

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); or 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: September 23, 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 § 180.628, amend the table in paragraph (a) by adding alphabetically an entry for "Palm, oil" to read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) \* \* \*

Table with 5 columns: Commodity, Parts per million, and three asterisks. Row 1: Palm, oil^2, 1.5, \*, \*, \*

^2 There are no U.S. registrations for use of chlorantraniliprole on this commodity.

\* \* \* \* \*

\* \* \* \* \*

[FR Doc. 2019-21541 Filed 10-4-19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0779; FRL-9996-14]

Thiamethoxam; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of thiamethoxam in or on rice. 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 the pesticide on rice. This regulation establishes a maximum permissible level for residues of thiamethoxam in or on these commodities. The time-limited tolerances expire on December 31, 2024. This action is also associated with the utilization of a crisis exemption under the FIFRA authorizing use of the pesticide on rice.

DATES: This regulation is effective October 7, 2019. Objections and requests for hearings must be received on or before December 6, 2019 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-2018-0779, 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 Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-id?&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-ocsp> 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-2018-0779 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 December 6, 2019. 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-2018-0779, 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 time-limited tolerances for residues of thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine, in or on rice, grain at 6 parts per million (ppm) and rice, straw at 2 ppm. These time-limited tolerances expire 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

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.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of thiamethoxam in or on rice. 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 these time-limited tolerances expire 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.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether thiamethoxam meets FIFRA's registration requirements for use on rice or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of thiamethoxam 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 this pesticide 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 thiamethoxam, 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 and the time-limited tolerances for residues of thiamethoxam on rice, grain at 6 ppm rice, straw at 2 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 thiamethoxam used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of February 15, 2017 (82 FR 10714) (FRL-9957-00).

##### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the time-limited tolerances established by this action as well as all existing thiamethoxam tolerances in 40 CFR 180.565. EPA assessed dietary exposures from thiamethoxam in food as follows:

i. *Acute exposure.* Acute effects were identified for thiamethoxam. 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 100 percent crop treated.

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 field-trial average residues and 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that thiamethoxam 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 thiamethoxam. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thiamethoxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiamethoxam. 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 Flooded Applications Model (PFAM) or Tier 1 Rice Model and Pesticide in Water Calculator (PWC)), the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 20 ppb parts per billion (ppb) for surface water and 63 ppb for ground water.

For chronic exposures for non-cancer assessments EDWCs are estimated to be 1.05 ppb for surface water and 58 ppb for ground 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 63 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 58 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).

Thiamethoxam is currently registered for the following uses that could result in residential exposures: Turfgrass (including golf courses, residential lawns, and athletic fields), residential landscapes, structural/perimeter applications (indoors and outdoors in schools, apartments, etc.), and indoor control of bed bugs. EPA assessed residential exposure using the following assumptions: Short-term exposures, lasting from 1 to 30 days, may occur from uses of thiamethoxam in residential settings. These exposures may occur by dermal, inhalation, and incidental oral (children <6 years old) routes.

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 thiamethoxam to share a common mechanism of toxicity with any other substances, and thiamethoxam does not appear to produce a toxic metabolite produced by other substances. Thiamethoxam and its clothianidin metabolite have different mechanisms of toxicity in mammals, and since clothianidin has a complete database owing to its registration as a pesticide active ingredient, it is appropriate for EPA to evaluate its risks separately. For the purposes of this tolerance action, therefore, EPA has assumed that thiamethoxam 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.* In mammals, toxicological effects are seen primarily in the liver, kidney, testes, and blood cellular (hematopoietic) system. In addition, developmental neurological effects were observed in rats. These developmental effects were used to assess risk associated with acute exposure to thiamethoxam, and the liver and testicular effects are the basis for assessing longer-term exposures. The PODs used for risk assessment are protective of all effects, including quantitative susceptibility observed in developmental and reproduction studies, and the exposure assessments do not underestimate exposures.

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 thiamethoxam is complete.

ii. Evidence of neurotoxicity was seen in the acute and DNT studies in the rat. However, there is a low degree of concern for the potential neurotoxic effects of thiamethoxam since: (1) Clear NOAELs were identified for the neurotoxic effects; (2) the neurotoxic effects were not the most sensitive endpoint in the toxicity database; and (3) the endpoints chosen for risk assessment are protective of any potential neurotoxicity.

iii. There is no evidence that thiamethoxam 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. There was no evidence of increased quantitative susceptibility in the core guideline toxicity studies. The maternal/parental NOAELs/LOAELs in the 1998 two-generation reproduction toxicity study and the core developmental toxicity studies (rats and rabbits) occur at doses lower than or equal to the developmental/offspring NOAELs/

LOAELs and are, therefore, not indicative of a quantitative susceptibility. Furthermore, the severity of effects in the parent and fetus/offspring generations in the three studies are comparable and therefore are not indicative of qualitative sensitivity. However, in the DNT and the 2004 2-generation reproduction toxicity studies in rats, developmental/offspring effects were seen in the absence of maternal toxicity; therefore, there is evidence of quantitative susceptibility. In the 2004 two-generation rat reproduction study, decreased total litter weights were observed in pups in the absence of parental adverse effects. In the rat DNT study, decreased body weight and body weight gain, as well as reduced brain weight and size were observed in the pups in the absence of adverse effects in dams. However, considering the overall toxicity profile and the doses and endpoints selected for risk assessment, the degree of concern for the effects observed in the studies is low because (1) the developmental/offspring effects observed in the studies are well characterized and (2) clear NOAELs/LOAELs have been identified in the studies for the effects of concern. Additionally, the Agency is confident that the endpoints and PODs selected for risk assessment are protective of potential developmental/reproductive effects.

iv. There are no residual uncertainties identified in the exposure databases. There are no residual uncertainties with respect to dietary or residential exposure. The dietary exposure assessments are based on high-end residue levels from crop field trials and empirical and default processing factors, both of which account for parent and metabolites of concern, and the assumption of 100 PCT for all agricultural commodities. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water, such that these exposures have not been underestimated. Therefore, the actual risk from exposure to thiamethoxam will likely be much lower than calculated risk estimates. In addition, the residential exposure estimates are conservative and do not underestimate exposure and risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to thiamethoxam in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of youth and children as well as incidental oral exposure of children 1 to 2 years old ( $1 < 2$ ). These assessments will not

underestimate the exposure and risks posed by thiamethoxam.

#### 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 thiamethoxam will occupy 12% of the aPAD for children 1 to 2 years 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 thiamethoxam from food and water will utilize 74% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure.

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).

Thiamethoxam 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 thiamethoxam.

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 ranging from 130 for adults to 330 for children less than 6 years old. Because EPA's level of concern for thiamethoxam 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, thiamethoxam 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, thiamethoxam 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 thiamethoxam 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 tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto: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.

Neither the Codex nor Canada has established specific MRLs for thiamethoxam residues in rice commodities. Canada has established an "All food crops" MRL at 0.02 ppm for thiamethoxam that would apply to rice, but it is not specific to a use on rice.

#### VI. Conclusion

Therefore, time-limited tolerances are established for residues of thiamethoxam, 3-[[2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine, in or

on rice, grain at 6 ppm and rice, straw at 2 ppm. These tolerances expire 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.*).

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### 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 § 180.565, revise paragraph (b) to read as follows:

#### § 180.565 Thiamethoxam; tolerances for residues.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the table are established for residues of the insecticide thiamethoxam, including its metabolites and degradates. Compliance with the tolerance levels specified below is to be determined by measuring only thiamethoxam 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite CGA-322704 N-[(2-chloro-thiazol-5-yl)methyl]-N'-methyl-N''-nitro-guanidine, calculated as the stoichiometric equivalent of thiamethoxam, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Rice, grain .....	6	12/31/2024
Rice, straw .....	2	12/31/2024

\* \* \* \* \*

[FR Doc. 2019-21539 Filed 10-4-19; 8:45 am]

**BILLING CODE 6560-50-P**

### 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 October 7, 2019. Objections and requests for hearings must be received on or before December 6, 2019 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](mailto: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](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