action must be filed in the United States Court of Appeals for the appropriate circuit by August 27, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action 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* CAA section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: May 28, 2019.

Mary S. Walker,

Regional Administrator, Region 4.

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 S—Kentucky

■ 2. Section 52.920 is amended by:

■ a. Adding, in paragraph (d), the entry ''Louisville Gas and Electric Mill Creek Electric Generating Station'' at the end of the table; and

■ b. Adding, in paragraph (e), the entries ''2010 1-hour SO_2 Attainment Demonstration for the Jefferson County Area,'' ''2010 1-hour SO_2 Jefferson County Nonattainment Plan for 172(c)(3) 2011 Base-Year Emissions Inventory'', and ''2010 1-hour SO_2 Jefferson County Nonattainment Plan for 172(c)(5) New Source Review Requirements'' at the end of the table.

The additions read as follows:

§ 52.920 Identification of plan.

* * * * *

(d) * * *

EPA-Approved Kentucky Source-Specific Requirements

Name of source	Permit No.	State effective date	EPA approval date	Explanations
* *	*	*	* *	*
Louisville Gas and Electric Mill Creek Electric Generating Station.	145–97–TV(R3)	6/23/2017	6/28/2019 [Insert citation of publication].	Plant-wide Specific condition S1-Standards, S2-Monitoring and Record Keeping and S3-Reporting in title V permit 145–97–TV(R3) for EGU U1, U2, U3 and U4.

* * * * *

(e) * * *

EPA-Approved Kentucky Non-Regulatory Provisions

Name of non-regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA approval date	Explanations
* *	*	*	* *	*
2010 1-hour SO_2 Attainment Demonstration for the Jefferson County Area.	Jefferson County	6/23/2017	6/28/2019 [Insert citation of publication].	
2010 1-hour SO_2 Jefferson County Nonattainment Plan for 172(c)(3) 2011 Base-Year Emissions Inventory.	Jefferson County	6/23/2017	6/28/2019 [Insert citation of publication].	
2010 1-hour SO_2 Jefferson County Nonattainment Plan for 172(c)(5) New Source Review Requirements.	Jefferson County	6/23/2017	6/28/2019 [Insert citation of publication].	

[FR Doc. 2019–13736 Filed 6–27–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0493; FRL–9985–41]

Ethiprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide ethiprole in or on coffee, green bean. Bayer CropScience LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 28, 2019. Objections and requests for

hearings must be received on or before August 27, 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–2009–0493, 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 L. Goodis, P.E., Director, Registration Division (750P), 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 Printing 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–2009–0493 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 27, 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–2009–0493, 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 October 24, 2018 (83 FR 53594) (FRL–9983–46), 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 7E8586) by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709–2014. The petition requested that 40 CFR 180.652 be amended by establishing tolerances for residues of the insecticide ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1*H*-pyrazole-3-carbonitrile, in or on coffee (green beans) and roasted coffee and instant coffee at 0.1 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience LP, the registrant, which is available in the docket, *http://www.regulations.gov.* These tolerances were requested to cover residues of ethiprole in or on coffee resulting from uses of this pesticide on coffee outside the United States. There is no current U.S. registration for use of ethiprole on coffee. The only comment submitted to this docket supported this rulemaking.

Based upon review of the data supporting the petition, EPA has concluded that tolerances are not needed for the processed coffee commodities since available data demonstrate that residues of ethiprole did not concentrate in these processed commodities.

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 ethiprole including exposure resulting from the tolerances established by this action.

EPA's assessment of exposures and risks associated with ethiprole follows.

A. Toxicological Profile

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

Ethiprole has a low acute toxicity via the oral, dermal, and inhalation routes of exposure, and is not a skin sensitizer nor a skin or eye irritant. In the mammalian toxicology database, the critical effects of ethiprole are liver toxicity and thyroid toxicity. The rat was the most sensitive species overall after administration of ethiprole. Evidence of hepatotoxicity is seen in the rat, dog, and mouse and was manifested as increased liver weight and hepatocellular hypertrophy and changes in clinical chemistry such as increased alanine transaminase and alkaline phosphates activities; increased cholesterol and triglycerides levels; and increased total protein concentration. Thyroid toxicity was observed in the rat and was manifested as increased thyroid weight, thyroid follicular hypertrophy along with higher TSH plasma levels, and reduced T4 (thyroxine) plasma levels. Mechanism studies of thyroid toxicity suggested that ethiprole acts by disrupting thyroid hormone homeostasis and indirectly influences the thyroid by inducing the hepatic microsomal enzyme T4- glucuronyl transferase.

Ethiprole is neither a reproductive nor a developmental toxicant. Although no teratogenic effects were observed in the existing database, there is uncertainty regarding the potential impact of ethiprole on thyroid hormone homeostasis in the developing organism.

In the acute neurotoxicity study, clinical signs showed consistent effects that might be anticipated for a chemical interacting with neurotransmitter chloride channels, including low arousal levels, increased eye closure, increased incidence of body tremors, and decreased rearing counts in females at the mid dose. However, no neurotoxicity effects were noted in the subchronic neurotoxicity study up to and including the highest dose of 400 ppm (33.0 mg/kg/day). There were no effects on neuropathology in any of the studies.

Based on a battery of mutagenicity studies, ethiprole is not considered to be genotoxic. In accordance with the *EPA's Final Guidelines for Carcinogen Risk Assessment* (March 2005), ethiprole is classified as ''Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenicity Potential'' based on increased incidences of hepatocellular adenomas in females at the highest dose tested in the carcinogenicity study in mice. While the evidence from animal data is suggestive of carcinogenicity, a cancer risk to humans from dietary exposure to ethiprole is of low concern, and a nonlinear approach is appropriate for assessing potential cancer risk based on the following weight-of-evidence considerations:

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

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

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

4. There is no concern for mutagenicity/genotoxicity;

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

6. The reduction of the Food Quality Protection Act Safety Factor (FQPA SF) to 1x yields a chronic Population Adjusted Dose (cPAD) of 0.03 mg/kg/day. The Agency has determined that the cPAD will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to ethiprole.

More detailed information on the studies received and the nature of the adverse effects caused by ethiprole as well as the NOAEL and the LOAEL from the toxicological studies can be found in the document entitled, ''Ethiprole: Human Health Risk Assessment for a Proposed Tolerance without U.S. Registration in/on Imported Coffee, Green Bean,'' dated April 29, 2019, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information.

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 ethiprole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHIPROLE 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 = 35 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x Combined UFs = 100x	Acute RfD = 0.35 mg/kg/day. aPAD = 0.35 mg/kg/ day	Acute Neurotoxicity in Rats Study. LOAEL = 250 mg/kg/day based on decreased locomotor activity and functional observational battery (FOB) findings in both sexes on the day of treatment.
Chronic Dietary (All populations).	NOAEL = 0.85 mg/ kg/day. UF_A = 3x UF_H = 10x FQPA SF = 1x Combined UFs = 30x	Chronic RfD = 0.03 mg/kg/day. cPAD = 0.03 mg/kg/ day	Combined Chronic/Carcinogenicity Oral (Dietary) Toxicity in Rats. LOAEL = 3.21/4.40 mg/kg/day M/F based on observed effects in the thyroid and/or liver (histopathologic changes, increased organ weights, and/or altered thyroid hormone or bilirubin levels).
Cancer Dietary (Oral, Dermal, Inhalation).	Classification: ''Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenicity Potential'' Quantification using a cancer potency factor is not needed; a nonlinear approach based on the cRfD is protective of potential cancer risk.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

More detailed information on the toxicological endpoints for ethiprole can be found in the document entitled, ''Ethiprole: Human Health Risk Assessment for a Proposed Tolerance without U.S. Registration in/on Imported Coffee, Green Bean,'' dated April 29, 2019, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethiprole, EPA considered exposure under the petitioned-for tolerances as well as all existing ethiprole tolerances in 40 CFR 180.652 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. In estimating acute dietary (food and drinking water) exposure, EPA used food consumption information from the Dietary Exposure Evaluation Model—Food Commodity Intake Database (DEEM–FCID™, Version 3.18), which incorporates 2003–2008 consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). An unrefined, acute dietary exposure assessment was conducted assuming tolerance-level residues and assuming 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used DEEM–FCID™, Version 3.18, which incorporates 2003–2008 consumption data from the USDA's NHANES/WWEIA. An unrefined chronic dietary risk analysis was conducted assuming tolerance-level residues and 100 PCT.

iii. *Cancer.* As explained in unit III.A., quantification of risk using a non-linear approach (*i.e.,* a cPAD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to ethiprole. No separate exposure assessment pertaining to cancer risk was performed for ethiprole; rather, EPA relied on the chronic exposure assessment described in this Unit for assessing the risk of all chronic effects, including cancer.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue information in the dietary assessment for ethiprole. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

More detailed information on the acute and chronic dietary (food only) exposure and risk assessment for ethiprole can be found in the document entitled, ''Ethiprole: Human Health Risk Assessment for a Proposed Tolerance without U.S. Registration in/on Imported Coffee, Green Bean,'' dated April 29, 2019, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2009–0493. Double-click on the document to view the referenced information.

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

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ethiprole is not registered for any specific use patterns that would result in residential exposure.

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

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other

substances that have a common mechanism of toxicity.'' EPA has not made a common mechanism of toxicity finding as to ethiprole and any other substances, and ethiprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action; therefore, EPA has not assumed that ethiprole has a common mechanism of toxicity with other substances.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity, and to evaluate the cumulative effects of such chemicals, *see* the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10x) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data are available to EPA support the choice of a different safety factor.

2. *Prenatal and postnatal sensitivity.* Although no teratogenic effects were observed in the existing toxicology database, there is uncertainty regarding the potential impact of ethiprole on thyroid hormone homeostasis in the developing organism. Observations demonstrated that thyroid hormones were affected in several studies throughout the ethiprole database. Thyroid hormones may play a critical role in the development of the nervous system.

3. *Conclusion.* EPA has determined that reliable hazard and exposure 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 toxicology database for ethiprole is complete for establishing tolerances without U.S. registration purposes. Previously the Agency determined that a CTA is required based on the weight-of-evidence. Subsequently, the registrant submitted a request for a CTA waiver. Based on a weight-of-evidence approach that considered the relatively low exposure to the highest exposed populations and the fact that had the 10x been retained, the exposure levels would still result in estimated risks below the levels of concern, the Agency concludes that a CTA in pregnant animals, fetuses, postnatal animals, and adult animals is not required for ethiprole at this time.

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

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

iv. There are no residual uncertainties identified in the exposure database for ethiprole. The dietary assessment is based on high end assumptions, assuming tolerance-level residues and 100 PCT. The assessment will not underestimate the exposure and risk posed by ethiprole.

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). Since there are no registered or proposed uses of ethiprole that result in residential exposure, the acute and chronic aggregate exposure and risk assessments are equal to the acute and chronic dietary exposure and risk estimates (food only), respectively. 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this Unit for dietary and non-dietary acute exposures, EPA has concluded that acute dietary exposure to ethiprole from food only will utilize <1% of the aPAD for the general U.S. population. The most highly-exposed population subgroup, all infants (<1 year old), utilized 2.1% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this Unit for chronic exposure, EPA has concluded that chronic dietary exposure to ethiprole from food only will utilize 2.0% of the cPAD for the general U.S. population. The most highly-exposed population subgroup, all infants (<1 year old), utilized 5.7% of the cPAD. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of ethiprole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, ethiprole is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for ethiprole.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, ethiprole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic

dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for ethiprole.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA concluded that the nonlinear approach for assessing potential cancer risk from exposure to ethiprole is appropriate. As noted in this Unit, the chronic risk aggregate exposure to ethiprole is below the Agency's level of concern; therefore, the Agency concludes that there is not a cancer risk of concern from exposure to ethiprole.

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 U.S. population, or to infants and children from aggregate exposure to ethiprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The HPLC/MS–MS enforcement method, Method 01128, is acceptable for determination of residues of ethiprole and its sulfone metabolite RPA 097973 for data collection in plant commodities. The GC–ECD method (Report No. B003572) is suitable for determining residues of parent ethiprole and RPA in milk, eggs and tissues. The FDA multiresidue method testing study for ethiprole is adequate and indicates that PAM multiresidue methods are not suitable for enforcing tolerances for residues of ethiprole.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; 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. Codex has not established maximum residue limits (MRLs) for residues of ethiprole in coffee commodities; therefore, there are no harmonization issues at this time.

V. Conclusion

Therefore, a tolerance is established for residues of the insecticide ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1*H*-pyrazole-3-carbonitrile, including its metabolites and degradates, in or on coffee, green bean at 0.1 ppm. EPA is also amending the footnote in the table in paragraph (a) to accommodate the coffee commodity.

VI. Statutory and Executive Order Reviews

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

This 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: June 19, 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 § 180.652, revise paragraph (a) to read as follows:

§ 180.652 Ethiprole; tolerances for residues.

(a) General. Tolerances are established for residues of ethiprole, 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 ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1*H*-pyrazole-3-carbonitrile.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Coffee, green bean [1]	0.1
Rice, grain [1]	1.7
Tea, dried [1]	30

[1] There are no U.S. registrations for this commodity as of June 28, 2019.

* * * * *

[FR Doc. 2019–13546 Filed 6–27–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0002; FRL–9994–51]

Mefentrifluconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefentrifluconazole in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 28, 2019. Objections and requests for hearings must be received on or before August 27, 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–2018–0002, 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–2018–0002 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 27, 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–2018–0002, 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 May 18, 2018 (83 FR 23247) (FRL–9976–87), 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 7F8612) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, North Carolina 27709–3528. The petition requested to establish tolerances in 40 CFR part 180 for residues of the fungicide mefentrifluconazole (BAS 750 F); 2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1*H*-1,2,4-triazole-1-yl)propan-2-ol] in or on the following raw agricultural commodities: almond, hulls at 4 parts per million (ppm); barley, hay at 15 ppm; barley, straw at 30 ppm; cattle, fat at 0.3 ppm;