levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: September 4, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.591 is added to read as follows:

§ 180.591 Trifloxysulfuron; tolerances for residues

(a) *General.* Tolerances are established for residues of the herbicide trifloxysulfuron, *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(2,2,2-trifluoroethoxy)-2-pyridinesulfonamide in or on the following raw agricultural commodities.

Commodity	Parts per million
Almond	0.02
Almond, hulls	0.01
Fruit, citrus, Group 10	0.03
Cotton, undelinted seed	0.05
Cotton, gin byproducts	1.0
Sugarcane	0.01
Tomato	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 03–23428 Filed 9–16–03; 8:45am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0306; FRL–7327–5]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite in or on imported coffee, pecan, stone fruit, succulent bean, and sunflower. Syngenta Crop Protection, Inc. and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 17, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0306, must be received on or before November 17, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5409; e-mail address: *daniel.dani@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:

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

This listing is not intended to be exhaustive, but rather provides 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0306. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 2, 2003 (68 FR 16040) (FRL–7298–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Pub. L. 104–170), announcing the filing of pesticide petitions (3E06524, 2E06505, 2E06508, 1E06349, and 0F6142) by IR-4, 681 U.S. Highway #1 South, North Bunswick, NJ 08902–3390 and Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. That notice included a summary on the petitions prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.565 be amended by establishing tolerances for the combined 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-ylmethyl)-*N'*-methyl-*N'*-nitro-guanidine), in or on imported coffee at 0.05 parts per million (ppm) (1E6349), pecan at 0.02 ppm (0F6142), stone fruit group 12 at 0.5 ppm (2E6505), succulent bean at 0.02 ppm (2E6508), and sunflower at 0.02 ppm (3E6524).

Section 408(b)(2)(A)(i) of the 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 the 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 the 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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, consistent with section 408(b)(2) of the FFDCA, for tolerances for the combined residues of thiamethoxam and its metabolite on imported coffee at 0.05 ppm, pecan at 0.02 ppm, stone fruit group 12 at 0.5 ppm, succulent bean at 0.02 ppm, and sunflower at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic 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 reviewed are discussed in Unit III.A. of the **Federal Register** of November 1, 2002 (67 FR 66561) (FRL–7279–6).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA safty factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF 10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for thiamethoxam used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.1 mg/kg/day	Acute mammalian neurotoxicity study in the rat LOAEL = 500 mg/kg/day based on treatment-related neurobehavioral effects observed in the FOB and LMA testing (drooped palpebral closure, decreased rectal temperature and locomotor activity, increased forelimb grip strength)
Chronic dietary (all populations)	NOAEL = 0.6 mg/kg/day UF = 100 Chronic RfD = 0.006 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.0006 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 F1 generation males
Oral non-dietary (all durations)	NOAEL = 0.6 mg/kg/day	LOC for MOE = 1,000 (Residential)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males
Dermal (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (dermal absorption rate = 27%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males
Inhalation (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males
Cancer (oral, dermal, inhalation)	Likely carcinogen for humans based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice. Quantification of risk based on most potent unit risk: Male mouse liver adenoma and/or carcinoma combined tumor rate. The upper bound estimate of unit risk, Q_1* $(mg/kg/day)^{-1}$ is 3.77 x 10^{-2} in human equivalents		

*The reference to the FQPA safty factor refers to any additional safty factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.565) for the combined residues of thiamethoxam and its metabolite, in or on a variety of raw agricultural commodities. Tolerances for thiamethoxam are established on barley, canola, cotton, sorghum, wheat, tuberous and corm vegetables crop subgroup, fruiting vegetables crop group, tomato paste, cucurbit vegetables crop group, pome fruits crop group, field corn forage, field corn stover, sweet corn stover, field corn grain, popcorn grain, and sweet corn (kernal and cob with husk removed) milk and the meat and meat by products of cattle, goats, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam in food as follows:

i. *Acute exposure.* Acute dietary 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. The Dietary Exposure Evaluation Model (DEEM™) with the Food Commodity Intake Database (FCID) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The residues of concern for the acute analysis are thiamethoxam and its metabolite. The assessment assumed that 100% of the registered and proposed crops were treated and that all treated crops and livestock had residues of concern at the tolerance level. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed subgroup is children 1 to 2 years of age, which utilizes 3% of the aPAD.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM™ with the FCID analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The residues of concern for the chronic analysis are thiamethoxam and its metabolite. The chronic analysis was based on average field trial residue values as well as percent crop estimates. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed subgroup is children 1 to 2 years of age, which utilizes 17% of the cPAD.

iii. *Cancer*. The residue of concern for the cancer analysis is thiamethoxam, per se. The residues of its metabolite were removed from the cancer analysis because the metabolite was found to be ''not likely to be carcinogenic to humans'' when it was evaluated as an active ingredient. The cancer analysis was based on average field trial residue values as well as percent crop treated (PCT) estimates. The estimated cancer risk from dietary exposure to thiamethoxam is 9.04×10^{-7}.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT. The Agency used PCT information in the following Table 2:

TABLE 2.—THIAMETHOXAM USES AND ESTIMATES OF CROP TREATED

Commodity	Percent Crop Treated[1]
Apples	5
Casabas	44
Cherries (sweet)	37
Cherries (tart)	88
Coffee	100
Crabapples	53
Crenshaws	44
Cucumbers	5
Field corn	6
Fruiting vegetables (except cucurbits - crop group 8)	15
Lima beans (fresh)	37
Lima beans (processed)	52
Loquats	53
Melons	13
Peaches	45

TABLE 2.—THIAMETHOXAM USES AND ESTIMATES OF CROP TREATED—Continued

Commodity	Percent Crop Treated[1]
Pears	9
Pecans	38
Plums	60
Prunes	43
Pumpkins	44
Quinces	53
Snap beans (fresh)	26
Snap beans (processed)	38
Squash	44
Sunflower	25
Tuberous and corm vegetables - crop subgroup 1C	9

The Agency believes that the three conditions listed in this Unit have been met. With respect to condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which thiamethoxam may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for thiamethoxam in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of thiamethoxam.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to thiamethoxam, they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of thiamethoxam for acute exposures are estimated to be 7.1 parts per billion (ppb) for surface water and 1.94 ppb for

ground water. The EECs for chronic non-cancer exposures are estimated to be 0.43 ppb for surface water and 1.94 ppb for ground water. The EECs for cancer exposures are estimated to be 0.13 ppb for surface water and 1.94 ppb for ground 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 not registered for use on any sites that would result in residential exposure.

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

EPA does not have, at this time, available data to determine whether thiamethoxam has a common mechanism of toxicity with other substances. 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 released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The developmental toxicity studies indicated no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetus to *in utero* exposure based on the fact that the developmental NOAELs are either higher than or equal to the maternal NOAELs. However, the reproductive studies indicate effects in males rats in the form of increased incidence and severity of testicular tubular atrophy. These data are considered to be evidence of increased quantitative susceptibility for male pups when compared to the parents.

3. *Conclusion*. There is a complete toxicity data base for thiamethoxam and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be retained. The 10X safety factor is retained based on the following factors: Effects on endocrine organs observed across species; the significant decrease in alanine amino transferase levels in the companion animal studies in the dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetyl choline 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.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to thiamethoxam will occupy 3% of the aPAD for the U.S. population, 2% of the aPAD for females 13 years and older, 9% of the aPAD for all infants (less than 1 year old), and 10% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to thiamethoxam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.1	3	7.1	1.94	2,400
All infants (<1 year old)	0.1	9	7.1	1.94	910
Children (1 - 2 years old)	0.1	10	7.1	1.94	900
Females (13 - 49 years old)	0.1	2	7.1	1.94	2,900

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiamethoxam from food will utilize 6% of the cPAD for the U.S. population, 14% of the cPAD for all infants (less than 1 year old), and 17% of the cPAD for children 1 to 2 years old. There are no residential uses for thiamethoxam that result in chronic residential exposure to thiamethoxam. In addition, there is potential for chronic dietary exposure to thiamethoxam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIAMETHOXAM

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0006	6	0.43	1.94	20
All infants (<1 year old)	0.0006	14	0.43	1.94	5.1
Children (1 - 2 years old)	0.0006	17	0.43	1.94	5.0

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. The dietary cancer risk from residues in food is 9.04×10^{-7}. A cancer DWLOC is calculated only for the general U.S. population. For risk management purposes, EPA considers a cancer risk to be greater than negligible when it exceeds the range of 1 in 1 million. EPA has generally treated cancer risks up to 3 in 1 million as within the range of 1 in 1 million. The DWLOC for cancer aggregate risk (no residential uses) is calculated using the following equations:

DWLOC cancer (µg/L) = chronic water exposure milligrams/kilogram/day (mg/kg/day) x (body weight/kg) /consumption (L) x 10^{-3} mg/µg

Chronic water exposure (mg/kg/day) = negligible risk / Q* - (chronic food exposure)(mg/kg/day)

Assuming that the negligible risk value could be as high as 3×10^{-6}, the chronic water exposure value is estimated to be: $3 \times 10^{-6} / 3.77 \times 10^{-2}$ - 0.000024 = 0.000056 mg/kg/day

The DWLOC cancer = 0.000056 mg/kg/day x 70 kg / 2L x 10^{-3} mg/µg = 1.95 µg/L

The surface water EEC is 0.13 µg/L and the ground water EEC is 1.94 µg/L. Since the ground water value is greater than the surface water value, it will be used for comparison purposes and will protect for any concerns for surface water concentrations. Since the cancer DWLOC is not exceeded by the ground water EEC, the cancer risk is below EPA's level of concern.

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, and to infants and children from aggregate exposure to thiamethoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (solvent extraction, liquid-liquid partitioning and solid-phase extraction cleanup, and high performance liquid chromatography using ultra-violet detection (HPLC/UV) analysis) 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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no international residue limits for thiamethoxam.

V. Conclusion

Therefore, the tolerances are established for combined 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-ylmethyl)-*N*'-methyl-*N*'-nitro-guanidine), in or on imported coffee at 0.05 ppm, pecan at 0.02 ppm, stone fruit

group 12 at 0.5 ppm, succulent bean at 0.02 ppm, and sunflower at 0.02.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0306 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 17, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0306, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve 1 or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: September 10, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.565 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Bean, succulent	0.02
* * * * * * *	
Coffee[1]	0.05
* * * * * * *	
Fruit, stone, group 12	0.5
* * * * * * *	
Pecans	0.02
* * * * * * *	
Sunflower	0.02

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

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[FR Doc. 03–23852 Filed 9–15–03; 1:28 pm]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03–2830; MM Docket No. 01–244, RM–10234; MM Docket No. 01–245, RM–10235]

Digital Television Broadcast Service; Tyler and Lufkin, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, by this document, denies a petition for reconsideration filed by International Broadcasting Network of the Report and Order, which substituted DTV channel 10 for DTV channel 38 at Tyler, Texas, and DTV channel 11 for DTV channel 43 at Lufkin, Texas. *See* 67 FR 63852, October 16, 2002. With this action, this proceeding is terminated.