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[Pages 13548-13552]

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[FR Doc No: 2020-04524]

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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.

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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 March 9, 2020. Objections and

requests for hearings must be received on or before May 8, 2020, 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](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

May 8, 2020. 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-

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2019-0061, by one of the following methods:

 Federal eRulemaking Portal: [http://www.regulations.gov](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](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](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

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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

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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.

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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]

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

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

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2. In Sec. 180.605, add alphabetically the entry ``Artichoke, globe''

to the table in paragraph (a) to read as follows:

Sec. 180.605 Penoxsulam; tolerances for residues.

 (a) \* \* \*

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 Parts per

 Commodity million

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Artichoke, globe............................................ 0.01

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[FR Doc. 2020-04524 Filed 3-6-20; 8:45 am]

 BILLING CODE 6560-50-P