submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 5, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

David Gray was designated the Acting Regional Administrator on May 28, 2019 through the order of succession outlined in Regional Order R6–1110.13, a copy of which is included in the docket for this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: May 28, 2019.

David Gray,

Acting Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart SS—Texas

§ 52.2270 [Amended]

■ 2. In § 52.2270 the table in paragraph (c) entitled ''EPA Approved Regulations in the Texas SIP'' is amended by removing the entry for ''Section 114.86'' under Chapter 114 (Reg 4)—Control of Air Pollution from Motor Vehicles.

[FR Doc. 2019–11760 Filed 6–5–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0674; FRL–9994–08]

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 that are identified and discussed later in this document. In addition, this regulation removes certain established penthiopyrad tolerances that are superseded by new tolerances established in this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 6, 2019. Objections and requests for hearings must be received on or before August 5, 2019, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0674, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2017–0674 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 August 5, 2019. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0674, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 24, 2018 (83 FR 34968) (FRL–9980–31), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8616) by Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.658 be amended by establishing tolerances for residues of the fungicide penthiopyrad, (N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide), in or on Brassica, leafy greens, subgroup 4–16B at 50 parts per million (ppm); Bushberry subgroup 13–07B at 6 ppm; Caneberry subgroup 13–07A at 10 ppm; Celtuce at 30 ppm; Fennel, Florence at 30 ppm; Fruit, stone, group 12–12 at 4.0 ppm; Kohlrabi at 5.0 ppm; Leaf petiole vegetable subgroup 22B at 30 ppm; Leafy greens subgroup 4–16A at 30 ppm; Nut, tree, group 14–12 at 0.06 ppm; Oilseed group 20 at 1.5 ppm; and Vegetable, brassica, head and stem, group 5–16 at 5.0 ppm.

The petitioner also requested that the following established tolerances be removed upon establishment of the petitioned-for tolerances: Brassica, head and stem, subgroup 5A at 5.0 ppm; *Brassica,* leafy greens, subgroup 5B at 50 ppm; Canola at 1.5 ppm; Cotton, seed at 1.5 ppm; Fruit, stone, group 12 at 4.0 ppm; Nut, tree, group 14 at 0.06 ppm; Pistachio at 0.06 ppm; Sunflower, seed at 1.5 ppm and Vegetable, leafy, except Brassica, group 4 at 30 ppm. That document referenced a summary of the petition prepared by DuPont, 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 made certain corrections and modifications to petitioned-for tolerances. 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure 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 their 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.

The liver and thyroid are target organs for penthiopyrad toxicity. Metabolism studies show higher radioactive residues in the liver, compared to other tissues. Short-term oral exposure resulted in liver alterations (weight increases, enzyme changes, hypertrophy, and/or histopathology) in rats and mice at similar doses, and dogs at higher doses. Of the three species, the liver effects observed in rats were more significant (fatty change, hepatocellular degeneration, and Kupffer cell proliferation) than the liver effects in the other species (*e.g.,* increased liver weight, hepatocellular hypertrophy).

Short-term exposure also resulted in thyroid changes in mice (hypertrophy) and rats (decreased weight, hypertrophy/proliferation, and hormone changes). Other effects observed were body weight changes and hematological alterations in rats and dogs, along with gallbladder effects (inflammation and edema) in dogs. Short-term dermal exposure did not result in dermal irritation or systemic effects up to the limit dose.

Subchronic rat studies are also available for penthiopyrad metabolites PCA and DM–PCA. Short-term exposure to PCA did not result in treatment-related effects up to the limit dose. Short-term exposure to DM–PCA resulted in decreased body weight gain and food consumption at high doses. However, the effects with DM–PCA were seen at higher doses than the effects observed in subchronic rat studies with the technical grade active ingredient.

Long-term exposure in rats (at lower doses) resulted in liver effects comparable to those seen in subchronic studies, as well as adrenal and thyroid hypertrophy. Higher doses resulted in more progressive liver effects (vacuolation, periportal cell swelling, and necrosis), thyroid tumors (males), and ovarian hypertrophy. No effects were observed in the ovaries in other toxicity studies. In mice, chronic exposure led to liver and thyroid effects and liver tumors (males). Alveolar foamy cell accumulation was also seen in mice, but it was not considered to be an adverse effect. In dogs, effects noted (liver, gallbladder, and adrenal gland) were similar to those seen in subchronic dog studies, with the addition of gallbladder hypertrophy/hyperplasia.

In the developmental toxicity study in rats, comparable toxicity was noted in fetal and maternal animals. Effects observed were decreased body weight gain and food consumption, increased resorptions (resulting in decreased post-implantation survival), decreased litter size, and decreased gravid uterine weight at the limit dose. No effects were noted in a preliminary study in rats up to the limit dose. In the developmental toxicity study in rabbits, decreased fetal body weight was seen in the presence of maternal toxicity. Abortion was noted in one maternal animal, preceded by a period of markedly reduced food consumption and body weight loss, at the highest dose tested. In a preliminary study, decreased fetal body weight was seen at the limit dose. At lower doses, maternal effects including decreased water and food consumption, body

weight loss, and abnormal feces were seen. At the limit dose, increased abortions and mortality were noted in maternal animals. In the reproductive toxicity study in rats, body weight changes, liver, adrenal, and thyroid effects were seen in maternal animals in preliminary and definitive studies. Offspring effects included body weight changes, delay in preputial separation, and decreased thymus weights at similar doses. Decreased spleen weights were seen in offspring animals in the preliminary reproduction study. No reproductive toxicity was observed.

In the developmental neurotoxicity study in rats (definitive study), decreased body weight, increased motor activity, and tremors were seen in offspring animals in the absence of maternal toxicity. In the preliminary study, decreased pup weight, deterioration, and mortality were seen in offspring animals in the absence of maternal toxicity. Clinical signs were observed in the acute neurotoxicity study with penthiopyrad. Transient functional alterations (hunched posture, unsteady gait, reduced body temperature, and increased landing footsplay) and decreased motor activity were seen at the estimated time-to-peak-effect (4 hours). In a subchronic neurotoxicity study, decreased body weight gain was seen at the highest dose tested; however, no clinical signs were observed, and there was no evidence of neurotoxicity.

Immunotoxicity studies were conducted in both mice and rats for penthiopyrad. 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. General toxicity noted in the rat study included decreased body weight gain and food consumption, increased liver weight, and decreased spleen weight.

A mutagenicity battery is available for penthiopyrad technical ingredient and the majority of the studies were negative; however, chromosome aberrations were observed at cytotoxic concentrations in an *in vitro* assay. Mutagenicity studies are also available for several penthiopyrad metabolites (PCA, DM–PCA, PAM, and 753–A–OH). These studies were usually negative; however, the PAM metabolite induced chromosome aberrations (-S9 after 24 hours) and PCA induced a weakly positive mutant frequency (after 24 hours); however, based on the overall analysis of the available data, penthiopyrad is not considered to be mutagenic.

EPA classified penthiopyrad as having ''suggestive evidence of carcinogenicity,'' based on an increased incidence of treatment-related liver tumors in male mice. Thyroid tumors were observed in male rats but were not considered to be treatment related. In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), the Agency has determined that the quantification of risk using a non-linear approach based on the chronic reference dose (*i.e.,* cRfD) which is 7x lower than the dose at which tumors were observed will adequately account for all chronic toxicity, including carcinogenicity, that could result from penthiopyrad exposure.

Specific information on the studies received and the nature of the adverse effects caused by penthiopyrad as well as the no-observed-adverse-effects-level (NOAEL) and the lowest-observed-adverse-effects-level (LOAEL) identified from the toxicity studies can be found at *http://www.regulations.gov* in document SUBJECT: Penthiopyrad. Human Health Risk Assessment for Proposed New Use on Caneberry Subgroup 13–07A and Bushberry Subgroup 13–07B; and Crop Group/Subgroup Conversions and Expansions at page 39 in docket ID number EPA–HQ–OPP–2017–0674.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (PODs) 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the previously applied penthiopyrad toxicological endpoints for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of March 9, 2012 (77 FR 14291) (FRL–9335–7). That database was recently re-evaluated/updated based on current practices and includes updated dermal endpoints and PODs selected for adults and children. As a result of the database update, one endpoint and POD based on the 28-day oral toxicity study in the dog is used for all populations, and also used to derive the endpoints/PODs for the incidental oral and inhalation routes of exposure. The updated NOAELs, LOAELs, and the PODs are summarized below for the affected exposure/scenarios:

i. *Children and adult dermal exposures.* Children and adult dermal exposures were previously assessed with separate endpoints/PODs. Dermal exposure is now being evaluated using the same endpoint and POD for all ages, from the 28-day dog study. The revised dermal NOAEL is 80 milligrams per kilogram (mg/kg/day), based on mucosal edema in gall bladder as well as clinical chemistry and increased organ weight/histopathology in the livers of females at the LOAEL of 269 mg/kg/day.

ii. *Previous adult dermal assessment.* The developmental rabbit study was previously used for the adult dermal assessment with a NOAEL of 75 mg/kg/day based on abortions in one animal at the LOAEL of 225 mg/kg/day. The endpoint is not strong, and the dose spacing is comparable to the selected 28-day dog study.

iii. *Previous children's dermal assessment.* Previously the developmental neurotoxicity (DNT) was selected for the children's dermal assessment. The respective NOAEL and LOAEL for that study are 100 mg/kg/day and 250 mg/kg/day. Again, due to dose spacing, the study is comparable to the 28-dog study, whose NOAEL is protective of the DNT NOAEL. In addition, the effects seen in the 28-day dog study include gallbladder effects, an organ rats do not have, which is a potentially human-relevant effect.

iv. *Inhalation and incidental oral assessments.* The 28-day dog study, which previously was used and continues to also be used for the inhalation and incidental oral assessments was also updated. The NOAEL is now 80 mg/kg/day, based on mucosal edema in the gallbladder; as well as clinical chemistry, increased

organ weight and histopathology in the liver of females at the LOAEL of 269 mg/kg/day. The updated NOAEL is comparable to or protective of other NOAEL and LOAEL values in the database, including those relating to susceptibility.

v. *Residential incidental oral, inhalation, and dermal exposures.* The 28-day dog study is now being used to assess residential incidental oral, inhalation, and dermal exposures.

A summary of the toxicological endpoints for penthiopyrad used for dietary and non-occupational human health risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PENTHIOPYRAD FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, level of concern 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 footsplay) 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 (NOAEL = 27 mg/kg/day). 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. (NOAEL = 25 mg/kg/day).
Incidental oral short-term (1–30 days) and Intermediate-term (1–6 months).	NOAEL = 80 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	28-Day Oral Toxicity in Dogs. LOAEL = 269 mg/kg/day, based on mucosal edema in the gall bladder; clinical chemistry, increased organ weight and histopathology in the liver of females.
Dermal short-term (1–30 days); Intermediate-term (1–6 months).	NOAEL = 80 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x DAF = 40%	Residential LOC for MOE = 100.	28-Day Oral Toxicity in Dogs. LOAEL = 269 mg/kg/day, based on mucosal edema in the gall bladder; clinical chemistry, increased organ weight and histopathology in the liver of females.
Inhalation short-term (1–30 days); Intermediate-term (1–6 months).	NOAEL = 80 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	28-Day Oral Toxicity in Dogs. LOAEL = 269 mg/kg/day, based on mucosal edema in the gall bladder; clinical chemistry, increased organ weight and histopathology in the liver of females.
Cancer (oral, dermal, inhalation).	Classification: ''Suggestive Evidence of Carcinogenicity'' based on liver tumors in male mice. The Agency has determined that a nonlinear approach based on the chronic reference dose will be protective of potential carcinogenicity.		

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 estimates associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DAF = dermal absorption factor. IAF = inhalation absorption factor.

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 as well as all existing penthiopyrad tolerances in 40 CFR 180.658. 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 2003–2008 food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA). The acute dietary (food and drinking water) exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID), Version 3.16. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all existing and proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003–2008 food consumption information from the USDA NHANES/WWEIA. The chronic dietary (food and drinking water) exposure assessment was conducted using DEEM–FCID, Version 3.16. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all existing and proposed commodities.

iii. *Cancer.* EPA classified penthiopyrad as having ''suggestive evidence of carcinogenicity,'' based on an increased incidence of treatment-related liver tumors in male mice and determined that the quantification of risk using a non-linear approach (*i.e.,* RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from penthiopyrad exposure.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for penthiopyrad. Tolerance level residues and 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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of penthiopyrad are based on the use pattern of highest exposure, which is the currently labeled use on turf at 2.9 lbs active ingredient per acre per year. The residues of concern assessed in drinking water included penthiopyrad and its cleavage product PAM. For acute exposures, EDWCs are estimated to be 240 parts per billion (ppb) for surface water and 1,330 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 131 ppb for surface water and 978 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1,330 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 978 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).

Although the proposed new uses do not include any residential use, registered residential uses including turf, lawn, and sod could result in residential exposure and have been reassessed in support of this rulemaking to reflect updates to new dermal, inhalation, and incidental oral PODs. There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with penthiopyrad. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

i. Adult dermal post-application exposure resulting from contact with treated turf;

ii. Dermal post-application exposure to youth 11–16 yrs. old resulting from mowing and playing golf on turf;

iii. Dermal post-application exposure to children 6–11 yrs. old resulting from playing golf on turf;

iv. Dermal post-application exposure to children 1 to <2 yrs. old resulting from playing on turf; and

v. Incidental oral post-application exposure to children 1 to <2 yrs. old resulting from playing on turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* 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 DNT studies in rats. Decreased body weight (250 mg/kg/day), and increased motor activity and tremors were seen in offspring animals at 500 mg/kg/day. Decreased body weight was seen at 300 mg/kg/day, and mortality was noted at 1,000 mg/kg/day in offspring animals. The effects observed in offspring animals in the DNT studies were seen in the absence of maternal toxicity.

EPA concluded that there is a low concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of penthiopyrad, notwithstanding observed increased susceptibility seen in the preliminary and definitive DNT studies, based on the following data:

i. The pup body weight changes noted in the definitive and preliminary DNT studies were also observed in developmental and reproduction studies at similar doses. Additionally, the body weight changes in these studies occurred in the presence of significant maternal toxicity. Although clinical signs (tremors and increased motor activity) were noted in offspring animals in the definitive study, the neurotoxic potential of penthiopyrad has been adequately characterized in the available neurotoxicity studies. Tremors and changes in motor activity were observed at very high doses in the acute neurotoxicity study and were not present in the subchronic neurotoxicity study. 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.

ii. A clear NOAEL has been identified for all offspring effects in the DNT studies, and the PODs used in the risk assessments are protective of the observed 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. The database 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. As discussed in Unit IV.D.2., EPA has concluded that there are no residual uncertainties concerning prenatal and postnatal effects, that would warrant retaining the 10X FQPA safety factor.

iv. There are no residual uncertainties identified in the exposure databases. There are no residual uncertainties with regard to dietary and residential exposure. The dietary food exposure assessments were performed based on conservative assumptions that ensure that exposures to penthiopyrad are not underestimated, including tolerance-level residues and 100 PCT estimates for all registered commodities. The use of default assumptions did not result in risk estimates of concern for the proposed new uses. Actual exposures and risk estimates from penthiopyrad will likely be lower. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water and residential sources, such that these exposures have not been underestimated. 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 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 21% of the aPAD for all infants (<1-year-old), the population group receiving the greatest exposure.

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 29% of the cPAD for all infants (<1-year-old), the population group receiving the greatest exposure.

3. *Short-and Intermediate-term risk.* Short- and intermediate-term risk aggregate exposure takes into account short- and intermediate-term risk residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The short- and 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. These assessments include exposure through the dermal route for adults and youth, and from dermal and incidental oral exposure for children (1 to <2 yrs.).

EPA selected the following two residential exposure scenarios which represent the highest exposure and risk scenarios for each population: (1) Adult post-application exposure and (2) children's (1 to <2 yrs.) post-application exposure resulting from contact with treated turf. The level of concern for these assessments is 100. The chronic dietary exposure estimate for adults was the background exposure added to the dermal residential post-application exposure estimates. The adult short-term aggregate risk assessment resulted in estimated MOEs of 440. The chronic dietary exposure estimate for the subgroup children 1 to <2 years old was the background exposure added to the children's dermal and incidental oral residential post-application exposure estimates. The children's short-term aggregate risk assessment resulted in estimated MOEs of 220. These risk estimates are not of concern to EPA.

5. *Aggregate cancer risk for U.S. population.* EPA classified penthiopyrad as having ''suggestive evidence of carcinogenicity'' based on liver tumors in male mice. The quantification of risk using a non-linear approach (*i.e.,* the RfD) adequately accounts for all chronic toxicity, including carcinogenicity, therefore cancer risk is not of concern.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a Liquid chromatography-tandem mass spectrometry (LC/MS/MS) method known as Method CEM 3399–001) 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; 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 United Nations 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 U.S. tolerance definition for penthiopyrad is harmonized with those of Canada and Codex and most relevant established tolerance levels are harmonized with Canadian and Codex MRLs. There are currently no established Canadian or Codex MRLs for

the proposed new uses for bushberries or caneberries.

C. Revisions to Petitioned-For Tolerances

In accordance with its authority in FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances in this rule that vary slightly from what the petitioner sought. These variations are explained below.

1. The petitioner requested tolerances in Fruit, stone, group 12–12 at 4.0 ppm, Kohlrabi at 5.0 ppm, and Vegetable, brassica, head and stem, group 5–16 at 5.0 ppm; EPA is establishing those tolerances without the additional zero to be consistent with OECD calculation procedures.

2. The petitioner requested a tolerance for ''Fennel, Florence''; EPA is establishing a tolerance for the commodity ''Fennel, Florence, fresh leaves and stalk'' to be consistent with commodity terms the Agency uses in tolerances.

3. EPA is establishing a tolerance for the Nut, tree group 14–12 tolerance at 0.05 ppm instead of 0.06 ppm as requested in order to harmonize with Codex MRL. The established tolerance level is appropriate as the highest average field trial residue was 0.037 ppm while other residues were below LOQ (0.01 ppm).

D. International Trade Considerations

In this final rule, EPA is reducing the existing tolerances for the commodities in the nut, tree group 14–12 from 0.06 ppm to 0.05 ppm. The Agency is reducing these tolerances to harmonize with Codex MRLs, and available residue data demonstrates that tolerances at 0.05 ppm are sufficient to cover residues on these commodities.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision. In addition, the SPS Agreement requires that members provide a ''reasonable interval'' between the publication of a regulation subject to the agreement and its entry into force to allow time for producers in exporting member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address the requirement to provide a reasonable interval. After the six-month period expires, residues of penthiopyrad on commodities included in the nut, tree group 14–12 cannot exceed the newly established tolerances of 0.05 ppm.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

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 Brassica, leafy greens, subgroup 4–16B at 50 ppm; Bushberry subgroup 13–07B at 6 ppm; Caneberry subgroup 13–07A at 10 ppm; Celtuce at 30 ppm; Fennel, Florence, fresh leaves and stalk at 30 ppm; Fruit, stone, group 12–12 at 4 ppm; Kohlrabi at 5 ppm; Leaf petiole vegetable subgroup 22B at 30 ppm; Leafy greens subgroup 4–16A at 30 ppm; Nut, tree, group 14–12 at 0.05 ppm; Oilseed group 20 at 1.5 ppm; and Vegetable, brassica, head and stem, group 5–16 at 5 ppm. In addition, EPA is removing the following tolerances from paragraph (a)(1) because they are superseded by the new tolerances being established in this rulemaking: Brassica, head and stem, subgroup 5A at 5.0 ppm; Brassica, leafy greens, subgroup 5B at 50 ppm; Canola at 1.5 ppm; Cotton, seed at 1.5 ppm; Fruit, stone, group 12 at 4.0 ppm; Sunflower, seed at 1.5 ppm; and Vegetable, leafy, except brassica, group 4 at 30 ppm. Finally, EPA is establishing a six-month expiration date for the established pistachio and tree nut group tolerances.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action 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 FFDCA section 408(d), 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: May 29, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In the table in § 180.658(a)(1):
■ a. Remove the entries ''Brassica, head and stem, subgroup 5A'' and ''Brassica, leafy greens, subgroup 5B'';
■ b. Add alphabetically the commodities ''Brassica, leafy greens, subgroup 4–16B'', ''Bushberry subgroup 13–07B'', and ''Caneberry subgroup 13–07A'';
■ c. Remove the entry ''Canola'';
■ d. Add alphabetically the commodity ''Celtuce'';
■ e. Remove the entry ''Cotton, seed'';
■ f. Add alphabetically the commodity ''Fennel, Florence, fresh leaves and stalk'';
■ g. Remove the entry ''Fruit, stone, group 12'';
■ h. Add alphabetically the commodities ''Fruit, stone, group 12–12'', ''Kohlrabi'', ''Leaf petiole vegetable subgroup 22B'', and ''Leafy greens subgroup 4–16A'';
■ i. Revise the entry ''Nut, tree, group 14'';
■ j. Add alphabetically the commodities ''Nut, tree, group 14–12'' and ''Oilseed group 20'';
■ k. Revise the entry ''Pistachio'';
■ l. Remove the entry ''Sunflower, seed'';
■ m. Add alphabetically the commodity ''Vegetable, brassica, head and stem, group 5–16'';
■ n. Remove the entry ''Vegetable, leafy, except brassica, group 4''; and
■ o. Add footnote 1 to the table.

The additions and revisions read as follows:

§ 180.658 Penthiopyrad; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B	50
Bushberry subgroup 13–07B	6
Caneberry subgroup 13–07A	10
Celtuce	30
* * * * *	
Fennel, Florence, fresh leaves and stalk	30
* * * * *	
Fruit, stone, group 12–12	4
* * * * *	
Kohlrabi	5
Leaf petiole vegetable subgroup 22B	30
Leafy greens subgroup 4–16A	30
* * * * *	
Nut, tree, group 14 [1]	0.06
Nut, tree, group 14–12	0.05
* * * * *	
Oilseed group 20	1.5
* * * * *	
Pistachio [1]	0.06
* * * * *	
Vegetable, *brassica,* head and stem, group 5–16	5
* * * * *	

[1] This tolerance expires on December 6, 2019.

* * * * *

[FR Doc. 2019–11676 Filed 6–5–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R05–RCRA–2018–0228; FRL–9994–75–Region 5]

Michigan: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is granting Michigan final authorization for changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a proposed rule on October 10, 2018, and provided for public comment. No comments were received on the proposed revisions. No further opportunity for comment will be provided.

DATES: This final authorization is effective June 6, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R05–RCRA–2018–0228. The Docket ID No. was identified as EPA–R05–RCRA–2017–0381 in the proposed rule published in the October 10, 2018, **Federal Register** at 83 FR 50868, but that Docket ID No. was incorrect. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* 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 electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Judith Greenberg, RCRA C and D Section, Land and Chemicals Branch, Land, Chemicals and Redevelopment Division, U.S. Environmental Protection Agency, 77 W Jackson Blvd., Chicago, IL 60604, phone number: (312) 886–4179, email: *greenberg.judith@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. What changes to Michigan's hazardous waste program is EPA authorizing with this action?

On March 2, 2018, Michigan submitted a complete program revision application seeking authorization of changes to its hazardous waste program in accordance with 40 CFR 271.21. EPA now makes a final decision that Michigan's hazardous waste program revisions that are being authorized are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all the requirements necessary to qualify for final authorization. For a list of State rules being authorized with this final rule, please see the proposed rule published in the October 10, 2018, **Federal Register** at 83 FR 50869.

B. Which revised state rules are different from the federal rules?

See the October 10, 2018, proposed rule for a description of which state rules are different from the federal rules, with one exception. The proposed rule incorrectly stated that Michigan has proposed additions to its Universal Wastes that will add Antifreeze, Aerosol Cans and Paint Wastes that are not already regulated as hazardous waste. This statement should be disregarded.