



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2015-0787; FRL-9977-25]**

**Pyroxasulfone; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyroxasulfone and its metabolites in or on vegetable, tuberous and corm, subgroup 1C; vegetable, bulb, group 3-07; and potatoes, granules/flakes. K-I Chemical USA, Inc. 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-2015-0787, 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](mailto: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](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-2015-0787 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-2015-0787, by one of the following methods:

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

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

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

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

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of January 26, 2018 (83 FR 3659) (FRL-9971-46), 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 5F8521) by K-I Chemical USA, Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606. The petition requested that 40 CFR part 180.659 be amended by establishing tolerances for residues of the herbicide pyroxasulfone, (3-[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)pyrazol-4-yl methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) in or on Crop Subgroup 1C, tuberous and corm vegetables (except granular/flakes and chips) at 0.05 parts per million (ppm); Crop Subgroup 3-07, bulb vegetables at 0.15 ppm; potatoes, granular/flakes at 0.3 ppm; and potato chips at 0.06 ppm. That document referenced a summary of the petition prepared by K-I Chemical USA, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

Because the January 26, 2018, document identified the K-I Chemical petition by the wrong petition number, EPA published another document in the Federal Register assigning the correct petition number to the K-I Chemical petition—PP6F8521. That document was published in the Federal Register on March 15, 2018 (83 FR 11448) (FRL-9974-72). No relevant comments were received on the notice of filing.

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.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 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.

The toxicology database for pyrooxasulfone is adequate for evaluating and characterizing toxicity and selecting endpoints for purposes of this risk assessment. Pyrooxasulfone acute toxicity to mammals is low by all routes of exposure. Subchronic and chronic oral studies in mice, rats and dogs produced a variety of effects including cardiac toxicity (increased cardiomyopathy), liver toxicity (centrilobular hepatocellular hypertrophy, histopathological and/or clinical pathological indicators), kidney toxicity (nephropathy), neurotoxicity (impaired hind limb function, ataxia, tremors, sciatic nerve lesions, axonal/myelin degeneration in the sciatic nerve and spinal cord sections), skeletal muscle myopathy, urinary bladder mucosal hyperplasia, and urinary bladder transitional cell papillomas. Minimal to mild cardiac myofiber degeneration and local inflammation were also seen in a rat dermal toxicity study. Neurotoxicity was also seen in a developmental neurotoxicity study in rats (decreased brain weight, decreased thickness of the hippocampus, corpus callosum and cerebellum in offspring). Dogs appear to be the most sensitive species to the neurotoxic effects of pyrooxasulfone. Immunotoxicity studies in rats and mice show no evidence of immunotoxic effects from pyrooxasulfone.

There is evidence of fetal and offspring susceptibility in the developmental neurotoxicity study in rats as effects occurred in the absence of maternal toxicity. There is no concern for reproductive toxicity. Pyroxasulfone is classified as “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. 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.

Specific information on the studies received and the nature of the adverse effects caused by pyroxasulfone as the no-observed-adverse effect level (NOAEL) and 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 the Section 3 New Uses of Pyroxasulfone on Crop Subgroup 1C, tuberous and corm vegetables and Crop Group 3-07, bulb vegetables” at pages 39 - 53 in docket ID number EPA-HQ-OPP-2015-0787.

#### *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 the NOAEL and the

LOAEL are identified. 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 use <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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

<b>Table 1 - Toxicological Doses and Endpoints for Pyrooxasulfone for Use in Dietary Human Health Risk Assessments</b>				
<b>Exposure/ Scenario</b>	<b>Point of Departure</b>	<b>Uncertainty/ FQPA Safety Factors</b>	<b>RfD &amp; PAD</b>	<b>Study and Toxicological Effects</b>
Acute Dietary (General Population, including Infants and Children)	NOAEL= 100 mg/kg	UF <sub>A</sub> = 10 x UF <sub>H</sub> =10 x FQPA SF=1x	Acute RfD = 1.0 mg/kg  aPAD = 1.0 mg/kg	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 postnatal day (PND) 21 female offspring.

Table 1 - Toxicological Doses and Endpoints for Pyoxasulfone for Use in Dietary Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD & PAD	Study and Toxicological Effects
Chronic Dietary (All Populations)	NOAEL= 2 mg/kg/day	UF <sub>A</sub> = 10 x UF <sub>H</sub> =10 x 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 (all routes)	"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.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyoxasulfone, EPA considered exposure under the petitioned-for tolerances as well as all existing pyoxasulfone tolerances in 40 CFR 180.659. EPA assessed dietary exposures from pyoxasulfone 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 data from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination 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 the USDA 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 classified pyrooxasulfone as “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. 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.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and PCT information in the dietary assessment for pyrooxasulfone. Tolerance-level residues and 100% crop treated (CT) 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 *at* <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-riskpesticides>.

Based on the Pesticide Root Zone Model Ground Water (PRZM version 3.122) / Exposure Analysis Modeling System-Superseded (EXAMS version 2.98.04), the estimated concentrations of pyrooxasulfone in surface water were minimal, and the highest estimated drinking water concentrations (EDWCs) of pyrooxasulfone residues were from a Tier II PRZM-GW modeling at an application rate of 0.267 lbs active ingredient /Acre for registered crops. The same EDWCs have been used for the current human health dietary risk assessment. The EDWCs for peak concentration (used in the acute assessment) and 30-year average concentration (used in the chronic assessment) were 0.210 and 0.174 mg/L (ppm), respectively. Water residues were incorporated in the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID) into the food categories “water, direct, all sources” and “water, indirect, all sources.”

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 FFDCFA 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-riskpesticides>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCFA 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 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 offspring at 300 mg/kg/day in the rat 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 pyroxasulfone is complete.
- ii. Available data indicates that pyroxasulfone produces neurotoxic effects in rats. The toxicity database includes specific acute and subchronic neurotoxicity tests, as well as a DNT study. Although the DNT indicated offspring are more sensitive to neurotoxic effects of pyroxasulfone, 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. Evidence of increased susceptibility of fetuses and offspring was seen in a DNT study in rats and a developmental study in rabbits following *in utero* or post-natal exposure to pyrooxasulfone. However, no susceptibility was seen in the rat developmental or reproduction studies. 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. This increased susceptibility is occurring at high doses. NOAELs and LOAELs have been identified for all effects of concern and thus, a clear dose response has been well defined. Therefore, residual uncertainties or concerns for pre- and/or post-natal toxicity are minimal, and EPA concludes that reducing the FQPA safety factor to 1X will be protective of such effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT 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 population adjusted dose (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 50% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure.

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

Although short-term and intermediate-term adverse effects were identified, pyrooxasulfone is not registered for any use patterns that would result in residential exposure. Therefore, EPA relies on the chronic dietary risk assessment for evaluating short-term 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) methods) are available to enforce the tolerance expression.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for pyrooxasulfone in any of the proposed commodities.

##### *C. Revisions to Petitioned-For Tolerances*

The vegetable, tuberous and corm, subgroup 1C tolerance is being established at 0.08 ppm instead of 0.05 ppm. The petitioner's requested tolerance level included only residues from the parent and M1 metabolite. The Agency is establishing this tolerance at 0.08 ppm to account for the measurement of parent and four metabolites. Applying processing factors in accordance with the Agency's policy for determining such factors when measuring multiple pesticide residues, the Agency has determined that 0.20 ppm is an appropriate tolerance level for granules/flakes. In addition, The Agency has determined that a tolerance for potato chips is not required because residues will be within the tolerance level established for subgroup 1C.

## **V. Conclusion**

Therefore, tolerances are established for residues of pyroxasulfone including its metabolites and degradates, in or on potatoes, granules/flakes at 0.20 ppm; vegetable, bulb, group 3-07 at 0.15 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.08 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval

under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

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

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

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

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: May 8, 2018.

Daniel Rosenblatt,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

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

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

2. In § 180.659, add alphabetically “Potato, granules/flakes”, “Vegetable, bulb, group 3-07”, and “Vegetable, tuberous and corm, subgroup 1C” to the table in paragraph (a)(5) to read as follows:

**§ 180.659 Pyrooxasulfone; tolerances for residues.**

(a) \* \* \*

(5) \* \* \*

Commodity	Parts per million
* * * *	* * *
Potato, granules/flakes	0.20
* * * *	* * *
Vegetable, bulb, group 3-07	0.15
* * * *	* * *
Vegetable, tuberous and corm, subgroup 1C	0.08

\* \* \* \*

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