Commodity	Parts per million
Almond, hulls	15
* * * * *	
Nut, tree, group 14	0.20
Okra	2.0
* * * * *	
Peppermint, tops	25
Pistachio	0.20
* * * * *	
Spearmint, tops	25
* * * * *	
Vegetable, cucurbit, group 9.	0.75
Vegetable, fruiting, group 8.	2.0

(2) Tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate); diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in or on the following food commodities:

Commodity	Parts per million
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

* * * * *

[FR Doc. 03–24370 Filed 9–25–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0304]; FRL–7325–8]

Thiacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiacloprid ([3-[(6-chloro-3-pridinyl)methyl]-2-thiazolidinylidene]cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on apple, wet pomace; cotton, undelinted seed; cotton, gin by-products; fruit, pome group 11; fat, meat, liver, kidney and meat by-products of cattle, sheep, goat and horse; and milk. Bayer CropScience requested these tolerances 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0304], must be received on or before November 25, 2003.

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

FOR FURTHER INFORMATION CONTACT: Marilyn Mautz, Registration Division, 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703 305–6785; e-mail address: *mautz.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0304. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_(_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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

facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 7, 2003 (68 FR 24458) (FRL–7303–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 9F6060) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide, thiacloprid, in or on apple, wet pomace; cattle, meat and meat byproducts; cotton, gin byproducts; cotton, undelinted seed; fruit, pome, group 11; and milk at 0.6; 0.2; 11.0; 1.0; 0.3; and 0.1 parts per million (ppm), respectively. Upon review and evaluation of the data submitted in support of the petition, the Agency determined that the residues of concern are thiacloprid plus metabolites retaining the thiazolidine ring intact. Excluded from the residues of concern are metabolites such as 6-nicotinic acid (6-CNA) for which the thiazolidine ring is broken. These metabolites are excluded based on the finding that the toxic effects of thiacloprid are considered to be associated with the entire thiacloprid molecule (with both the thiazolidine ring and the chloropyridine ring intact). Because metabolism and degradation studies have shown that the thiazolidine ring is less stable than the chloropyridine ring, it is understood that metabolites retaining the thiazolidine ring also retain the chloropyridine ring intact. Metabolites retaining the thiazolidine ring generally constitute most of the residue in foods and feeds. The petition was subsequently revised to:

1. Request that 40 CFR part 180 be amended by establishing tolerances for the insecticide thiacloprid in or on the commodities: Meat, meat byproducts, liver, fat, and kidney of sheep, goat and horse; liver; fat and kidney of cattle; and

2. Lowering the previously proposed tolerance levels for the food commodities, cattle, meat from 0.2 ppm to 0.03 ppm; cattle, meat byproducts from 0.2 ppm to 0.05 ppm; cotton, undelinted seed from 1.0 ppm to 0.02 ppm and milk from 0.1 ppm to 0.03 ppm based on measurement of thiacloprid per se rather than measurement of the common moiety, 6-nicotinic acid (6-CNA) upon which the original proposed tolerances were based; as summarized in Table 1 of this unit.

TABLE 1—PROPOSED TOLERANCE LEVELS FOR FOOD COMMODITIES.

Commodity	Original, Measured as 6-CNA (ppm)	Revised, Measured as Thiacloprid (ppm)
Apple, wet pomace	0.6	0.6
Cattle, meat	0.2	0.03
Cattle, meat byproducts	0.2	0.05
Cotton, gin byproducts	11.0	11.0
Cotton, undelinted seed	1.0	0.02
Cattle, sheep, goat and horse fat		0.02
Cattle, sheep, goat and horse kidney		0.05
Cattle, sheep, goat and horse liver		0.15
Fruit, pome, group 11	0.3	0.3
Milk	0.1	0.03
Sheep, goat and horse meat		0.03
Sheep, goat and horse meat byproducts		0.05

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (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 the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for combined residues of thiacloprid and metabolites

retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se* on apple, wet pomace; cattle, sheep, goat and horse meat; meat byproducts; liver; kidney; and fat; cotton, undelinted seed; cotton, gin byproducts; fruit, pome, group 11; and milk at 0.6; 0.03; 0.05; 0.15; 0.05; 0.02; 0.02; 11.0; 0.3; and 0.03 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 thiacloprid are discussed in Table 2 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = rats: males, 7.3 mg/kg/day ; females, 7.6 mg/kg/day; mice, females, 27.3 mg/kg/day ; males 102.6 milligram/kilogram/day (mg/kg/day) LOAEL = rats: males,28.6 mg/kg/day; females, 35.6 mg/kg/day; mice: females, 27.2 mg/kg/day; males, 542.4 mg/kg/day based on rats: decreased body weight throughout treatment: mice: females based on adrenal X-zone changes. males based on liver effects (weight and hypertrophy).
870.3150	90-Day oral toxicity in nonrodents	NOAEL = males. 8.5, females, 8.9 mg/kg/day LOAEL = ~34.9 mg/kg/day based on mainly liver enzyme changes, thyroid hormone level (T4) and binding capacity changes and prostatic weight change and prostatic hypertrophy.
870.3200	21/28-Day dermal toxicity	NOAEL = females, 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on liver and thyroid effects and clinical signs.
870.3465	28 Day inhalation toxicity	NOAEL = 0.542 mg/kg/day LOAEL = 4.93 mg/kg/day based on [liver effects (hypertrophy and increased N-DEM).
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on decreased body weights, body weight gains, food consumption, increased urination, and changes in water consumption. Developmental NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on increased resorptions (complete and late), skeletal retardations, variations (wavy ribs and asymmetrical sternebrae), and malformations (dysplastic humerus, radius, and scapulae) and on decreased fetal weights
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on decreased body weight gains, food consumption, and fecal output. Developmental NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on decreased fetal weights
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = males, 3.5 mg/kg/day LOAEL = 21 mg/kg/day based on increased liver and thyroid weights and on hepatocytomegaly, liver necrosis, and thyroid follicular cell hypertrophy. Reproductive NOAEL = females, 4 .2 mg/kg/day LOAEL = 26 mg/kg/day based on dystocia Offspring NOAEL = females, 4.2 mg/kg/day LOAEL = females, 21 mg/kg/day based on decreased pup weight during lactation.
870.4100	Chronic toxicity dogs	No firm LOAEL was established for this chronic feeding study with dogs; 1,000 ppm highest dose tested (HDT). There were no effects that were of sufficient magnitude or consistency to justify that they were definite responses to treatment. Certain effects noted in the subchronic dog study on the prostate and other male organs and an apparent effect on uterine weight in the subchronic dog study were not seen in this chronic study. This may be because the dogs in this study had reached maturity
870.4300	Combined chronic feeding/cacinogenicity rats	NOAEL = males, 1.2 mg/kg/day ; females, 1.6 mg/kg/day LOAEL = males, 2.5 mg/kg/day; females, 3.3 mg/kg/day based on [liver toxicity (hepatocellular hypertrophy and cytoplasmic change and increased enzyme activity), thyroid follicular epithelial hypertrophy in males and oculotoxicity (retinal atrophy) in females Evidence of carcinogenicity based on increased incidence of thyroid follicular cell adenomas in males and possibly also in females and increased incidence of uterine tumors (adenocarcinomas)

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4200	Carcinogenicity mice	NOAEL = males,5.7 mg/kg/day; females: 10.9 mg/kg/day LOAEL = males, 234.1mg/kg/day; females, 475.3 mg/kg/day based on liver toxicity and microscopic lymph node changes in both sexes and increased X-zone vacuolization of the adrenal glands in female mice Evidence of carcinogenicity based on increased incidence of ovarian luteomas
870.5100	Gene Mutation	Negative in a battery of tests
870.5300	Gene Mutation	Negative in a battery of tests
870.5375	Cytogenetics	Negative in battery of tests
870.5395	Cytogenetics	Negative in battery of tests
870.5500	Cytogenetics	Negative in battery of tests
870.5550	Other Effects	Negative
870.6200	Acute neurotoxicity screening battery	NOAEL = males, 11 mg/kg bodyweight (bw); females, 3.1 mg/kg/day LOAEL = males, 22 mg/kg bw; females, 11 mg/kg/day In females, based on reductions in motor and locomotor activity.; in males, (based on FOB observations of slight tremors and ptosis of the eyelids on the day of treatment)
870.6200	Subchronic neurotoxicity screening battery	NOAEL = males , 24.2 mg/kg/day; females, 27.9 mg/kg/day LOAEL = males, 101 mg/kg/day; females, 115 mg/kg/day based on decreased body weight gains and food consumption in both sexes and decreased hindlimb grip strength in males.
870.6300	Developmental neurotoxicity	Maternal NOAEL = 4.4 mg/kg/day LOAEL = 25.6 mg/kg/day based on decreased body weight gain and food consumption during early gestation (gestation day (GD) 0-6. Offspring NOAEL = Tentative Offspring , 4.4 mg/kg/day LOAEL = Tentative Offspring, 25.6 mg/kg/day based on decreased pre-weaning and post-weaning body weights in both sexes and delayed sexual maturation in the males, and altered performance in passive avoidance testing.
870.7485	Metabolism and pharmacokinetics	Thiacloprid is rapidly absorbed and is rapidly excreted after the following metabolic processes, with little remaining in the tissues. The metabolic processes were summarized as: 1. Hyroxylation of the thiazolidine ring and subsequent glucuronidation (as shown by metabolite PIZ 1270), 2. Hydroxylation of the cyanamide moiety (metabolite KNO 1891), 3. Opening of the thiazolidine ring (e.g., metabolites KNO2672, PIZ1297F/WAK 6935), 4. Formation of an oxazole ring (metabolite PIZ 1253), 5. Oxidation and subsequent methylation of the thiazolidine ring (e.g., PIZ 1297E and PIZ 1269X), and 6. Oxidative cleavage of the methylene bridge (PIZ 1243). Only minor gender-related quantitative differences in metabolite profiles were observed.
870.7600	Dermal penetration	A 5% dermal absorption value is appropriate for estimating the risk resulting from dermal exposure to Thiacloprid formulated as a 40.4% liquid formulation (SC 480). This 5% value is also appropriate for other liquid thiacloprid formulations that are similar to the SC 480 liquid formulation product tested and for aqueous dilutions of most thiacloprid formulations.

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 intra species differences. As explained in Unit III.D.3., EPA determined that the FQPA SF be reduced to 3X.

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 factors (SF) 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 SF.

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 thiacloprid used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIACLOPRID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All population groups)	NOAEL = 3.1 mg/kg UF = 300* Acute RfD = 0.01 mg/kg.	Special FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.01 mg/kg	Acute Neurotoxicity - rats LOAEL = 11 mg/kg/day based on decreased motor activity in females.
Chronic Dietary (All populations)	NOAEL= 1.2 mg/kg/day UF = 300* Chronic RfD = 0.004 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.004 mg/kg/day	Chronic feeding in rats. LOAEL = 2.5 mg/kg/day based on hepatic hypertrophy and cytoplasmic change and thyroid hypertrophy and retinal degeneration.
Cancer (Oral, dermal, inhalation)	Q_1* $(mg/kg/day)^{-1}$ = 4.06×10^{-2}	Classified as a likely human carcinogen based on thyroid tumors and uterine tumors in rats and ovary tumors in mice	

UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. There are no tolerances established for residues of thiacloprid. Risk assessments were conducted by EPA to assess dietary exposures from thiacloprid 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 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: A moderately refined, Tier 3 acute dietary exposure assessment, which incorporated field trial data, estimates of % market share, and empirical processing factors, was conducted for the general U.S. population and various population subgroups. Monitoring data are not available for thiacloprid as it is a new chemical. EPA estimated exposure at the 99.9th exposure percentile.

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 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 chronic exposure assessments: A partially refined, Tier 3 chronic dietary exposure assessment, which incorporated field trial data, empirical processing factors, and projected percent crop treated estimates, was conducted for the general U.S. population and various population subgroups. Monitoring data are not available for thiacloprid as it is a new chemical.

iii. *Cancer*. A cancer assessment was performed using the same assumptions as the chronic assessment in Unit III.C.1. ii. The cancer dietary exposure estimate for the general U.S. population is 1.3×10^{-6}.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information for both the acute and chronic dietary risk assessment as follows:

A routine acute and chronic dietary exposure analysis for thiacloprid was based on 61% of apple crop treated, 51% of pear crop treated and 1% of cotton crop treated.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described in the preceding paragraph for thiacloprid used on these crops is reliable and has a valid basis. The PCT estimates are based on use of existing alternate insecticides against insects that thiacloprid will control. As per Agency practice, the PCT estimates are what the Agency expects to be likely upper bound market penetrations for various crop/pest niches. Maximal percent crop treated estimates were projected for apples, pears, and cotton. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which thiacloprid 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 thiacloprid 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 thiacloprid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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.

The Tier II screening model, PRZM/EXAMS, was used to estimate residues of thiacloprid and one of its major degradates, YRC 2984 amide in surface water. The SCI-GROW model was used to estimate the ground water residues.

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 thiacloprid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of thiacloprid and one of its major degratates, YRC 2894 amide for acute exposures are estimated to be 10.2 parts per billion (ppb) for surface water and 0.06 ppb for ground water. The EECs for chronic exposures are estimated to be 2.36 ppb for surface water and 0.06 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).

Thiacloprid is not registered or proposed for use on any sites that would result in residential exposure.

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

EPA does not have, at this time, available data to determine whether thiacloprid has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thiacloprid and any other substances and thiacloprid does not appear to produce a toxic metabolite produced by other substances. Thiacloprid does produce 6-CNA, a metabolite also produced by another registered chloronicotinoid pesticide. However, the limiting toxic endpoints used in this assessment for thiacloprid are not based upon the toxicity of 6-CNA. For the purposes of this tolerance action, therefore, EPA has not assumed that thiacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* Developmental studies did not show either qualitative or quantitative susceptibility. There is no increase in quantitative susceptibility demonstrated in the rat developmental neurotoxicity, rabbit developmental or rat reproduction studies. There is an apparent qualitative increase in susceptibility in the rat developmental toxicity study as indicated by increases in resorptions, increases in skeletal variations and retardations and malformations, and decreases in fetal body weight that occurred at the same dose showing a decrease in maternal body weight, but the concern is low since:

i. There is a well characterized dose response with a clear NOAEL and LOAEL;

ii. The fetal effects were noted in the presence of maternal toxicity; and

iii. There are no residual uncertainties.

3. *Conclusion.* In evaluating whether to retain the 10X SF to protect infants and children or to select a different safety factor, EPA considered the following factors:

i. There are no special concerns regarding pre- or post-natal toxicity exposure;

ii. The exposure databases (food and drinking water) are complete and/or employ conservative assumptions;

iii. There is no residential exposure;

iv. The risk assessments cover or approximate all the metabolites and degradates of concern;

v. The assessments do not underestimate the potential risk for infants and children; and

vi. The toxicity database is complete except that there is a lack of morphometric assessments for the low- and mid-dose group animals in the developmental neurotoxicity study (DNT).

Although the lack of morphometric assessments in the DNT raised some uncertainty, EPA determined that there were sufficient reliable data to select an additional safety factor of 3X instead of 10X. The FQPA safety factor of 3X is in the form of a database uncertainty factor of 3X. A 3X factor was judged to be adequate because the dose selected for overall risk assessments is already based on the most sensitive end points for acute (i.e. clinical signs indicative of neurotoxicity) and chronic (i.e. liver and thyroid effects) dietary and non-dietary exposure scenarios, and the available data indicate that the full characterization of brain morphometrics from the DNT study would not be expected to lower the dose used for risk assessments by more than 3-fold.

To elaborate, since the magnitude (4-14%) of the morphometric histopathology changes seen in the offspring at the highest dose (40.8 mg/kg/day) in the developmental neurotoxicity study were considered to be at or near the limit of detection for differences in morphometric measurements, it is unlikely that measurable morphometric changes will be seen at lower doses. Any possible slight effects at lower doses are highly unlikely to change the regulatory level. The actual doses used to establish the acute RfD (3.1 mg/kg/day) and the chronic RfD (1.2 mg/kg/day) are 13 and 34 fold lower, respectively, than the 40.8 mg/kg/day dose where the effects of minimal magnitude were seen. Applying the 3 X factor further renders the adjusted doses 39 and 102-fold lower than the dose level where the effects of minimal magnitude were seen. Morever, even if the slight morphometric changes are seen at the mid, and even the low, dose of the DNT, a RfD calculated on such findings is highly unlikely to be lower than current acute and chronic RfDs adjusted by 3X given that the effects seen at the high dose were marginal. Therefore it is concluded that 3X is adequate to account for any possible morphometric effects that may be noted in the lower doses for which the additional readings are being sought.

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: 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 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 thiacloprid will occupy 20% of the aPAD for the U.S. population, 8.5 % of the aPAD for females 13 years and older, 51 % of the aPAD for all infants and 47 % of the aPAD for children 1-2 years old. In addition, there is potential for acute dietary exposure to thiacloprid 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 4 of this unit:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.01	20	10.2	0.06	281
All infants < 1 year old	0.01	51	10.2	0.06	49
Children 1-2 years old	0.01	47	10.2	0.06	53
Children 3-5 years old	0.01	33	10.2	0.06	67
Females 13-49 years old	0.01	8.5	10.2	0.06	274

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiacloprid from food will utilize <1.0 % of the cPAD for the U.S. population, 4.4 % of the cPAD for all infants and 4.2% of the cPAD for children 1-2 years old . There are no residential uses for thiacloprid that result in chronic residential exposure to thiacloprid. In addition, there is potential for chronic dietary exposure to thiacloprid 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 5 of this unit:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.004	<1.0	2.36	0.06	139
All Infants < 1 year old	0.004	4.4	2.36	0.06	38
Children 1-2 years old	0.004	4.2	2.36	0.06	38
Children 3-5 years old	0.004	2.9	2.36	0.06	38
Children 6-12 years old	0.004	1.3	2.36	0.06	39
Females 13-49 years old	0.004	<1.0	2.36	0.06	120

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).

Thiacloprid is not registered or proposed 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).

Thiacloprid is not registered or proposed 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*. In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment: (July 1999), thiacloprid was classified into the category Likely to be Carcinogenic to Humans. A linear low-dose extrapolation approach is applied to the quantifications of risk to be estimated, based upon male rat thyroid, rat uterine, and mouse ovarian tumors. The data did not support a mode of action. The Q1* is 4.06×10^{-2} in human equivalents based on the rat uterine adenoma, adenocarcinoma and/or adenosquamous carcinoma combined tumor rates.

The dietary cancer risk from residues in food is $1.3X\ 10^{-6}$. A cancer DWLOC is calculated only for the general U.S. Population. For this population the calculated DWLOC of 1.5ug/L is the same as the calculated EEC of 1.5 ug/L.

DWLOC = $3\ X\ 10^{-6}/Q_1$* - average food exposure (mg/kg/day)]*bwt* 1,000 ug/mg÷Water consumption (liter/day)

DWLOC (US Pop.) = 1.5 ug/L. Since the surface water EEC for cancer is 1.5 ug/L the risk cup is exactly filled to $3\ X\ 10^{-6}$.

For risk management purposes, EPA considers a cancer risk to be greater than negligible when it exceeds the range of 1 in 1 million. EPA has generally treated cancer risks up to 3 in 1 million as within the range of 1 in 1 million.

EPA believes that the lifetime exposure will be result in negligible cancer risk for the following reason:

The cancer risk from the food uses alone is 1.3×10^{-6}.The dietary risk is based on residue data derived from the average of field trials. It is not unusual in the Agency's experience for field trial data to be an order of magnitude above actual monitoring. Since thiacloprid is a new chemical, actual monitoring data are not yet available. It is likely that the actual risk contribution from food will be much lower than current data indicate, which would result in a larger DWLOCcancer.

Thus, EPA does not expect that the general population would be exposed to levels that would exceed a neglible cancer risk over a lifetime.

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 thiacloprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner proposed a high performance liquid chromatography mass spectrometry (HPLC/MS/MS) method for determining thiacloprid, YRC-2894 amide and 4-hydroxy-YRC2894 amide in plants which has been found to be appropriate for use in the enforcement of the plant tolerances associated with this petition. The available radiovalidation and metabolism data supports this method. An adequate Independent Lab Validation (ILV) has been provided for the method and adequate confirmatory ions were also identified in the ILV.

The petitioner has proposed a HPLC/MS/MS method for determining thiacloprid in livestock tissues which has been found to be appropriate for use in the enforcement of the animal tissue tolerances associated with this petition. Existing radiovalidation and metabolism data supports this method as well as does an ILV. Mass spectrometry provides an adequate confirmatory method. This conclusion is based upon the successful use of mass spectrometry as a confirmatory method for thiacloprid in plants, the similarity between the HPLC/MS/MS methods for thiacloprid in plants and animals, and the Agency's familiarity with mass spectrometry in general. As a condition of registration, the registrant will be required to submit a description of the procedures for the use of mass spectrometry for thiacloprid in animals.

Thiacloprid, parent only, has been tested through the FDA PAM I multi-residue protocol. Upon request, the methods will be available prior to the harvest 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 established Codex, Canadian or Mexican maximum residue limits (MRLs) for thiacloprid.

C. Conditions

The following information must be submitted as a condition for product registrations related to these tolerances: The registrant will be required to submit a description of the procedures for the use of mass spectrometry for thiacloprid in animals.

V. Conclusion

Therefore, tolerances are established for combined residues of thiacloprid and metabolites retaining the thiazolidine ring intact, measured and expressed as thiacloprid, *per se*, in or on apple, wet pomace at 0.6 ppm; cattle, sheep, goat, and horse meat at 0.03 ppm; cattle, sheep, goat and horse meat byproducts at 0.05 ppm; cattle, sheep, goat, and horse liver at 0.15 ppm; cattle, sheep, goat, and horse kidney at 0.05 ppm; and cattle sheep, goat, and horse fat at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; cotton, gin byproducts at 11.0 ppm; fruit, pome, group 11 at 0.3 ppm; and milk at 0.03 ppm.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0304 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 25, 2003.

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

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

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your

copies, identified by docket ID number OPP–2003–0304, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve 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 the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 16, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.594 is added to read as follows:

§ 180.594 Thiacloprid; tolerances for residues.

(a) *General.* Tolerances for combined residues of the insecticide thiacloprid

([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat by-products	0.050
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat by-products	0.050
Milk	0.030
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat by-products	0.050

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

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

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

[FR Doc. 03–24371 Filed 9–25–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0301; FRL–7326–7]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenhexamid in or on cucumber; fruit, stone, group 12, except plum, prune, fresh, postharvest; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; plum, prune, dried; plum, prune, fresh; vegetable, fruiting, group 8, except nonbell pepper. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain fenhexamid tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0301, must be received on or before November 25, 2003.

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

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@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:

- Industry (NAICS 111), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0301. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

II. Background and Statutory Findings

In the **Federal Register** of May 21, 2003 (68 FR 27799) (FRL–7308–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2E6463, 2E6496, 3E6532, and 3E6541) by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide