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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0141; FRL-9996-15]

Clothianidin; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of clothianidin in or on rice, grain. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of thiamethoxam on rice. Emergency use of thiamethoxam on rice results in potential clothianidin (a major metabolite of thiamethoxam) residues that when combined with the residues from legal use of clothianidin on rice, require an increase in the tolerance for residues of clothianidin in rice. Although there is an existing regulation establishing a maximum permissible level for residues of clothianidin in or on rice, grain at 0.01 ppm, this rule would establish a new, time-limited maximum permissible level at 0.5 ppm for clothianidin in or on rice, grain. The time-limited tolerance expires on December 31, 2024. This action is also associated with the utilization of a crisis exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of thiamethoxam on rice.

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-2019-0141, 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 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp.* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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-2019-0141 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-2019-0141, 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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of clothianidin, (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N′*-methyl-*N″*-nitroguanidine, in or on rice, grain at 0.5 parts per million (ppm). This time-limited tolerance expires on December 31, 2024.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited

tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . ."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Thiamethoxam on Rice and FFDCA Tolerances for Clothianidin Residues

During 2015, the first year the rice delphacid pest appeared in Texas, the Texas Department of Agriculture (TDA) reported ratoon rice losses as high as 25%. TDA claims that they are experiencing high numbers of rice delphacid in ratoon rice and recently, pest

populations over 8,000 nymphs and adult rice delphacids per 10 sweeps were observed in a rice field in Galveston county. Approximately 60% of Texas' rice crop is ratooned and in 2018, this represented more than 100,000 acres. There are no insecticides labeled specifically for rice delphacid, and TDA says that products registered for leafhopper control in rice are not efficacious in controlling rice delphacid. On October 31, 2018, the TDA issued a crisis exemption for use of thiamethoxam on rice. The crisis exemption expired on November 9, 2018. Due to the short duration of the crisis exemption, the pest was not fully controlled and therefore, TDA submitted a quarantine request for this use pattern.

After having reviewed the submission, EPA determined that an emergency condition existed in this State, and that the criteria for approval of an emergency exemption were met. On March 3, 2019, EPA authorized a quarantine exemption under FIFRA section 18 for the use of thiamethoxam on rice for control of rice delphacid in Texas. EPA is establishing a time-limited tolerance for thiamethoxam on rice through a separate rulemaking. The emergency use of thiamethoxam in rice can potentially result in residues of clothianidin (a major metabolite of thiamethoxam) which might exceed the existing tolerance level of 0.01 ppm clothianidin in rice. Therefore, a time-limited tolerance for residues of clothianidin in rice, grain is being established.

As part of its evaluation of the emergency exemption application for thiamethoxam, EPA assessed the potential risks presented by residues of clothianidin in or on rice, since clothianidin is a major metabolite of thiamethoxam. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these

tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2024, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on rice after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

This time-limited tolerance increase is being approved to address the potential increase in clothianidin residues from the use of thiamethoxam under emergency conditions. The clothianidin risk assessment appears in the February 6, 2019 memorandum titled "Thiamethoxam. 19TX02 and 19TX03. Human Health Risk Assessment for Section 18 Emergency Exemption Use on Rice in Texas." Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of clothianidin by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than Texas to use clothianidin on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for clothianidin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with 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 expected as a result of this emergency exemption request for thiamethoxam, and the time-limited tolerances for residues of clothianidin on rice, grain at 0.5 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for clothianidin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of August 29, 2012 (77 FR 52248) (FRL-9360-4).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to clothianidin, EPA considered exposure from application of thiamethoxam under the time-limited tolerances established by this action 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*. Acute effects were identified for clothianidin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and that 100% of the commodities in the assessment were treated (100 PCT) with both clothianidin and thiamethoxam.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed field-trial average residues and that 100% of the commodities in the assessment were treated (100 PCT) with both clothianidin and thiamethoxam.

iii. *Cancer*. Based on the data summarized in Unit IV.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 anticipated residue and/or PCT information in the dietary assessment for clothianidin. Tolerance level residues and 100% CT were assumed for all food commodities with both clothianidin and thiamethoxam.

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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticides in Water Calculator and Tier 1 Rice 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. For chronic exposures for non-cancer assessments are estimated to be 67 ppb for surface water and 139 ppb for ground water. This is based on use of clothianidin as a pesticide active ingredient and does not include clothianidin as a thiamethoxam metabolite, because when thiamethoxam is applied to crops, the clothianidin metabolite is not a major residue in drinking water.

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

For 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 and indoor surfaces. EPA assessed residential exposure using the following assumptions: short-term handler (adults) and post-application exposures (adults

and children) may occur in accordance with existing uses.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found clothianidin to share a common mechanism of toxicity with any other substances, and clothianidin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clothianidin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

C. 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no residual concern for increased qualitative or quantitative susceptibility in the rat or rabbit developmental toxicity studies; however, there was increased quantitative susceptibility in the two-generation reproduction and developmental neurotoxicity studies in the rat, as the offspring NOAELs were below the parental NOAELs. Clear NOAELs were identified for the offspring effects in these rat studies. There were indications of potential immunotoxicity in the database. Decreased absolute and relative thymus and spleen weights were observed in multiple studies. Juvenile rats in the two-generation reproduction study appeared to be more susceptible to these effects, indicating a concern for qualitative susceptibility. However, a guideline immunotoxicity study showed no evidence of clothianidin-mediated immunotoxicity in adult rats, and a developmental immunotoxicity study demonstrated no susceptibility with respect to offspring immunotoxicity. Therefore, the residual concern for immunotoxicity in adults and offspring is reduced. Since there is evidence of increased quantitative susceptibility of the young following exposure to clothianidin in the rat reproduction study and the rat developmental neurotoxicity study (DNT), the Agency performed a degree of concern analysis to: (1) determine the level of concern for the effects observed when considered in the context of all available toxicity data; and, (2) identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the clothianidin risk assessment. If residual uncertainties are identified, the Agency examines whether the residual uncertainties can be addressed by a FQPA safety factor, and if so, what factors should be retained. Considering the overall toxicity profile and the endpoints and doses

selected for the clothianidin risk assessment, the Agency characterized the degree of concern for the effects observed in the clothianidin two-generation reproduction and DNT studies as *low* because: (1) there are clear NOAELs for the offspring effects and regulatory doses were selected to be protective against these effects; (2) no other residual uncertainties were identified with respect to susceptibility of infants and children; and (3) the endpoints and doses selected for clothianidin are protective against adverse effects in both offspring and adults.

3. *Conclusion*. EPA has determined that reliable data show 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, and includes developmental neurotoxicity, adult immunotoxicity and developmental immunotoxicity studies.

ii. The degree of concern for the quantitative susceptibility observed in the clothianidin two-generation reproduction and DNT studies is low based on the clear NOAELs for the offspring effects and the selection of regulatory doses that are protective of those effects.

iii. The rat is the most sensitive species tested, and the NOAEL and LOAEL selected from the two-generation reproduction study in rats are protective of effects observed in other species throughout the toxicology database.

iv. There are no residual uncertainties for pre- and/or post-natal toxicity.

v. The Agency is regulating the use of clothianidin based upon the most sensitive offspring effects observed in the reproduction toxicity study, and therefore the risk assessment is protective of these and other effects that occurred at higher doses.

vi. The exposure databases (dietary food, drinking water, and residential) are complete.

vii. The risk assessment for each potential exposure scenario includes all metabolites

and/or degradates of concern and does not underestimate potential exposure and risk for infants or children. 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 as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

D. 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 19% of the aPAD for infants less than 1-year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to clothianidin from food and water will utilize 9% of the cPAD for (infants less than 1-year old), the population group receiving the greatest exposure. Based on the explanation in the unit 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 use**s** 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 for 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 non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, clothianidin is not expected to pose an intermediate-term risk.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate method using liquid solvent extraction, solvent and solid-phase extraction clean-up, and high-performance liquid chromatography (HPLC) Method AG-675, is available to enforce the tolerances.

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.

The time-limited tolerance of 0.5 ppm in or on rice, grain is consistent with the existing Codex MRL of 0.5 ppm. EPA is recommending that the tolerance level of 0.4 ppm suggested by the OECD Calculation Procedures be raised to 0.5 ppm to harmonize with the Codex MRL. The Agency notes that the compliance residue definitions for the US, Canada, and Codex are harmonized; all specify only clothianidin.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of clothianidin, (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N′*-methyl-*N″*-nitroguanidine, in or on rice, grain at 0.5 ppm. This tolerance expires on December 31, 2024.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances 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).

VIII. 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: September 19, 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 "Rice, grain" to the table in paragraph (b) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

* * * * *

Commodity	Parts per million	Expiration date
* * * * * * *		
Rice, grain	0.5	12/31/2024

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[FR Doc. 2019-21540 Filed: 10/4/2019 8:45 am; Publication Date: 10/7/2019]