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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0771; FRL-10000-64]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on persimmon. Valent U.S.A., LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2008-0771, 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-2008-0771 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-2008-0771, 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 June 7, 2019 (84 FR 26630) (FRL-9993-93), 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 8E8672) by Valent U.S.A., LLC, P.O. Box 8025, Walnut Creek, CA 94596. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide clothianidin (*E*)-*N*-[(2-Chloro-5-thiazolyl)methyl]-*N′*-methyl-*N″*-nitroguanidine in or on persimmon at 0.5 parts per million (ppm). As use of clothianidin has not been approved for domestic pesticide registrations, this tolerance is requested to cover residues of clothianidin in or on persimmon imported into the United States. That document referenced a summary of the petition prepared by Valent U.S.A., LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. No comments were received for 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 clothianidin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clothianidin 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 toxicity database for clothianidin is complete. In mammals, toxicological effects are seen primarily in the liver, hematopoietic system, and kidneys. In subchronic oral studies, the dog seemed to be more sensitive to clothianidin than the rat. In addition to decreases in body weight and body weight gains observed in both animals, dogs also displayed decreased white blood cells, albumin, and total protein, as well as some anemia. Long-term dietary administration of clothianidin did not result in a wider spectrum of effects in the dog; in contrast, the chronic feeding studies in rats showed additional effects in the liver, ovaries, and kidneys. In the mouse chronic oral study, increases in vocalization and decreases in body weight gain were noted.

Neurotoxicity was observed in acute neurotoxicity studies in the rat and mouse and in the developmental neurotoxicity study in rats but was not observed in the subchronic neurotoxicity study or any other study in the toxicity database. No increased quantitative or qualitative susceptibility was observed in the developmental rat or rabbit studies. However, there was an increase in quantitative susceptibility in the developmental neurotoxicity and reproductive

toxicity studies; offspring effects were observed in the absence of maternal toxicity. There was evidence of possible effects on the immune system in the database; however, a developmental immunotoxicity study indicated no evidence of susceptibility with regard to immunotoxicity. No toxic effects were observed up to the limit dose in the 28-day dermal study in rats. Clothianidin is not carcinogenic or mutagenic.

A summary of the toxicological effects of clothianidin, the specific information on the studies received, the nature of the adverse effects caused by clothianidin, and the NOAEL and lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in docket ID number EPA-HQ-OPP-2011-0865 under Draft Human Health Risk Assessment in Support of Registration Review.

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 clothianidin used for human risk assessment can be found in docket ID number EPA-HQ-OPP-2011-0865 under Draft Human Health Risk Assessment in Support of Registration Review.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to clothianidin, EPA considered exposure under the petitioned-for tolerances as well as all existing clothianidin tolerances in 40 CFR 180.586. EPA assessed dietary exposures from clothianidin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for clothianidin. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated and tolerance-level residues for all commodities with established or proposed tolerances for clothianidin.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA assumed 100 percent crop treated and average residues from crop field trials

for all commodities with established or proposed tolerances for clothianidin.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that clothianidin does not pose a cancer risk to humans. Therefore, a 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 PCT estimates in the dietary assessment for clothianidin. 100% CT were assumed for all food commodities. Average residue levels from field-trial were used in the chronic dietary assessment.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

Based on the Tier I Pesticide Root Zone Model - Ground Water (PRZM-GW) and Tier I

Screening Concentration in Ground Water (SCI-GROW) models and the Tier II surface water concentration calculator (SWCC) computer model, the estimated drinking water concentrations (EDWCs) of clothianidin for acute exposures are estimated to be 67 parts per billion (ppb) for surface water and 180 ppb for ground water, and for chronic exposures are estimated to be 67 ppb for surface water and 139 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 180 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration value of 139 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).

Clothianidin is currently registered for the following uses that could result in residential exposures: turf, ornamental plants, interior plantscapes, and use in residential and commercial buildings. EPA assessed residential exposure using the following assumptions: for adults, combined dermal/inhalation exposure from application of pesticides via an aerosol can in indoor environments; for children 1 to <2 years old, the combined dermal/inhalation/incidental oral (i.e., oral hand-to-mouth) exposures from post-application exposure to indoor-surface directed/perimeter/mattress (bed bug application); for children 6 to <11 years old, dermal exposures from post-application exposure to treated gardens; and for children 11 to <16 years old, dermal exposure from post-application exposure to treated turf while golfing.

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."

Clothianidin is a member of the neonicotinoid class of pesticides and is a metabolite of another neonicotinoid, thiamethoxam. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nAChRs, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for clothianidin is based on unrelated effects in mammals, including changes in body and thymus weights, delays in

sexual maturation, and still births. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (such as testicular tubular atrophy with thiamethoxam, and mineralized particles in thyroid colloid with imidaclopid). Thus, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. 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 the policy statements concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism released by OPP on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

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*. There is no indication of increased quantitative or qualitative susceptibility, as compared to adults, of rat and rabbit fetuses following in utero exposure to clothianidin in developmental studies. However, increased quantitative susceptibility was observed in both the developmental neurotoxicity and rat multi-generation reproduction

studies. In the developmental neurotoxicity study, offspring toxicity (decreased body weight gains, motor activity and acoustic startle response) was seen at a lower dose than that which caused maternal toxicity. In the 2-generation rat reproduction study, offspring toxicity (decreased body weight gains, delayed sexual maturation in males, decreased absolute thymus weights in F1 pups of both sexes and an increase in stillbirths in both generations) was seen at a dose lower than that which caused parental toxicity.

3. *Conclusion*. The EPA has determined that 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 clothianidin is complete.

ii. There are no residual concerns regarding potential pre- and post-natal toxicity in the young. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for pre- and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility.

iii. As explained in Unit III.D.2 "Prenatal and postnatal sensitivity", while the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL has been selected as the POD for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for pre- and postnatal

toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments assumed 100 PCT and tolerance-level residues (acute assessment) or average residues from field trials designed to produce high-end residue levels (chronic assessment). EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by clothianidin.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clothianidin will occupy 18% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to clothianidin from food and water will utilize 9.0% 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 clothianidin 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).

Clothianidin 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 clothianidin.

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 390 for adults and 150 children. Because EPA's level of concern for clothianidin is an 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).

Clothianidin is currently registered for uses that could result in intermediate-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 clothianidin. The short-term assessment is protective of any potential intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, clothianidin is not expected to pose a cancer risk to humans.

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 clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods based on solvent extraction and liquid chromatography with tandem mass spectrometry separation, identification, and quantification, are available for plant (Morse Method #Meth-164 – modified, RM-39C-1, or Bayer Method 00552) and livestock (Bayer Method 00624) matrices.

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.

Codex has established an MRL for residues of clothianidin in persimmon at 0.4 ppm. EPA is establishing the tolerance at 0.5 ppm at the request of the petitioner, to harmonize with

the higher Japanese MRL. EPA believes the higher tolerance will facilitate more trade rather than the lower Codex MRL. The higher tolerance is greater than the highest value observed in field trials and is expected to be a suitable enforcement limit for residues in imported persimmon.

V. Conclusion

Therefore, a tolerance is established for residues of clothianidin in or on persimmon at 0.5 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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: October 30, 2019.

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 § 180.586, add alphabetically the entry "Persimmon[1]" to the table in paragraph (a)(1) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * * * *	
Persimmon[1]	0.5
* * * * * * *	

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[FR Doc. 2019-25535 Filed: 11/22/2019 8:45 am; Publication Date: 11/25/2019]