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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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 13, 2000.

James Jones,

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.

§ 180.425 [Amended]

2. Section 180.425 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

(a)* * *

Commodity	Parts per million
* * *	* *
Rice, grain	0.02
Rice, straw	0.02
* * *	* *

* * * * *

[FR Doc. 00–32571 Filed 12–20–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301087; FRL–6758–1]

RIN 2070–AB78

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite in or on barley, canola, cotton, sorghum, wheat, milk, and the meat and meat byproducts of cattle, goats, hogs, horses, and sheep. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 21, 2000. Objections and requests hearings, identified by docket control number OPP–301087, must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301087 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301087. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 5, 1999 (64 FR 24153) (FRL–6072–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (9F5046 and 9F5051) for tolerance by Novartis Crop Protection, P. O. Box 18300 Greensboro, NC 27419–8300. This notice included a summary of the petition prepared by Novartis Crop Protection, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for the combined residues of the insecticide thiamethoxam, ([3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine) and its CGA-322704 metabolite (*N*-(2-chloro-thiazol-5-ylmethyl)--*N*′-methyl*N*′-nitro-guanidine) in or on the raw agricultural commodity rapeseed (canola), tuberous and corm vegetables crop subgroup, barley grain, sorghum grain, sorghum forage, sorghum stover, wheat grain, wheat hay, wheat straw, and milk at 0.02 ppm; barley straw at 0.03 ppm; barley hay at 0.05 ppm; undelinted cottonseed at 0.10 ppm; cucurbit vegetables crop group, and pome fruit crop group at 0.20 ppm; fruiting vegetables crop group at 0.25 ppm; wheat forage at 0.50 ppm; tomato paste at 0.80 ppm; head and stem Brassica vegetables crop subgroup at 1.00 ppm; cotton gin byproducts at 1.50 ppm; leafy vegetables crop group, and leafy Brassica greens crop subgroup at 2.00 parts per million (ppm). In addition, meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm.

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) 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) 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 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), 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), for tolerances for the combined residues of thiamethoxam and its metabolite in or on barley grain at 0.02 ppm; barley hay at 0.05 ppm; barley straw at 0.03 ppm; undelinted cottonseed at 0.10 ppm; cotton gin byproducts at 1.5 ppm; sorghum forage at 0.02 ppm; sorghum grain at 0.02 ppm; sorghum stover at 0.02 ppm; wheat forage at 0.50 ppm; wheat grain at 0.02 ppm; wheat hay at 0.02 ppm; wheat straw at 0.02 ppm; milk at 0.02 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm respectively. EPA's assessment of exposures and risks associated with establishing the tolerance 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 are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity - rat	NOAEL = 1.74 (males), 92.5 (females) mg/kg/day LOAEL = 17.64 (males), 182.1 (females) mg/kg/day based on increased incidence of hyaline change of renal tubular epithelium (males), fatty change in adrenal gland of females, liver changes in females, all at the LOAEL.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity - mouse	NOAEL = 1.41 (males), 19.2 (females) mg/kg/day LOAEL = 14.3 (males), 231 (females) mg/kg/day based on increased incidence of hepatocellular hypertrophy. At higher dose levels: decrease in body weight and body weight gain, necrosis of individual hepatocytes, pigmentation of Kupffer cells, and lymphocytic infiltration of the liver in both sexes; slight hematologic effects and decreased absolute and relative kidney weights in males; and ovarian atrophy, decreased ovary and spleen weights, and increased liver weights in females.
870.3150	90–Day oral toxicity - dog	NOAEL = 8.23 (males), 9.27 (females) mg/kg/day LOAEL = 32.0 (males), 33.9 (females) mg/kg/day based on slightly prolonged prothrombin times and decreased plasma albumin and A/G ratio (both sexes); decreased calcium levels and ovary weights and delayed maturation in the ovaries (females); decreased cholesterol and phospholipid levels, testis weights, spermatogenesis, and occurrence of spermatic giant cells in testes (males).
870.3200	28–Day dermal toxicity - rat	NOAEL = 250 (males), 60 (females) mg/kg/day LOAEL = 1,000 (males), 250 (females) mg/kg/day based on increased plasma glucose, triglyceride levels, and alkaline phosphatase activity and inflammatory cell infiltration in the liver and necrosis of single hepatocytes in females and hyaline change in renal tubules and a very slight reduction in body weight in males. At higher dose levels in females, chronic tubular lesions in the kidneys and inflammatory cell infiltration in the adrenal cortex were observed.
870.3700a	Prenatal developmental - rat	Maternal NOAEL = 30 mg/kg/day LOAEL = 200 mg/kg/day based on decreased body weight, body weight gain, and food consumption. Developmental NOAEL = 200 mg/kg/day LOAEL = 750 mg/kg/day based on decreased fetal body weight and an increased incidence of skeletal anomalies.
870.3700b	Prenatal developmental - rabbit	Maternal NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on maternal deaths, hemorrhagic uterine contents and hemorrhagic discharge, decreased body weight and food intake during the dosing period. Developmental NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on decreased fetal body weights, increased incidence of post-implantation loss and a slight increase in the incidence of a few skeletal anomalies/variations.
870.3800	Reproduction and fertility effects - rat	Parental/Systemic NOAEL = 1.84 (males), 202.06 (females) mg/kg/day LOAEL = 61.25 (males), not determined (females) mg/kg/day based on increased incidence of hyaline change in renal tubules in F_0 and F_1 males.Reproductive NOAEL = 0.61 (males), 202.06 (females) mg/kg/day LOAEL = 1.84 (males), not determined (females) mg/kg/day based on increased incidence and severity of tubular atrophy observed in testes of the F_1 generation males. Offspring NOAEL = 61.25 (males), 79.20 (females) mg/kg/day LOAEL = 158.32 (males), 202.06 (females) mg/kg/day based on reduced body weight gain during the lactation period in all litters .
870.4100	Chronic toxicity - dog	NOAEL = 4.05 (males), 4.49 (females) mg/kg/day LOAEL = 21.0 (males), 24.6 (females) mg/kg/day based on increase in creatinine in both sexes, transient decrease in food consumption in females, and occasional increase in urea levels, decrease in ALT, and atrophy of seminiferous tubules in males.
870.4200	Carcinogenicity - mouse	NOAEL = 2.63 (males), 3.68 (females) mg/kg/day LOAEL = 63.8 (males), 87.6 (females) mg/kg/day based on hepatocyte hypertrophy, single cell necrosis, inflammatory cell infiltration, pigment deposition, foci of cellular alteration, hyperplasia of Kupffer cells and increased mitotic activity; also, an increase in the incidence of hepatocellular adenoma (both sexes). At higher doses, there was an increase in the incidence of hepatocellular adenocarcinoma (both sexes) and the number of animals with multiple tumors. Evidence of carcinogenicity.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4300	Combined chronic carcinogenicity - rat	NOAEL = 21.0 (males), 50.3 (females) mg/kg/day LOAEL = 63.0 (males), 155 (females) mg/kg/day based on increased incidence of lymphocytic infiltration of the renal pelvis and chronic nephropathy in males and decreased body weight gain, slight increase in the severity of hemosiderosis of the spleen, foci of cellular alteration in liver and chronic tubular lesions in kidney in females. No evidence of carcinogenicity.
870.5100 870.5265	Gene mutation in *S. typhimurium* and *E. coli*	No evidence of gene mutation when tested up to 5,000 μg/plate. There was no evidence of cytotoxicity.
870.5265	Gene mutation in *S. typhimurium*	No evidence of gene mutation when tested up to 5,000 μg/plate. The S9 fraction was from non-induced mouse liver, Aroclor 1,254 induced mouse liver, or thiamethoxam induced mouse liver, following dietary administration of thiamethoxam for 14 days at concentrations up to 2,500 ppm.
870.5300	Gene mutation in chinese hamster V79 cells at HGPRT locus	No evidence of gene mutation when tested up to solubility limit.
870.5375	CHO cell cytogenetics	No evidence of chromosomal aberrations when tested up to cytotoxic or solubility limit concentrations.
870.5395	In vivo mouse bone marrow micronucleus	Negative when tested up to levels of toxicity in whole animals; however no evidence of target cell cytotoxicity.
870. 5550	UDS assay	Negative when tested up to precipitating concentrations.
870.6200a	Acute neurotoxicity screening battery - rat	NOAEL = 100 mg/kg/day LOAEL = 500 mg/kg/day based on drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength (males only). At higher dose levels, mortality, abnormal body tone, ptosis, impaired respiration, tremors, longer latency to first step in the open field, crouched-over posture, gait impairment, hypoarousal, decreased number of rears, uncoordinated landing during the righting reflex test, slight lacrimation (females only) and higher mean average input stimulus value in the auditory startle response test (males only).
870.6200b	Subchronic neurotoxicity screening battery - rat	NOAEL = 95.4 (males), 216.4 (females) mg/kg/day, both highest dose tested. LOAEL = not determined. No treatment-related observations at any dose level. LOAEL was not achieved. May not have been tested at sufficiently high dose levels; however, new study not required because the weight of the evidence from the other toxicity studies indicates no evidence of concern.
870.7485	Metabolism and pharmacokinetics - rat	Absorbed rapidly and extensively, widely distributed, followed by very rapid elimination, mostly in urine. Highest tissue concentrations in skeletal muscle: 10–15% of administered dose. Half life times from tissues ranged from 2–6 hours. Tissue residues after 7 days extremely low. Approximately 84–95% of administered dose excreted in urine and 2.5–6% excreted in feces within 24 hours. <0.2% detected in expired air. Most excreted as unchanged parent: 70–80% of dose. The major biotransformation reaction is cleavage of oxadiazine ring to corresponding nitroguanidine compound. Minor pathways: (1) cleavage of nitroguanidine group yielding guanidine derivative, (2) hydrolysis of guanidine group to corresponding urea, (3) demethylation of guanidine group, and (4) substitution of the chlorine of the thiazole ring by glutathione. Cleavage between thiazole- and oxadiazine ring occurs to a small extent. Glutathione derivatives prone to further degradation of the glutathione moiety resulting in various sulfur-containing metabolites (e.g. mercapturates, sulfides, and sulfoxides). Both the thiazole and oxadiazine moiety susceptible to oxidative attack. Small but measurable amounts exhaled, most probably as CO_2. Metabolites eliminated very rapidly. Enterohepatic circulation negligible.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics - mouse	Approximately 72% of administered dose excreted in the urine; 19% excreted in feces. Small but measurable amount detected in expired air (approximately 0.2% of dose). Predominant metabolites: unchanged parent (33–41% of administered dose; 2 other metabolites: 8–12% and 9–18% of administered dose. These are the same structures that were most commonly observed in rat excreta, however the proportions are quite different in mouse excreta. One additional significant metabolite (mouse R6) was isolated from feces samples. Between 30–60% of the administered dose was excreted as metabolites.
870.7600	Dermal penetration - rat	Estimates of dermal absorption were based on the sum of radioactivity in skin test site, urine, feces, blood, and carcass. Percentage dermal absorption is 27.0, highest mean dermal absorption value across all groups. This value is considered to represent the potential cumulative dermal absorption of test material that might occur after a 10 hour dermal exposure. As the study design did not permit analysis of the fate of skin bound residues, residues at skin site were included in determination of dermal absorption.
	Hepatic cell proliferation study - mouse	NOAEL = 16 (males), 20 (females) mg/kg/day LOAEL = 72 (males), 87 (females) mg/kg/day based on proliferative activity of hepatocytes. At higher dose levels, increases in absolute and relative liver wts, speckled liver, hepatocellular glycogenesis/fatty change, hepatocellular necrosis, apoptosis and pigmentation were observed.
	Replicative DNA synthesis in 28– day feeding study - male rat	NOAEL = 711 mg/kg/day (highest dose tested) LOAEL = not established. Immunohistochemical staining o liver sections from control and high-dose animals for proliferating cell nuclear antigen gave no indication for a treatment-related increase in the fraction of DNA synthesizing hepatocytes in S-phase. CGA 293343 did not stimulate hepatocyte cell proliferation in male rats.
	Special study to assess liver biochemistry in mouse	NOAEL = 17 (males), 20 (females) mg/kg/day LOAEL = 74 (males), 92 (females) mg/kg/day based on marginal to slight increases in absolute and relative liver weights, a slight increase in the microsomal protein content of the livers, moderate increases in the cytochrome P450 content, slight to moderate increases in the activity of several microsomal enzymes, slight to moderate induction of cytosolic glutathione S-transferase activity. Treatment did not affect peroxisomal fatty acid Beta-oxidation.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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 lowest dose at which adverse effects of concern are identified (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 (acute RfD or chronic RfD) 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 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 is expressed as 1×10^{-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 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES 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	FQPASF = 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	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 F_1 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 F_1 generation males.
Inhalation (all durations) (Residential)	Oralstudy NOAEL= 0.6 mg/kg/day (inhalationabsorption 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 F_1 generation males.
Cancer (oral, dermal, inhalation)	Q_1* (mg/kg/day)$^{-1}$ is 3.77 x 10^{-2}	greater than 1 x 10^{-6}	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 Safety Factor re fers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The dietary exposure is based on the combined residues of thiamethoxam and its metabolite in or on the following raw agricultural commodities: barley, canola, cotton, sorghum, wheat, milk, and the meat and meat byproducts of cattle, goats, hogs, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam and its metabolite 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM)

analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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: tolerence level residues and 100% crop treated.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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 chronic exposure assessments: percent crop treated (based on projected market shares) and anticipated residues (Tier 3).

iii. *Cancer*. The dietary exposure for determining cancer risk is based on the chronic exposure explained in the previous paragraph using the same assumptions.

Section 408(b)(2)(E) 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), 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) 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows in Table 3.

TABLE 3.—THIAMETHOXAM USES AND ESTIMATES OF PERCENT CROP TREATED

Crop	Percent Crop Treated
Barley	1.0
Wheat	2
Canola	55
Sorghum	9
Cotton	20

The Agency used information provided by the registrant and Agency to determine percent crop treated based on projected percent market share information. The Agency believes that the procedures used were the best available, because thiamethoxam is a new chemical and has never been used. 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 regional populations.

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/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. 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 below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of thiamethoxam for acute exposures are estimated to be 8.0 parts per billion (ppb) for surface water and 5.0 ppb for ground water. The EECs for chronic exposures are estimated to be 0.6 ppb for surface water and 5.0 ppb for ground water. These levels are extremely conservative, because they are based on foliar and seed treatment uses. These levels are anticipated to be much lower based on the seed treatment use alone.

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 exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. FFDCA section 408 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. There is not 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. The reproductive studies indicate effects in males 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.

iii. *Conclusion*. Base on: (1) Effects endocrine organs observed across species (2) the significant decrease in alanine amino transferadse levels in the companion animal studies and in the dog studies (3) the mode of action of this chemical in insects (interferes with the nicotinic acetyl choline receptors of the insect's nervous system) thus a developmental neurotoxicity study is required); (4) the transient clinical signs of neurotoxicity in several studies across the species; and (5) the suggestive evidence of increased quantitative susceptibility in the rat reproduction study, the Agency is retaining the FQPA factor which is 10X.

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 the USEPA Office of Water are used to calculate DWLOCs: 2L/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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 1% of the aPAD for the U.S. population, <1 of the aPAD for females 13 years and older, 1% of the aPAD for all infants <1 year and 2% of the aPAD for children 1–6 years. In addition, there is potential for acute dietary exposure to thiamethoxam in drinking water. The surface water EEC is 8.0 µg/L and the ground water EEC is 5.0 µg/L. The estimated EEC levels are very conservative, because they are based on both foliar uses and seed treatment applications. Since the surface water value is greater than the ground water value, the surface water value will be used for comparison purposes and will protect for any concerns for ground water concentrations. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM

Population Subgroup[a]	aPAD (mg/kg)	%aPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Acute DWLOC (ppb)[b]
U.S. General Population	0.1	1	8	5	3500

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM—Continued

Population Subgroup[a]	aPAD (mg/kg)	%aPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Acute DWLOC (ppb)[b]
All infants (<1 year)	0.1	1	8	5	990
Children (1–6 years)	0.1	2	8	5	980
Children (7–12 years)	0.1	1	8	5	990
Females (13–50 years)	0.1	<1	8	5	3000

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 <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year and 1% of the cPAD for children 1–6 years. Proposed residential uses are not being addressed in this risk assessment. In addition to chronic dietary exposure, there is potential for chronic dietary exposure to thiamethoxam in drinking water. The surface water EEC is 0.6 µg/L and the ground water EEC is 5.0 µg/L. The estimated EEC levels are very conservative, because they are based on both foliar uses and seed treatment applications. Since the ground water value is greater than the surface water value, the ground water value will be used for comparison purposes and will protect for any concerns for surface water concentrations. After calculating the DWLOCs and comparing them to the EECs for ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD as shown in the following Table 5.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIAMETHOXAM

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0006	5	0.6	5	21
All infants (<1 year)	0.0006	13	0.6	5	6
Children (1–6 years)	0.0006	13	0.6	5	6
Children (7–12 years)	0.0006	7	0.6	5	6
Females (13–50 years)	0.0006	3	0.6	5	18

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 cancer risk estimate associated with the use of thiamethoxam as a seed treatment on barley, canola, cotton, sorghum and wheat is 4.1×10^{-8} for the U.S. population based on an exposure estimate of 0.000001 mg/kg/day. The above cancer risk estimates show that the cancer risk is negiligible. Based on modeling estimates, exposure through drinking water will not significantly increase the dietary risk in food.

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 (HPLC/UV or MS) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no international residue limits for thiamethoxam.

C. Conditions

Developmental neurotoxicity (Guideline #870.6300) and soil residue dissipation (Guideline #875.2200) studies are required as conditions of registration.

V. Conclusion

Therefore, the tolerance is established for combined residues of thiamethoxam ([3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine) and its metabolite (*N*-(2-chloro-thiazol-5-ylmethyl)-*N*′-methyl-*N*′-nitro-guanidine) in or on barley grain at 0.02 ppm; barley hay at 0.05 ppm; barley straw at 0.03 ppm; undelinted cottonseed at 0.10

ppm; cotton gin byproducts at 1.5 ppm; sorghum forage at 0.02 ppm; sorghum grain at 0.02 ppm; sorghum stover at 0.02 ppm; wheat forage at 0.50 ppm; wheat grain at 0.02 ppm; wheat hay at 0.02 ppm; wheat straw at 0.02 ppm; milk at 0.02 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm respectively.

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. 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301087 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 February 20, 2001.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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.

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.

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.2. Mail your copies, identified by docket control number OPP–301087, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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 1, 2000.

Joseph J. Merenda,

Acting 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), (346a) and 371.

2. Section 180.565 is amended by adding text to paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerance for residues.

(a) *General.* A tolerance is established for the combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine] (CAS Reg. No. 153719–23–4) and its metabolite [*N*-(2-chloro-thiazol-5-ylmethyl)-*N*′-methyl-*N*′-nitro-guanidine] in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.02
Barley, hay	0.05
Barley, straw	0.03
Canola, seed	0.02
Cattle, mbyp	0.02
Cattle, meat	0.02
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.10
Goat, mbyp	0.02
Goat, meat	0.02
Hog, mbyp	0.02
Hog meat	0.02
Horse, mbyp	0.02
Horse, meat	0.02
Milk	0.02
Sheep, mbyp	0.02
Sheep, meat	0.02
Sorghum, forage	0.02
Sorghum, grain	0.02
Sorghum, stover	0.02
Wheat, forage	0.50
Wheat, grain	0.02
Wheat, hay	0.02
Wheat, straw	0.02

* * * * *

[FR Doc. 00–32570 Filed 12–20–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301082; FRL–6755–9]

RIN 2070–78AB

Avermectin B1; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of avermectin B_1 and its delta-8,9-isomer in or on celeriac (roots and tops) at 0.05 parts per million (ppm). The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 21, 2000. Objections and requests for hearings, identified by docket control number OPP–301082, must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI.. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301082 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing