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.

V. 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: December 20, 2004,

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.

§ 180.275 [Amended]

■ 2. In § 180.275, amend paragraph (b) by revising the date ''12/31/03'' to read ''12/31/07.''

[FR Doc. 05–51 Filed 1–4–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0394; FRL–7689–7]

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite, (CGA–322704) in or on legume vegetables, root vegetables (except sugar beet), strawberries, bushberries, juneberries, lingonberries, salal, cranberries, spearmint, peppermint, rapeseed, mustard, flax, safflower, crambe, borage, and potatoes. In addition, the tolerance expression for tuberous and corm vegetable crop subgroup (1C) is revised to a tolerance expression for tuberous and corm crop subgroup (except potato) (1D). Syngenta Crop Protection, Inc. and Interregional Research Project 4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective January 5, 2005. Objections and requests for hearings must be received on or before March 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0394. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., 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.

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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Access Electronic Copies of This Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 2, 2004 (69 FR 31110) (FRL–7361–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2E6363, 3E6781, 3E6800, 3E6805, 3E6806, 3E6807, 4E6819, and 0F6142) by Syngenta Crop Protection, Inc., P.O. Box 18300 Greensboro, NC 27419–8300, and Interregional Research Project 4 (IR–4), 681 US Highway 1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.565 be amended by establishing tolerances for 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 CGA-322704 (N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N''-nitro-guanidine), in or on legume vegetables group 6 at 0.02 parts per million (ppm) (3E6805), peppermint and spearmint at 4.0 ppm (2E6363); root vegetables (except sugar beet) crop subgroup 1B at 0.1 ppm and for radish tops at 0.80 ppm (4E6819); strawberry at 0.30 ppm (3E6800); cranberry at 0.01 ppm (3E6781); bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.25 ppm (3E6807); rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm (3E6806); and potato at 0.25 ppm (0F6142). In addition, due to the establishment of the individual tolerance for potato, it was requested that the tolerance expression for tuberous and corm crop subgroup 1C be revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D. That notice included a summary of these petitions prepared by Syngenta Crop Protection, Inc. and IR-4, the registrant. As a result of the residue data submitted to support these requests, the proposed tolerance level for peppermint and spearmint was subsequently revised to 1.5 ppm; the proposed tolerance level for root vegetables (except sugar beet) crop subgroup 1B was subsequently revised to 0.02 ppm; the proposed tolerance level for bushberry crop subgroup 13B and juneberry, lingonberry and salal was subsequently revised to 0.20 ppm; and the proposed tolerance for cranberry was revised to 0.02 ppm. There were no comments received in response to the notice of filing.

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. . . .''

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 FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of thiamethoxam and its metabolite CGA–322704 on legume vegetables group 6 at 0.02 ppm, peppermint and spearmint at 1.5 ppm; root vegetables (except sugar beet) crop subgroup 1B at 0.02 ppm and for radish tops at 0.80 ppm; strawberry at 0.30 ppm; cranberry at 0.02 ppm; bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.20 ppm; rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm; and potato at 0.25 ppm. In addition, due to the establishment of the individual tolerance for potato, it was requested that the tolerance expression for tuberous and corm crop subgroup 1C be revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

In assessing the human health risks associated with the existing and proposed uses of thiamethoxam, EPA has included exposure to thiamethoxam as well as its metabolite CGA–322704 when evaluating exposure from the dietary (food only) pathway. This approach was developed when the Agency received the first food-use request for registration of thiamethoxam and determined that the CGA–322704 metabolite/degradate, as well as the parent compound, are residues of concern in food; no exposure to CGA–322704 in drinking water was considered likely following application of thiamethoxam. At the time, toxicological information regarding CGA–322704 was not available, and it was assumed that thiamethoxam and this metabolite are toxicologically equivalent for estimation of dietary risk. Subsequently, the Agency received a petition requesting registration of the insecticide clothianidin. Upon review of that petition, the Agency discovered that CGA–322704 and clothianidin are identical. With the registration of clothianidin uses, the Agency has largely complete toxicological databases for both thiamethoxam and CGA–322704 (referred to in the remainder of this rule as clothianidin). While some of the toxic effects observed following dosing with the two active ingredients are similar, it is not clear that they are toxicologically equivalent.

To date, the Agency has not formally examined the toxicity data to determine if it is appropriate to separate exposure to the parent compound thiamethoxam

from exposure to thiamethoxam's metabolite clothianidin when assessing the aggregate risk associated with thiamethoxam tolerances. Therefore, EPA has taken the very conservative approach of analzying the non-cancer risk of thiamethoxam by both (1) aggregating exposure to thiamethoxam and its metabolite clothianidin resulting from use of thiamethoxam and clothianidin residues resulting from use of clothianidin as an active ingredient and comparing this aggregate exposure to relevant endpoints for thiamethoxam; and (2) aggregating exposure to clothianidin resulting from thiamethoxam use and from use of clothianidin as an active ingredient and comparing this aggregate exposure to relevant endpoints for clothianidin. EPA has taken the further conservative step of assuming that, in instances where both thiamethoxam and clothianidin are registered for use on a crop, both pesticides will, in fact, be used on that crop. Despite this very conservative approach, thiamethoxam non-cancer risks (taking into account clothianidin exposure) are well below the Agency's level of concern (LOC).

Pending formal reconsideration of toxicological equivalency for thiamethoxam and the clothianidin metabolite, aggregate risks from both thiamethoxam and clothianidin are presented below.

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 the **Federal Register** of September 17, 2003 (68 FR 54386) (FRL–7327–5). The nature of the toxic effects caused by the metabolite clothianidin are discussed in the **Federal Register** of May 30, 2003 (68 FR 32390) (FRL–7306–8).

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 LOC. However, 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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 Table 1 of this unit:

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 LOC 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)

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
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 F^1 generation males.
Oral nondietary (all durations)	NOAEL = 0.6 mg/kg/day	Residential LOC for MOE = 1,000	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.
Dermal (all durations)	Oral study NOAEL = 0.6 mg/kg/day (dermal absorption rate = 27%)	Resdiential LOC for MOE = 1,000	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.
Inhalation (all durations)	Oral study NOAEL = 0.6 mg/kg/day(inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000	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.
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, Q1* (mg/kg/day) ^{2} is 3.77 x 10 ^{2} in human equivalents.		

A summary of the toxicological endpoints for the metabolite clothianidin used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	Developmental NOAEL = 25 mg/kg/day UF = 1,000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Developmental rabbit study Developmental LOAEL = 75 mg/kg/day based on an increased litter incidence of a missing lobe of the lung.
Acute dietary (General population)	NOAEL = 25 mg/kg/day UF = 1,000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Special Neurotoxicity/Pharmacology Study in Mice and Rats LOAEL = 50 mg/kg based on transient signs of decreased spontaneous motor activity, tremors and deep respirations.
Chronic dietary (All populations)	Offspring NOAEL = 9.8 mg/kg/day UF = 1,000 Chronic RfD = 0.0098 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.0098 mg/kg/day	2–Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Incidental Oral (All durations)	NOAEL = 9.8 mg/kg/day	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Dermal (All durations)	Oral study NOAEL = 9.8 mg/kg/day (dermal absorption rate = 1%)	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Inhalation (All durations)	Oral study NOAEL = 9.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

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 clothianidin in or on a variety of raw agricultural commodities. Tolerances for thiamethoxam are established on barley, canola, cotton, sorghum, wheat, imported coffee, pecan, stone fruit, succulent bean, sunflower, 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, sweet corn (kernal and cob with husk removed), milk, and the meat and meat by products of cattle, goats, horses, and sheep. Since clothianidin is a major metabolite of thiamethoxam, residues of clothianidin that would theoretically result from registered and pending uses of clothianidin and residues that would theoretically result from the metabolism of thiamethoxam are included in the analysis. 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. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States 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: EPA conducted the acute dietary exposure analysis based on highly conservative assumptions. The residues of concern for the acute analysis are thiamethoxam and its metabolite clothianidin. The assessment for thiamethoxam 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. The exposure estimate for children 1 to 2 years of age is 0.01099 mg/kg/day, which is equivalent to 11% of the aPAD.

For the metabolite clothianidin, the acute analysis is a conservative assessment that was based on tolerance level residues and the assumption of 100 percent crop treated (PCT) for established and proposed clothianidin uses. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, milk, and pome fruit), the proposed clothianidin tolerances are added to the residues that could result from use of thiamethoxam. 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 population subgroup is infants less than 1 year old, which utilizes 80% of the aPAD.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data 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 clothianidin. The chronic analysis for thiamethoxam was based on anticipated residues in the form of average field trial residue values, and the analysis included 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. The exposure estimate for children 1 to 2 years of age is 0.000103 mg/kg/day, which is equivalent to 17% of the cPAD.

For clothianidin, the chronic analysis is a relatively conservative assessment that was based on tolerance level residues and the assumption of 100% crop treated for established and proposed clothianidin uses, with the exception of anticipated residues (AR) for apples and pears. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, and milk), the

proposed clothianidin tolerances are added to the residues that could result from use of thiamethoxam. For apples and pears, the highest average field trial (HAFT) levels from the residue field trials were added to the residues that could result from use of thiamethoxam. 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 population subgroup is children 1 to 2 years of age, which utilizes 15% of the cPAD.

iii. *Cancer*. The residue of concern for the cancer analysis is thiamethoxam, *per se*. The residues of its metabolite clothianidin 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 PCT estimates. The estimated dietary exposure to the U.S. population is 0.000263 mg/kg/day.

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 pursuant to section 408(f)(1) 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. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of 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 FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:For existing uses, the Agency used estimates of PCT for the chronic exposure assessment which was determined using USDA's National Agricultural Statistics Service (NASS) Usage Data (1999–2003) and EPA Proprietary Usage Data (2001–2003). The chronic PCT estimates that were used for existing uses are shown in Table 3:

TABLE 3.—THIAMETHOXAM ESTIMATES OF CROP TREATED FOR EXISTING USES

Commodity	Percent Crop Treated
Apples	5
Barley	1
Canola	55
Cantaloupes	13
Casabas	44
Cottonseed	20
Crabapples	20
Cucumbers	5
Field corn, grain	6
Fruiting vegetables (except cucurbits - Crop group 8)	15
Honeydew melons	13
Loquats	53
Pears	9
Popcorn	6
Potatoes	41
Pumpkins	44
Quinces	53
Sorghum (including milo)	9
Squash	44
Sunflowers	25
Sweet corn	6
Tuberous and Corm Vegetables - Crop subgroup 1C (except potatoes)	33
Watermelons	13
Wheat	2

For the new uses, the Agency used PCT estimates for the chronic exposure assessment based on usage data and market share projections as follows. Market share projections for the new uses for thiamethoxam were obtained from the registrant and compared to 1999–2003 USDA NASS Usage Data and EPA 2001–2003 Proprietary Usage Data for the historically, most widely used insecticide for control of insect pests for each crop. As a result of this comparison, the highest, most conservative PCT estimate for each crop was used for the chronic exposure assessment. These highly conservative estimates should not underestimate actual usage of thiamethoxam on the new crops/sites. To further support the reliability of these PCT estimates, as a condition of registration, the registrant will be required to agree to report annually on the market share attained for the new uses for which thiamethoxam is registered. As a condition of registration, they will also be required to agree to mitigate dietary risk as deemed appropriate by the Agency should the market share data raise a concern for increased dietary risk. The Agency will then compare that market share information with the PCT estimates used to evaluate potential dietary risk. In those instances where percent market share is approaching or exceeding the predicted PCT estimate used in the Agency's risk assessment, EPA will conduct a new dietary risk assessment to evaluate the new dietary risk. If the market share data raise a concern for increased pesticide risk, the Agency will act to mitigate that dietary risk and could employ several approaches, including but not limited to production caps, geographical limitations, removal of uses, or other means deemed appropriate by the Agency. The chronic PCT estimates that were used for existing uses are shown in Table 4:

TABLE 4.—THIAMETHOXAM ESTIMATES OF CROP TREATED FOR NEW USES

Commodity	Percent Crop Treated
Beans, lima	38
Beans, snap	37
Bushberries	55
Carrots	20
Cranberries	29
Mint	9
Peas, green processed	36
Peas (including dried peas)	44
Soybeans	11
Strawberries	46

The Agency believes that the three conditions listed in this Unit III. 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. 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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCIGROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 E.

Based on the PRZM/EXAMS and SCIGROW models, the EECs of thiamethoxam for acute exposures are estimated to be 11.4 parts per billion (ppb) for surface water and 5 ppb for ground water. The EECs for chronic non-cancer exposures are estimated to be 0.77 ppb for surface water and 1.94 ppb for ground water. The EECs for cancer exposures are estimated to be 0.31 ppb for surface water and 1.94 ppb for ground water.

Clothianidin is not a significant degradate of thiamethoxam in water. Therefore, residues of clothianidin in water were estimated based on applications of clothianidin as an active ingredient. Based on the FIRST and SCIGROW models, the EECs of clothianidin for acute exposures are estimated to be 7.29 parts per billion (ppb) for surface water and 5.84 ppb for ground water. The EECs for chronic exposures are estimated to be 1.35 ppb for surface water and 5.84 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.

Clothianidin is currently registered for use on turfgrasses. Exposures and risk resulting from clothianidin residues on turfgrasses are included in the aggregate risk assessment for clothianidin.

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.''

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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of 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 based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

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 special safety factor to protect infants and children should be 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 and 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 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 the 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 4% of the aPAD for the U.S. population, 2% of the aPAD for females 13 years and older, 10% of the aPAD for infants less than one year old, and 11% 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 and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 5 of this unit:

TABLE 5.—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	4	11.4	5	3,400
All infants (less than one year old)	0.1	10	11.4	5	900
Children 1–2 years old	0.1	11	11.4	5	890
Females 13–49 years old	0.1	2	11.4	5	2,900

Sources of clothianidin residues in food include uses of both thiamethoxam and clothianidin. Toxicological doses and endpoints for clothianidin were used to calculate risk. The acute dietary exposure from food to the metabolite clothianidin will occupy 18% of the aPAD for the U.S. population, 12% of the aPAD for females 13 years and older, 80% of the aPAD for infants less than one year old, and 60% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to clothianidin 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 Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOTHIANIDIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. Population	0.025	18	7.29	5.84	710
All infants (less than one year old)	0.025	80	7.29	5.84	48
Children 1–2 years old	0.025	60	7.29	5.84	92
Females 13–49 years old	0.025	12	7.29	5.84	640

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, 11% of the cPAD for infants less than one 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 and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 7 of this unit:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIAMETHOXAM

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0006	6	0.77	1.94	20
All infants (less than one year old)	0.0006	11	0.77	1.94	5.4
Children 1–2 years old	0.0006	17	0.77	1.94	5
Females 13–49 years old	0.0006	5	0.77	1.94	17

Sources of clothianidin residues in food include uses of both thiamethoxam and clothianidin. Toxicological doses and endpoints for clothianidin were used to calculate risk. Exposure to the metabolite clothianidin from food will utilize 6% of the cPAD for the U.S. population, 13% of the cPAD for infants less than one year old, and 15% of the cPAD for children 1 - 2 years old. Combined residential exposure estimates range from an MOE of 1,300 for combined oral and dermal exposure to toddlers (treated turf + treated soil + dermal) to 8,900 for dermal exposure to adults (application + post-application) adults. In addition, there is potential for chronic dietary exposure to the metabolite clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 8 of this unit:

TABLE 8.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOTHIANIDIN

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0098	6	1.35	5.84	320
All infants (less than one year old)	0.0098	13	1.35	5.84	85
Children 1–2 years old	0.0098	15	1.35	5.84	83
Females 13–49 years old	0.0098	5	1.35	5.84	280
Adults 50+ years old	0.0098	5	1.35	5.84	330

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 LOC.

Short-term aggregate exposures from the metabolite clothianidin result in aggregate MOEs of 5,900 for the general U.S. population, 1,100 for children 1 to 2 years old, and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of clothianidin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in Table 9 of this unit:

TABLE 9.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CLOTHIANIDIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
General U.S. population	5,900	1,000	1.35	5.84	280
Children 1–2 years old	1,100	1,000	1.35	5.84	8.7
Females 13–49 years old	6,200	1,000	1.35	5.84	250

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 LOC.

Intermediate-term aggregate exposures from the metabolite clothianidin result in aggregate MOEs of 5,900 for the general U.S. population, 1,100 for children 1 to 2 years old, and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of clothianidin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC, as shown in Table 10 of this unit:

TABLE 10.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CLOTHIANIDIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
General U.S. population	5,900	1,000	1.35	5.84	280
Children 1–2 years old	1,100	1,000	1.35	5.84	8.7
Females 13–49 years old	6,200	1,000	1.35	5.84	250

5. *Aggregate cancer risk for U.S. population*. In conducting the aggregate cancer risk assessment, only dietary and drinking water pathways of exposure were considered. At this time, there are no uses for thiamethoxam that would result in any non-occupational, non-dietary exposure (i.e., there are no dermal or inhalation routes of exposure that should be included in an aggregate assessment). A DWLOC was derived for the general U.S. population based on EPA's LOC for cancer or a risk in the range of 1 in 1 million. The DWLOC is compared to the estimated environmental concentrations of thiamethoxam in surface and ground water and is used to determine whether or not aggregate cancer exposures are likely to result in risk estimates that exceed EPA's LOC. Table 11 of this unit summarizes the drinking water estimated concentrations of thiamethoxam in surface water and ground water and the associated DWLOC for cancer:

TABLE 11.—AGGREGATE RISK ASSESSMENT FOR CANCER EXPOSURE TO THIAMETHOXAM

Population Subgroup	Maximum Exposure mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure mg/kg/day	Cancer DWLOC ppb	Ground Water EEC ppb	Surface Water EEC ppb
General U.S. population	7.96×10^{-5}	7.96×10^{-5}	7.96×10^{-5}	1.87	1.94	0.31

For cancer, the DWLOC is slightly less than the ground water EEC. However, the cancer DWLOC is based on a conservative estimate of dietary exposure. Available information from actual prospective ground water monitoring data demonstrates that actual thiamethoxam residues in groundwater occur at or below 0.05 ppb. This interim analysis suggests that actual long-term residues of thiamethoxam in ground water will be significantly less than the levels predicted by the SCIGROW model. A significant decrease in the level of thiamethoxam in drinking water results in an aggregate risk estimate that is unlikely to exceed EPA's LOC for cancer. Further, the DWLOC numerical computation was done using a cancer risk figure of 1 in 1 million although EPA has repeatedly found that risk figures marginally higher than 1 in 1 million fall within the range of a 1 in 1 million 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, and to infants and children from aggregate exposure to thiamethoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (aqueous acetonitrile solvent extraction, liquid-liquid partitioning and solid-phase extraction cleanup, and high pressure liquid chromatography/ultraviolet (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 tolerance is 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 legume vegetables group 6 at 0.02 ppm, peppermint and spearmint at 1.5 ppm; root vegetables (except sugar beet) crop subgroup 1B at 0.02 ppm and for radish tops at 0.80 ppm; strawberry at 0.30 ppm; cranberry at 0.02 ppm; bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.20 ppm; rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm; and potato at 0.25 ppm. In addition, the tolerance expression for tuberous and corm crop subgroup 1C is revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 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–2004–0394 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 March 7, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0394, 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 **ADDRESSES**. 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 one 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 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 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 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: December 22, 2004.

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 180.565 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Borage, seed	0.02
* * *	* *
Bushberry, subgroup 13B	0.20
* * *	* *
Crambe, seed	0.02
Cranberry	0.02
Flax, seed	0.02
* * *	* *
Juneberry	0.20
Lingonberry	0.20
* * *	* *
Mustard, seed	0.02
Peppermint	1.5
Potato	0.25
Radish, tops	0.80
Rapeseed, seed	0.02
Safflower, seed	0.02
Salal	0.20
* * *	* *
Spearmint	1.5
Strawberry	0.3
* * *	* *
Vegetable, legume, group 6	0.02
Vegetable, root, except sugar beet, subgroup 1B	0.02

* * * * *

■ 3. Section 180.565 is amended by revising the tolerance expression for Tuberous and Corm Vegetables Crop Subgroup in the table in paragraph (a) to

read Vegetable, tuberous and corm, except potato, subgroup 1D.

* * * * *

[FR Doc. 05–89 Filed 1–4–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96–128; FCC 04–251]

The Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration.

SUMMARY: By this document, we consider four petitions for reconsideration of our *Report and Order* which established detailed rules (the ''rules'' or ''Payphone Compensation Rules'') ensuring that payphone service providers (PSPs) are ''fairly compensated'' for each and every completed payphone-originated call. This *Order on Reconsideration* does not change the compensation framework adopted last year, but rather refines and builds upon its approach. The Commission provides guidance on the types of contracts that it would deem to be reasonable methods of compensating PSPs, extends the time period that carriers must retain certain payphone records, and clarifies the rules' reporting, certification, and audit requirements.

DATES: Effective January 5, 2005, except for § 64.1310(g) which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date of that section.

ADDRESSES: A copy of any comments on the Paperwork Reduction Act information collection requirements contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Darryl Cooper Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–7131, or via the Internet at *darryl.cooper@fcc.gov* or Denise A. Coca, Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0574, or via the Internet at *denise.coca@fcc.gov.* For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Judith B. Herman at 202–418–0214, or via the Internet to *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order on Reconsideration*, CC Docket No. 96–128, FCC 04–251, adopted October 20, 2004, and released October 22, 2004. Filings and comments are also available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. They may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1 (800) 378–3160 or (202) 4880–5300, facsimile (202) 488–5563, or via e-mail at *http://www.bcpiweb.com.*

Synopsis of the Order on Reconsideration and the Report and Order

I. Introduction

1. In this *Order on Reconsideration*, we consider four petitions for reconsideration of our *Report and Order* adopted on September 30, 2003, which established detailed rules ensuring that PSPs are ''fairly compensated'' for each and every completed payphone-originated call (Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96–128, *Report and Order*, 68 FR 62751–01, (November 6, 2003)). This *Order on Reconsideration*, released on October 22, 2004, does not change this compensation framework, but rather refines and builds upon its approach. In the *Order on Reconsideration*, the Commission provides guidance on the types of contracts that it would deem to be reasonable methods of compensating PSPs, extends the time period that carriers must retain certain payphone records, and clarifies the rules' reporting, certification, and audit requirements.

II. Background

2. The *Report and Order* held that the last facilities-based long distance carrier in a call path—either an interexchange carrier (IXC) or a switched-based reseller (SBR)—is responsible for compensating PSPs. For local calls, where a local exchange carrier (LEC) completes a call, that LEC is responsible for compensation. The Payphone Compensation Rules define these responsible carriers as ''Completing Carriers'' and require them to develop their own system of tracking calls to completion, the accuracy of which must be confirmed and attested to by a third party auditor. Completing Carriers are required to compensate the PSPs on a quarterly basis for calls that are completed on the Competing Carriers' platforms; to provide quarterly reports to the PSPs; and their chief financial officers (CFOs) must attest to the accuracy of the quarterly payment amount. The Payphone Compensation Rules also imposed reporting requirements on an ''Intermediate Carrier,'' defined in the rules as ''a facilities-based long distance carrier that switches payphone calls to other facilities-based long distance carriers.'' Additionally, the Payphone Compensation Rules also give parties flexibility to agree to alternative compensation arrangements (ACA) so that small Completing Carriers may avoid the expense of instituting a tracking system and undergoing an audit.

III. Discussion

3. In the *Order on Reconsideration*, the Commission considers four petitions for reconsideration filed in response to the *Report and Order* in this docket. The *Order on Reconsideration* clarifies and modifies the *Report and Order* by adopting the following changes: (1) Clarifying that a Completing Carrier must give a PSP adequate notice of an ACA prior to its effective date, with sufficient time for the PSP to object to an ACA, and prior to the termination of an ACA; (2) clarifying that, in a complaint proceeding under the Payphone Compensation Rules, a Completing Carrier may assert as an affirmative defense that the PSP's objection to an ACA was unreasonable; (3) clarifying that Completing Carriers are required to report only completed calls in their quarterly reports; (4) extending the time period that carriers must retain certain payphone records, for dispute resolution purposes, from 18 to 27 months; (5) clarifying that quarterly reports should use industry standard formats; (6) clarifying the responsibilities of LECs under the Payphone Compensation Rules; (7) clarifying that a Completing Carrier may post its System Audit Report and § 64.1320(e) statement on its website or on a clearinghouse's website, instead of transmitting these documents to every PSP; (8) clarifying that a Completing Carrier's CFO may issue a single blanket