

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 FFDC, 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 FFDC. 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: February 7, 2005.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.449 is amended as follows.

- i. By alphabetically adding the following commodities to the table in paragraph (a) to read as follows
- ii. By removing the entries for the commodities “Celery”; “Lettuce, head”; “Pepper”; and “Tomato”; in the table in paragraph (a).
- iii. The text of paragraph (b) is removed and reserved.

§ 180.449 Avermectin B₁ and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	*
Avocado	0.020
* * *	*
Food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts)	0.01
Goat, meat	0.02
Goat, meat byproducts	0.02
* * *	*
Herbs, crop subgroup 19A (except chives)	0.030
Hog, meat	0.02
Hog, meat byproducts	0.02
* * *	*
Horse, meat	0.02
Horse, meat byproducts	0.02
* * *	*
Mint	0.010
* * *	*
Plum	0.010
Plum, prune, dried	0.025
* * *	*
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02
* * *	*
Vegetable, fruiting, crop group 8	0.020
Vegetable, leafy, except Brassica, crop group 4	0.10
* * *	*

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0406; FRL-7690-2]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clothianidin in or on pome fruit. Arvesta Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0406. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7546; e-mail address: kenny.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers;

greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgst/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gpo/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of December 31, 2003 (68 FR 75504) (FRL-7334-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F6342) by Arvesta Corporation, 100 First St., Suite 1700, San Francisco, CA 94105. The petition requested that 40 CFR 180.586 be amended by establishing a tolerance for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on pome fruit at 1.0 parts per million (ppm). That notice included a summary of the petition prepared by Arvesta Corporation, the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.”

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of clothianidin on pome fruit at 1.0 ppm. 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 clothianidin as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of May 30, 2003 (68 FR 32390) (FRL-7306-8).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL

is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor"

is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1 x 10⁻⁵), one in a million (1 x 10⁻⁶), or one in ten million (1 x 10⁻⁷). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for clothianidin used for human risk assessment is shown in Table 1 of this unit:

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	Developmental NOAEL = 25 mg/kg/day UF = 1000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Developmental rabbit study Developmental LOAEL = 75 mg/kg/day based on an increased litter incidence of a missing lobe of the lung.
Acute dietary (General population)	NOAEL = 25 mg/kg/day UF = 1000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Special Neurotoxicity/Pharmacology Study in Mice and Rats LOAEL = 50 mg/kg based on transient signs of decreased spontaneous motor activity, tremors and deep respirations.
Chronic dietary (All populations)	Offspring NOAEL = 9.8 mg/kg/day UF = 1000 Chronic RfD = 0.0098 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.0098 mg/kg/day	2-Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F ₁ pups and an increase in stillbirths in both generations.
Incidental Oral (All Durations)	NOAEL = 9.8 mg/kg/day	Residential LOC for MOE = 1000	2-Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F ₁ pups and an increase in stillbirths in both generations.

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Dermal (All Durations)	Oral study NOAEL= 9.8 mg/kg/day (dermal absorption rate = 1%)	Residential LOC for MOE = 1000	2-Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F ₁ pups and an increase in stillbirths in both generations.
Inhalation (All durations)	Oral study NOAEL = 9.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 1000	2-Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F ₁ pups and an increase in stillbirths in both generations.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.586) for the residues of clothianidin, in or on a variety of raw agricultural commodities. Tolerances for clothianidin are established on canola, field corn, pop corn, sweet corn, and milk. Since clothianidin is a major metabolite of thiamethoxam, which has many registered uses and several pending uses, residues of clothianidin that would theoretically result from the metabolism of thiamethoxam are included in the analysis. Risk assessments were conducted by EPA to assess dietary exposures from clothianidin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDTM), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute analysis is a conservative assessment that was based on tolerance level residues and the assumption of 100% crop treated (PCT) for established and proposed

clothianidin uses. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, milk, and pome fruit), the proposed clothianidin tolerances are added to the residues that could result from use of thiamethoxam. The assumptions made for the acute exposure assessments for thiamethoxam are discussed in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL–7689–7). The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed population subgroup is infants less than 1 year old, which utilizes 80% of the aPAD.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCIDTM, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis is a relatively conservative assessment that was based on tolerance level residues and the assumption of 100% CT for established and proposed clothianidin uses, with the exception of anticipated residues (AR) for apples and pears. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, and milk), the proposed clothianidin tolerances are added to the residues that could result

from use of thiamethoxam. For apples and pears, the highest average field trial (HAFT) levels from the residue field trials were added to the residues that could result from use of thiamethoxam. The assumptions made for the chronic exposure assessments for thiamethoxam are discussed in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL–7689–7). The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed population subgroup is children 1 to 2 years of age, which utilizes 15% of the cPAD.

iii. *Cancer.* EPA has determined that clothianidin is not likely to be a human carcinogen. As a result, a quantitative cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of 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 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.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clothianidin 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 clothianidin.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

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

Based on the FIRST and SCI-GROW models, the EECs of clothianidin for acute exposures are estimated to be 7.29 parts per billion (ppb) for surface water and 5.84 ppb for ground water. The EECs for chronic exposures are estimated to be 1.35 ppb for surface water and 5.84 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Clothianidin is currently registered for use on the following residential non-dietary sites: *Turfgrasses*. The risk assessment was conducted using the following residential exposure assumptions: Due to the use patterns on turfgrasses, a number of residential or recreational post-application exposures are possible. In a residential setting, a "homeowner" may be exposed during application of the material to his or her lawn. Further, the "homeowner" may also experience post-application dermal exposure. Toddlers may be exposed via "hand-to-mouth" oral exposures and/or dermal exposures. "Aggregated" exposures are presented for toddlers (i.e., hand-to-mouth turf plus hand-to-mouth soil plus dermal post-application). EPA considers hand-to-mouth ingestion of granules to be episodic in nature, that is, a "one-time" event. Therefore the exposure from ingestion of granules is not combined with believed multiple exposures from "mouthing" of turf or soil or from post-application dermal exposure. The estimated exposures and risks are presented below in Table 2 of this unit:

TABLE 2.—SUMMARY OF RESIDENTIAL POST-APPLICATION EXPOSURES AND RISKS TO CLOTHIANIDIN

Activity	Exposure (Dose)/mg a.i./kg bw/day	MOE
Toddler oral hand to mouth from contacting treated turf	0.0059	1,700
Toddler incidental oral ingestion of treated soil	0.00002	490,000

TABLE 2.—SUMMARY OF RESIDENTIAL POST-APPLICATION EXPOSURES AND RISKS TO CLOTHIANIDIN—Continued

Activity	Exposure (Dose)/mg a.i./kg bw/day	MOE
Adult dermal post-application turf contact	0.00108	9,100
Adult combined dermal exposure = application + post-application	0.000026 + 0.00108	8,900
Toddler dermal post-application turf contact	0.00155	6,300
Toddler combined oral (except granules) and dermal exposures (treated turf + treated soil + dermal)	0.00747	1,300
Adult golfer post-application turf contact	0.000075	130,000
Child golfer post-application turf contact	0.000128	77,000

A MOE of 1,000 is adequate to protect adults and children from residential non-dietary post-application exposures to clothianidin. The estimated MOE's are based upon conservative assumptions and are greater than 1,000. Therefore, the estimated risks from residential non-dietary post-application exposures do not exceed EPA's LOC.

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

EPA does not have, at this time, available data to determine whether clothianidin 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 clothianidin and any other substances and clothianidin 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 clothianidin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* No quantitative or qualitative susceptibility was observed in either of the developmental rat or rabbit studies. Quantitative susceptibility was observed in both the reproduction and developmental neurotoxicity studies; however, the degree of concern for these studies is low because the observed effects are well characterized and there

are clear NOAELs/LOAELs in each case. In addition, the endpoint of concern is the one that is being used for short-, intermediate- and long-term dietary and non-dietary exposure risk assessments. There are no residual uncertainties. Therefore, there are no low concerns with regard to prenatal and/or postnatal toxicity.

3. *Conclusion.* The toxicology database for clothianidin is not complete for FQPA purposes. A complete complement of acceptable developmental, reproduction, developmental neurotoxicity, mammalian neurotoxicity and special neurotoxicity studies are available; however, due to evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin data base, and since juvenile rats in the 2-generation reproduction study appear to be more susceptible to these effects, EPA has determined that testing should be conducted to assess immune system function in adults and in young animals following developmental exposures (i.e., a developmental immunotoxicity study).

In the absence of the developmental immunotoxicity study, EPA determined that there is insufficient data to justify selection of an additional safety factor for the protection of infants and children lower than the default value of 10X for both single and repeated dose exposure scenarios. Therefore, an additional FQPA safety factor of 10X, in the form of a data base uncertainty factor (UFDB), will be applied to both single and repeated dose exposure scenarios (i.e., acute and chronic RfDs, short- and intermediate-term incidental oral exposures, and short-, intermediate-, and long-term dermal and inhalation exposure resulting from residential uses of clothianidin) to account for the lack of the developmental immunotoxicity study with clothianidin.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the

Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

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

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clothianidin will occupy 18% of the aPAD for the U.S. population, 12% of the aPAD for females 13 years and older, 80% of the aPAD for infants less than one year old, and 60% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

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

Population/Subgroup	aPAD(mg/kg)	%aPAD/(Food)	Surface Water EEC/(ppb)	Ground Water EEC/(ppb)	Acute DWLOC (ppb)
General U.S. Population	0.025	18	7.29	5.84	710
All infants (less than one year old)	0.025	80	7.29	5.84	48
Children 1–2 years old	0.025	60	7.29	5.84	92
Females 13–49 years old	0.025	12	7.29	5.84	640
Adults 50+ years old	0.025	14	7.29	5.84	1,500

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clothianidin from food will utilize 6% of the cPAD for the U.S. population, 13% of the cPAD for infants less than one year old, and 15% of the cPAD for children 1–2 years old. There are also registered uses on turfgrasses

for clothianidin that may result in chronic residential exposure. Combined residential exposure estimates range from an MOE of 1,300 for combined oral and dermal exposure to toddlers (treated turf + treated soil + dermal) to 8,900 for dermal exposure to adults (application + post-application) adults. In addition, there is potential for chronic dietary

exposure to clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

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

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

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Clothianidin is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for clothianidin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 5,900 for the general U.S. population; 1,100 for children 1–2 years old; and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency’s LOC for aggregate exposure to

food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of clothianidin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency’s LOC, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CLOTHIANIDIN

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

4. *Intermediate-term risk.* Intermediate-term aggregate exposure

takes into account residential exposure plus chronic exposure to food and water

(considered to be a background exposure level).

Clothianidin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for clothianidin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that

food and residential exposures aggregated result in aggregate MOEs of 5,900 for the general U.S. population; 1,100 for children 1–2 years old; and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were

calculated and compared to the EECs for chronic exposure of clothianidin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC, as shown in Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CLOTHIANIDIN

Population/Subgroup	Aggregate/ MOE/(Food + Residen- tial)	Aggregate/ LOC	Surface Water EEC/ (ppb)	Ground/ Water EEC/ (ppb)	Inter- mediate- Term DWLOC (ppb)
General U.S. Population	5,900	1000	1.35	5.84	280
Children 1–2 years old	1,100	1,000	1.35	5.84	8.7
Females 13–49 years old	6,200	1,000	1.35	5.84	250

5. *Aggregate cancer risk for U.S. population.* Clothianidin has been classified as a “not likely human carcinogen.” Therefore, it is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectroscopy/mass spectroscopy LC/MS/MS analysis) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established for residues of clothianidin.

V. Conclusion

Therefore, the tolerance is established for residues of clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on pome fruit at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0406 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 April 18, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions

on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0406, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the

location of the PIRIB described in ADDRESSES. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 7, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.586 is amended by alphabetically adding the commodity "Pome fruit" to the table in paragraph (a) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Pome fruit	1.0

* * * * *

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