EPA time necessary to develop a further proposal to address storm water discharges from such activities.

I. National Technology Transfer And Advancement Act

As noted in the proposed rule, 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) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. However, EPA is exploring the availability and potential use of voluntary consensus standards developed consistent with the NTTAA and the requirements of the CWA as a means of addressing storm water runoff from oil and gas construction activities as part of a future rulemaking.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 9, 2005.

K. Petitions for Judicial Review

Under section 509(b)(1) of the Clean Water Act, judicial review of this action may only be had by filing a petition for review in the United States Court of Appeals within 120 days after March 9, 2005.

List of Subjects in 40 CFR Part 122

Administrative practice and procedure, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 3, 2005.

Stephen L. Johnson,

Acting Administrator.

■ For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

Subpart B—[Amended]

■ 2. Revise § 122.26(e)(8) to read as follows:

§ 122.26 Storm water discharges (applicable to State NPDES programs, see § 123.25).

* * * * *

(e) * * *

(8) For any storm water discharge associated with small construction activity identified in paragraph (b)(15)(i) of this section, see § 122.21(c)(1). Discharges from these sources, other than discharges associated with small construction activity at oil and gas exploration, production, processing, and treatment operations or transmission facilities, require permit authorization by March 10, 2003, unless designated for coverage before then. Discharges associated with small construction activity at such oil and gas sites require permit authorization by June 12, 2006.

* * * * *

[FR Doc. 05–4467 Filed 3–8–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0022; FRL–7699–8]

Clofentezine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clofentezine in or on grapes and persimmons. Makhteshim-Agan of North America, Inc. and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 9, 2005. Objections and requests for hearings must be received on or before May 9, 2005.

ADDRESSES: To submit a written objection or hearing request, follow the detailed instructions as provided in Unit VI of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0022. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Room 119, Crystal Mall #2, 1801 S. Bell Street, Arlington, VA 22202–4501. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax number: (703) 305–6596; e-mail address: *rodia.carmen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

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

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

II. Background and Statutory Findings

In the **Federal Register** of July 12, 2000 (65 FR 43004) (FRL–6591–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6119) by Aventis CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.446 be amended by establishing a tolerance for residues of the miticide clofentezine [(3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine), in or on grapes at 0.35 parts per million (ppm). Subsequently, Aventis CropScience sold all proprietary rights for clofentezine to Makhteshim-Agan of North America, Inc., 551 Fifth Avenue, Suite 1100, New York, NY 10176. Further, in the **Federal Register** of August 27, 2004 (69 FR 52688) (FRL–7676–3), EPA issued a similar notice announcing the filing of a pesticide petition (PP 4E6824) by the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902, requesting that 40 CFR 180.446 be amended by establishing a tolerance for residues of clofentezine, in or on persimmons at 0.05 ppm. These notices included a summary of the petitions prepared by the registrants. In order to harmonize with existing Codex maximum residue limits (MRLs) for grapes, the proposed tolerance level for grapes was subsequently revised to 1.0 ppm. There were no substantive comments received in response to these notices.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of clofentezine *per se* on grapes at 1.0 ppm and on persimmons at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clofentezine are discussed below in 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 AND CHRONIC TOXICITY PROFILE OF CLOFENTEZINE TECHNICAL.

Guideline No.	Study Type	Results
870.3100	90–Day subchronic feeding toxicity, mouse	Incorporated into the 2–year mouse oncogenicity study.
870.3100	90–Day subchronic feeding toxicity, rat	NOAEL (systemic): 2.0 mg/kg/day LOAEL (systemic): 20.0 mg/kg/day based on increased cholesterol levels, liver-to-body weight ratios, liver weights, and centrilobular hepatocellular enlargement.
870.3150	90–Day subchronic feeding, non-rodent (dog)	NOAEL was not established. LOAEL (systemic): <80.0 mg/kg/day based on increased liver weights in both sexes and electrocardiographic changes in females.

TABLE 1.—SUBCHRONIC AND CHRONIC TOXICITY PROFILE OF CLOFENTEZINE TECHNICAL.—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal Developmental Toxicity, Rat	Maternal NOAEL: 1,280 mg/kg/day (above the Limit Dose of 1,000 mg/kg/day) Maternal LOAEL: 3,200 mg/kg/day based on differential staining and slight enlargement of the centrilobular hepatocytes. Developmental NOAEL: >3,200 mg/kg/day (above the Limit Dose) Developmental LOAEL: >3,200 mg/kg/day (above the Limit Dose)
870.3700	Prenatal Developmental Toxicity, Rabbit	Maternal NOAEL: 1,000 mg/kg/day (Limit Dose) Maternal LOAEL: 3,000 mg/kg/day based on decreased body weight and food consumption. Developmental NOAEL: 1,000 mg/kg/day (Limit Dose) Developmental LOAEL: 3,000 mg/kg/day based on decreased mean fetal weight.
870.3800	2-Generation Reproductive and Fertility Effects, Rat	Parental/Systemic NOAEL: ≥20.0 mg/kg/day Parental/Systemic LOAEL: >20.0 mg/kg/day Reproductive NOAEL: ≥20.0 mg/kg/day Reproductive LOAEL: >20.0 mg/kg/day Offspring NOAEL: ≥20.0 mg/kg/day Offspring LOAEL: >20.0 mg/kg/day
870.4100	Chronic Feeding Toxicity, Nonrodent (Dog)	NOAEL (systemic): 1.25 mg/kg/day LOAEL (systemic): 25.0 mg/kg/day based on increased liver weights, hepatocellular enlargement, and increased serum cholesterol, triglycerides, and alkaline phosphatase levels.
870.4200	Chronic Carcinogenicity (Feeding), Mouse	NOAEL (systemic): 50.70 mg/kg/day LOAEL (systemic): 543.0 mg/kg/day based on decreased body weights and body weight gains, increased incidence of eosinophilic areas in hepatocytes of males. In females, increased incidence of basophilic and/or eosinophilic foci or areas of hepatocyte alterations, mortality with amyloidosis as a contributing factor for increased mortality. No evidence of carcinogenicity.
870.4300	Combined Chronic Feeding Toxicity/Carcinogenicity Study, Rat	NOAEL (systemic): 1.72 mg/kg/day LOAEL (systemic): 17.3 mg/kg/day based on increased liver weights and liver-to-body weight ratios and increased thyroxin levels; and centrilobular hepatocellular hypertrophy and vacuolation, focal cystic degeneration of hepatocytes, and diffuse distribution of fat deposits in liver (M). Evidence of carcinogenicity in male rats [thyroid tumors].
870.5200	Mouse Lymphoma	Non-mutagenic (±) activation.
870.5250	Gene Mutation, *Salmonella*	Non-mutagenic (±) activation.
870.5395	*In vitro* Mammalian Cytogenetics Test (Erythocyte Micronucleus Assay), Mice	Non-mutagenic.
870.5450	Rodent Dominant Lethal Assay, Rat	Non-mutagenic.
870.5575	Mitotic Gene Conversion in *Saccharomyces cerevisiae*	Non-mutagenic and negative for mitotic recombination.
870.7485	General Metabolism, Rat	Male and female rats given clofentezine technical at 1,000 mg/kg manifested peak plasma levels of between 14 and 16 ppm at 6-8 hours post-dosing which then declined to 3 ppm at 24 hours post-dosing. Plasma half-life was approximately 3.5 hours. Whole body autoradiography of rats given a 10 mg/kg dose indicated poor gastrointestinal absorption with 60-70% of the given dose excreted in the feces during the first 24 hours and about 20% excreted in the urine. Major metabolites were 3-(2′-methyl-thio-3′ hydroxy phenyl)-6-(2′-chlorophenyl)-1,2,4,5-tetrazine and 3-,4-, and 5-hydroxyclofentezine. Both liver and kidney had the highest tissue concentration after 72 hours.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intraspecies differences.

Three other types of safety or uncertainty factors may be used: The ''traditional uncertainty factor;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10x safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a ''traditional uncertainty factor'' or a ''special FQPA safety factor'').

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

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

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

In general, clofentezine has low acute toxicity by the oral, dermal and inhalation routes of exposure (Categories III and IV) although mild eye irritation has been observed in rabbits. No appropriate toxicological endpoint (effect) attributable to a single exposure (dose) was identified in any study including the available oral studies in the rat and developmental studies in the rat and rabbit; therefore, an acute RfD was not established and no risk is expected from acute exposure. Long-term dermal exposure and risk is not expected, based on the current use pattern. In addition, based on the overall low toxicity of clofentezine, there is minimal concern for short-, intermediate-, and long-term inhalation exposure and risk. A summary of the toxicological endpoints used for the clofentezine human health risk assessment is shown below in Table 2.

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (General U.S. Population including infants and children)	NOAEL= 1.25 mg/kg/day UF = 100 Chronic RfD = 0.013 mg/kg/day	Special FQPA SF = 1x cPAD = chronic RfD Special FQPA SF = 0.013 mg/kg/day	Chronic Feeding Toxicity, Nonrodent (Dog) LOAEL = 25.0 mg/kg/day based on histopathology in the liver and elevated serum cholesterol, triglycerides, and alkaline phosphatase observed at the LOAEL.
Short-Term Dermal (1 to 30 days) (Residential)	Oral study NOAEL = 2 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	90–Day subchronic feeding toxicity, Rat LOAEL = 20 mg/kg/day based on increased cholesterol, increased liver weights, thyroid colloid depletion and thyroid follicular cell hypertrophy.
Intermediate-Term Dermal (1 to 6 months) (Residential)	Oral study NOAEL = 2 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	90–Day Subchronic Feeding Toxicity, Rat LOAEL = 20 mg/kg/day based on increased cholesterol, increased liver weights, thyroid colloid depletion and thyroid follicular cell hypertrophy.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.446) for the residues of clofentezine *per se*, in or on a variety of raw agricultural commodities (RACs). Specifically, tolerances for clofentezine are established for almonds, apples, apricots, cherries, nectarines, peaches, pears, and walnuts. Risk assessments were conducted by EPA to assess dietary exposures from clofentezine in food as follows:

i. *Acute exposure.* As discussed in Unit III.B, an acute dietary exposure assessment was not performed because an endpoint of concern attributable to a single oral dose was not selected for any population subgroup (including infants and children).

ii. *Chronic exposure.* In conducting the chronic and cancer dietary (food only) exposure assessments for clofentezine, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 2.03, and the Lifeline™Model, Version 2.0, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic and cancer dietary exposure assessments: The Agency has determined that clofentezine *per se* and the 3-(2-chloro-4-hydroxyphenyl)-6-(2-chlorophenyl)-1,2,4,5-tetrazine metabolite are the residues of concern for the chronic dietary analysis. The chronic dietary analysis for clofentezine was based on anticipated residue levels (ARs) in the form of average field trial residue values, and the analysis included estimates for percent crop treated (PCT).

iii. *Cancer.* As explained in Unit III.C.1.ii above, the Agency assessed cancer dietary exposure for clofentezine using the same assumptions used for chronic dietary exposure. Cancer risk is determined for the general U.S. population only. The estimated exposure of the general U.S. population to clofentezine is 0.000023 mg/kg/day.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must, pursuant to section 408(f)(1), 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. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

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

For existing uses, the Agency used estimates of PCT for the chronic dietary (food only) risk assessment, which was determined using USDA's National Agricultural Statistics Service (NASS) usage data and EPA 2003 proprietary usage data (DOANE 2003). Table 3 below displays the chronic PCT estimates used for the existing uses of clofentezine. When the PCT for a commodity is estimated as <1%, the PCT used for risk assessment purposes is 1%.

TABLE 3.—CLOFENTEZINE ESTIMATES OF PERCENT CROP TREATED FOR EXISTING USES.

Commodity	Percent Crop Treated
Almonds	<1
Apples	5
Apricots	5
Cherries	<1
Nectarines	10
Peaches	5
Pears	5
Prunes & Plums	<1
Walnuts	<1

For the new uses, the Agency used PCT estimates for the chronic dietary (food only) risk assessment based on ''screening level'' usage data for agricultural crops. This information was retrieved from 1998–2003 USDA National Agricultural Statistics Service (NASS) usage data and EPA 2003 proprietary usage data (DOANE 2003) for the historically, most widely used miticide for control of pests for each crop. The 2003 NASS data were compared to the DOANE 2003 data, both yielded similar results and did not make a difference. As a result of this comparison, the highest, most conservative PCT estimate for each crop was used for the chronic dietary (food only) risk assessment. These highly conservative estimates should not underestimate actual usage of clofentezine on the new crops/sites. Some of these numbers may be based on information that does not cover all 50 states; therefore, it is possible that if the remaining (usually minor states for the crop) had been included, the quantity (pounds) of active ingredient would be slightly higher.

To further support the reliability of these PCT estimates, as a condition of registration, the registrant will be required to agree to report annually on the market share attained for the new uses for which clofentezine is registered. As a condition of registration, they will also be required to agree to mitigate dietary risk as deemed appropriate by the Agency should the market share data raise a concern for increased dietary risk. The Agency will then compare that market share information with the PCT estimates used to evaluate potential dietary risk. In those instances where percent market share is approaching or exceeding the predicted PCT estimate used in the Agency's risk assessment, EPA will conduct a new dietary risk assessment to evaluate the new dietary risk. If the market share data raise a concern for increased pesticide risk, the Agency will act to mitigate that dietary risk and

could employ several approaches, including but not limited to production caps, geographical limitations, removal of uses, or other means deemed appropriate by the Agency. Table 4 below displays the chronic PCT estimates used for the new uses of clofentezine. When the PCT for a commodity is estimated as <1%, the PCT used for risk assessment purposes is 1%.

TABLE 4.—CLOFENTEZINE ESTIMATES OF PERCENT CROP TREATED FOR NEW USES.

Commodity	Percent Crop Treated
Grapes	13
Persimmons	<1

The Agency believes that the three conditions listed in this Unit 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. 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 clofentezine 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 clofentezine 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 clofentezine.

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to clofentezine, they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of clofentezine for acute exposures are estimated to be 4.2 parts per billion (ppb) for surface water and 0.1 ppb for ground water. The EECs for chronic exposures are estimated to be 0.2 ppb for surface water and 0.1 ppb for ground water.

3. *From nondietary exposure.* The term ''residential exposure'' is used in this document to refer to nonoccupational, nondietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Clofentezine is not registered for use on any sites that would result in residential exposure. Therefore, a residential exposure assessment was not conducted.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to clofentezine and any other substances and clofentezine 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 clofentezine has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of an MOE analysis or through using uncertainty (safety) factors in calculating a dose

level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10x when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no indication of an increased susceptibility of rat or rabbit fetuses/pups to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies.

3. *Conclusion*. EPA has determined that there are reliable data supporting removal of the additional 10x factor for the protection of infants and children. This decision was based on the following conclusions:

i. The toxicology database is complete;

ii. There is no indication of increased susceptibility of rats or rabbit fetuses/pups [quantitatively or qualitatively] to *in utero* and/or postnatal exposure to clofentezine in the developmental and reproductive toxicity studies;

iii. A developmental neurotoxicity study (DNT) is not required;

iv. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures; and

v. There are currently no registered residential uses of clofentezine.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through 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 toxicological endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

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

Human health aggregate risk assessments have been conducted for the chronic and cancer (food + drinking water) exposure scenarios. An acute aggregate risk assessment was not performed because an endpoint of concern attributable to a single oral dose was not identified for any population subgroup (including infants and children). Short-, intermediate- and long-term aggregate risk assessments were not performed because there are no registered or proposed residential uses for clofentezine. All potential exposure pathways were assessed in the aggregate risk assessment. All aggregate exposure and risk estimates do not exceed EPA's LOC for the chronic and cancer (food + drinking water) exposure scenarios.

1. *Acute risk*. As discussed in Unit III.E., clofentezine is not expected to pose an acute risk because an endpoint of concern attributable to a single oral dose was not identified for any population subgroup (including infants and children).

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clofentezine from food will utilize 0.1% of the cPAD for the general U.S. population, 0.3% of the cPAD for all infants (<1 year old), and 0.4% of the cPAD for children (1–2 years old). There are no residential uses for clofentezine that result in chronic residential exposure to clofentezine. In addition, there is potential for chronic dietary exposure to clofentezine 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 below in Table 5.

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

Population/Subgroup	cPAD/mg/kg/day	%/cPAD/(Food)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC (ppb)
General U.S. population	0.013	0.1	0.2	0.1	450
All infants (<1 year old)	0.013	0.3	0.2	0.1	130
Children (1–2 years old)	0.013	0.4	0.2	0.1	130
Females (13–49 years old)	0.013	0.1	0.2	0.1	390

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clofentezine is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clofentezine is not

registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. In conducting the aggregate cancer risk assessment, only food and drinking water pathways of exposure were considered. At this time, there are no uses for clofentezine that would result in any non-occupational, non-dietary exposure (i.e., there are no dermal or inhalation routes of exposure that should be included in an aggregate assessment). The cancer risk from exposure to clofentezine residues in food was calculated as 4.31×10^{-7}. This is below EPA's level of concern for cancer risk (risks in the range of one in a million). A DWLOC was derived for the general U.S. population based on EPA's LOC for cancer or a risk in the range of one in one million (using the value of 1×10^{-6} as a first Tier value in calculating a conservative estimate of DWLOC that is consistent with the range of one in one million). The DWLOC is compared to the EECs of clofentezine in surface and ground water and is used to determine whether or not aggregate cancer exposures are likely to result in risk estimates that exceed EPA's LOC. Table 6 below summarizes the cancer aggregate exposure estimates to clofentezine residues.

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR CANCER EXPOSURE TO CLOFENTEZINE.

Population/Subgroup	Maximum Exposure (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)	Cancer DWLOC (ppb)	Ground/Water EEC/(ppb)	Surface Water EEC/(ppb)
General U.S. Population	2.66×10^{-5}	1.1×10^{-5}	1.56×10^{-5}	0.6	0.1	0.2

The EECs calculated for ground and surface water are less than EPA's calculated cancer DWLOC. Therefore, the cancer aggregate risk associated with the proposed use of clofentezine does not exceed EPA's level of concern for the general U.S. population and all population subgroups.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

A high-performance liquid chromatography (HPLC) analytical method exists for the determination of clofentezine residues. A petition method validation (PMV) was successfully completed by the analytical chemistry laboratory (ACL), and the method was found acceptable. The limit of quantitation (LOQ) and limit of detection (LOD) reported were 0.01 ppm and 0.003 ppm, respectively. The Agency concluded that the method was suitable for enforcement purposes. The method was forwarded to FDA for inclusion in Pesticide Analytical Manual (PAM)-Volume II. PAM-Volume I multiresidue methods are not acceptable for tolerance enforcement.

Adequate enforcement methodology (example —gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Codex MRLs exist for clofentezine on grapes. The Codex MRLs for grapes and the U.S. tolerances established for clofentezine on grapes by this rule are harmonized at 1.0 ppm. No Codex MRLs exist for clofentezine on persimmons.

V. Conclusion

Therefore, tolerances are established for residues of clofentezine *per se*, (3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine), in or on grapes at 1.0 ppm and persimmons at 0.05 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0022 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 May 9, 2005.

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

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th Street, NW., Washington, DC 20005–3419. The

Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A, you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0022, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 25, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.446 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Grapes	1.0
* * *	* *
Persimmons	0.05
* * *	* *

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[FR Doc. 05–4335 Filed 3–8–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0410; FRL–7699–2]

Fenbuconazole; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites *cis*- and*trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, expressed as fenbuconazole in or on bananas (whole fruit); pecans; and stone fruit crop group (except plums and prunes). Dow AgroSciences, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on December 31, 2008.

DATES: This regulation is effective March 9, 2005. Objections and requests for hearings must be received on or before May 9, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the**SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2004–0410. All documents in the docket are listed in the EDOCKET index at*http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: J. R. Tomerlin, Registration Division (0705C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0598; e-mail address: *tomerlin.bob@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

II. Background and Statutory Findings

In the **Federal Register** of November 17, 2004 (69 FR 67351) (FRL–7686–6), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1F3989, 1F3995, and 2F4154) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petitions requested that 40 CFR 180.480 be amended by establishing a tolerance for combined residues of the fungicide fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites *cis*- and*trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, in or on banana (whole fruit) at 0.3 parts per million (ppm) (2F4154); fruit, stone, group 12 (except plum, prune) at 2.0 ppm (1F3989); pecan at 0.1 ppm (1F3995). This notice included a summary of the petition prepared by Dow AgroSciences, LLC, the registrant.

The tolerances will expire on December 31, 2008.

Comments were received in response to the notice of filing from one individual. These comments are addressed in Unit IV.C.

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