State Air Pollution Rule (CSAPR) federal implementation plans (FIPs). EPA has completed final calculations for the second round of NUSA allowance allocations for the 2016 compliance year of the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 Trading Programs. EPA has posted spreadsheets showing the second-round 2016 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances to new units as well as the allocations to existing units of the remaining CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances not allocated to new units in either round of the 2016 NUSA allocation process. EPA will record the allocated CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances in sources' Allowance Management System (AMS) accounts by February 15, 2017.

DATES: February 15, 2017.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Robert Miller at (202) 343–9077 or *miller.robertl@epa.gov* or to Kenon Smith at (202) 343–9164 or *smith.kenon@epa.gov*.

SUPPLEMENTARY INFORMATION: Under the CSAPR FIPs, a portion of each state budget for each of the CSAPR trading programs is reserved as a NUSA from which allowances are allocated to eligible units through an annual one- or two-round process. EPA has described the CSAPR NUSA allocation process in five NODAs previously published in the **Federal Register**: 81 FR 33636 (May 27, 2016); 81 FR 50630 (August 2, 2016); 81 FR 63156 (September 14, 2016); 81 FR 80593 (November 16, 2016) and 81 FR 89035 (December 9, 2016). In the most recent of these previous NODAs, EPA provided notice of preliminary lists of new units eligible for second-round 2016 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances and provided an opportunity for the public to submit objections.

EPA received no objections to the preliminary lists of new units eligible for second-round 2016 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, or SO_2 Group 2 allowances whose availability was announced in the December 9 NODA. EPA is therefore making second-round 2016 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances to the new units identified on these lists in accordance with the procedures set forth in 40 CFR 97.412(a)(9) and (12), 97.612(a)(9) and (12), and 97.712(a)(9) and (12).

As described in the December 9 NODA, any allowances remaining in the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 NUSAs for a given state and control period after the second round of NUSA allocations to new units is completed are to be allocated to the existing units in the state according to the procedures set forth in 40 CFR 97.412(a)(10) and (12), 97.612(a)(10) and (12), and 97.712(a)(10) and (12). EPA has determined that CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances do remain in the NUSAs for a number of states following completion of second-round 2016 NUSA allocations; accordingly, EPA is allocating these allowances to existing units. The NUSA allowances are generally allocated to the existing units in proportion to the allocations previously made to the existing units under 40 CFR 97.411(a)(1), 97.611(a)(1), and 97.711(a)(1), adjusted for rounding.

Under 40 CFR 97.412(b)(10), 97.612(b)(10), and 97.712(b)(10), any allowances remaining in the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 Indian country NUSAs for a given state and control period after the second round of Indian country NUSA allocations to new units are added to the NUSA for that state or are made available for allocation by the state pursuant to an approved SIP revision. No new units eligible for allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances from any 2016 Indian country NUSA have been identified, and no state has an approved SIP revision governing allocation of 2016 CSAPR NUSA allowances. The Indian country NUSA allowances are therefore being added to the NUSAs for the respective states and are included in the pools of allowances that are being allocated to existing units under 40 CFR 97.412(b)(10) and (12), 97.612(b)(10) and (12), and 97.712(b)(10) and (12).

The final unit-by-unit data and allowance allocation calculations are set forth in Excel spreadsheets titled ''CSAPR_NUSA_2016_NOx_Annual_2nd_Round_Final_Data_New_Units'', ''CSAPR_NUSA_2016_SO2_2nd_Round_Final_Data_New_Units'', ''CSAPR_NUSA_2016_NOx_Annual_2nd_Round_Final_Data_Existing_Units'', and ''CSAPR_NUSA_2016_SO2_2nd_Round_Final_Data_Existing_Units'', available on EPA's Web site at *https://www.epa.gov/csapr/csapr-compliance-year-2016-nusa-nodas.*

Pursuant to CSAPR's allowance recordation timing requirements, the allocated NUSA allowances will be recorded in sources' AMS accounts by February 15, 2017. EPA notes that an allocation or lack of allocation of allowances to a given unit does not constitute a determination that CSAPR does or does not apply to the unit. EPA also notes that NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances are subject to potential correction if a unit to which NUSA allowances have been allocated for a given compliance year is not actually an affected unit as of January 1 of the compliance year.[1]

Authority: 40 CFR 97.411(b), 97.611(b), and 97.711(b).

January 27, 2017.

Richard Haeuber,

Acting Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2017–03069 Filed 2–14–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0705; FRL–9957–00]

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of thiamethoxam in or on bananas. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 15, 2017. Objections and requests for hearings must be received on or before April 17, 2017, 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–2015–0705, 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.*

[1] *See* 40 CFR 97.411(c), 97.611(c), and 97.711(c).

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 Printing 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–2015–0705 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 April 17, 2017. 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–2015–0705, 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 November 23, 2015 (80 FR 72941) (FRL–9936–73), 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 5E8401) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27409–8300. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the insecticide, thiamethoxam, in or on banana at 0.04 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the level at which the tolerance is being established. The reason for this change is explained in Unit IV.D.

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. . . .''

Tolerances for residues of thiamethoxam are listed in 40 CFR 180.565 and are expressed in terms of the combined residues of the insecticide thiamethoxam and its metabolite CGA–322704. Metabolite CGA–322704 is also the registered active ingredient clothianidin (tolerance listings in 40 CFR 180.586). Clothianidin (hereinafter referred to as CGA–322704) has a complete toxicological database and appears to have effects in mammals that are different from those of thiamethoxam. A separate risk assessment that addresses risks from CGA–322704 residues resulting from the direct application of CGA–322704 (clothianidin), as well as risks from residues of CGA–322704 coming from thiamethoxam uses has been conducted, and there are no risk estimates of concern as a result of the proposed tolerance for thiamethoxam residues in imported bananas. This risk assessment can be found at *http:www.regulations.gov* in docket ID number EPA–HQ–OPP–2015–0705.

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 thiamethoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiamethoxam 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.

In mammals, toxicological effects are seen primarily in the liver, kidney, testes, and blood cellular system. In addition, developmental neurological effects were observed in rats. These developmental effects are being used to assess risks associated with acute exposures to thiamethoxam, and the liver and testicular effects are the basis for assessing longer-term exposures.

There is no indication of quantitative or qualitative susceptibility in the developmental toxicity studies. There is evidence of quantitative susceptibility in the developmental neurotoxicity study and both two-generation reproductive studies. However, clear no observed adverse effects levels (NOAELs) were identified for the susceptibility in the 2-generation reproduction and developmental neurotoxicity (DNT) studies and the endpoints and doses chosen for risk assessment are protective of the susceptibility observed in these studies.

Thiamethoxam is classified as ''not likely to be carcinogenic to humans'' at levels below which certain amounts of metabolites are produced. The liver tumors that were observed in the mouse have been demonstrated to be a result of a non-genotoxic mode of action dependent on sufficient amounts of a hepatotoxic metabolite being produced. Although humans are qualitatively capable of producing the active metabolite, thiamethoxam is unlikely to pose a cancer risk to humans unless sufficient amounts of metabolites are persistently formed to drive a carcinogenic response. The chronic endpoint selected for regulating exposure to thiamethoxam is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action. At those levels, the Agency does not expect sufficient generation of the necessary metabolites to elicit a carcinogenic response; therefore, separate quantification of carcinogenic potential is not required.

Specific information on the studies received and the nature of the adverse effects caused by thiamethoxam as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http:www.regulations.gov* in the document titled ''*Thiamethoxam. Human Health Risk Assessment for Tolerances on Imported Bananas*'' on page 33 in docket ID number EPA–HQ–OPP–2015–0705.

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 thiamethoxam used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations including infants and children).	NOAEL = 34.5 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Acute RfD = 0.35 mg/kg/day. aPAD = 0.35 mg/kg/day.	Rat Developmental Neurotoxicity study. LOAEL = 298.7 mg/kg/day based on decreased body weight and reduced brain morphometric measurements.
Chronic dietary (All populations)	NOAEL= 1.2 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.012 mg/kg/day. cPAD = 0.012 mg/kg/day.	2-Generation reproduction study. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study, LOAEL = 156 mg/kg/day (males), not determined (females) based on sperm abnormalities and germ cell loss in F_1 males.
Incidental oral short-term infants/children <6 years old (1 to 30 days).	NOAEL= 31.6 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-day Dog study. LOAEL = 47.7/43.0 (M/F) mg/kg/day based on body weight loss; leukopenia and increased hematocrit, hemoglobin and erythrocyte count; increased plasma urea and creatinine; reduced thymus weight in males and females, increased thyroid weight in males and reduced brain weight in females; and, histopathological changes in liver, thymus and spleen.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term adults (1 to 30 days).	Oral study NOAEL = 1.2 mg/kg/day (dermal absorption rate = 5%. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation reproduction study; 1998. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study; 2004. LOAEL = 156 mg/kg/day (males), not determined (females) based on sperm abnormalities and germ cell loss in F_1 males.
Dermal short-term infants/children <6 years old (1 to 30 days).	Dermal study NOAEL= 60 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Rat 28-Day Dermal Toxicity Study. LOAEL = 250 (females) mg/kg/day based on increased plasma glucose, triglyceride levels, and alkaline phosphatase activity and inflammatory cell infiltration in the liver and necrosis of single hepatocytes in females.
Inhalation short-term adults (1 to 30 days).	Oral study NOAEL= 1.2 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation reproduction study. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study. LOAEL = 156 mg/kg/day (males), not determined (females) based on sperm abnormalities and germ cell loss in F_1 males.
Inhalation short-term infants/children <6 years old (1 to 30 days).	Inhalation (or oral study NOAEL = 31.6 mg/kg/day (inhalation toxicity = oral toxicity). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-day Dog study. LOAEL = 47.7/43.0 (M/F) mg/kg/day based on body weight loss; leukopenia and increased hematocrit, hemoglobin and erythrocyte count; increased plasma urea and creatinine; reduced thymus weight in males and females, increased thyroid weight in males and reduced brain weight in females; and, histopathological changes in liver, thymus and spleen.
Cancer (Oral, dermal, inhalation).	"Not Likely to be Carcinogenic to Humans" based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse. Quantification of cancer risk is *not* required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the petitioned-for tolerances 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.* 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 thiamethoxam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) 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 (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from USDA's NHANES/WWEIA. As to residue levels in food, the chronic analysis is based on tolerance levels and anticipated residues calculated from field trial data for selected commodities and 100 PCT.

iii. *Cancer.* Based on the data summarized in Unit III.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 PCT information.* 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 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 *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 131.77 parts per billion (ppb) for surface water and 4.66 ppb for ground water and for chronic exposures are estimated to be 11.31 ppb for surface water and 4.66 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 131.77 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 11.31 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: Turf and indoor environments (crack-and-crevice uses). EPA assessed residential exposure using the following assumptions: For residential handlers, short-term dermal and inhalation exposure is anticipated from both the lawn/turf and indoor crack-and-crevice uses. In terms of post application exposure, short-term dermal and incidental oral exposures are anticipated from both the lawn/turf and the crack-and-crevice uses. These exposures are expected from activities on turf such as playing, mowing, golfing, hand-to-mouth, object-to-mouth, incidental soil ingestion, and from contacting treated carpets. Post application inhalation exposure is also anticipated from indoor crack-and-crevice applications. The Agency selected only the most conservative, or worst case, residential adult and child scenarios to be included in the aggregate estimates, based on the lowest overall MOE (*i.e.,* highest risk estimates). The worst case residential exposures for adults and children 1 to 2 years old were associated with post-application exposure to treated turf. 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.''

Thiamethoxam is a member of the neonicotinoid class of pesticides and produces, as a metabolite, another neonicotinoid, CGA–322704. 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 (EPA, 2002). Although CGA–322704 and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for CGA–322704, 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 CGA–322704 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 CGA–322704 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 imidacloprid). Therefore, unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thiamethoxam and any other substances and thiamethoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that thiamethoxam has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity, and to evaluate the cumulative effects of such chemicals, see 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 Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (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.* In the developmental studies, there was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure to thiamethoxam. Effects in the young were seen in the presence of maternal toxicity. There was evidence of quantitative susceptibility in the developmental neurotoxicity study and both two-generation reproductive studies. Although there was evidence of increased quantitative susceptibility, there are no residual uncertainties with regard to pre- and/or postnatal toxicity following *in utero* exposure to rats or rabbits and pre and/or post-natal exposures to rats. 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 the developmental/offspring effects observed in the studies are well characterized and 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.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for thiamethoxam is complete.

ii. Evidence of neurotoxicity was seen in the acute and developmental neurotoxicity studies. However, there is a low degree of concern for the potential neurotoxic effects of thiamethoxam since clear NOAELs were identified for the neurotoxic effects, the neurotoxic effects were not the most sensitive endpoint in the toxicity database and 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. There was evidence of quantitative susceptibility in the developmental neurotoxicity study and both two-generation reproductive studies, however, for the reasons cited above in section III.D.2., 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. The dietary exposure assessments are based on high-end residue levels and processing factors, both of which account for parent and metabolites of concern, and the assumption of 100 PCT for all registered crops. 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 children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

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 thiamethoxam will occupy 9.5% of the aPAD for children 1–2 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 45% of the cPAD for children 1–2 years 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 thiamethoxam 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).

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 of 500 for adults and 580 for children 1<2 years old. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, thiamethoxam is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for thiamethoxam.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A. and based on the lack of chronic risk discussed in Unit III.E.2., 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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) 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.*

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 thiamethoxam in bananas at 0.02 mg/kg which is different than the U.S. tolerance of 0.3 ppm. At this time, the Codex and EPA residue definitions are different (Codex's MRL is for the parent compound, thiamethoxam only, while EPA's is thiamethoxam plus metabolite CGA–322704); therefore, it is not possible to harmonize with the Codex MRL.

C. Response to Comments

Three comments were received in response to the Notice of Filing. One

simply said ''Good.'' The other two comments noted general concerns about approving ''more herbicides and pesticides from Dow, Bayer, and Monsanto'' and the toxicity of this chemical, stating, in part, that ''food should not be contaminated with these chemicals.'' The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops; however, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. These comments provide no information to support a different conclusion.

D. Revisions to Petitioned-For Tolerances

The submitted banana field trial data support a tolerance of 0.03 ppm, instead of the petitioned-for tolerance of 0.04 ppm, in whole bananas. The petitioner used a combined limit of quantitation (LOQ) different from that used by the Agency for the input dataset of the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure. The combined LOQ used by EPA resulted in a recommended tolerance of 0.03 ppm.

V. Conclusion

Therefore, a tolerance is established for residues of thiamethoxam, including its metabolites and degradates, in or on banana at 0.03 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). 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: January 13, 2017.

Michael Goodis,

Acting 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, add alphabetically the commodity ''Banana'' to the table in paragraph (a) and revise footnote 1 to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Banana [1]	0.03
* * * * *	

[1] There are no U.S. registrations for these commodities as of February 15, 2017.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2016–0068]

42 CFR Parts 70 and 71

RIN 0920–AA63

Control of Communicable Diseases; Delay of Effective Date

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule; delay of effective date.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces a change in the effective date of the final rule titled ''Control of Communicable Diseases'' that was published on January 19, 2017. This action is undertaken in accordance with the memorandum of January 20,