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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0061; FRL-10004-86]

Penoxsulam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of penoxsulam in or on globe artichoke. Interregional Research Project Number 4 (IR-4) requested this tolerance 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-2019-0061, 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 Publishing 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-2019-0061 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-2019-0061, 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 May 9, 2019 (84 FR 20320) (FRL-9992-36), 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 8E8727) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.605 be amended by establishing a tolerance for residues of the herbicide penoxsulam, including its metabolites and degradates, in or on artichoke, globe at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed 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 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 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 kidney was the major target organ for penoxsulam in the rat and dog following subchronic and chronic dietary exposure. There are no mechanistic studies characterizing the mode of action for renal toxicity of penoxsulam or other triazolopyrimidine herbicides, but the presence of crystals in the urinary tract and lack of tissue bioaccumulation suggest that cellular inflammation and damage may occur secondary to their presence. Hyperplasia (rat and dog) and inflammation (rat) of the renal pelvic epithelium were observed by week 4 in dietary dose range-finding studies. The dog was the more sensitive species in studies of all durations. The rat, but not the dog, showed progression of the severity of kidney toxicity with prolonged exposure. In dogs, renal toxicity in the subchronic and chronic studies occurred at comparable dose levels and measurable effects on renal function were not observed. In the rat, effects on renal function (increased blood urea nitrogen in both sexes, urinary bladder mucosal hyperplasia, and increased severity of chronic glomerulonephropathy in males) were observed only following chronic exposure, although the doses at which kidney toxicity occurred were comparable to doses tested in the subchronic study. A consistent pattern that identified a greater sensitivity of either sex was not observed.

Other effects in the rat included decreased red blood cell parameters and decreased body weight and/or weight gain. Liver effects were observed at the higher dose levels in the dog 4-week feeding study but not in other studies in the database. The findings of liver and/or kidney effects are consistent with effects observed for other triazolopyrimidine herbicides.

No effects of toxicological significance were observed in the mouse. Penoxsulam showed no evidence of neurotoxicity or immunotoxicity in the rodent, and no effects were seen in rats following dermal exposure. The Agency waived the requirement for inhalation data based on high inhalation margins of exposure using an oral endpoint, lack of observed irritation effects, and low vapor pressure.

There was no evidence of increased pre- and/or post-natal susceptibility. No developmental effects were observed in the rat or rabbit. Maternal effects in the rat included decreased body weight gain and food consumption and increased kidney weights. In the rabbit, maternal effects included mortality, clinical signs of toxicity, and decreased body weight gain and food consumption. In the rat 2-generation reproductive toxicity study, delayed preputial separation and lactation body weights were observed in F1 offspring at a dose that caused kidney lesions in parental females.

Although there is evidence of an increased incidence of mononuclear cell leukemia (MNCL) in Fisher 344 rats from exposure to penoxsulam, EPA has concluded that a quantitative assessment of cancer is not necessary and that the chronic reference dose (cRfD) is considered protective of possible cancer effects.

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 the document titled "Penoxsulam: Human Health Risk Assessment for the Proposed Use on Globe Artichoke" (Penoxsulam HHRA) on pages 32-37 in docket ID number EPA-HQ-OPP-2019-0061. For further discussion of the Agency's rationale for its cancer conclusion, see page 16 of the Penoxsulam HHRA.

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-pesticide*.

A summary of the toxicological endpoints for penoxsulam used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of March 2, 2016 (81 FR 10771) (FRL-9940-36).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to penoxsulam, EPA considered exposure under the petitioned-for tolerance 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 food consumption data from the United States Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the chronic dietary exposure assessment was unrefined and used tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that the cRfD is protective of potential cancer risk from exposure to penoxsulam.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for penoxsulam. Tolerance-level residues and 100 PCT were assumed for all food commodities as well as contribution to the 5-OH-penoxsulam metabolite in fish.

2. *Dietary exposure from drinking water*. 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 the chronic dietary risk assessment, the water concentration value of 150 ppb was used to assess the contribution to drinking water. This value is likely to be an overestimate of actual residues in 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) dermal and inhalation exposures. Residential post-application exposure is also assumed to be short-term (1 to 30 days) in duration, resulting from the following exposure scenarios:

Physical activities on turf: Adults (dermal) and children 1 to 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 exposure for the aggregate assessment for children 3 to <6 years old is based on post-application combined inhalation and ingestion exposures during aquatic activities. The oral exposure for the aggregate assessment for children 1 to <2 years old 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to penoxsulam and any other substances and penoxsulam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that penoxsulam has 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*. 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 uncertainty factors 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 by using the high-end EDWC of 150 ppb from the aquatic weed use pattern to assess exposure to penoxsulam in drinking water. EPA used similarly conservative assumptions to assess post-application 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 5.6% of the cPAD for all infants less than 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 5,500 for adults, 1,700 for children 1 to 2 years old, and 4,500 for children 3 to 5 years old. 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 has determined that an RfD approach based on the chronic point of departure is appropriate for evaluating cancer risk. As there are not chronic aggregate risks of concern, there are no cancer aggregate risk concerns.

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 methodologies using high performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) 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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for penoxsulam on globe artichoke.

C. Response to Comments

Two comments were received in response to the notice of filing. One was against the Agency granting the use of penoxsulam and one was against the use of pesticides in general. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these penoxsulam tolerances are safe. The commenters have provided no information to support an Agency conclusion that penoxsulam is not safe.

V. Conclusion

Therefore, tolerances are established for residues of penoxsulam, including its metabolites and degradates, in or on artichoke, globe at 0.01 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), nor is it considered a regulatory action under 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: February 6, 2020.

Michael Goodis,

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, add alphabetically the entry "Artichoke, globe" to the table in paragraph (a) to read as follows:

§ 180.605 Penoxsulam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* * * *
Artichoke, globe	0.01
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[FR Doc. 2020-04524 Filed: 3/6/2020 8:45 am; Publication Date: 3/9/2020]