



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0171; FRL-9959-25]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) and K-I Chemical requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0171, is available at <http://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION, CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0171 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 *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0171, by one of the following methods:

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

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

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of May 19, 2016 (81 FR 31581) (FRL-9946-02), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8454) by IR-4, Rutgers University, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances 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 (5-(difluoromethoxy)-1-methyl-3-

(trifluoromethyl)-1*H*-pyrazol-4- carboxylic acid (M-3); 5-(difluoromethoxy)-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methanesulfonic acid (M-25); 3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid (M-28); and 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methanesulfonic acid (M-1)) calculated as the stoichiometric equivalent of pyroxasulfone in or on the raw agricultural commodity sunflower subgroup 20B at 0.2 parts per million. That document 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>. A comment supporting IR-4's petition requesting this tolerance was received in response to the notice of filing.

In the **Federal Register** of December 20, 2016 (81 FR 92758) (FRL-9956-04), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8417) by K-I Chemical USA. Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide, pyroxasulfone (3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-ylmethylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) and its metabolites in or on dried shelled peas and beans (crop subgroup 6C) at 0.15 ppm, pea hay at 0.40 ppm, pea vines at 0.20 ppm, cowpea hay at 0.07 ppm, cowpea forage at 3.0 ppm, flax at 0.07 ppm, peanut at 0.20 ppm, peanut hay at 3.0 ppm, peanut meal at 0.40 ppm, and vegetable, foliage of legume, except soybean, subgroup 7A at 3.0 ppm. That document referenced a

summary of the petition prepared by K-I Chemical U.S.A. Inc., the registrant, which is available in docket number EPA-HQ-OPP-2015-0787, <http://www.regulations.gov>.

The December 20, 2016 notice of filing supersedes a notice of filing published in the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL-9947-32), which was based on an earlier version of the same petition (5F8417). Following that June 2016 publication, K-1 amended its petition to include additional crops and adjust the tolerance levels requested. The December 20, 2016 document provided notice of that updated petition. Although no comments were received in response to the December 20, 2016 notice of filing, one comment was received in response to the June 22, 2016 notice. EPA is carrying that earlier comment forward as a comment on the petition noticed in December 2016 and provides a response to that comment in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established and also modified some of the crop definitions. The reasons for these changes are explained in Unit IV.D.

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 pyrooxasulfone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrooxasulfone 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.

Subchronic and chronic toxicity testing of pyrooxasulfone in mice, rats and dogs produced a variety of adverse effects in several target organs, but the most sensitive effect is neurotoxicity in dogs. Effects seen in animal studies ranged from 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. Toxic adverse effects (impaired hind limb function, ataxia, hind limb twitching and tremors; increased creatine kinase, aspartate aminotransferase; axonal/myelin degeneration of the sciatic nerve and spinal cord sections) in dogs occurred at ≥ 10 mg/kg/day doses while in the mouse toxic adverse effects (degeneration of sciatic and trigeminal nerve axons and their associated myelin sheaths and chronic progressive nephropathy, renal tubular adenomas) occurred at higher doses (131 mg/kg/day and above).

Comparing effects by route of administration, pyrooxasulfone 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 of 1,000 mg/kg/day with a NOAEL of 100 mg/kg/day. No adverse effects were noted in an inhalation study following exposure for 28 days at 200 mg/m³/day (equivalent to 52.2 mg/kg/day oral dose), the highest dose tested of an aerosol dust.

In cancer studies in mice and rats, renal tubular adenomas were observed in male mice at a dietary dose of 0.6 and 255 mg/kg/day (but not at an intermediate dose of 18 mg/kg/day) and urinary bladder transitional cell papillomas were observed in male rats at 42 and 84 mg/kg/day. Based on available information, the Agency concluded that the kidney adenomas in male mice were not treatment-related. The Agency considered the transitional cell bladder tumors in male rats to be treatment-related based on statistically

significant trends for urinary bladder transitional cell papillomas and combined papillomas and carcinomas, the occurrence of preneoplastic lesions at 42 and 84 mg/kg/day and the rare occurrence of bladder transitional cell tumors. The Agency concluded that the mode of action for bladder tumors has been adequately established based on submitted data that support both a dose-response and temporal concordance of the key events and bladder tumors. The available data indicate that the formation of urinary bladder calculi is the prerequisite for subsequent hyperplasia and neoplasia and that tumors do not develop at doses too low to produce calculi. The Agency has determined that the quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyrooxasulfone. There is a clear threshold of 1,000 ppm (42.55 mg/kg/day) for tumorigenesis. A point of departure (POD) of 50 ppm (2.0 mg/kg/day) is not expected to result in urinary bladder calculi formation which is a prerequisite for subsequent hyperplasia and neoplasia.

Pyrooxasulfone did not exhibit developmental toxicity in the rat developmental toxicity study at the limit dose of 1,000 mg/kg/day and it exhibited slight developmental toxicity in rabbits (reduced fetal weight and resorptions) at the limit dose of 1,000 mg/kg/day. However, developmental effects were noted in post-natal day (PND) 21 offspring at 300 mg/kg/day 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 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).

Pyroxasulfone did not produce immunotoxic effects in mice following dietary feeding for 28 days up to 4,000 ppm (633/791 mg/kg/day, M/F) or in rats at dietary concentrations of 7,500 ppm (529/570 mg/kg/day in M/F).

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 the document title “*Pyroxasulfone Human Health Risk Assessment for the Section 3 New Uses of Pyroxasulfone on Crop Subgroup 6C, Sunflower Subgroup 20B, Flax, and Peanut*” on page 44 in docket ID number EPA-HQ-OPP-2016-0171.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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

Table 1. Summary of Toxicological Doses and Endpoints for Pyroxa sulfone 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)	NOAEL = 100 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day	Developmental neurotoxicity study (DNT) in rats. The LOAEL of 300 mg/kg/day is based on decreased brain weight in both sexes, reduced thickness of the hippocampus, corpus callosum and cerebellum in PND 21 female offspring
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	One- year chronic dog study. The LOAEL of 10 mg/kg/day is 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		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. 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 pyrooxasulfone, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrooxasulfone tolerances in 40 CFR 180.659. EPA assessed dietary exposures from pyrooxasulfone 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 pyrooxasulfone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) 2003-2008 National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues adjusted for metabolites which are not in the tolerance expression.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance level residues adjusted for metabolites which are not in the tolerance expression.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pyrooxasulfone.

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

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

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyrooxasulfone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrooxasulfone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the 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 pyrooxasulfone for acute exposures are estimated to be 16.7 parts per billion (ppb) for surface water and 210 ppb for ground water. EDWCs of pyrooxasulfone for chronic exposures for non-cancer assessments are estimated to be 4.5 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 the acute dietary risk assessment, the water concentration value of 210 ppb was used to assess the contribution to drinking water. For the chronic

dietary risk assessment, the water concentration value of 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).

Pyrooxasulfone 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 pyrooxasulfone to share a common mechanism of toxicity with any other substances, and pyrooxasulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrooxasulfone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* Pyroxasulfone did not exhibit developmental toxicity in the rat guideline study at the limit dose of 1,000 mg/kg/day and it exhibited slight developmental toxicity in rabbits (reduced fetal weight and resorptions) at the limit dose of 1,000 mg/kg/day. However, developmental effects were noted in PND 21 offspring at 300 mg/kg/day 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 rat reproductive toxicity study, reduced pup weight and body weight gains during lactation occurred at similar 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).

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 pyrooxasulfone is complete.

ii. Available data indicates that pyrooxasulfone produces neurotoxic effects in rats.

The toxicity database includes specific acute and subchronic neurotoxicity tests, as well as a developmental neurotoxicity study (DNT). Although the DNT indicated offspring are more sensitive to neurotoxic effects of pyrooxasulfone, the dose-response is well characterized for neurotoxicity and a NOAEL is identified; therefore, there is no residual uncertainty with regard to neurotoxic effects for which a 10X must be retained.

iii. As discussed in Unit III.D.2., there is evidence of increased quantitative susceptibility of fetuses and offspring following *in utero* or post-natal exposure to pyrooxasulfone (based on a DNT study in rats and a developmental study in rabbits). In rabbits, developmental toxicity was only seen at the limit dose of 1000 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 was seen at 300 mg/kg/day compared to no maternal toxicity at 900 mg/kg/day. Notwithstanding, the Agency concludes that there is no residual uncertainty concerning these effects. The available studies show clear NOAELs and LOAELs for these effects, which are occurring only at doses much higher than the endpoints on which the Agency is regulating.

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 pyrooxasulfone in drinking water. These assessments will not underestimate the exposure and risks posed by pyrooxasulfone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrooxasulfone will occupy 3.7% of the aPAD for all 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 pyrooxasulfone from food and water will utilize 49% of the cPAD for all infants less than 1-year-old, the population group receiving the greatest exposure. There are no residential uses for pyrooxasulfone.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, pyrooxasulfone is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for pyrooxasulfone.

4. *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 pyrooxasulfone. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., pyrooxasulfone is not expected to pose a cancer risk to humans.

5. *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 pyrooxasulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography/triple quadrupole mass spectrometry (LC/MS/MS)) 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 any MRLs for residues of pyrooxasulfone in or on any of the commodities in this document.

C. Response to Comments

One comment was received in response to the June 22, 2016 Notice of Filing (81 FR 40594) (FRL-9947-32). The comment stated in part that most Americans “don’t need or want more toxic chemicals” and that EPA should deny this submission. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCFA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The citizen’s comment does not provide any information upon which the Agency could base a decision deny the petition.

D. Revisions to Petitioned-For Tolerances

The sunflower subgroup 20B tolerance is being established at 0.30 ppm instead of the proposed level of 0.2 ppm. This is because the petitioner did not convert the metabolites to parent equivalents and when those total residues are put into the tolerance calculator the correct value is 0.30 ppm. Also, based on the Agency’s review of the residue data, the tolerances for peanut and peanut hay are being established at 0.30 ppm and 4.0 ppm, respectively. In addition, separate tolerances are not being established on field pea hay and vines and cowpea hay and forage because they will be covered by the tolerance being established on “vegetable, foliage of legume, except soybean, subgroup 7A.”

V. Conclusion

Therefore, tolerances are established for residues of pyroxasulfone, including its metabolites and degradates, in or on: flax, seed at 0.07 ppm; pea and bean, dried shelled,

except soybean, subgroup 6C at 0.15 ppm; peanut at 0.30 ppm; peanut, hay at 4.0 ppm; peanut, meal at 0.40 ppm; sunflower subgroup 20B at 0.30 ppm; and vegetable, foliage of legume, except soybean, subgroup 7A at 3.0 ppm.

VI. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2017,

Meredith F. Laws, Acting,

Director, Registration Division, 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. In § 180.659, add paragraph (a)(5) to read as follows:

§ 180.659 Pyroxasulfone; tolerances for residues.

(a) * * *

(5) 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)pyrazol-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole), and its metabolites, M-1 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl) methanesulfonic acid), M-3 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid), M-25 (5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid) and M-28 (3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid) calculated as the stoichiometric equivalent of pyroxasulfone, in or on the following commodities:

Commodity	Parts per million
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Flax, seed	0.07
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Peanut	0.30
Peanut, hay	4.0
Peanut, meal	0.40
Sunflower subgroup 20B	0.30
Vegetable, foliage of legume, except soybean, subgroup 7A	3.0

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