consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: December 1, 2000.

Joseph J. Merenda,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

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

§ 180.565 Thiamethoxam; tolerance for residues.

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

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

* * * * *

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301082; FRL–6755–9]

RIN 2070–78AB

Avermectin B1; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301082. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of September 27, 2000 (65 FR 58081) (FRL–6746–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 0E6118) for tolerance by IR-4, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902–3390. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.449 be amended by establishing tolerances for combined residues of the insecticide avermectin B_1, (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_{1a}) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de(1- methylpropyl)-25-(1-methylethyl) avermectin A_{1a})) and its delta-8,9-isomer, in or on celeriac roots and tops at 0.05 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of avermectin B_1 and its delta-8,9-isomer on celeriac roots and tops at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by avermectin B_1 are discussed in Unit III A of the Final Rule on Avermectin Pesticide Tolerance published in the **Federal Register** on September 7, 1999 (FRL 6380–7).

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 extrapolatin 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.

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for avermectin B_1 used for human risk assessment is as follows:

A summary of the toxicological endpoints for avermectin B_1 used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AVERMECTIN B_1 FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary U.S. population	NOAEL = 0.25 mg/kg/day UF = 100 Acute RfD = 0.0025 mg/kg/day	FQPA SF = 1 aPAD = acute RfD FQPA SF = 0.0025 mg/kg/day	Chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils seen at week 1 of dosing.
Acute Dietary females 13+ years of age, and infants and children	NOAEL = 0.25 mg/kg/day UF = 100 Acute RfD = 0.0025 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.00025 mg/kg/day	Chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils seen at week 1 of dosing.
Chronic Dietary U.S. population	NOAEL= 0.12 mg/kg/day UF = 100 Chronic RfD = 0.0012 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.0012 mg/kg/day	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings.
Chronic Dietary females 13+ years of age, and infants and children	NOAEL = 0.12 mg/kg/day UF = 100 Chronic RfD = 0.0012 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.00012 mg/kg/day	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings.
Short-Term Dermal (1 to 7 days) (Residential)	oral study NOAEL = 0.25 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Intermediate-Term Dermal (1 week to several months) (Residential)	oral study NOAEL = 0.25 mg/kg/day(dermal absorption rate = 1%	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Long-Term Dermal (several months to lifetime) (Residential)	oral study NOAEL= 0.12 mg/kg/day (dermal absorption rate = 1% when appropriate)	LOC for MOE = 1,000 (Residential)	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings.
Short-Term Inhalation (1 to 7 days) (Residential)	oral study NOAEL = 0.25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Intermediate-Term Inhalation (1 week to several months) (Residential)	oral study NOAEL = 0.25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Long-Term Inhalation (several months to lifetime) (Residential)	oral study NOAEL = 0.12 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F_{2b} weanlings.
Cancer (oral, dermal, inhalation)	Not Applicable	Cancer Group E—absence of significant tumor increases in two adequate rodent carcinogenicity studies.	Rodent carcinogenicity study—was negative carcinogens.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.449) for the combined residues of avermectin B_1 and its delta-8,9-isomer, in or on a variety of raw agricultural commodities including apples, almonds, citrus, cottonseed, grapes, hops, peppers, potatoes, cattle meat and meat by-products and milk. Risk assessments were conducted by EPA to assess dietary exposures from avermectin B_1 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 following assumptions were made for the acute exposure assessments: The acute dietary exposure assessment was conducted using probabilistic Monte Carlo'' modeling incorporating anticipated residue and percent of crop treated refinements to calculate the Anticipated Residue Contribution (ARC). Residue Data Files (RDF) and percent crop treated were used on all but a few low consumption food items. Reduction factors for fractionation and processing were utilized for citrus and pome fruit. Monitoring data were not used for mixed/blended commodities. EPA was able to further refine the acute dietary estimate from food by using updated PCT data, resetting the processing factor for dried potatoes to 1 which reflects the non-concentration of avermectin B_1 in potato processed commodities, correcting the residue files above to use one half the level of detection or one half the level of quantification, where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, the analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin B_1 residues from the raw agricultural commodity, EPA used the reduction factor for apples in the analysis.

ii. *Chronic exposure.*In conducting this chronic dietary (food only) risk assessment, EPA used anticipated residues and percent crop-treated data for many crops. This chronic dietary (food only) exposure should be viewed as a highly refined risk estimate; further refinement using additional percent crop-treated values would not result in a significantly lower dietary exposure estimate. Thus, in making a safety determination for this tolerance, EPA is taking into account this refined chronic exposure assessment.

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

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

The Agency used percent crop treated (PCT) information as follows: For each crop in the dietary (food only) model the following percent crop treated values were used for the acute and chronic analyses (respectively): almond 100%, 100%; apple 6.1%, 1.9%; avocado 100%, 100%; basil 100%, 100%; cantaloupe 5%, 1.3%; celeriac 100%, 100%; celery 60%, 49%; citrus, other 43%, 32%; cotton 4.8%, 3.2%; cucumber 100%, 31%; grapefruit, juice and peel 60.9%, 46%; grapefruit, peeled fruit 43%, 46%; grape 14%, 14%; hops 100%, 84%; lemon, juice and peel 34.4%, 17%; lemon, peeled fruit 43%, 17%; head lettuce 28%, 22%; lime, juice and peel 63.2%, 32%; lime, peeled fruit 43%, 32%; melons 5%, 1.3%; orange, juice and peel 36.3%, 28%; orange, peeled fruit 43%, 28%; pear 75%, 56%; peppers 15%, 6.3%; potato 5%, 0.3%; spinach 18%, 8.9%; squash 100%, 31%; strawberry 47%, 42%; tangelo 43%, 57%; tangerine, juice 74.3%, 53%; tangerine, fresh 43%, 53%; tomato 8%, 3.7%; walnut 100%, 100%; watermelon 5%, 1.3%. For fresh, peeled citrus a weighted average (43%) was calculated pooling all types of citrus; this value was used in the analysis of chronic dietary exposure from citrus.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which avermectin B_1 may be applied in a particular area.

2. *Dietary exposure from drinking water.* Avermectin B_1 is moderately persistent and non-mobile. It is not expected to reach surface or ground

water in significant quantities. It is stable to hydrolysis at pH 5, 7, and 9. It is also moderately persistent in aerobic soil (topsoil) with half-lives of 37–131 days. The major pathways of avermectin B_1 dissipation are binding to soil and sediment, degradation in aerobic soil, and photolysis in water. In shallow, well-mixed surface water with no suspended sediments, avermectin B_1 degraded rapidly with a photodegradation half-life of 3 days. However, in most surface waters, suspended sediments and lack of mixing would decrease the rate of photodegradation significantly. In water, avermectin B_1 residues would be tightly bound to sediment, reducing aqueous concentrations. There are no Maximum Contaminant Levels (MCL) or Health Advisories (HA) established for avermectin B_1 residues in drinking water.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for avermectin B_1 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 avermectin B_1.

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

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

EPA decided to rely on the strawberry model to assess aggregate risk since strawberries were considered a higher exposure scenario (four applications per season allowed for strawberries). However, EPA noted that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin B_1 on black plastic compared to soil. In order to refine the model in the future, the Agency has required the registrant, as a condition of product registration, to conduct additional tests on the effects of plastic mulch on surface water pesticide concentrations.

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 avermectin B_1 they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of avermectin B_1 for acute exposures are estimated to be [0.88] parts per billion (ppb) for surface water and 0.0015 ppb for ground water. The EECs for chronic exposures are estimated to be 0.57 ppb for surface water and 0.002 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).

Avermectin B_1 is currently registered for use on the following residential non-dietary sites: residential lawns for fire ant control, and residential indoor crack and crevice for cockroaches. Registered uses may result in short-term to intermediate exposures. However, based on current use patterns, chronic exposure to avermectin B_1 is not expected. The risk assessment was conducted using the following residential exposure assumptions:

i. *Short and intermediate exposure—residential lawn applications.* For exposure of residential applicators, three scenarios were used: (a) granular bait dispersed by hand, (b) belly grinder-granular open pour-mixer/loader/applicator and (c) push type granular.

For postapplication exposure from treated lawns, EPA default assumptions such as dermal transfer coefficient (TC), exposure time (ET), hand surface area (SA), ingestion frequency (FQ), residue dissipation, and ingestion rates were used. These defaults estimated postapplication exposure to children and adults from treated lawns. The application rate (AR) used for this assessment is based on the label for Affirm Fire Ant Insecticide (0.011% avermectin B_1). The label recommends a broadcast application rate on lawns of 1 lb of product/acre, the maximum rate for all registered lawn uses.

ii. *Short and intermediate exposure—residential indoor crack and crevice uses.* For residential applicators, exposure and risk estimates for homeowners applying crack and crevice baits were estimated using the EPA DRAFT Standard Operating Procedure (SOP) for Residential Exposure Assessments (12/18/97). The amount of active ingredient (ai) handled was based on the assumption that one 30 gram package of Whitmire Avert Prescription Bait Prescription Treatment 310 (0.05% ai) would be applied in a day. The unit exposure from the EPA default wettable powder, open mixing and loading scenarios was used as a surrogate for estimating dermal and inhalation exposure to residential applicators.

For estimating postapplication exposure from indoor treatment, two postapplication exposure studies were conducted with crack and crevice products containing avermectin B_1: (1) Evaluation of Avert Prescription Treatment 310 Residual Study in Air, Food and on Surfaces, dated November 8, 1990 and (2) Evaluation of Indoor Exposure to a Crack and Crevice Application of Whitmire Avert Crack and Crevice Prescription Treatment 310 and Prescription TC 93A Bait, dated October 27, 1995 (see Unit III.C. of the Final Rule on Avermectin Pesticide Tolerance published in the **Federal Register** on September 7, 1999 (FRL 6380–7)).

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available

information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether avermectin B_1 has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, avermectin B_1 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 avermectin B_1 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

ii. *Prenatal and postnatal sensitivity*. There was evidence of increased susceptibility to the offspring following prenatal and postnatal exposure to avermectin B_1 in the 2-generation reproduction study in rats.

iii. *Conclusion*. There is a complete toxicity data base for avermectin B_1 and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency is retaining the 10-fold safety factor for increased susceptibility of infants and children for this pesticide and is applying it to females 13+, infants, and children population subgroups for acute, chronic, and residential exposure.

The 10X Safety Factor is being retained because: (1) There was evidence of increased susceptibility to the offspring following pre- and postnatal exposure to avermectin B_1 in the 2–generation reproduction study in rats. (2) There is evidence of neurotoxicity manifested as clinical signs of neurotoxicity in mice, rats, and dogs in developmental, reproduction, chronic and/or carcinogenicity studies in mice, rats and/or dogs. (3) There is concern for Structure Activity Relationship: Avermectin induced cleft palate in fetal rats, and cleft palate and clubbed forefoot in fetal rabbits. (4) EPA determined that a developmental neurotoxicity study in rats is required for avermectin B_1. This study could provide additional information on potential increased susceptibility, effects on the development of the fetal nervous system, as well as the functional development of the young. (5) There is concern for post-application exposure to infants and children in treated areas, including incidental hand-to-mouth ingestion of the pesticide.

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to avermectin will occupy 4% of the aPAD for the U.S. population, 37% of the aPAD for females 13 years and older nursing, 47% of the aPAD for non-nursing infants and 70% of the aPAD for children 1–6 years. In addition, there is potential for acute dietary exposure to avermectin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, the acute exposure for aggregate risk slightly exceeds the aPAD for children 1–6 years old. However EPA believes that acute exposure to avermectin from drinking water will not pose an unacceptable risk to human health. Neither surface nor ground water models used by EPA were designed specifically for estimating concentrations in drinking water. There are significant uncertainties in both the toxicology used to derive the DWLOC and the exposure estimate from the PRZM-EXAMS model. EPA has compensated for these uncertainties by using reasonable high-end assumptions. Given this approach, the Agency does not attach great significance to such a small difference. However, EPA may do additional analyses and, as a condition of product registration, the Agency has required the registrant to submit (1) data on the effects of plastic mulch on surface water pesticide concentrations and (2) data characterizing the effectiveness of various types of drinking water treatment on removing avermectin. These data are expected to confirm that the actual concentration of avermectin in drinking water is less than the level of concern for all sub-populations, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AVERMECTIN B_1

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.0025	4	0.88	0.0015	84
Children 1–6 years old	0.00025	70	0.88	0.0015	0.74
Females 13+ nursing	0.00025	37	0.88	0.0015	4.7

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to avermectin B_1 from food will utilize less than 1% of the cPAD for the U.S. population, 17% of the cPAD for non-nursing infants and 13% of the cPAD for children 1–6 years old. Based the use pattern, chronic residential exposure to residues of avermectin B_1 is not expected. In addition, there is potential for chronic dietary exposure to avermectin B_1 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 the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AVERMECTIN B_1

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0012	<1	0.57	0.002	42
Infant, non-nursing	0.00012	17	0.57	0.002	1
Female 13+, nursing	0.00012	6	0.57	0.002	3

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

Avermectin B_1 is currently registered for use that could result in short- and intermediate term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-and intermediate term exposures for avermectin B_1.

Short- and intermediate-term total MOEs (dermal + inhalation) are greater than 1,000 and therefore exceeds EPA's level of concern.

A margin of exposure (MOE) of 1,000 or greater is required for the most sensitive subgroups. All lawn postapplication MOEs exceeded this value and therefore is not of concern to EPA. The dermal short- and intermediate-term MOEs for adults and children are 83,000 and 86,000, respectively. The oral hand-to-mouth short- and intermediate-term MOEs for children are 14,000 and 6,500, respectively. The oral incidental ingestion short- and intermediate-term MOEs for children are 610,000 and 290,000, respectively.

The short- and intermediate-term MOEs for dermal and inhalation exposure are each 12 million, exceeds EPA's level of concern.

The short- and intermediate-term dermal MOE for children's postapplication dermal is 78,000. The short- and intermediate-term oral MOE for children's postapplication oral hand-to-mouth is 12,000. The short- and intermediate-term inhalation MOE for children's postapplication inhalation is 2,400.

The risk from children's post application exposure to crack and crevice products containing avermectin B_1 does not exceed EPA's level of concern. Avert Prescription Treatment 310 is a dust formulation that is intended for the application to crack and crevices only. Other formulations for similar crack and crevice products (i.e., gels, granulars, pressurized liquids, etc.) will have less migration from the treated area and are expected to result in lower risk from dermal, oral, and inhalation postapplication exposure.

Using the exposure assumptions described in this unit for short- and intermediate term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of dermal, inhalation, and oral exposures. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-and intermediate term DWLOCs were calculated and compared to the EECs for chronic exposure of avermectin B_1 in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-and intermediate term aggregate exposure to exceed the Agency's level of concern as shown in Table 4.

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

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-INTERMEDIATE-TERM EXPOSURE TO AVERMECTIN B_1

Population Subgroup	Aggregate MOE Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,7000	100	0.57	0.00023	87
Infants and children	1400	100	0.57	0.000077	0.77

4. *Aggregate cancer risk for U.S. population*. EPA classified avermectin B_1 as a Cancer Group E (evidence of non–carcinogenicity for humans) chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

5. *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 avermectin B_1 residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Separate analytical methods were employed to quantify residues in celeriac roots and tops: The method used for roots was a modified version of HPLC Fluorescence Determination for Avermectin B_1 and its Delta 8,9 Isomer in Raw Whole Potatoes (Method No. 936–92–4, 25 July 1992). Celeriac tops were analyzed using HPLC Fluorescence Determination for Avermectin B_1 and its Delta 8,9 Isomer in/on Fruits and Vegetables: Commodity - Stone Fruit (Method No. M-073, 15 November 1996). The methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRL) for avermectin B_1 on celeriac. Therefore, international harmonization is not an issue for the action.

V. Conclusion

Therefore, the tolerance is established for combined residues of avermectin B_1 and its delta-8,9-isomer in or on celeriac roots and tops at 0.05 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301082 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 20, 2001.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301082, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: December 7, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.449 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * *	
Celeriac, roots	0.05
Celeriac, tops	0.05
* * * * * *	

* * * * *

[FR Doc. 00–32569 Filed 12–20–00; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461, or (e-mail) *matt.miller@fema.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director for Mitigation certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended to read as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).
CALIFORNIA	
Solano County (Unincorporated Areas) (FEMA Docket No. B–7401)	
Gibson Canyon Creek:	
Approximately 2,250 feet downstream of Byrnes Road	*69
Approximately 100 feet upstream of Browns Valley Road	*143
South Branch Gibson Canyon Creek:	
Just downstream of Crocker Drive	*102
Just upstream of Browns Valley Road	*142
Horse Creek:	
Approximately 500 feet downstream of Willow Avenue	*77
Approximately 1,500 feet upstream of Willow Avenue	*79
Maps are available for inspection at Solano County Department of Environmental Management, 601 W. Texas Street, Fairfield, California.	
City of Vacaville, Solano County (FEMA Docket No. B–7401)	
Gibson Canyon Creek:	
Approximately 2,100 feet downstream of Interstate Highway 80 (Eastbound)	*78
Approximately 1,200 feet upstream of Eubanks Road	*113