Milwaukee Harbor during August through September 2007. This action is necessary to protect vessels and people from the hazards associated with fireworks displays. This safety zone will restrict vessel traffic from a portion of the Captain of the Port Lake Michigan Zone.

DATES: Effective from 10 p.m. on August 19, 2007 to 11 p.m. on September 8, 2007.

FOR FURTHER INFORMATION CONTACT: CWO Brad Hinken, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7154.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone, Milwaukee Harbor, Milwaukee, WI, 33 CFR 165.935 for the following events:

(1) *Irish Fest fireworks display* on August 19, 2007 from 10 p.m. through 11 p.m.; and

(2) *Mexican Fiesta fireworks display* on August 24, 2007 from 9 p.m. through 11 p.m.; and

(3) *Indian Summer fireworks displays* on September 8, 2007 from 9 p.m. through 11 p.m.

All vessels must obtain permission from the Captain of the Port or his on-scene representative to enter, move within or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI (published on June 13, 2007 at 72 FR 32522) and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners and Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. The Captain of the Port may be contacted via U.S. Coast Guard Sector Lake Michigan on channel 16, VHF–FM.

Dated: August 6, 2007.

Bruce C. Jones,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. E7–16018 Filed 8–14–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–1026; FRL–8141–8]

Pyrasulfotole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyrasulfotole in or on small cereal grains, including barley, oats, rye, triticale, and wheat; as well as livestock commodities. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 15, 2007. Objections and requests for hearings must be received on or before October 15, 2007, 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–2006–1026. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, 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–2006–1026 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 15, 2007.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006–1026, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of February 7, 2007 (72 FR 5706) (FRL–8111–8), 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 6F7059) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.631 be amended by establishing a tolerance for residues of the herbicide pyrasulfotole (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone, and its metabolite, 5-hydroxy-3-methyl-1*H*-pyrazol-4-yl) [2-methylsulfornyl)-4-(trifluoromethyl)phenyl]methanone, in or on barley, oat, rye, triticale, wheat, grain at 0.07 parts per million (ppm), barley, oat, rye, wheat, straw and oat, rye, wheat, forage at 0.25 ppm, barley, oat, wheat, hay at 0.8 ppm, wheat, aspirated grain fractions at 1.4 ppm. In addition, Bayer CropScience has requested permanent tolerances for pyrsulfotole *per se* for cattle, goat, hog, horse, sheep, meat and fat at 0.01 ppm, cattle, goat, hog, horse, sheep, meat byproducts at 0.3 ppm, and milk at 0.005 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the tolerance levels as follows: aspirated grain fractions at 0.40 ppm, barley, grain at 0.02 ppm, barley, hay at 0.30 ppm, barley, straw at 0.20 ppm, cattle, fat at 0.02 ppm, cattle, liver at 0.35 ppm, cattle, meat at 0.02 ppm, cattle, meat byproducts, except liver at 0.06 ppm, eggs at 0.02 ppm, goat, fat at 0.02 ppm, goat meat at 0.02 ppm, goat, meat byproducts, except liver at 0.06 ppm, hog, fat at 0.02 ppm, hog, meat at 0.02 ppm, hog, meat byproducts at 0.02 ppm, horse, fat at 0.02 ppm, horse, liver at 0.35 ppm, horse, meat at 0.02 ppm, horse, meat byproducts, except liver at 0.06 ppm, milk at 0.01 ppm, oat, forage at 0.10 ppm, oat, grain at 0.08 ppm, oat, hay at 0.50 ppm, oat, straw at 0.20 ppm, poultry, fat at 0.02 ppm, poultry, meat at 0.02 ppm, poultry, meat byproducts at 0.02 ppm, rye, forage at 0.20 ppm, rye, grain at 0.02 ppm, rye, straw at 0.20 ppm, sheep, fat at 0.02 ppm, sheep, liver at 0.35 ppm, sheep, meat at 0.02 ppm, sheep, meat byproducts, except liver at 0.06 ppm, wheat, forage at 0.20 ppm, wheat, grain at 0.02 ppm, wheat, hay at 0.80 ppm, and wheat, straw at 0.20 ppm.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the 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....'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in 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 the petitioned-for tolerance for residues of pyrasulfotole and pyrasulfotole-desmethyl on aspirated grain fractions at 0.40 ppm, barley, grain at 0.02 ppm, barley, hay at 0.30 ppm, barley, straw at 0.20 ppm, cattle, fat at 0.02 ppm, cattle, liver at 0.35 ppm, cattle, meat at 0.02 ppm, cattle, meat byproducts, except liver at 0.06 ppm, eggs at 0.02 ppm, goat, fat at 0.02 ppm, goat meat at 0.02 ppm, goat, meat byproducts, except liver at 0.06 ppm, hog, fat at 0.02 ppm, hog, meat at 0.02 ppm, hog, meat byproducts at 0.02 ppm, horse, fat at 0.02 ppm, horse, liver at 0.35 ppm, horse, meat at 0.02 ppm, horse, meat byproducts, except liver at 0.06 ppm, milk at 0.01 ppm, oat, forage at 0.10 ppm, oat, grain at 0.08 ppm, oat, hay at 0.50 ppm, oat, straw at 0.20 ppm, poultry, fat at 0.02 ppm, poultry, meat at 0.02 ppm, poultry, meat byproducts at 0.02 ppm, rye, forage at 0.20 ppm, rye, grain at 0.02 ppm, rye, straw at 0.20 ppm, sheep, fat at 0.02 ppm, sheep, liver at 0.35 ppm, sheep, meat at 0.02 ppm, sheep, meat byproducts, except liver at 0.06 ppm, wheat, forage at 0.20 ppm, wheat, grain at 0.02 ppm, wheat, hay at 0.80 ppm, and wheat, straw at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

For pyrasulfotole, aggregate exposure risk assessments were performed for the following scenarios: Acute aggregate exposure (food and drinking water), and chronic aggregate exposure (food and drinking water). Short- and intermediate-term assessments, which are used to evaluate aggregate dietary and residential exposures, were not performed because there are no registered or proposed residential non-food uses. Although pyrasulfotole is classified as ''Suggestive Evidence of Carcinogenicity,'' EPA determined that separate quantifications of cancer risks is not required noting that the progression of non-neoplastic related lesions in both the rats and mice was biologically plausible by non-genotoxic

modes of action for both the corneal tumors and the bladder tumors. Therefore, the chronic RfD will be protective of cancer and non-cancer effects.

Pyrasulfotole belongs to a class of herbicides that inhibit the liver enzyme 4-hydroxyphenylpyruvate dioxygenase (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 human 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 an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout 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 it of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposure to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. Nonetheless, because EPA has not yet developed an alternate risk assessment endpoint, model, or cross-species extrapolation method for pyrasulfotole, EPA has assessed chronic risk from exposure to pyrasulfotole based on its ocular effects in rats. Due to the limited relevance to humans of this endpoint, this approach to assessing chronic risk for pyrasulfotole must be regarded as worst case. In the future, assessment of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods.

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. Specific information on the studies received and the nature of the adverse effects caused by pyrasulfotole as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov*. The referenced document, entitled ''Pyrasulfotole: Human Health Risk Assessment for Proposed Uses on Small Cereal Grains,'' is available in the docket established by this action, (EPA–HQ–OPP–2006–1026).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

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

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRASULFOTOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment	Uncertainty/FQPA Safety Factors[1]	Study and Toxicological Effects
Acute Dietary (All populations)	NOAEL = 3.8 mg/kg/day	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	Developmental neurotoxicity (rat; dietary) offspring 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 UF_{FQPA} = 1X	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 hepatocellar hypertrophy along with increased serum cholesterol (males)
Incidental Oral Short-and Intermediate-Term (1–30 days and 1–6 months)	NOAEL= 2.5 mg/kg/day	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	Reproduction and fertility effects (rat; dietary) offspring LOAEL = 26.3/32.6 mg/kg bw/day (M/F) based on corneal opacity and/or corneal neovascularization (F_1 and F_2 generations)
Dermal Short- and Intermediate-Term (1–30 days and 1–6 months)	NOAEL = 10 mg/kg/day	UF_A = 10X UF_H = 10X	28–day dermal toxicity (rat) LOAEL = 100 mg/kg bw/day (M/F) based on focal degeneration of pancreas (both sexes) and alteration of thyroid colloid (males)
Dermal Long-Term (> 6 months)	NOAEL= 1.0 mg/kg/day Estimated dermal absorption factor = 2.5%	UF_A = 10X UF_H = 10X	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)
Inhalation (All durations)	NOAEL = 1.0 mg/kg/day 100% inhalation asumed	UF_A = 10X UF_H = 10X	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)		

[1]UF = Uncertainty factor, UF_A = Extrapolation from animal to human (interspecies), UF_H = Potential variation in sensitivity among members of the human population (intraspecies), and UF_{FQPA} = Food Quality Protection Act (FQPA) safety factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrasulfotole, 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 one-day or single exposure. 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 relied upon tolerance-level residues and assuming 100% crop treated information for all 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 relied upon tolerance-level residues and assuming 100% crop treated information for all commodities.

iii. *Cancer.* Pyrasulfotole has been classified by the EPA as having ''Suggestive Evidence of Carcinogenic Potential,'' based on increased incidences of corneal tumors in male rats at the highest dose tested (2,500 ppm) in the chronic toxicity/

carcinogenicity study in rat and urinary bladder transitional cell tumors in male and female mice at the highest dose tested (4,000 ppm) in the mouse carcinogenicity study. These tumors were observed at doses that were considered excessive due to increased mortality caused by urinary bladder stones. EPA noted that the progression of non-neoplastic related lesions in both the rats and mice was biologically plausible by non-genotoxic modes of action for both the corneal tumors and the bladder tumors. Therefore, the chronic RfD of 0.01 mg/kg/day, based on the rat chronic toxicity/carcinogenicity study (NOAEL= 25 ppm (1 mg/kg/day) and LOAEL of 250 ppm (10 mg/kg/day)) would be protective of both non-cancer and potential cancer precursor effects. Quantifications of separate cancer risk was not required.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for pyrasulfotole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 and SCI-GROW models, the estimated drinking water environmental concentrations (EDWCs) of pyrasulfotole for acute exposures are estimated to be 4.0 parts per billion (ppb) for surface water and 1.4 ppb for ground water. The EECs for chronic exposures are estimated to be 2.8 ppb for surface water and 1.4 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 4.0 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.8 ppb was used to access the contribution to drinking water.

The pyrasulfotole risk assessment team determined that the residue of concern in drinking water for risk assessment purposes is parent only. Pyrasulfotole-benzoic acid was identified as the only environmental degradate in the soil metabolism and terrestrial field dissipation studies. Based on available toxicology studies on pyrasulfotole-benzoic acid, EPA determined that it is not of toxicological concern, and thus, should not be included in the drinking water assessment for pyrasulfotole.

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 proposed or registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 belongs to a class of herbicides (including mesotrione, isoxaflutole, and topramezone) that inhibit the liver enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD). EPA has concluded that the ocular effects caused by these herbicides has limited relevance to humans. In the future, assessments of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold 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 data base 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Increased quantitative susceptibility of offspring was observed in the rabbit developmental toxicity study, since offspring toxicity (skeletal anomalies/variations) was observed at a lower dose than maternal toxicity (decreased body weight gain, food consumption). No evidence of quantitative susceptibility following *in utero* and/or postnatal exposure was observed in the prenatal developmental toxicity study in rats, the developmental neurotoxicity (DNT) study in rats, or in the 2-generation rat reproductive toxicity study. Offspring toxicity (skeletal variations; decreased body weight (males)) was observed at the same dose as maternal toxicity (clinical signs, decreased body weight, enlarged placenta) in the prenatal developmental toxicity study in rats. Offspring toxicity (e.g., ocular toxicity, effects on learning/memory, effects on brain morphometry) was also observed at the same dose as maternal toxicity (ocular opacity) in the DNT study. Last, offspring toxicity (ocular toxicity) was observed at the same as or higher doses than parental toxicity (thyroid effects) in the 2-generation rat reproductive toxicity study.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicology database is complete.

ii. There are no residual uncertainties concerning pre- and postnatal toxicity. Clear NOAELs were established for all exposure scenarios and these are considered protective of the offspring susceptibility observed in the rabbit developmental toxicity study. The concern for increased susceptibility seen in rabbit developmental toxicity study is low because a) there is well established developmental NOAEL in the rabbit developmental toxicity study in rabbits protecting fetuses from skeletal anomalies/variations, b) the increased succeptibility was not seen in rat developmental toxicity study, developmental neurotoxicity study in rats and two generation reproduction study in rats, c) the NOAEL of the study chosen for the chronic RfD is 10x lower than the rabbit developmental toxicity study NOAEL (10 mg/kg/day).

iii. There are no registered or proposed uses of pyrasulfotole which would result in residential exposure.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues for

all proposed commodities. By using this screening-level assessment, the acute and chronic exposures/risks will not be underestimated. The dietary drinking water assessment (unrefined estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrasulfotole and pyrasulfotole-desmethyl will occupy 2% of the aPAD for the general U.S. population and at 4% of the aPAD for children 1–2 years old, the most highly exposed population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyrasulfotole and pyrasulfotole-desmethyl from food and water will utilize 2% of the cPAD for the general U.S. population and at 7% of the cPAD for children 1–2 years old, the most highly exposed population subgroup.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyrasulfotole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyrasulfotole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Pyrasulfotole has been classified by EPA as having ''Suggestive Evidence of Carcinogenic Potential,'' based on increased incidences of corneal tumors in male rats at the highest dose tested (2,500 ppm) in the chronic toxicity/carcinogenicity study in rat and urinary bladder transitional cell tumors in male and female mice at the highest dose tested (4,000 ppm) in the mouse carcinogenicity study. The chronic RfD of 0.01 mg/kg/day, based on the rat chronic toxicity/carcinogenicity study (NOAEL = 25 ppm (1 mg/kg/day) and LOAEL of 250 ppm (10 mg/kg/day)) would be protective of both non-cancer and cancer effects.

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 and pyrasulfotole-desmethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology high-performance liquid chromatography (HPLC)/mass spectrometry (MS)/MS method (Method AI–004–A05–01) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established Mexican, Canadian, or Codex MRLs for the proposed uses. Pyrasulfotole was evaluated as part of a trilateral joint review with Canada and Australia. All EPA-recommended tolerances are the same as those being established in Canada and Australia. Therefore, harmonization is not an issue at this time.

V. Conclusion

Therefore, the tolerance is established for residues of pyrasulfotole and pyrasulfotole-desmethyl, (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone, and its metabolite, 5-hydroxy-3-methyl-1*H*-pyrazol-4-yl) [2-methylsulfornyl)-4-(trifluoromethyl)phenyl]methanone, in or on aspirated grain fractions at 0.40 ppm, barley, grain at 0.02 ppm, barley, hay at 0.30 ppm, barley, straw at 0.20 ppm, cattle, fat at 0.02 ppm, cattle, liver at 0.35 ppm, cattle, meat at 0.02 ppm, cattle, meat byproducts, except liver at 0.06 ppm, eggs at 0.02 ppm, goat, fat at 0.02 ppm, goat meat at 0.02 ppm, goat, meat byproducts, except liver at 0.06 ppm, hog, fat at 0.02 ppm, hog, meat at 0.02 ppm, hog, meat byproducts at 0.02 ppm, horse, fat at 0.02 ppm, horse, liver at 0.35 ppm, horse, meat at 0.02 ppm, horse, meat byproducts, except liver at 0.06 ppm, milk at 0.01 ppm, oat, forage at 0.10 ppm, oat, grain at 0.08 ppm, oat, hay at 0.50 ppm, oat, straw at 0.20 ppm, poultry, fat at 0.02 ppm, poultry, meat at 0.02 ppm, poultry, meat byproducts at 0.02 ppm, rye, forage at 0.20 ppm, rye, grain at 0.02 ppm, rye, straw at 0.20 ppm, sheep, fat at 0.02 ppm, sheep, liver at 0.35 ppm, sheep, meat at 0.02 ppm, sheep, meat byproducts, except liver at 0.06 ppm, wheat, forage at 0.20 ppm, wheat, grain at 0.02 ppm, wheat, hay at 0.80 ppm, and wheat, straw at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 6, 2000) do not apply to this rule. In addition, This 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) (Public Law 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: August 1, 2007.

Debra Edwards,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 added to read as follows:

§ 180.631 Pyrasulfotole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pyrasulfotole and pyrasulfotole-desmethyl, (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone, and its metabolite, 5-hydroxy-3-methyl-1*H*-pyrazol-4-yl) [2-methylsulfornyl)-4-(trifluoromethyl)phenyl]methanone, in or on the following agricultural commodities:

Commodity	Parts per million
Aspirated grain fractions	0.40
Barley, grain	0.02
Barley, hay	0.30
Barley, straw	0.20
Cattle, fat	0.02
Cattle, liver	0.35
Cattle, meat	0.02
Cattle, meat byproducts, except liver	0.06
Eggs	0.02
Goat, fat	0.02
Goat, liver	0.35
Goat, meat	0.02
Goat, meat byproducts, except liver	0.06
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, liver	0.35
Horse, meat	0.02
Horse, meat byproducts, except liver	0.06
Milk	0.01
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	0.02
Rye, forage	0.20
Rye, grain	0.02
Rye, straw	0.20
Sheep, fat	0.02
Sheep, liver	0.35
Sheep, meat	0.02
Sheep, meat byproducts, except liver	0.06
Wheat, forage	0.20
Wheat, grain	0.02
Wheat, hay	0.80
Wheat, straw	0.20

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

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0329; FRL–8137–9]

Zucchini Yellow Mosaic Virus-Weak Strain; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the zucchini yellow mosaic virus-weak strain (ZYMV-WK) on cucurbits, including, cucumbers, cantaloupes, watermelons, muskmelons, winter and summer squash, pumpkins, zucchini and other cucurbits when applied/used as a viruscide to protect curcurbit crop plants against severe strains of zucchini yellow mosaic virus. Bio-Oz Biotechnologies Limited submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ZYMV-WK strain.

DATES: This regulation is effective August 15, 2007. Objections and requests for hearings must be received on or before October 15, 2007, 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–2006–0329. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information