V. Conclusion

Therefore, tolerances are established for residues of metiram (a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides), including its metabolites and degradates, in or on banana at 3 ppm and grape, wine at 5 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 20, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.217 is amended by revising the section heading and paragraph (a) to read as follows:

§ 180.217 Metiram; tolerances for residues.

(a) *General.* Tolerances are established for residues of a metiram (a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those metiram residues convertible to and expressed in terms of the degradate carbon disulfide.

Commodity	Parts per million
Apple	0.5
Apple, pomace, wet	2
Banana [1]	3
Grape, wine [1]	5
Potato	0.2

[1] There are no U.S. registrations on bananas and grape, wine as of April 29, 2011.

* * * * *

[FR Doc. 2011–10333 Filed 4–28–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0266; FRL–8869–5]

Pyrasulfotole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes or revises tolerances for residues of pyrasulfotole in or on grain sorghum, grass, and livestock commodities. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 29, 2011. Objections and requests for hearings must be received on or before June 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see* also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0266. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available,

e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–5218; *e-mail address: stanton.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0266 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0266, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL–8831–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7680) by Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pyrasulfotole, (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone, in or on sorghum, grain at 0.8 parts per million (ppm); sorghum, forage at 1.2 ppm; sorghum, stover at 0.35 ppm; grass, hay at 2.5 ppm; and grass, forage at 10 ppm. The petition also requested that established tolerances in 40 CFR 180.631 for residues of pyrasulfotole on livestock commodities be increased to the following levels: Cattle, goat, hog, sheep, horse, meat at 0.04 ppm; cattle, goat, hog, sheep, horse, fat at 0.04 ppm; cattle, goat, hog, sheep, horse, meat byproducts, except liver at 2 ppm; and cattle, goat, hog, sheep, horse, liver at 8 ppm. The petition requested that the new and revised tolerances be established for residues of pyrasulfotole, including its metabolites and degradates, but that compliance with the specified tolerance levels be determined by measuring only residues of pyrasulfotole, (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)-[2-(methylsulfonyl)-4-(trifluoromethyl)-phenyl]-methanone, and its desmethyl metabolite, (5–Hydroxy-3-methyl-1*H*-pyrazol-4-yl)-[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone, calculated as the stoichiometric equivalent of pyrasulfotole, in or on the commodities. That notice referenced a summary of the petition prepared by Bayer CropScience LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the sorghum commodity terms and the proposed tolerances levels for sorghum, grass; and livestock commodities. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure

of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyrasulfotole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrasulfotole 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.

Pyrasulfotole has low to moderate acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a dermal sensitizer or skin irritant but has been shown to be a moderate eye irritant.

Chronic oral exposure of rats to pyrasulfotole resulted in extensive eye toxicity at almost all doses tested. Eye effects included corneal opacity, neovascularization of the cornea, inflammation of the cornea, regenerative corneal hyperplasia, corneal atrophy, and/or retinal atrophy. Ocular toxicity is believed to be an indirect result of tyrosinemia caused by inhibition of hepatic HPPD (4-hydroxyphenylpyruvate dioxygenase). In mice, ocular toxicity was not observed at any dose, thereby reflecting accepted differences in effects among rodent species for HPPD inhibitors. Long-term exposure of mice to pyrasulfotole did cause toxicity of the urinary system, including the kidney, urinary bladder, and ureters at the highest dose tested (HDT), as well as gallstone formation at all doses tested. Dogs treated with pyrasulfotole for 1 year exhibited toxicity of the urinary system (kidneys and bladder) at mid and high doses, as well as cataracts at a very low incidence at the HDT.

In the combined chronic/carcinogenicity study in rats, two male rats had rare treatment-related corneal tumors at the HDT (104/140 milligrams/kilograms/day (mg/kg/day), M/F)), a dose associated with widespread corneal inflammation, hyperplasia, metaplasia, neurovascularization and atrophy. In the mouse carcinogenicity study, treatment-related urinary bladder transitional cell tumors were seen in males and females only at the HDT (560/713 mg/kg/day, M/F). The evidence from animal data is suggestive of carcinogenicity, which raises a concern for carcinogenic effects but is judged not sufficient for quantification of cancer risk in humans. In the case of pyrasulfotole, cancer risk from dietary exposure is less of a concern based on the following weight of evidence considerations:

- The incidence of ocular tumors was low (2/55), seen only at the high dose, and was associated with widespread corneal inflammation, hyperplasia, metaplasia, neurovascularization, and atrophy;
- It is biologically plausible for corneal tumors to result from a nongenotoxic mode of action that is secondary to corneal inflammation and regenerative hyperplasia caused by tyrosine;
- The urinary bladder tumors in mice were seen only at the high dose (one-half of the Limit Dose), which was determined to be an excessive dose due to occurrence of death, bladder stones, and bladder hyperplasia;
- Data from available toxicity studies showed dose and temporal concordance among putative key events for the biological plausibility for a nongenotoxic proliferative mechanism for the bladder tumors. This was evidenced by the concurrent presence of secondary inflammation and hyperplastic lesions in the urinary bladder induced by the urinary stones;
- In both species tumors were observed only at the highest dose tested (i.e., lack of dose-response);
- Pyrasulfotole and its benzoic metabolite, AE B197555, do not pose a mutagenic concern; and
- The NOAEL of 1.0 mg/kg/day used for deriving the chronic RfD is approximately 100- to 500-fold lower than the doses that induced ocular tumors in rats (104 mg/kg/day) and urinary bladder tumors in mice (560 mg/kg/day).

Thus, for all these reasons, the Agency has determined that a non-linear approach is adequate for assessing cancer risk and that the chronic PAD (0.01 mg/kg/day) will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to the pyrasulfotole.

Signs of potential neurotoxicity were observed in the acute neurotoxicity study in rats (decreased locomotor activity on the day of treatment), as well as in the rat subchronic neurotoxicity study (urine staining in the high dose females during the Functional Observational Battery) and rat developmental neurotoxicity (DNT) study (decreased brain weights, learning deficits, and the changes in brain morphometry).

In the prenatal developmental toxicity study in rats, an increased incidence of skeletal variations was observed in fetal offspring at the mid dose, as was decreased fetal body weight in male offspring. Both effects were observed in the presence of maternal toxicity (decreased body weight gain, enlarged placenta, clinical signs) at the same dose. In the DNT study in rats, ocular toxicity as well as several adverse developmental effects (delayed preputial separation, morphometric changes, and delays in learning/memory) were observed at the mid dose. Ocular toxicity was also observed at this dose in maternal animals; an identical NOAEL was established in both dams and offspring. In the prenatal developmental toxicity study in rabbits, an increased incidence of skeletal variations was observed in fetal offspring at the mid dose. However, maternal toxicity (decreased body weight gain and food consumption) was observed only at the next highest dose tested. Therefore, increased quantitative susceptibility of offspring was observed in the rabbit developmental toxicity study, but not in the developmental toxicity or DNT studies in rats.

In the 2-generation reproductive toxicity study in rats, ocular toxicity (keratitis, corneal opacity and/or corneal neovascularization), was observed at the mid and high doses in the adults and offspring of 2-generations. Thyroid (colloid alteration, pigment deposition) and kidney (tubular dilation) toxicity were observed in adult animals of each generation. Colloid alteration and pigment deposition were also observed in rats following short-term dermal and chronic oral exposure of rats, although they were attributed to aging in the latter case. At the highest dose tested, decreased viability and decreased body weight were observed in offspring of both generations. At the mid and/or high doses, delays in balanopreputial separation (males) and vaginal patency (females) were observed in first-generation offspring.

Specific information on the studies received and the nature of the adverse effects caused by pyrasulfotole as well as the NOAEL and the lowest-observed-

adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Pyrasulfotole: Human-Health Risk Assessment for Proposed Section 3 Uses on Grain Sorghum and Grass Grown for Seed," p. 30 in docket ID number EPA–HQ–OPP–2010–0266.

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 pyrasulfotole used for human risk assessment is shown in the following Table:

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRASULFOTOLE 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 = 3.8 milligrams/kilograms/day (mg/kg/day). UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.038 mg/kg/day ..... aPAD = 0.038 mg/kg/day	Developmental neurotoxicity (rat; dietary). LOAEL = 37 mg/kg/day based on delayed preputial separation (males), decreased cerebrum length (PND 21 females), and decreased cerebellum height (PND 21 males).
Chronic dietary (All populations)	NOAEL= 1.0 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day ..... cPAD = 0.01 mg/kg/day	Combined chronic toxicity/carcinogenicity (rat; dietary). LOAEL = 10/14 mg/kg/day (M/F) based on corneal opacity, neovascularization of the cornea, inflammation of the cornea, regenerative corneal hyperplasia, corneal atrophy, and/or retinal atrophy (both sexes), and hepatocellular hypertrophy along with increased serum cholesterol (males).
Cancer (Oral, dermal, inhalation) ..	Classification: "Suggestive Evidence of Carcinogenic Potential" based on increased incidences of corneal tumors in male rats (oral carcinogenicity study) and urinary bladder tumors in male and female mice (oral carcinogenicity study).		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrasulfotole, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrasulfotole tolerances in 40 CFR 180.631. EPA assessed dietary exposures from pyrasulfotole 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 pyrasulfotole. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with pyrasulfotole. Dietary Exposure Evaluation Model (DEEM) ™ 7.81 default concentration factors were used to estimate residues of pyrasulfotole in processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) and used DEEM™ 7.81 default concentration factors to estimate residues of pyrasulfotole in processed commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If

sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pyrasulfotole. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyrasulfotole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrasulfotole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of pyrasulfotole for acute exposures are estimated to be 6.9 parts per billion (ppb) for surface water and 2.4 ppb for ground water. For chronic exposures for non-cancer assessments the EDWCs are estimated to be 4.8 ppb for surface water and 2.4 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 6.9 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.8 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). Pyrasulfotole is not registered for any specific use patterns that would result in residential exposure.

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."

Pyrasulfotole, mesotrione, isoxaflutole, and topramezone belong to a class of herbicides that inhibit the liver enzyme HPPD, which is involved in the catabolism (metabolic breakdown) of tyrosine (an amino acid derived from proteins in the diet). Inhibition of HPPD can result in elevated tyrosine levels in the blood, a condition called tyrosinemia. HPPD-inhibiting herbicides have been found to cause a number of toxicities in laboratory animal studies including ocular, developmental, liver, and kidney effects. Of these toxicities, it is the ocular effect (corneal opacity) that is highly correlated with the elevated blood tyrosine levels. In fact, rats dosed with tyrosine alone show ocular opacities similar to those seen with HPPD inhibitors. Although the other toxicities may be associated with chemically-induced tyrosinemia, other mechanisms may also be involved.

There are marked differences among species in the ocular toxicity associated with inhibition of HPPD. Ocular effects following treatment with HPPD-inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. The explanation of this species-specific response in ocular opacity is related to the species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves a liver enzyme called tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities, because the activity of TAT in these species is much greater compared to rats. Thus, humans and mice have a highly effective metabolic process for handling excess tyrosine.

HPPD inhibitors (e.g., nitisinone) are used as effective therapeutic agents to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout the patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, due to an efficient metabolic process to handle excess tyrosine, exposure to environmental residues of HPPD-inhibiting herbicides is unlikely to result in high blood levels of tyrosine and ocular toxicity in humans; and EPA has concluded that a cumulative risk assessment with other HPPD inhibitors is unnecessary. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for pyrasulfotole includes developmental toxicity studies in rats and rabbits, a DNT study in rats and a 2-generation reproductive toxicity study in rats. As discussed in unit III.A, there was quantitative evidence of increased susceptibility of fetal offspring in the developmental toxicity study in rabbits. In this study, an increased incidence of skeletal variations was observed in fetal offspring at the mid dose; whereas maternal toxicity (decreased body weight gain and food consumption) was observed only at the next highest dose tested.

The concern for increased susceptibility seen in the rabbit developmental toxicity study is low because a) there is well established developmental NOAEL in this study, b) the increased susceptibility was not seen in the rat developmental toxicity study, the DNT study in rats, or the 2-generation reproduction study in rats,

and c) the NOAEL of the study chosen for the chronic RfD (1 mg/kg/day) is 10-fold lower than the NOAEL observed in the rabbit developmental toxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyrasulfotole is largely complete, lacking only an immunotoxicity study. There is no evidence of potential immunotoxicity (such as effects on the spleen or thymus, or increased globulins) in the available toxicity studies for pyrasulfotole; and EPA is using critical studies for the chronic and acute RfDs that have the lowest NOAELs in the database for those exposure durations. Therefore, EPA does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment, and a database uncertainty factor (UF_{DB}) is not needed to account for lack of this study.

ii. Although there were signs of neurotoxicity observed in the acute, subchronic and developmental neurotoxicity studies, EPA's concern for these effects is low. The critical study (developmental neurotoxicity study in rats) chosen for the acute RfD has a well-defined NOAEL that is 54-fold lower than the dose at which effects (decreased locomotor activity on day 0) were seen in the acute neurotoxicity study. The critical study (chronic toxicity/carcinogenicity study in the rat) chosen for the chronic RfD also has a well-defined NOAEL that is 42- and 37-fold lower than the doses at which effects were observed in the subchronic and developmental neurotoxicity studies, respectively. Therefore, EPA does not believe that an additional uncertainty factor is needed to account for neurotoxicity.

iii. Although there is evidence of increased quantitative susceptibility of *in utero* rabbits in the prenatal developmental toxicity study, the degree of concern for developmental effects is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyrasulfotole.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyrasulfotole in drinking water. These assessments will not underestimate the exposure and risks posed by pyrasulfotole.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrasulfotole will occupy 9% of the aPAD for children 1 to 2 years 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 pyrasulfotole from food and water will utilize 16% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for pyrasulfotole.

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, pyrasulfotole 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 pyrasulfotole.

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, pyrasulfotole 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 pyrasulfotole.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A, risk assessments based on the endpoint selected for chronic risk assessment are considered to be protective of any potential carcinogenic risk from exposure to pyrasulfotole. Based on the results of the chronic risk assessment discussed above in Unit III.E.2, EPA concludes that pyrasulfotole is not expected to pose a cancer risk.

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 pyrasulfotole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Bayer Method AI–001–P04–02 (a high-performance liquid chromatography (HPLC)/mass spectrometry (MS)/MS method) is available to enforce pyrasulfotole tolerances in plants. Bayer Method AI–006–A08–01 (an HPLC–MS/MS method) is suitable as an enforcement method for livestock commodities. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyrasulfotole on grain sorghum, grass, or livestock commodities.

C. Revisions to Petitioned-For Tolerances

EPA has revised the sorghum commodity terms and the tolerance levels for both sorghum and grass commodities. The sorghum commodity terms have been revised (from "sorghum, grain;" sorghum, forage;" and sorghum, stover" to "sorghum, grain, grain;" "sorghum, grain, forage;" and "sorghum, grain, stover") to agree with the accepted terminology in the Agency's Food and Feed Vocabulary. The tolerance levels for sorghum and grass commodities have been revised as follows based on analysis of the field trial data using the Agency's NAFTA-harmonized tolerance/MRL calculator in accordance with the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data:* Sorghum, grain, grain from 0.8 ppm to 0.70 ppm; sorghum, grain, forage from 1.2 ppm to 1.5 ppm; sorghum, grain, stover from 0.35 ppm to 0.80 ppm; grass, forage from 10 ppm to 25 ppm; and grass, hay from 2.5 ppm to 3.5 ppm.

Based on the results of the cattle feeding study and the calculated maximum reasonable dietary burden (MRDB) for cattle, EPA determined that the existing tolerance of 0.02 ppm in or on the meat of cattle, goat, horse, and sheep is adequate and need not be raised to 0.04 ppm, as proposed; but that tolerances should be established for residues of pyrasulfotole and its desmethyl metabolite in or on milk at 0.03 ppm (no increase in the established tolerance of 0.01 ppm was proposed); fat of cattle, goat, horse and sheep at 0.03 ppm (proposed at 0.04 ppm); liver of cattle, goat, horse, and sheep at 3.0 ppm (proposed at 8 ppm); and meat byproducts, except liver, of cattle, goat, horse, and sheep at 0.70 ppm (proposed at 2 ppm).

Based upon a MRDB for hogs, there is no reasonable expectation of finding quantifiable residues of pyrasulfotole or its desmethyl metabolite in hog muscle and fat; thus, the current tolerances of 0.02 ppm are adequate (proposed at 0.04 ppm). There is a reasonable expectation of residues of pyrasulfotole and/or its desmethyl metabolite in hog liver and kidney, and EPA has determined that tolerances for these commodities should be set at the following levels: hog, meat byproducts, except liver at 0.05 ppm (proposed at 2 ppm); and hog, liver at 0.30 ppm (proposed at 8 ppm).

The petitioner did not propose changes to the existing poultry tolerances for pyrasulfotole; however, based on the results of the poultry metabolism study and the calculated MRDB for poultry, EPA has determined that the existing tolerance for residues of pyrasulfotole and its desmethyl metabolite in or on poultry, meat byproducts should be increased from 0.02 ppm to 0.20 ppm.

V. Conclusion

Therefore, tolerances are established for residues of pyrasulfotole, including its metabolites and degradates as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 21, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.631 is amended by revising the introductory text and table in paragraph (a) to read as follows:

§ 180.631 Pyrasulfotole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pyrasulfotole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyrasulfotole ((5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone) and its desmethyl metabolite (5-hydroxy-3-methyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone), calculated as the stoichiometric equivalent of pyrasulfotole, in or on the commodities:

Commodity	Parts per million
Aspirated grain fractions	0.40
Barley, grain	0.02
Barley, hay	0.30
Barley, straw	0.20
Cattle, fat	0.03
Cattle, liver	3.0
Cattle, meat	0.02
Cattle, meat byproducts, except liver	0.70
Eggs	0.02
Goat, fat	0.03
Goat, liver	3.0
Goat, meat	0.02
Goat, meat byproducts, except liver	0.70
Grass, forage	25
Grass, hay	3.5
Hog, fat	0.02
Hog, liver	0.30
Hog, meat	0.02
Hog, meat byproducts, except liver	0.05
Horse, fat	0.03
Horse, liver	3.0
Horse, meat	0.02
Horse, meat byproducts, except liver	0.70
Milk	0.03
Oat, forage	0.10
Oat, grain	0.08
Oat, hay	0.50
Oat, straw	0.20
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.20
Rye, forage	0.20
Rye, grain	0.02
Rye, straw	0.20
Sheep, fat	0.03
Sheep, liver	3.0
Sheep, meat	0.02
Sheep, meat byproducts, except liver	0.70
Sorghum, grain, forage	1.5
Sorghum, grain, grain	0.70
Sorghum, grain, stover	0.80
Wheat, forage	0.20
Wheat, grain	0.02
Wheat, hay	0.80
Wheat, straw	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0267; FRL–8870–9]

Mefenpyr-diethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenpyr-diethyl in or on multiple commodities. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also moves established tolerances for canola and soybean commodities to correct an administrative error.

DATES: This regulation is effective April 29, 2011. Objections and requests for hearings must be received on or before June 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0267. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8072; e-mail address: *benbow.bethany@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under 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–