifies certain rules. This document also modifies certain initial filing deadlines required to comply with the Paperwork Reduction Act requirements, and finds good cause to delete certain rules that are now obsolete.

DATES: Effective April 9, 2012, except for §§ 54.313(a)(9), 54.313(f)(2), and 54.1003(b), which contain information collection requirements that are not effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date for those sections.