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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0879; FRL-9940-36]

Penoxsulam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of penoxsulam in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances associated with pesticide petition number (PP#) 4E8330, 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-2014-0879, 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: Susan Lewis, 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-2014-0879 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-2014-0879, 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 March 4, 2015 (80 FR 11611) (FRL-9922-68), 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#) 4E8330 by Interregional Research Project Number 4 (IR-4), 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR 180.605 be amended by establishing tolerances for residues of the herbicide penoxsulam, (2-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4] triazolo[1,5-

c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide), in or on fruit, pome, group 11-10 at 0.01 parts per million (ppm); fruit, stone, group 12-12 at 0.01 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit at 0.01 ppm; nut, tree, group 14-12 at 0.01 ppm; olive at 0.01 ppm; and pomegranate at 0.01 ppm. In addition, the petitioner proposed removal of existing tolerances on grape; nut, tree, group 14; and pistachio as they are superseded by this rule. That document referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences LLC, the registrant, which is available in the docket EPA-HQ-OPP-2014-0879 at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

In subchronic and chronic feeding studies in rats and dogs, the kidney was the most sensitive target organ. Hyperplasia of the renal pelvic epithelium was observed in both species, and in the rat, effects on renal function and increased severity of chronic glomerulonephropathy were also observed following chronic exposure. Effects on the liver, hematological parameters, and body weight were observed sporadically in some studies. In subchronic and chronic feeding studies in mice, no effects of toxicological significance were observed.

There was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring, as compared to adults. In developmental toxicity studies in rats and rabbits, no developmental toxicity was observed at maternally toxic dose levels. In a 2-

generation reproduction study in rats, delays in preputial separation were noted in the presence of parental toxicity. No treatment-related neurotoxicity or immunotoxicity were observed in any of the available studies on penoxsulam. No systemic or dermal toxicity was noted in a 28-day dermal toxicity study in rats.

Although an increased incidence of mononuclear cell leukemia (MNCL) was observed in a chronic toxicity/carcinogenicity study in Fisher 344 rats, EPA determined that human cancer risk is likely to be minimal and is not conducting a separate quantitative cancer assessment for the following reasons: (1) lack of a dose-response, suggesting that the tumor may not be treatment-related; (2) the tumors were found in only one gender and one species (they were not found in female rats or mice); (3) the tumors are of questionable relevance to humans since there is no similar tumor occurring in humans; (4) penoxsulam is negative for mutagenicity; and (5) MNCL is not associated with exposure to other triazolopyrimidines, which is the chemical class of herbicides to which penoxsulam belongs. Therefore, based on the current (2005) Agency guidelines for cancer assessment, EPA has determined that the chronic assessment will be protective of any potential cancer risks.

Specific information on the studies received and the nature of the adverse effects caused by penoxsulam 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, "Penoxsulam. Human Health New Use Risk Assessment to Support the Registration of Proposed Use on Pome Fruit, Stone Fruit, Olive, Pomegranate, and Fruit, Small, Vine Climbing (Subgroup 13-07F, Except Fuzzy

Kiwifruit); and Crop Group Conversion for Tree Nuts" on pages 10-16 in docket ID number EPA-HQ-OPP-2014-0879.

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 penoxsulam used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Penoxsulam for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All Populations, including Infants and Children and Females 13-49 years of age)	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on penoxsulam. This exposure scenario was therefore not assessed for human health risk.		
Chronic dietary (All populations)	NOAEL= 14.7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.147 mg/kg/day cPAD = 0.147 mg/kg/day	1 Year Chronic Feeding Study in Dogs LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the renal pelvic epithelium.
Incidental oral short-term (1 to 30 days)	NOAEL= 17.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	13-Week Feeding Study in Dogs LOAEL = 49.4 mg/kg/day based on multifocal hyperplasia of the renal pelvic epithelium and crystals in the renal pelvis and collecting ducts.
Dermal (All Durations)	An endpoint for systemic toxicity was not identified in the rat 28-day dermal study and there were no neurotoxic, developmental, or immunotoxic effects observed for penoxsulam. This exposure scenario was not assessed for		

	human health risk.		
Inhalation Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months)	NOAEL= 17.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	13-Week Feeding Study in Dogs LOAEL = 49.4 mg/kg/day based on multifocal hyperplasia of the renal pelvic epithelium and crystals in the renal pelvis and collecting ducts.
Cancer (Oral, dermal, inhalation)	Classification: A separate quantitative cancer assessment is not being conducted as the cRfD is considered protective of potential carcinogenic effects.		

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 penoxsulam, EPA considered exposure under the petitioned-for tolerances as well as all existing penoxsulam tolerances in 40 CFR 180.605. EPA assessed dietary exposures from penoxsulam 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. No such effects

were identified in the toxicological studies for penoxsulam; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA tolerance-level residues, 100 percent crop treated (PCT) for all commodities, and DEEM (Version 7.81) default processing factors.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that the chronic assessment for penoxsulam is considered protective of potential cancer risks. Therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water*. In drinking water, the residues of concern include penoxsulam parent, along with the following degradates: BSTCA; 2-amino TCA; 5-OH-penoxsulam; SFA; sulfonamide; and 5,8-diOH. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for penoxsulam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of penoxsulam. 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*.

Penoxsulam is registered for control of aquatic weeds. For that use pattern, the maximum application rate is 150 parts per billion (ppb) in the water column. For chronic dietary risk assessment, the water concentration value of 150 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).

Penoxsulam is currently registered for the following uses that could result in residential exposures: residential and commercial turf (lawns and golf courses) and aquatic use sites. EPA assessed residential exposure using the following assumptions: For handlers, it is assumed that residential use will result in short-term (1 to 30 days) duration dermal and inhalation exposures. Residential post-application exposure is also assumed to be short-term (1-30 days) in duration, resulting from the following exposure scenarios:

- physical activities on turf: Adults (dermal) and children 1-2 years old (dermal and incidental oral);
- mowing turf: Adults (dermal) and children 11 to <16 years old (dermal);
- exposure to golf courses during golfing: Adults (dermal), children 11 to <16 years old (dermal), and children 6 to <11 years old (dermal); and

- exposure during aquatic activities (e.g. swimming): Adults (dermal, inhalation, ingestion) and children 3 to <6 years old (dermal, inhalation, ingestion).

Due to the lack of a dermal endpoint, EPA did not quantify exposure and risk estimates from dermal exposure scenarios. EPA did not combine exposure resulting from adult handler and post-application exposure resulting from treated gardens, lawns, golfing, and/or aquatic areas in residential settings because of the conservative assumptions and inputs within each estimated exposure scenario. The Agency believes that combining exposures resulting from handler and post-application activities would result in an overestimate of adult exposure. EPA selected the most conservative adult residential scenario (adult handler inhalation exposure from backpack sprayer applications to lawns/turf) as the contributing source of residential exposure to be combined with the dietary exposure for the aggregate assessment. The children's 3 to <6 oral exposure is based on post-application ingestion exposures during aquatic activities. The children's 1 to <2 oral exposure is based on post-application hand-to-mouth exposures from applications to lawns/turf. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth would overestimate the potential for oral exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 penoxsulam to share a common mechanism of toxicity with any other substances, and penoxsulam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that penoxsulam 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 Food Quality Protection Act Safety Factor (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*. No evidence of quantitative or qualitative increased susceptibility, as compared to adults, of rat fetuses to *in utero* or postnatal

exposure was observed in developmental toxicity studies in rats or rabbits or a reproduction study in rats. Developmental toxicity was not observed in the rat or rabbit up to doses resulting in maternal toxicity. In the rat reproductive toxicity study, slightly increased time to preputial separation in F1 males and decreased pup weight gain were observed in the presence of parental toxicity (kidney lesions in females).

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 penoxsulam is complete.

ii. There is no indication that penoxsulam is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that penoxsulam results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

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 penoxsulam in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by penoxsulam.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, penoxsulam is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to penoxsulam from food and water will utilize 6% of the cPAD for all infants <1 year old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of penoxsulam is not expected.

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). Penoxsulam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to penoxsulam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 5,400 for adults and 2,100 for children 1-2 years old, the two population subgroups receiving the greatest combined dietary and non-dietary exposure. Because EPA's level of concern for penoxsulam is a MOE of 100 or below, these MOEs are not of concern.

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**,** penoxsulam 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 penoxsulam**.**

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., EPA determined that the chronic assessment is protective of the potential cancer risks. Based on the chronic assessment, there is no concern for an aggregate cancer risk from exposure to penoxsulam.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to penoxsulam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, high performance liquid chromatography (HPLC) methods with positive-ion electro spray interface (ESI) and tandem mass spectroscopy-mass spectroscopy detector (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. There are currently no established Codex MRLs for the residues of penoxsulam.

C. Revisions to Petitioned-For Tolerances

EPA has revised the tolerance expression to clarify first, that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of penoxsulam not specifically mentioned; and second, that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of penoxsulam, (2-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide), in or on fruit, pome, group 11-10 at 0.01 ppm; fruit, small, vine climbing subgroup 13-07F, except fuzzy kiwifruit at 0.01 ppm; fruit, stone, group 12-12 at 0.01 ppm; nut, tree, group 14-12 at 0.01 ppm; olive at 0.01 ppm; and pomegranate at 0.01 ppm. Additionally, the existing tolerances for grape; nut, tree, group 14; and pistachio are removed.

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 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: February 23, 2016.

Susan Lewis,

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 § 180.605, paragraph (a) is revised to read as follows:

§ 180.605 Penoxsulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of penoxsulam, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only penoxsulam 2-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide, in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.01
Fish	0.01
Fish, shellfish, crustacean	0.01
Fish, shellfish, mollusc	0.02
Fruit, pome, group 11-10	0.01
Fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit	0.01
Fruit, stone, group 12-12	0.01

Nut, tree, group 14-12	0.01
Olive	0.01
Pomegranate	0.01
Rice, grain	0.02
Rice, straw	0.50

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[FR Doc. 2016-04598 Filed: 3/1/2016 8:45 am; Publication Date: 3/2/2016]