

the free form of its acide metabolite CG-321113 [(E,E)-(methoxyimino)-[2-[1-(3-(trifluoromethylphenyl)-ethylideneaminoxy)methyl]-phenyl]acetic acid, in or on imported coffee, green bean at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Lois Rossi,

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. Section 180.555 is amended by alphabetically adding the following commodity and footnote 2 to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Coffee, green bean ²	0.02

Commodity	Parts per million
* * * * *	*
* * * * *	*
² There are no U.S. registrations as of January 18, 2012 for use on coffee, green bean.	
* * * * *	*

[FR Doc. 2012-4977 Filed 3-1-12; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-1079; FRL-9331-8]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiamethoxam in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 2, 2012. Objections and requests for hearings must be received on or before May 1, 2012, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-1079. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Gene Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-0235; email address: Benbow.Gene@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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-2010-1079 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be

received by the Hearing Clerk on or before May 1, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-1079, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL-8884-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7805) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.565 be amended by establishing tolerances for residues of the insecticide thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite, N-[(2-chloro-thiazol-5-yl)methyl]-N'-methyl-N'-nitro-guanidine], in or on: buckwheat, grain at 0.02 per million (ppm); buckwheat, forage at 0.50 ppm; buckwheat, hay at 0.02 ppm; buckwheat, straw at 0.02 ppm; oat, grain at 0.02 ppm; oat, forage at 0.50 ppm; oat, hay at 0.02 ppm; oat, straw at 0.02 ppm; millet, pearl, grain at 0.02 ppm; millet, pearl, forage at 0.02 ppm; millet, pearl, stover at 0.02 ppm; millet, proso, grain at 0.02 ppm; millet, proso, forage at 0.02 ppm; millet, proso,

stover at 0.02 ppm; millet, proso, straw at 0.02 ppm; rye, grain at 0.02 ppm; rye, forage at 0.50 ppm; rye, straw at 0.02 ppm; teosinte, grain at 0.02 ppm; teosinte, forage at 0.10 ppm; teosinte, stover at 0.05 ppm; triticale, grain at 0.02 ppm; triticale, forage at 0.05 ppm; triticale, hay at 0.02 ppm; triticale, straw at 0.02 ppm; wild rice, grain at 0.02 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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.

Thiamethoxam shows toxicological effects primarily in the liver, kidney, testes, and hematopoietic system. In addition, developmental neurological effects were observed in rats. This developmental effect is 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. Although thiamethoxam causes liver tumors in mice, the Agency has classified thiamethoxam as “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 and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer.

Specific information on the studies received and the nature of the adverse effects caused by thiamethoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in section 4.5.1 in the document “Thiamethoxam—Human Health Risk Assessment for Crop Group 15 (including buckwheat, pearl

millet, proso millet, oats, rye, teosinte, triticale) and Crop Group 16 Commodities (forage, fodder and straw of cereal grains group)” in docket ID number EPA-HQ-OPP-2010-1079 at <http://www.regulations.gov>.

Thiamethoxam produces a metabolite known as CGA-322704 (referred to in the remainder of this rule as clothianidin). Clothianidin is also registered as a pesticide. While some of the toxic effects observed following testing with thiamethoxam and clothianidin are similar, the available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately. A separate risk assessment of clothianidin has been completed in conjunction with the registration of clothianidin. The most recent assessment, which provides details regarding the toxicology of clothianidin, is available in the docket EPA-HQ-OPP-2008-0945, at <http://www.regulations.gov>. Refer to the document “Clothianidin: Human Health Risk Assessment for the Requested New Use on Mustard Seed as well as New Uses of Thiamethoxam on Peanuts, Alfalfa, in Food-Handling Establishments, and as a Seed Treatment for Cereal Grains.”

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 (U/S F) 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://www.epa.gov/pesticides/factsheets/riskassess.htm>.

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 = 1	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 delayed sexual maturation in male pups, and reduced brain morphometric measurements.
Chronic dietary (All populations including infants and children).	NOAEL = 1.2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1	Chronic RfD = 0.012 mg/kg/day. cPAD = 0.012 mg/kg/day.	2-Generation reproduction study. 1. 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. 2. LOAEL = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F ₁ males.
Incidental oral (all durations).	NOAEL = 8.23 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1	MOE = 100 (residential)	90-day Dog study. LOAEL = 32 (males) 33.9 (females) mg/kg/day based on slightly prolonged prothrombin times and decreased plasma albumin and A/G ratio (both sexes); decreased calcium levels and ovary weights and delayed maturation in the ovaries (females); decreased cholesterol and phospholipid levels, testis weights, spermatogenesis, and spermatid giant cells in testes (males).

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 (all durations) (Adults).	Oral study NOAEL = 1.2 mg/kg/day (dermal absorption rate = 5%) UF _A = 10x UF _H = 10x FQPA SF = 1	MOE = 100 (residential)	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 = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F ₁ males.
Dermal (all durations) (infants/children 1–6 yrs).	Dermal study NOAEL = 60 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1	MOE = 100 (residential)	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 (all durations)	Oral study NOAEL = 1.2 mg/kg/day (inhalation absorption rate = 100% of oral absorption) UF _A = 10x UF _H = 10x FQPA SF = 1	MOE = 100 (residential)	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 = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F ₁ males.

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. mg/kg/day = milligrams/kilogram/day.

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:

For both acute and chronic exposure assessments for thiamethoxam, EPA combined residues of clothianidin coming from thiamethoxam with residues of thiamethoxam *per se*. As discussed in this unit, thiamethoxam's major metabolite is CGA-322704, which is also the registered active ingredient in clothianidin. Available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately; however, these exposure assessments for this action incorporated the total residue of thiamethoxam and clothianidin from use of thiamethoxam because the total residue for each commodity for which thiamethoxam has a tolerance has not been separated between thiamethoxam and its clothianidin metabolite. The combining of these residues, as was done in this assessment, results in highly conservative estimates of dietary exposure and risk. A separate assessment was done for clothianidin. The clothianidin assessment included clothianidin residues from use of

clothianidin as a pesticide and clothianidin residues from use of thiamethoxam on those commodities for which the pesticide clothianidin does not have a tolerance. As to these commodities, EPA has separated total residues between thiamethoxam and clothianidin.

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 (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). For residue levels in food, EPA assumed tolerance level residues of thiamethoxam and clothianidin. It was further assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. For residue levels in food, EPA assumed tolerance level and/or anticipated residues (averages) from field trial data. It was again assumed that 100% of crops with

registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated.

A complete listing of the inputs used in these assessments can be found in the following documents: “Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration on Crop Group 15/16 Commodities” available in the docket EPA–HQ–OPP–2010–1079, at <http://www.regulations.gov>; and “Clothianidin—Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments to Evaluate Requested Uses on Mustard Seed and Requested uses of Thiamethoxam on Peanuts, in Food-Handling Establishments, and as a Seed Treatment for Cereal Grains,” available in the docket EPA–HQ–OPP–2008–0945, at <http://www.regulations.gov>.

iii. *Cancer.* EPA concluded that thiamethoxam is “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, and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of

action for cancer and thus a separate exposure assessment pertaining to cancer risk is not necessary. Because clothianidin is not expected to pose a cancer risk, a quantitative dietary exposure assessment for the purposes of assessing cancer risk was not conducted.

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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 0.13177 ppm for surface water and 0.00466 ppm for ground water. The chronic exposure for surface water and ground water is estimated to be 0.01131 ppm and 0.00466 ppm respectively. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

Since clothianidin is not a significant degradate of thiamethoxam in surface water or ground water sources of drinking water, it was not included in the EDWCs for the thiamethoxam dietary assessment. For the clothianidin assessments, the EDWC value of 0.0724 ppm for clothianidin was incorporated into the acute and chronic dietary assessments.

A complete listing of the inputs used in these assessments can be found in the following documents: "Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration on Crop Group 15/16 Commodities" available in the docket EPA-HQ-OPP-2010-1079, at <http://www.regulations.gov>; and "Tier I Drinking Water Exposure Assessment for the Section 3 New Uses of Clothianidin on Rice and Leafy Vegetables," available in the docket EPA-HQ-OPP-2008-0945, at <http://www.regulations.gov>.

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 on golf courses, residential lawns, commercial grounds, parks, playgrounds, athletic fields, landscapes, interiorscapes, sod farms, and indoor crack and crevice or spot treatments to control insects in residential settings. EPA assessed residential exposure using the assumption that thiamethoxam is applied by commercial applicators only. However, entering areas previously treated with thiamethoxam could lead to exposures for adults and children. As a result, risk assessments have been completed for postapplication scenarios.

Short-term postapplication exposures (1 to 30 days of continuous exposure) may occur as a result of activities on treated turf or entering indoor areas previously treated with a thiamethoxam indoor crack and crevice product. EPA combined all non-dietary sources of children's post application exposure to obtain an estimate of potential combined exposure. These scenarios consisted of dermal postapplication exposure and oral (hand-to-mouth) exposures for children 3 to 6 years of age.

A complete listing of the inputs used in these assessments can be found in the document "Thiamethoxam—Human Health Risk Assessment for Crop Group 15 (including buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale) and Crop Group 16 Commodities (forage, fodder and straw of cereal grains group)" in docket ID number EPA-HQ-OPP-2010-1079 at <http://www.regulations.gov>. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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, clothianidin. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although clothianidin and thiamethoxam bind

selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, 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 thiamethoxam is based on unrelated effects in mammals, including effects on the liver, kidney, testes, and hematopoietic system. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidacloprid).

Thus, EPA has not found thiamethoxam or clothianidin to share a common mechanism of toxicity with any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiamethoxam and clothianidin do 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 Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of

safety is commonly referred to as the FQPA 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 is no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure to thiamethoxam. The developmental NOAELs are either higher than or equal to the maternal NOAELs. The toxicological effects in fetuses do not appear to be any more severe than those in the dams or does. In the rat developmental neurotoxicity study, there was no quantitative evidence of increased susceptibility; however, there was increased qualitative susceptibility because the effects in the pups (reduced brain weight and significant changes in brain morphometric measurements) were considered to be more severe than findings in the dams (decreased body weight gain and food consumption).

There is evidence of increased quantitative susceptibility for male pups in both 2-generation reproductive studies. In one study, there are no toxicological effects in the dams; whereas, for the pups, reduced bodyweights are observed at the highest dose level, starting on day 14 of lactation. This contributes to an overall decrease in bodyweight gain during the entire lactation period. The reproductive effects in males appear in the F₁ generation in the form of increased incidence and severity of testicular tubular atrophy (see developmental/reproductive section). These data are considered to be evidence of increased quantitative susceptibility for male pups (increased incidence of testicular tubular atrophy at 1.8 mg/kg/day) when compared to the parents (hyaline changes in renal tubules at 61 mg/kg/day; NOAEL is 1.8 mg/kg/day).

In a more recent 2-generation reproduction study, the most sensitive effect was sperm abnormalities at 3 mg/kg/day (the NOAEL is 1.2 mg/kg/day) in the F₁ males. This study also indicates increased susceptibility for the offspring for this effect.

Although there is evidence of increased quantitative susceptibility for male pups in both reproductive studies, NOAELs and LOAELs were established in these studies and the Agency selected the NOAEL for testicular effects in F₁ pups as the basis for risk assessment. The Agency has confidence that the NOAEL selected for risk assessment is protective of the most sensitive effect

(testicular) for the most sensitive subgroup (pups) observed in the toxicological database.

3. *Conclusion.* i. In the final rule published in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL-7689-7), EPA had previously determined that the FQPA SF should be retained at 10X for thiamethoxam, based on the following factors: Effects on endocrine organs observed across species; significant decrease in alanine amino transferase levels in companion animal studies and in dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetylcholine receptors of the insect's nervous system); the transient clinical signs of neurotoxicity in several studies across species; and the suggestive evidence of increased quantitative susceptibility in the rat reproduction study. Since that determination, EPA has received and reviewed a developmental neurotoxicity (DNT) study in rats, and an additional reproduction study in rats. Taking the results of these studies into account, as well as the rest of the data on thiamethoxam, 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 (June 23, 2010, 75 FR 35653; FRL-8830-4); (June 22, 2007, 72 FR 34401). That decision is based on the following findings:

a. The toxicity database for thiamethoxam is largely complete, including acceptable/guideline developmental toxicity, 2-generation reproduction, and DNT studies designed to detect adverse effects on the developing organism, which could result from the mechanism that may have produced the decreased alanine amino transferase levels. The available data for thiamethoxam show the potential for immunotoxic effects. In the subchronic dog study, leukopenia (decreased white blood cells) was observed in females only, at the highest dose tested (HDT) of 50 mg/kg/day; the NOAEL for this effect was 34 mg/kg/day. The overall study NOAEL was 9.3 mg/kg/day in females (8.2 mg/kg/day in males) based on hematology and other clinical chemistry findings at the LOAEL of 34 mg/kg/day (32 mg/kg/day in males). In the subchronic mouse study, decreased spleen weights were observed in females at 626 mg/kg/day; the NOAEL for this effect was the next lowest dose of 231 mg/kg/day. The overall study NOAEL was 1.4 mg/kg/day (males) based on increased hepatocyte hypertrophy observed at the LOAEL of 14.3 mg/kg/day. The decreased absolute spleen weights were

considered to be treatment related, but were not statistically significant at 626 mg/kg/day or at the HDT of 1,163 mg/kg/day. Since spleen weights were not decreased relative to body weights, the absolute decreases may have been related to the decreases in body weight gain observed at higher doses. Overall, the Agency has a low concern for the potential for immunotoxicity related to these effects for the following reasons: In general, the Agency does not consider alterations in hematology parameters alone to be a significant indication of potential immunotoxicity. In the case of thiamethoxam, high-dose females in the subchronic dog study had slight microcytic anemia as well as leukopenia characterized by reductions in neutrophils, lymphocytes and monocytes; the leukopenia was considered to be related to the anemic response to exposure. Further, endpoints and doses selected for risk assessment are protective of the observed effects on hematology. Spleen weight decreases, while considered treatment-related, were associated with decreases in body weight gain, and were not statistically significant. In addition, spleen weight changes occurred only at very high doses, more than 70 times higher than the doses selected for risk assessment.

In addition to the previous considerations, a 28-day immunotoxicity study in female mice was recently received and has undergone a preliminary review. There were no immunotoxic effects observed at doses exceeding the limit dose of 1,000 mg/kg/day.

b. For the reasons discussed in Unit III.D.2., there is low concern for an increased susceptibility in the young.

c. Although there is evidence of neurotoxicity after acute exposure to thiamethoxam at doses of 500 mg/kg/day including drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength, no evidence of neuropathology was observed. These effects occurred at doses at least 14-fold and 416-fold higher than the doses used for the acute, and chronic risk assessments, respectively; thus, there is low concern for these effects since it is expected that the doses used for regulatory purposes would be protective of the effects noted at much higher doses.

In the developmental neurotoxicity study (DNT), there was no evidence of neurotoxicity in the dams exposed up to 298.7 mg/kg/day; a dose that was associated with decreases in body weight gain and food consumption. In pups exposed to 298.7 mg/kg/day, there

were significant reductions in absolute brain weight and size (i.e., length and width of the cerebellum was less in males on day 12, and there were significant decreases in Level 3–5 measurements in males and in Level 4–5 measurements in females on day 63). However, there is low concern for this increased qualitative susceptibility observed in the DNT study because the doses and endpoints selected for risk assessment are protective of the effects in the offspring. As noted previously, for risk assessment the Agency selected the NOAEL for testicular effects in F₁ pups based on two reproductive toxicity studies to be protective of all sensitive subpopulations.

d. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using tolerance-level and/or anticipated residues that are based on reliable field trial data observed in the thiamethoxam field trials. Although there is available information indicating that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately, the residues of each have been combined in these assessments to ensure that the estimated exposures of thiamethoxam do not underestimate actual potential thiamethoxam exposures. An assumption of 100 percent crop treated (PCT) was made for all foods evaluated in the assessments. For the acute and chronic assessments, the EDWCs of 131.77 parts per billion (ppb) and 11.3 ppb, respectively, were used to estimate exposure via drinking water. Compared to the results from small scale prospective ground water studies where the maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for clothianidin, the modeled estimates are protective of what actual exposures are likely to be. EPA used similarly conservative (protective) assumptions to assess postapplication exposure to children and adults including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

ii. In the final rule published in the **Federal Register** of February 6, 2008 (73 FR 6851) (FRL–8346–9), EPA had previously determined that the FQPA SF for clothianidin should be retained at 10X because EPA had required the submission of a developmental immunotoxicity study to address the combination of evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin database, and

evidence showing that juvenile rats in the 2-generation reproduction study appear to be more susceptible to these potential immunotoxic effects. In the absence of a developmental immunotoxicity study, EPA concluded that there was sufficient uncertainty regarding immunotoxic effects in the young that the 10X FQPA factor should be retained as a database uncertainty factor.

Since that determination, EPA has received and reviewed an acceptable/guideline developmental immunotoxicity study, which demonstrated no treatment-related effects. Taking the results of this study into account, as well as the rest of the data on clothianidin, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for clothianidin were reduced to 1X (February 11, 2011, 76 FR 7712) (FRL–8858–3). That decision is based on the following findings:

a. The toxicity database for clothianidin is complete. As noted, the prior data gap concerning developmental immunotoxicity has been addressed by the submission of an acceptable developmental immunotoxicity study.

b. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for prenatal and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility; therefore, there are no residual concerns regarding effects in the young.

c. While the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL and LOAEL have been selected for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for prenatal and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

d. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments were performed based on assumptions that were judged to be highly conservative and health-protective for all durations and population subgroups, including tolerance-level residues, adjustment factors from metabolite data, empirical processing factors, and 100 PCT for all commodities. Additionally, EPA made conservative (protective) assumptions in the ground water 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 and adults as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thiamethoxam will occupy 9.5% of the aPAD for All infants (<1 year), the population group receiving the greatest exposure. Acute dietary exposure from food and water to clothianidin is estimated to occupy 23% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* In examining chronic aggregate risk, EPA has assumed that the only pathway of exposure relevant to that time frame is dietary exposure. Using this assumption for chronic exposure, EPA has concluded that chronic exposure to thiamethoxam from food and water will utilize 43% of the cPAD for Children 1 to 2 years old, the population group receiving the greatest exposure. Chronic exposure to clothianidin from food and water will utilize 19% 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 for thiamethoxam result in aggregate MOEs of: 370 for the general U.S. population; 490 for all infants (<1 year); 440 for children 1 to 2 years; 450 for children 3 to 5 years; 370 for children 6 to 12 years; 380 for youth 13 to 19 years, adults 20 to 49 years, adults 50+ years, and females 13 to 49 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for clothianidin result in aggregate MOEs of: 1,200 for the general U.S. population; 480 for all infants (<1 year); 370 for children 1 to 2 years; 490 for children 3 to 5 years; 1,000 for children 6 to 12 years; 1,400 for youth 13 to 19 years, adults 20–49 years, and females 13 to 49 years; and 1,300 for adults 50+ years. Because EPA's level of concern for clothianidin 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).

Thiamethoxam is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to thiamethoxam.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures for thiamethoxam result in aggregate MOEs of: 370 for the general U.S. population; 540 for all infants (<1 year); 470 for children 1 to 2 years; 490 for children 3 to 5 years; 370 for children 6 to 12 years; 380 for youth 13 to 19 years, adults 20 to 49 years, adults 50+ years, and females 13 to 49 years. Because EPA's level of concern for

thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for intermediate exposures, EPA has concluded the combined intermediate food, water, and residential exposures for clothianidin result in aggregate MOEs of: 1,200 for the general U.S. population; 480 for all infants (<1 year); 370 for children 1 to 2 years; 490 for children 3 to 5 years; 1,000 for children 6 to 12 years; 1,400 for youth 13 to 19 years, adults 20 to 49 years, and females 13 to 49 years; and 1,300 for adults 50+ years. Because EPA's level of concern for clothianidin is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified thiamethoxam as not likely to be a human carcinogen based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. Therefore, thiamethoxam is not expected to pose a cancer risk. Clothianidin has been classified as “not likely to be a human carcinogen” and is not expected to pose a cancer risk.

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 or clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The High Production Liquid Chromatography (HPLC) Method AG–675 with ultraviolet (UV) or Mass Spectrometry (MS) detection was previously submitted in conjunction with thiamethoxam petitions. Method AG–675 has been determined to be adequate for enforcing the tolerance expression for residues of thiamethoxam and CGA–322704 in crop and livestock commodities. Syngenta Crop Protection, Inc., has submitted a revised Method AG–675, i.e., Method GRM.009.04A. The full extraction steps for plant and livestock commodities, including the microwave extraction step for liver, have been incorporated. The limits of quantitation (LOQs) of Method GRM.009.04A have been established at 0.01 ppm each for residues of thiamethoxam, CGA–322704 and CGA–265307. Method validation data are available for Method GRM.009.04A.

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 U.N. 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.

EPA is increasing the barley grain tolerance to 0.4 ppm in order to harmonize with the Codex MRL of 0.4 ppm. The MRL expressions continue to remain different, as the Codex MRL is for the parent compound only.

C. Revisions to Petitioned-For Tolerances

Although the petitioner sought tolerances for many of the commodities in Crop Groups 15 and 16, the petitioner did not request crop group tolerances. EPA has determined that a tolerance for either Crop Group 15 or Crop Group 16 commodities is not appropriate except for Crop Group 15 grains (except barley), because the use pattern is not the same for all Crop Group 15 commodities. Specifically, there is a foliar use on barley and there are much higher tolerances for barley hay and straw associated with this foliar use. It is for similar reasons that a Crop Group 16 tolerance would not be appropriate.

In addition, there are also significant differences in the tolerances for the different cereal forages, i.e., wheat forage at 0.5 ppm, corn forage at 0.10 ppm, and sorghum forage at 0.02 ppm. Therefore, tolerances for each individual commodity have been established by translating residue data from the most appropriate representative commodity, except for grains which all have the same tolerance (excluding barley). Tolerances are not required for triticale and wild rice because these commodities are covered by the wheat and rice tolerances, as

specified in 40 CFR 180.1. Tolerances are also not needed for teosinte forage and stover as these are not considered significant livestock feed items and are not consumed by humans.

V. Conclusion

Therefore, 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 and its metabolite, N-[(2-chloro-thiazol-5-yl)methyl]-N'-methyl-N"-nitro-guanidine, in or on barley, grain at 0.4 ppm; buckwheat, forage at 0.50 ppm; buckwheat, hay at 0.02 ppm; buckwheat, straw at 0.02 ppm; grain, cereal, group 15, except barley at 0.02 ppm; oat, forage at 0.50 ppm, oat, hay at 0.02 ppm; oat, straw at 0.02 ppm; millet, pearl, forage at 0.02 ppm; millet, pearl, stover at 0.02 ppm; millet, proso, forage at 0.02 ppm; millet, proso, stover at 0.02 ppm; millet, proso, straw at 0.02 ppm; rye, forage at 0.50 ppm; rye, straw at 0.02 ppm. Tolerances are revoked for corn, field, grain; corn, pop, grain; rice, grain; sorghum, grain; wheat, grain. These tolerances are no longer needed, since residues on these commodities will be covered by the crop group 15 tolerances being established in this rule.

In addition, administrative corrections are being made to the existing tolerances for grain, aspirated fractions and soybean, hulls, as follows: The tolerance for grain, aspirated fractions at 0.08 ppm is being corrected to grain, aspirated fractions at 2.0 ppm; the tolerance for soybean, hulls at 2.0 ppm is being corrected to soybean, hulls at 0.08 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not

a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Daniel J. Rosenblatt,

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. Section 180.565 paragraph (a) is revised to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide thiamethoxam, including its metabolites and degradates, in or on the following commodities. 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 following commodities:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.12
Almond, hulls	1.2
Artichoke, globe	0.45
Avocado	0.40
Barley, grain	0.4
Barley, hay	0.40
Barley, straw	0.40
Bean, succulent	0.02
Berry, low growing, subgroup 13-07G, except cranberry ..	0.30
Borage, seed	0.02
Brassica, head and stem, subgroup 5-A	4.5
Brassica, leafy greens, subgroup 5-B	3.0
Buckwheat, forage	0.50
Buckwheat, hay	0.02
Buckwheat, straw	0.02
Bushberry subgroup 13-07B, except lingonberry and blueberry, lowbush	0.20
Canistel	0.40
Canola, seed	0.02
Cattle, meat	0.02

Commodity	Parts per million	Commodity	Parts per million
Cattle, meat byproducts	0.04	Vegetable, fruiting, group 8	0.25
Citrus, dried pulp	0.60	Vegetable, leafy, except bras-	
Coffee, bean, green ¹	0.05	sica, group 4	4.0
Corn, field, forage	0.10	Vegetable, legume, group 6	0.02
Corn, field, stover	0.05	Vegetable, root, subgroup 1A	0.05
Corn, pop, forage	0.10	Vegetable, tuberous and	
Corn, pop, stover	0.05	corn, except potato, sub-	
Corn, sweet, forage	0.10	group 1D	0.02
Corn, sweet, kernel plus cob		Wheat, forage	0.50
with husks removed	0.02	Wheat, hay	0.02
Corn, sweet, stover	0.05	Wheat, straw	0.02
Cotton, gin byproducts	1.5		
Cotton, undelinted seed	0.10		
Crambe, seed	0.02		
Cranberry	0.02		
Flax, seed	0.02		
Food commodities and feed			
commodities (other than			
those covered by a higher			
tolerance as a result of use			
on growing crops) in food/			
feed handling establish-			
ments	0.02		
Fruit, citrus, group 10	0.40		
Fruit, pome, group 11	0.2		
Fruit, small, vine climbing,			
subgroup 13-07F, except			
fuzzy kiwifruit	0.20		
Fruit, stone, group 12	0.5		
Goat, meat	0.02		
Goat, meat byproducts	0.04		
Grain, aspirated fractions	2.0		
Grain, cereal, group 15, ex-			
cept barley	0.02		
Grape, raisin	0.30		
Hog, meat	0.02		
Hog, meat byproducts	0.02		
Hop, dried cones	0.10		
Horse, meat	0.02		
Horse, meat byproducts	0.04		
Mango	0.40		
Milk	0.02		
Millet, pearl, forage	0.02		
Millet, pearl, stover	0.02		
Millet, proso, forage	0.02		
Millet, proso, stover	0.02		
Millet, proso, straw	0.02		
Oat, forage	0.50		
Oat, hay	0.02		
Oat, straw	0.02		
Peanut	0.05		
Peanut, hay	0.25		
Peanut, meal	0.15		
Peppermint, tops	1.5		
Pistachio	0.02		
Potato	0.25		
Radish, tops	0.80		
Rapeseed, seed	0.02		
Rye, forage	0.50		
Rye, straw	0.02		
Sapodilla	0.40		
Sapote, black	0.40		
Sapote, mamey	0.40		
Sheep, meat	0.02		
Sheep, meat byproducts	0.04		
Sorghum, forage	0.02		
Sorghum, grain, stover	0.02		
Soybean, hulls	0.08		
Spearmint, tops	1.5		
Star apple	0.40		
Sunflower	0.02		
Tomato, paste	0.80		
Vegetable, cucurbit, group 9 ..	0.2		

¹ There are no U.S. registrations as of September 17, 2003.

* * * * *

[FR Doc. 2012-4983 Filed 3-1-12; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0524; FRL-9337-9]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). **DATES:** This regulation is effective March 2, 2012. Objections and requests for hearings must be received on or before May 1, 2012, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0524. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-

4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: benbow.bethany@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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