regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does 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.

D. Unfunded Mandates Reform Act; and Executive Orders 13132, and 13175

This order 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 order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538).

E. Executive Orders 13045, 13211 and 12898

As indicated previously, this action is not a ''regulatory action'' as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045, entitled ''*Protection of Children from Environmental Health Risks and Safety Risks'',* (62 FR 19885, April 23, 1997) and Executive Order 13211 entitled ''*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'',* (66 FR 28355, May 22, 2001). In addition, this order also does not 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).

F. National Technology Transfer and Advancement Act

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

IV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.* does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

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

Dated: February 10, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

§ 180.157 [Removed]

■ 2. Remove § 180.157.

[FR Doc. 2012–4065 Filed 2–28–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0717; FRL–9334–2]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone, including its metabolites and degradates, in or on field corn, pop corn, and sweet corn commodities. K–I Chemical U.S.A., Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 29, 2012. Objections and requests for hearings must be received on or before April 30, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0717. 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 email 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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under the FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0717 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 April 30, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0717, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online 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 January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7560) by K–I Chemical U.S.A., Inc., c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide pyroxasulfone and establishing tolerances therein for residues of pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites M-1, 5-difluoromethoxy-1-methyl-3-trifluoromethyl-1*H*-pyrazol-4-ylmethanesulfonic acid; M-3, 5-difluoromethoxy-1-methyl-3-trifluoromethyl-1*H*-pyrazol-4-carboxylic-acid; and M-25, (5-difluoromethoxy-3-trifluoromethyl-1*H*-pyrazol-4-yl)methanesulfonic acid in or on field corn kernel at 0.01 parts per million (ppm); field corn forage at 0.15 ppm; field corn stover at 0.15 ppm; field corn meal at 0.01 ppm; field corn grits at 0.01 ppm; field corn flour at 0.01 ppm; field corn starch at 0.01 ppm; field corn oil (wet and dry milled) at 0.01 ppm; sweet corn ears at 0.02 ppm; sweet corn forage at 0.15 ppm; sweet corn stover at 0.15 ppm; wheat grain at 0.02 ppm; wheat forage at 0.2 ppm; wheat straw at 0.2 ppm; soybean seed at 0.05 ppm; soybean forage at 1.0 ppm; soybean hay at 2.0 ppm; soybean meal at 0.05 ppm; soybean hulls at 0.02 ppm; and soybean refined oils at 0.01 ppm. That notice referenced a summary of the petition prepared by K–I Chemical U.S.A., Inc., 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 tolerance expression, commodity terms, and tolerance levels for corn commodities. The Agency has also determined that the submitted data are not adequate to support tolerances on soybean or wheat commodities and is, therefore, not establishing tolerances on these commodities at this time. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

Pyroxasulfone acute toxicity to mammals is low by all routes of exposure. Subchronic and chronic oral toxicity testing of pyroxasulfone in mice, rats, and dogs produced a variety of adverse effects in several target organs. Effects seen in animal studies included cardiac toxicity (increased cardiomyopathy in mice and rats), liver toxicity (centrilobular hepatocellular hypertrophy, histopathological, and/or clinical pathological indicators), neurotoxicity characterized by axonal/myelin degeneration in the sciatic nerve (dog, mouse, and rat) and spinal cord sections (dog), skeletal muscle

myopathy, kidney toxicity (increased incidence of chronic progressive nephropathy in dogs and retrograde nephropathy in mice), urinary bladder mucosal hyperplasia, inflammation, and urinary bladder transitional cell papillomas (rats). Decreased body weight and enzyme changes were noted in some studies. Immunotoxicity studies in rats and mice showed no evidence of immunotoxic effects from pyroxasulfone.

Pyroxasulfone was moderately toxic to rats following a 4-week dermal exposure producing local inflammation and systemic effects of minimal to mild cardiac myofiber degeneration at the limit dose. No adverse effects were noted in a 28-day inhalation study at the highest-dose tested.

Pyroxasulfone did not exhibit developmental toxicity in the rat developmental toxicity study and exhibited only slight developmental toxicity in rabbits (reduced fetal weight and resorptions) at the limit dose. However, developmental effects were noted in post-natal day (PND) 21 offspring in the rat developmental neurotoxicity (DNT) study characterized as decreased brain weight and morphometric changes. Developmental effects in the rabbit developmental study and DNT study occurred in the absence of maternal toxicity, indicating potential increased quantitative susceptibility of offspring. In a reproductive toxicity in rats reduced pup weight and body weight gains during lactation occurred at similar or higher doses causing pronounced maternal toxicity (reduced body weight, body weight gain, and food consumption and increased kidney weight, cardiomyopathy, and urinary bladder mucosal hyperplasia with inflammation).

In cancer studies in mice and rats, renal tubular adenomas were observed in male mice and urinary bladder transitional cell papillomas were observed in male rats. The kidney adenomas in male mice were determined to be spontaneous and not treatment-related based on the following considerations:

1. Absence of any cytotoxicity (degeneration or individual cell necrosis) in studies ranging from 14 days to 18 months at doses up to 15,000 ppm.

2. Absence of cell regeneration leading to precursor lesions such as atypical tubular hyperplasia at all time points and doses up to 15,000 ppm.

3. Lack of exacerbation of chronic progressive nephropathy, a spontaneous disease in rodents that results in cell regeneration which can result in renal tubule tumors in chronic studies.

4. Lack of a clear dose response in the distribution of tumors between test substance treated groups.

The urinary bladder tumors seen in male rats were determined to be a threshold effect. Pyroxasulfone exposure causes the growth of crystals in the urinary tract with subsequent calculi formation resulting in cellular damage. Crystal formation in the absence of calculi is not associated with hyperplasia or urinary bladder tumors; therefore, the formation of urinary bladder calculi is the prerequisite for subsequent hyperplasia and neoplasia. In other words, urinary bladder tumors do not develop at doses too low to produce calculi. There is also a clear threshold of 1,000 ppm (42.55 milligrams/kilogram/day (mg/kg/day)) for development of calculi and tumorigenesis. The point of departure (POD) of 50 ppm (2.0 mg/kg/day) selected for chronic risk assessment is not expected to result in urinary bladder calculi formation, which is a prerequisite for subsequent hyperplasia and neoplasia. Therefore, the Agency has determined that the quantification of risk using a non-linear approach (i.e., Reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyroxasulfone. There is no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by pyroxasulfone 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* in document ''Pyroxasulfone Human Health Risk Assessment for Use of New Active Ingredient Pyroxasulfone on Corn,'' p. 34, in docket ID number EPA–HQ–OPP–2009–0717.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 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 pyroxasulfone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYROXASULFONE 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 (General population including infants and children and females 13–50 years of age).	NOAEL = 100 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1 mg/kg/day ..... aPAD = 1 mg/kg/day	Developmental neurotoxicity in rats LOAEL = 300 mg/kg/day based on decreased brain weight in both sexes, reduced thickness of the hippocampus, corpus callosum, and cerebellum in PND 21 female offspring.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL= 2 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day ..... cPAD = 0.02 mg/kg/day	1 year chronic dog study LOAEL = 10 mg/kg/day based on impaired hind limb function, ataxia, hind limb twitching and tremors; clinical pathology: Increased creatine kinase, aspartate aminotransferase; axonal/myelin degeneration of the sciatic nerve and spinal cord sections.
Cancer (Oral, dermal, inhalation) ..	''Not Likely to be Carcinogenic to Humans'' at doses that do not cause crystals with subsequent calculi formation resulting in cellular damage of the urinary tract. Risk is quantified using a non-linear (i.e., RfD) approach.		

DNT = neurotoxicity study, FQPA SF = Food Quality Protection Act Safety Factor.
LOAEL = lowest-observed-adverse-effect-level. LOC = Levels of Concern.
mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level.
PAD = population adjusted dose (a = acute, c = chronic). PND = post-natal day.
RfD = reference dose. UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyroxasulfone, EPA considered exposure under the petitioned-for tolerances on corn commodities only. EPA is not establishing the petitioned-for tolerances on soybean and wheat commodities and no other tolerances have previously been established for pyroxasulfone. EPA assessed dietary exposures from pyroxasulfone 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 pyroxasulfone. 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 Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that 100% of field, pop and sweet corn commodities are treated with pyroxasulfone and that residues on these commodities are present at tolerance levels, adjusted upward to account for metabolites of concern (M-1, M-3, and M-25) that are not included in the tolerance expression.

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 made the same assumptions (adjusted tolerance-level residues and 100 percent crop treated (PCT)) as in the acute dietary exposure assessment.

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 pyroxasulfone. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for pyroxasulfone. Tolerance level residues (adjusted upward to account for additional metabolites of concern) and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyroxasulfone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyroxasulfone. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of pyroxasulfone for acute exposures are estimated to be 17 parts per billion (ppb) for surface water and 210 ppb for ground water. EDWCs of pyroxasulfone for chronic exposures for non-cancer assessments are estimated to be 3.2 ppb for surface water and 174 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 210 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 174 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). Pyroxasulfone 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.''

EPA has not found pyroxasulfone to share a common mechanism of toxicity with any other substances, and pyroxasulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyroxasulfone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal 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. *Pre-natal and post-natal sensitivity.* The pre-natal and post-natal toxicity database for pyroxasulfone includes developmental toxicity studies in rats and rabbits, a DNT study in rats, and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A, evidence of increased susceptibility of fetuses and offspring was seen in the DNT study and developmental toxicity study in rabbits following *in utero* or post-natal exposure to pyroxasulfone. No increased susceptibility was seen in the rat developmental or reproduction toxicity studies. In rabbits, developmental toxicity was only seen at the limit dose of 1,000 mg/kg/day as reduced fetal weight and increased fetal resorptions with a NOAEL of 500 mg/kg/day for these effects, compared to no maternal toxicity at these doses. In a DNT study in rats, offspring toxicity (decreased brain weight and morphometric changes on PND 21) was seen at 300 mg/kg/day compared to no maternal toxicity at 900 mg/kg/day. The degree of concern for the increased susceptibility seen in these studies is low and there are no residual uncertainties based on the following considerations:

i. The increased susceptibility is occurring at high doses.

ii. NOAELs and LOAELs have been identified for all effects of concern, and thus a clear dose response has been well defined.

iii. The PODs selected for risk assessment are protective of the fetal/offspring effects.

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

i. The toxicity database for pyroxasulfone is complete.

ii. Pyroxasulfone is a neurotoxic chemical and there is evidence of increased susceptibility of offspring with regard to neurotoxic effects in the rat DNT study. There is also evidence of increased susceptibility of fetuses/offspring with regard to non-neurotoxic effects in the rabbit developmental toxicity study. However, the concern for the increased susceptibility is low and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors (UFs) to be used in the risk assessment for pyroxasulfone.

iii. There are no residual uncertainties in the exposure database. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues (adjusted upward to account for additional metabolites of concern not included in the tolerance expression), and EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyroxasulfone in drinking water. These assessments will not underestimate the exposure and risks posed by pyroxasulfone.

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 population adjusted dose (aPAD) +and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyroxasulfone will occupy 4.2% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyroxasulfone from food and water will utilize 60% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for pyroxasulfone.

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, pyroxasulfone 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 pyroxasulfone.

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, pyroxasulfone 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 pyroxasulfone.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., the Agency has determined that the quantification of risk using a non-linear (i.e., RfD) approach will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyroxasulfone. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., pyroxasulfone is not expected to pose a cancer risk to humans.

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 pyroxasulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyroxasulfone.

C. Revisions to Petitioned-For Tolerances

The petitioner proposed tolerances for residues of pyroxasulfone on corn, soybean, and wheat commodities. EPA is not establishing the proposed tolerances on soybean and wheat commodities at this time due to inadequate supporting data. In the case of soybeans, the residue analyses from the field trials did not measure the major metabolite M-28, which comprised approximately 50% of the total residue in soybean metabolism studies. Without data on M-28, an appropriate tolerance level for soybean cannot be determined. The submitted data for wheat were collected from field trials conducted in Australia and, therefore, are not considered to be geographically representative of wheat growing areas of the United States. Additionally, EPA requires that data be collected on wheat hay, and hay data were not collected in any of the submitted field trials. Further, the petitioner did not conduct processing studies with wheat, so the Agency cannot determine whether separate tolerances are needed for the processed commodities of wheat. The petitioner must address these deficiencies before the proposed soybean and wheat tolerances can be established.

The petitioner proposed tolerances for residues of pyroxasulfone and its metabolites M-1, M-3, and M-25 on ''field corn grain,'' ''field corn forage,'' ''field corn stover,'' ''sweet corn ears,'' ''sweet corn forage,'' ''sweet corn stover,'' and several processed field corn commodities (grits, meal, flour, starch, and oil). EPA has concluded that the metabolites M-1, M-3, and M-25 should be included as residues of concern for risk assessment purposes for all corn commodities; however, to harmonize with its global review partners, Australia and Canada, U.S. tolerances for corn grain commodities will be enforced by measuring only parent pyroxasulfone and the M-3 metabolite. Tolerances for corn forage and stover will be enforced by measuring the parent pyroxasulfone and all three metabolites. EPA has determined that the proposed tolerances on processed field corn commodities (grits, meal, flour, starch, and oil) are unnecessary, since residues on these commodities are not expected to exceed those in the raw agricultural commodities (RACs) and thus will be covered by the RAC tolerances.

EPA has revised the commodity terms for all field and sweet corn commodities and is establishing tolerances on pop corn commodities, separate from those on field corn, as follows to agree with the Agency's Food and Feed Vocabulary: ''Corn, field, grain;'' ''Corn, field, forage;'' ''Corn, field, stover;'' ''Corn sweet, kernel plus cob with husks removed;'' ''Corn, sweet, forage;'' ''Corn, sweet, stover;'' ''Corn, pop, grain;'' ''Corn, pop, stover.''

Finally, EPA has revised the tolerance levels for corn grain and forage commodities as follows based on analysis of the field trial data using the tolerance MRL calculator in accordance with the Organization for Economic Cooperation and Development's ''MRL Calculator User Guide Standard Operating Procedure (SOP).'' Field (and pop) corn grain was increased from 0.01 ppm to 0.015 ppm. Field corn forage was decreased from 0.15 ppm to 0.06 ppm. Sweet corn grain was decreased from 0.02 ppm to 0.015 ppm. Sweet corn forage was decreased from 0.15 ppm to 0.10 ppm.

V. Conclusion

Therefore, tolerances are established for residues of pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, including its metabolites and degradates, as set forth in the regulatory text.

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).

Since tolerances and exemptions that are established on the basis of a petition

under FFDCA section 408(d) such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This 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: February 15, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.659 is added to subpart C to read as follows:

§ 180.659 Pyroxasulfone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide pyroxasulfone, 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 pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolite, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-carboxylic acid (M-3), calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity.

Commodity	Parts per million
Corn, field, grain	0.015
Corn, pop, grain	0.015
Corn, sweet, kernel plus cob with husks removed	0.015

(2) Tolerances are established for residues of the herbicide pyroxasulfone, 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 pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methanesulfonic acid (M–1); 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-carboxylic acid (M-3); and [5-(difluoromethoxy)-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methanesulfonic acid (M-25), calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity.

Commodity	Parts per million
Corn, field, forage	0.06
Corn, field, stover	0.15
Corn, pop, stover	0.15
Corn, sweet, forage	0.10
Corn, sweet, stover	0.15

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

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

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

[FR Doc. 2012–4478 Filed 2–28–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 101126522–0640–02]

RIN 0648–XB044

Fisheries of the Economic Exclusive Zone Off Alaska; Shallow-Water Species by Amendment 80 Vessels in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for species that comprise the shallow-water species fishery by Amendment 80 vessels in the Gulf of Alaska (GOA). This action is necessary because the first seasonal apportionment of the sideboard limit for 2012 Pacific halibut prohibited species catch (PSC) specified for the shallow-water species fishery by Amendment 80 vessels in the GOA has been reached.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), February 24, 2012, through 1200 hrs, A.l.t., April 1, 2012.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7269.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.