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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0063; FRL–7180–5]

Triflumizole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole) and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on cucurbit vegetables, strawberries, sweet cherries, and tart cherries. Uniroyal Chemical Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346a(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. This regulatory action will count for 26 reassessments toward the August 2002 deadline.

DATES: This regulation is effective June 12, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0063, must be received on or before August 12, 2002.

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 ID number OPP–2002-0063 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0063. 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 July 6, 2001 (66 FR 35623) (FRL–6790–1), 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 pesticide petitions (PP) by Uniroyal Chemical Company, 74 Amity Road, Bethany, CT 06525. This notice included a summary of the petitions prepared by Uniroyal Chemical Company, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.476 be amended by establishing tolerances for residues of the fungicide triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole), in or on food commodities as follows:

1. PP 1F6297 proposed the establishment of tolerances for strawberries at 2.0 parts per million (ppm).

2. PP 0F6077 proposed the establishment of tolerances for the cucurbit crop group at 0.5 ppm.

3. PP 8F4938 proposed the establishment of tolerances for cherries at 2.0 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 a tolerance for combined residues of triflumizole and its metabolites containing 4-chloro-2-trifluoromethylaniline moiety, expressed as the parent on cucurbit vegetables, strawberries, and cherries at 0.5 ppm, 2.0 ppm, and 1.5 ppm, respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by triflumizole are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = Males: 15.3 mg/kg/day; Females: 17.2 mg/kg/day LOAEL = Males: 176.5 mg/kg/day; Females: 217.9 mg/kg/day based on increased kidney and liver weights and the accumulation of fat droplets in the liver.
870.3100	90-Day oral toxicity rodents (mouse)	NOAEL = Males: 33.1 mg/kg/day; Females: 42.6 mg/kg/day LOAEL = Males: 380.7 mg/kg/day; Females 466.2 mg/kg/day based on reduced growth.
870.3200	21/28-Day dermal toxicity (rat)	NOAEL ≥1,000 mg/kg/day LOAEL = not identified
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = 10 mg/kg/day LOAEL = 35 mg/kg/day based on decreased body weight gain and food consumption, and increased placental, spleen and liver weights. Developmental NOAEL = 10 mg/kg/day LOAEL = 35 mg/kg/day based on decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight, and increased incidences of cervical ribs.
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight gains, food consumption, and placental weights. Developmental NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on decreased 24-hour survival, decreased placental weights, and increased fetal and litter incidences of lumbar ribs.

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

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 8.5 mg/kg/day LOAEL = 21 mg/kg/day based on decreased body weight and overall body weight gain, increased relative liver weights, and increased mortality in females. Reproductive NOAEL = not identified LOAEL = 3.5 mg/kg/day based on increased gestation length in P. Offspring NOAEL = 8.5 mg/kg/day LOAEL = 21 mg/kg/day based on decreased pup body weight, survival indices, and litter sizes and a slight increased incidence of hydronephrosis in F_{1a} pups.
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 8.5 mg/kg/day LOAEL = not established Reproductive NOAEL = 1.5 mg/kg/day LOAEL = 3.5 mg/kg/day based on based on increased gestation length in dams of the F_{3a} interval. Offspring NOAEL = 3.5 mg/kg/day LOAEL = 8.5 mg/kg/day based on decreased pup weights, survival indices, and litter sizes in both F_3 litters, reduced litter size in the F_{1a} litter, increased total-litter mortality in the F_{3a} litter, and developmental effects in the F_{1b} and F_{2b} progeny.
870.4100	Chronic toxicity nonrodents (dog)	NOAEL = Males: 10.00 mg/kg/day; Females: 10.69 mg/kg/day LOAEL = Males: 34.10 mg/kg/day; Females: 35.17 mg/kg/day based on increased alkaline phosphatase activity and a mild, macrocytic anemia in males, increased absolute and relative liver weights in both sexes, and on macroscopic findings in the liver of both sexes.
870.4200	Carcinogenicity (mouse)	NOAEL = Males: 16.2 mg/kg/day; Females: 21.7 mg/kg/day LOAEL = Males: 67.4 mg/kg/day; Females: 86.1 mg/kg/day based on microscopic lesions of the liver. No evidence of carcinogenicity
870.4300	Combined chronic/oncogenicity (rat)	NOAEL = Males: <3.5-3.7 mg/kg/day; Females: <4.5-4.6 mg/kg/day LOAEL = Males: 3.5-3.7 mg/kg/day; Females: 4.5-4.6 mg/kg/day based on liver toxicity (eosinophilic foci in male rats and fatty vacuolation and inflammation and necrosis in female rats). No evidence of carcinogenicity.
870.5100	Bacterial reverse mutation	Negative with or without S9 activation at 5,000 μg/plate and less.
870.5100	Bacterial reverse mutation	Negative with or without S9 activation at 8,000 μg/plate and less.
870.5375	*In vitro* mammalian chromosome abberation (CHL)	Negative with or without S9.
870.5395	*In vitro* mammalian cytogenetics (mouse bone marrow)	Negative. Not clastogenic for the production of micronuclei in bone marrow polychromatic erythrocytes in mice at single oral doses up to 1,600 mg/kg.
870.5500	DNA damage/repair REC assay	Negative. No evidence of DNA damage up to 24,000 mg/disk. Study is unacceptable because a metabolic activation system was not used.

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

Guideline No.	Study Type	Results
870.5550	UDS in primary rat hepatocytes	Negative. No evidence of unscheduled DNA synthesis up to cytotoxic concentrations.
870.6200	Acute neurotoxicity screening battery	Data gap
870.6200	Subchronic neurotoxicity screening battery	Data gap
870.7485	Metabolism and pharmacokinetics (rat)	Following oral treatment of rats with [phenyl-U-^{14}C]-NF-114, no sex-related differences were observed in absorption, metabolism, distribution or excretion. Maximum concentrations of radioactivity in plasma were attained within 1 hour of dosing in both sexes. Low levels of radioactivity were detectable in all tissue, organ, and blood samples. Radioactivity in urine accounted for 69.5-74.4% of the dose and feces accounted for 21.7-21.9% of the dose. Based on themetabolite profile, the metabolism in rats primarily involves oxidation to FM-8-1 and FA-1-5, followed by sulfation and glucuronidation.
870.7485	Metabolism and pharmacokinetics (rat)	Following oral treatment of rats with [phenyl-U-^{14}C]-NF-114, approximately 93.8-100.6% of the administered dose was recovered. Urine was the major route of excretion. Low levels of radioactivity were detectable in all tissue, organ, and blood samples collected 2 days (10 mg/kg group) or 4 days (300 mg/kg group) post-dose with tissue concentrations generally higher in males than females. The metabolite profile in the excreta was quantitatively and qualitatively similar between the sexes and dose groups. Based on the metabolite profile, the biotransformation of NF-114 in rats primarily involved oxidation of parent to FM-8-1 and FA-1-5, followed by conjugation yielding sulfate and glucuronic acid conjugates.
Special studies	Hepatic enzyme induction	The study provides evidence that triflumizole induces hepatic microsomal enzymes when administered orally. However, no correlation between the increased enzyme activities and hepatic lesions observed following chronic administration was made since no histopathology was performed.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. Due to the lack of an acute neurotoxicity study and a subchronic neurotoxicity study, the Agency has applied an additional 3X uncertainty factor to this assessment to account for an incomplete toxicology data base.

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

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

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

summary of the toxicological endpoints for triflumizole used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13-50 years of age	NOAEL = 10 mg/kg/day UF = 3X Acute RfD = 0.03 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.03 mg/kg/day	Developmental Toxicity Study - Rat Developmental LOAEL = 35 mg/kg/day based on decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight, and increased incidences of cervical ribs.
Acute dietary general population including infants and children	No acute dietary endpoint of concern was chosen for the general population (including infants and children).		
Chronic dietary all populations	NOAEL = 1.5 mg/kg/day UF = 3X Chronic RfD = 0.005 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.005 mg/kg/day	Multi-generation Reproduction Study - Rat Reproductive LOAEL = 3.5 mg/kg/day based on increased gestation length in dams of the F_{3a} interval.
Short-term oral (1-30 days) (Residential)	oral NOAEL= 8.5 mg/kg/day	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation.
Intermediate-term oral (1-6 months) (Residential)	oral NOAEL= 8.5 mg/kg/day	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation and decreased body weight and body weight gain in parental animals.
Short-term dermal (1-30 days) (Residential)	oral NOAEL = 8.5 mg/kg/day (dermal absorption rate = 3.5%)	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation.
Intermediate- and long-term dermal (1-6 months and 6-month or longer) (Residential)	oral study NOAEL= 1.5 mg/kg/day (dermal absorption rate = 3.5%)	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 3.5 mg/kg/day based on increased gestation length in the dams of the F_{3a} interval.
Short-term inhalation (1-30 days) (Residential)	oral NOAEL= 8.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation.
Intermediate- and long-term inhalation (1-6 months and 6-month or longer) (Residential)	oral study NOAEL= 1.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300 (includes the total FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 3.5 mg/kg/day based on increased gestation length in the dams of the F_{3a} interval.
Cancer (oral, dermal, inhalation)	evidence for non-carcinogenicity for humans	Not applicable	Combined Chronic Toxicity/Carcinogenicity Study - Rat Carcinogenicity Study - Mouse No evidence of carcinogenicity in rats and mice.

*The reference to the Special FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA. The total or overall FQPA Safety Factor includes both the Special FQPA Safety Factor and any traditional, additional safety, or uncertainty factors.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.476) for the combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole) and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on a variety of raw agricultural commodities. The tolerance expression for meat, milk and poultry commodities also include residues of the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate. Risk assessments were conducted by EPA to assess dietary exposures from triflumizole and its metabolites 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. The Dietary

Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A conservative, unrefined Tier 1 acute dietary exposure assessment was conducted for females 13-50 years old using tolerance level residues and modified DEEM processing factors for apples and grapes, based on the results of previously submitted processing studies. The Agency assumed 100% crop treatment for all other registered and proposed triflumizole food uses.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A partially refined, Tier 3 chronic dietary assessment was conducted for the general U.S. population and all population subgroups (including infants and children) using anticipated residues, modified DEEM processing factors for apples and grapes based on the results of previously submitted processing studies, and average weighted percent crop treated information for apples, grapes, and pears.

iii. *Cancer*. Triflumizole is classified as a ''Group E'' (evidence of non-carcinogenicity in humans) chemical based on adequate studies in two species of animal. Therefore, a cancer dietary exposure assessment was not performed.

iv. *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 PCT information as follows. In conducting its chronic dietary risk assessment, EPA utilized PCT data for the registered uses on grapes, apples, and pears. EPA based these assumptions on use data for the period 1996 to 1997 and 1998 to 1999. For all other registered uses as well as the new uses (cucurbits, strawberries, and cherries), EPA assumed that 100% of the U.S. crop would be treated with triflumizole.

The Agency believes that the three conditions listed in Unit III.C. 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 triflumizole may be applied in a particular area.

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

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a

coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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

Based on the FIRST and SCI-GROW models the EECs of triflumizole for acute exposures are estimated to be 191 parts per billion (ppb) for surface water and 0.12 ppb for ground water. The EECs for chronic exposures are estimated to be 40 ppb for surface water and 0.12 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). Triflumizole is currently registered for use on the following residential non-dietary sites: Commercial applicators may treat ''woody'' ornamental species, such as trees, shrubs, and vines with triflumizole products. There are no proposed or registered uses for triflumizole on turf or lawns. EPA believes that residential, post-application, re-entry exposures from these use sites are not probable and, therefore, no residential exposure assessment has been conducted.

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 triflumizole 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, triflumizole 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 triflumizole 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. *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.

2. *Prenatal and postnatal sensitivity*. There is qualitative evidence of increased susceptibility demonstrated in the oral prenatal developmental toxicity studies in rats. Developmental toxicity resulted in fetal death as compared to maternal toxicity which included decreases in body weight gain and food consumption and increases in placental, spleen and liver weights at the same dosages.

No quantitative or qualitative evidence of increased susceptibility was demonstrated in the prenatal developmental toxicity studies in rabbits or the multi-generation reproduction studies in rats. In the rabbit developmental studies, 24-hour fetal survival was decreased at the highest dose tested. This endpoint is not a recommended guideline parameter and is generally believed to have limited value in the assessment of development toxicity; rather, it is more an indicator of fetal endurance in the absence of critical maternal care, following removal from the uterus. The Hazard Identification Assessment Review Committee did not consider this effect to be a measurement of treatment-related effects on fetal viability and, thus, did not consider it to be relevant to the assessment of fetal susceptibility. There was no evidence of quantitative or qualitative susceptibility in the 2-generation reproduction study in rats. In that study, increased gestation length was observed at the study LOAEL. In rats, this alteration in normal reproductive function can result in equally adverse consequences (i.e., mortality) in both dams and offspring.

3. *Conclusion*. The Agency has determined that a FQPA safety factor of 3X was safe for infants and children based upon the following considerations: (1) There was no quantitative or qualitative evidence of increased susceptibility in the rabbit fetuses following *in utero* exposure or the rat following prenatal and postnatal exposure; (2) while there was evidence of qualitative susceptibility in the developmental rat study, there are no residual uncertainties, and the use of the developmental NOAEL and the endpoint for the acute RfD for females 13-50 is protective of the prenatal toxicity following an acute dietary exposure; (3) while the toxicological data base is incomplete due to the lack of acute and subchronic neurotoxicity studies, the additional safety factor 3X is applied for acute and chronic dietary risk assessments to account for this uncertainty; and (4) in the exposure data base, there are no residual uncertainties identified. The drinking water exposure assessments incorporate conservative (Tier I) assumptions, and there are no residential exposures anticipated with the use of this chemical. The FQPA safety factor of 3X was found to be adequate based upon the following factors: (1) In the acute studies, clinical signs were seen at very high doses which resolved within 24 hours and no treatment-related effects were seen in the surviving animals; (2) in the chronic study, cholinesterase inhibition was seen during the first year, but not in a consistent manner; while plasma inhibition was seen in both sexes, erythrocyte was inhibited in males but not in females at the highest dose tested, no inhibition of brain cholinesterase activity was seen in either sex at any dose level; (3) there was no evidence of neurotoxicity in the subchronic studies in mice or rats; (4) there was no evidence of neuropathology in the data base; and (5) the doses used in risk assessments are significantly lower than the doses that induce the clinical signs following acute exposure or cholinesterase inhibition following repeated exposures.

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 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 triflumizole will occupy 19% of the aPAD for females 13 years and older. No acute dietary endpoint was selected by EPA for the general U.S. population, including infants and children. Therefore, an acute dietary exposure assessment was not performed for these population subgroups. In addition, there is potential for acute dietary exposure to triflumizole 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 the following Table 3:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females, 13-50 years	0.03	19	191	0.12	710

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triflumizole from food will utilize 18% of the cPAD for the U.S. population and all population subgroups. The most highly exposed subpopulation is children 1-6 years old at 18% of the cPAD. There are no residential uses for triflumizole that result in chronic residential exposure to triflumizole. In addition, there is potential for chronic dietary exposure to triflumizole 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 4:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.005	8	40	0.12	160
All infants, <1 year old	0.005	11	40	0.12	45
Children, 1-6 years old	0.005	18	40	0.12	41

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

For triflumizole, the Agency did not perform short-term or intermediate-term assessments because there are currently no registered or proposed uses for homeowner application and residential post-application exposures are expected to be negligible.

4. *Aggregate cancer risk for U.S. population.* Since triflumizole has been determined to not be carcinogenic, it is not expected to pose a cancer risk.

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 triflumizole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Suitable methods are available for collecting data on residues of triflumizole and its metabolites. For cucurbits, the Agency has determined that the GC/nitrogen/phosphorus detector (NPD) method (Uniroyal

Method CRM-3-96) is adequate for collecting data on residues of triflumizole and its metabolites. For strawberries, the GC/MSD (Morse Method METH-115, Revision #2) is adequate for collecting data on residues of triflumizole and its metabolites. For cherries, the GC/electron capture detection (ECD) method (Uniroyal Method CRM-3-96, modified) is adequate for data collection. For each of these commodities, the Agency has determined that a GC/nitrogen/phosphorus detector (NPD) method previously submitted to support petitions for the use of triflumizole on apples, grapes, and pears is similar to the above-referenced methods. This method is also acceptable as a tolerance enforcement method for these new commodities. This method has been forwarded to the Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM), Volume II, as Method I.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, U.S. Environmental Protection Agency, 701 Mapes Road, Fort George G. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for triflumizole residues in/on crop commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this risk assessment.

C. Conditions

A limited field rotation study in wheat will be required as a condition of the cucurbit registration. As a condition of registration, the Agency will require the submission of acute and subchronic neurotoxicity studies in order to better characterize the neurological effects seen in the rat and mouse acute oral, the rat acute inhalation, and the rat chronic studies.

V. Conclusion

Therefore, the tolerance is established for combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole) and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on cucurbit vegetables, strawberries, sweet cherries, and tart cherries at 0.5 ppm, 2.0 ppm, 1.5 ppm, and 1.5 ppm, respectively. In establishing the tolerances for sweet cherries and tart cherries, the Agency has determined that, based upon the submitted residue field trials, the appropriate tolerance level is 1.5 ppm since residues are not expected to exceed this value. In addition, the Agency is correcting the commodity definitions from the proposed ''cherries'' to ''cherry, tart'' and ''cherry, sweet'' to reflect currently accepted terminology.

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–2002–0063 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 August 12, 2002.

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 ID number OPP–2002–0063, 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 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). 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 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). 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. 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: May 31, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.476 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.476 Triflumizole; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * * * *	
Cherry, sweet	1.5
Cherry, tart	1.5
* * * * *	
Strawberry	2.0
Vegetable, cucurbit, Group 9	0.5

* * * * *

[FR Doc. 02–14768 Filed 6–11–02; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7228–1]

Nevada: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: The State of Nevada applied for final authorization of revisions to its hazardous waste management program under the Resource Conservation and Recovery Act (RCRA), as amended. The Environmental Protection Agency (EPA) has completed its review of Nevada's application and made a decision, subject to public review and comment, that Nevada's hazardous waste management program revisions satisfy all of the requirements necessary to qualify for final authorization. Thus, with respect to the revisions identified below, EPA is authorizing Nevada's hazardous waste management program revisions through this immediate final rule. EPA is publishing this rule to authorize the changes without a prior proposal because we believe that this action is not controversial and do not expect comments that oppose it. In the Proposed Rules section of this **Federal Register**, EPA is also publishing a proposal to authorize these changes to Nevada's hazardous waste management program. Unless we receive written comments that oppose this authorization during the comment period, the decision to authorize Nevada's changes to its hazardous waste management program will take effect as provided below. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect and the separate document in the proposed rules section of this **Federal Register** will serve as the proposal for purposes of this rulemaking action. EPA will respond to public comments in a later final rule based on the proposal. Nevada's application for program revision is available for public review and comment. EPA may not provide further opportunity for comment. Any parties interested in commenting on this action should do so at this time.

DATES: Final authorization for Nevada is effective August 12, 2002 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Nevada's program revision application must be received by the close of business July 12, 2002.

ADDRESSES: Copies of Nevada's program revision application are available during the business hours of 9 a.m. to 5 p.m. at the following addresses for inspection and copying:

Nevada Department of Conservation and Natural Resources, Division of Environmental Protection, 333 W. Nye Lane, Carson City, NV 89710 Phone: 775/687–5872 Contact Allen Biaggi, Administrator.

U.S. EPA Region IX Library-Information Center, 75 Hawthorne Street, San Francisco, CA 94105, Phone: 415/947–4406.

Written comments should be sent to Lisa McClain-Vanderpool, U.S. EPA Region IX (WST–2), 75 Hawthorne Street, San Francisco, CA 94105, Phone: 415/972–3316.

FOR FURTHER INFORMATION CONTACT: Lisa McClain-Vanderpool, U.S. EPA Region IX (WST–2), 75 Hawthorne Street, San Francisco, CA 94105 Phone: 415/972–3316.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste management program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must revise their programs and ask EPA to authorize the revisions. Revisions to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

Nevada initially received final authorization from EPA on August 19, 1985, effective October 18, 1985 (50 FR 33359), to implement the RCRA hazardous waste management program in Nevada. EPA has also authorized revisions to Nevada's authorized program to reflect changes in the Federal program. Currently Nevada's hazardous waste management program includes Federal changes through July 1, 1997. On March 13, 2000 and November 6, 2001, Nevada submitted final complete program revision applications for changes to the Federal program that occurred between July 1, 1997 and July 6, 1999, seeking authorization of its revisions in accordance with 40 CFR 271.21. This rulemaking action addresses those revisions.

B. What Decisions Have We Made in This Rule?

We conclude that Nevada's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Nevada final authorization to operate its hazardous waste management program with the changes described in this rulemaking. Nevada has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations on its authority retained by EPA in accordance with RCRA, including the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by HSWA regulations take effect as a matter of federal law in authorized States before those states are authorized for such requirements and prohibitions. Thus, EPA implements those requirements and new prohibitions in Nevada, including issuing permits, until the State is granted authorization to do so.