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

exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of banana (whole fruit) at 0.3 parts per million (ppm); fruit, stone, group 12 (except plum, prune) at 2.0 ppm; pecan at 0.1 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 fenbuconazole are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents - rats	NOAEL = 1.3/1.5 mg/kg/day (M/F) LOAEL = 5.1/6.3 mg/kg/day (M/F) based on liver histopathology
870.3100	90–Day oral toxicity rodents - mice	NOAEL = 3.8/5.7 mg/kg/day (M/F) LOAEL = 11.1/17.6 mg/kg/day (M/F) based on liver histopathology
870.3150	90–Day oral toxicity in nonrodents - dogs	NOAEL = 3.3/3.5 mg/kg/day (M/F) LOAEL = 13.3/14.0 mg/kg/day (M/F) based on liver histopathology
870.3200	21/28–Day dermal toxicity - rats	NOAEL = 1,000 mg/kg/day (HDT) LOAEL = > 1,000 mg/kg/day
870.3250	90–Day dermal toxicity	Not performed
870.3465	90–Day inhalation toxicity	Not performed
870.3700	Prenatal developmental in rodents - rats	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 75 mg/kg/day based on decreased body weight and body weight gain Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 75 mg/kg/day based on increased post-implantation loss and a decrease in the number of live fetuses/dam
870.3700	Prenatal developmental in nonrodents - rabbits	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 30 mg/kg/day based on decreased food consumption and increased incidence of clinical signs (soft/scant/no feces and red discharge) Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 60 mg/kg/day based on increased early resorptions
870.3800	Reproduction and fertility effects - rats	Parental systemic NOAEL = 4 mg/kg/day Parental systemic LOAEL = 40 mg/kg/day based on maternal death during delivery, decreased body weight and food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increased adrenal and thyroid/parathyroid weights Reproductive NOAEL = 40 mg/kg/day (HDT) Reproductive LOAEL = greater than 40 mg/kg/day Offspring systemic NOAEL: 4 mg/kg/day Offspring systemic LOAEL: 40 mg/kg/day based on decreased pup body weight, increased number of stillborn pups, decreased number of total offspring delivered and decreased viability indes
870.4100	Chronic toxicity - rodents	Requirements met by submission of studies according to OPPTS Harmonized Guideline 870.4300

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

Guideline No.	Study Type	Results
870.4100	Chronic toxicity - dogs	NOAEL = 3.75/0.38 mg/kg/day (M/F) LOAEL = 30/3.75 mg/kg/day (M/F) based on decreased body weight gain Note: Dose-related adaptive liver changes were observed in high-dose males and females
870.4200	Carcinogenicity - rats	Requirements met by submission of studies according to OPPTS Harmonized Guideline 870.4300
870.4200	Carcinogenicity - mice	NOAEL = 1.43 mg/kg/day (both M and F) LOAEL = 28.6/92.9 mg/kg/day (M/F) based on decreased body weight, increased relative and absolute liver weight, and hepatocellular hypertrophy and vacuolization Evidence of carcinogenicity
870.4300	Combined chronic toxicity/carcinogenicity - rat	NOAEL = 3.0/4.0 mg/kg/day (M/F) LOAEL = 30.6/43.1 mg/kg/day (M/F) based on decreased body weight gain (F), hepatocellular enlargement and vacuolization (F), increased thyroid weight (M and F), and histopathological lesions in the thyroid gland (M) Evidence of carcinogenicity
870.4300	Combined chronic toxicity/carcinogenicity - rat	NOAEL = Not established LOAEL = 30.4 mg/kg/day (M) based on decreased body weight gain, increased liver weight, and increased thyroid and parathyroid weights Note: Only males were used in this study. Insufficient evidence of carcinogenicity
870.5100	Gene mutation - bacterial reverse mutation assay	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay. Note: Only TA1535, TA1537, TA98, and TA100 were tested. This study is classified unacceptable.
870.5100	Gene mutation - bacterial reverse mutation assay	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay. Note: Only TA1535, TA1537, TA98, and TA100 were tested. This study is classified unacceptable.
870.5300	Cytogenetics - *in vitro* mammalian cell gene mutation test (CHO Cells)	No increase in mutant frequency at the HGPRT locus, in the presence or absence of S9 activation.
870.5385	Cytogenetics - mammalian bone marrow chromosomal aberration test (rats)	No increase in number of cells with aberrations or in aberrations per cell.
870.5550	Other effects - unscheduled DNA synthesis in mammalian cells in culture (rats)	No evidence (or a dose related positive response) that unscheduled DNA synthesis was induced.
870.7485	Metabolism and pharmacokinetics - rat	The mean recovery of radioactivity 4 days after exposure was 82.6–93.0% following single or repeated oral doses and 88.2–99.2% following single i.v. doses, indicating rapid absorption, distribution, and elimination. Rapid elimination and low tissue levels indicate low bioaccumulation of the parent and metabolites. Elimination occurred primarily by biliary excretion because recovery of radioactivity was mostly in the feces: 75.6–83.7% following oral exposure and 77.2–91.4% following i.v. exposure. In urine, radioactivity recovery was 5.5-12.6% for all dose scenarios. Peak radioactivity in the blood occurred 3 hours following a single low dose and 3–6 hours after a single high dose, indicating biphasic elimination. Only 8.5–14.8% and 0.0–2.7% of the parent compound was recovered in the feces and urine, respectively, indicating extensive metabolism. A number of major metabolites were identified; however, 50% and 20% of metabolites in the feces and urine, respectively, were not identified. Sex-related differences include a greater number of sulfate metabolites in female excreta compared to males, and a greater number of ketoacid metabolites in male urine compared to females.

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics - rat	The mean recovery of radioactivity 3–4 days after exposure was 90.4–104.5% following single or repeated oral doses, indicating rapid absorption, distribution, and elimination. Bioaccumulation of the parent compound and metabolites is low. There were no major sex- or dose-related differences in absorption, distribution, or elimination. Elimination occurred primarily by biliary excretion: Recovery of the administered dose occurred mainly in the bile (79.1–87.1%) 3 days after exposure and mostly in the feces (78.7–94.4%) 4 days after exposure. In contrast, radioactivity recovery in the urine was 3.2–11.5% at 3 and 4 days after exposure. Extensive metabolism occurred; numerous metabolites were found in the feces and urine. There is a dose-related difference in metabolism. A higher amount of parent compound was found in the feces following the single high dose compared to the single or repeated low dose(s), which suggests that saturation may be occurring at the high dose.
870.7600	Dermal penetration - rat	The highest dermal absorption was found in animals having the longest exposure dose. Mean % of the dose absorbed (sum of urine, feces, carcass, and skin) after 10 hours of exposure: *Dose (mg/kg)* *Percent Dermal Absorption* 0.125 4.25 1.25 2.08 125 0.45

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.

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 (SF).

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure(MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fenbuconazole used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENBUCONAOZLE 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 13–49 years of age)	NOAEL = 30 mg/kg/day UF = 100a Acute RfD = 0.3 mg/kg	Special FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.3 mg/kg	Developmental rat study Developmental LOAEL = 75 mg/kg/day based on increased resorptions and decreased live fetuses per dam

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	None	None	Not selected No appropriate dose and endpoint could be identified for these population groups.
Chronic dietary (all populations)	NOAEL = 3 mg/kg/day UF = 100a Chronic RfD = 0.03 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.03 mg/kg/day	Combined chronic toxicity/carcinogenicity - rat LOAEL = 30.6/43.1 (M/F) mg/kg/day based on decreased body weight gain, increased thyroid weight, and histopathological lesions in the liver and thyroid gland
Incidental oral (all durations)	None	None	Not selected No registered uses would result in residential exposure
Short-term (1 to 30 days) and intermediate-term (1 to 6 months) Dermal	None	None	Not selected No dermal or systemic toxicity was seen in a 21–day dermal toxicity study; poor absorption was seen in the dermal absorption study
Long-term dermal (several months to lifetime)	Oral study NOAEL = 3 mg/kg/day (dermal absorption rate = 4.25%)	Residential LOC for MOE = Not applicable Occupational LOC for MOE = 100[a]	Combined chronic toxicity/carcinogenicity - rat LOAEL = 30.6/43.1 (M/F) mg/kg/day based on decreased body weight gain, increased thyroid weight, and histopathological lesions in the liver and thyroid gland
Inhalation (all durations)	None	None	Not selected Low toxicity and use pattern does not indicate a need for risk assessment via inhalation.
Cancer (oral, dermal, inhalation)	Classification: Under the 1986 cancer classification scheme, fenbuconazole was classified as a Group C - Possible Human Carcinogen, with a low dose extrapolation model applied to the animal data for the quantification of human risk (Q1*). This was based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice and of thyroid follicular adenomas and combined adenomas/carcinomas in male rats. Based on mechanistic data, quantification of risk was derived using combined hepatocellular adenomas/carcinomas in female mice. The upper bound estimate of unit risk, Q1* $(mg/kg/day)^{-1}$ is 3.59×10^{-3} in human equivalents.		

*Database uncertainty factor reduced to 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.480) for the combined residues of fenbuconazole, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fenbuconazole 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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues were used for all food commodities, 100% of all commodities were assumed to be treated, and default processing factors were used for processed commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the DEEM™ analysis evaluated the food consumption as reported by respondents in the USDA 1994–1996 and 1998 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis is slightly refined in that it incorporates estimates of average percent crop treated (PCT), although it does use tolerance value residues for most commodities and default processing factors. Anticipated residues from USDA Pesticide Data Program monitoring data were used only for banana in the chronic dietary exposure analysis and risk assessment.

iii. *Cancer.* Chronic cancer risk for the overall U.S. population was estimated by multiplying the chronic exposure

estimate by the carcinogenic potential (Q*) of 0.0359 (mg/kg/day)$^{-1}$.

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

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

The Agency used PCT information as follows:

A routine chronic dietary exposure analysis for the fungicide fenbuconazole and its*cis* and *trans* metabolites was based on 10% of apricot crop treated, 25% of blueberry crop treated, 25% of cherry crop treated, 30% of grapefruit crop treated, 15% of nectarine crop treated, 15% of peach crop treated, and 10% of pecan crop treated.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information for fenbuconazole is reliable and has a valid basis. Time-limited tolerances have existed for all crop commodities included in the risk assessment, and the Agency obtained estimates of fenbuconazole use from recognized pesticide use data bases. 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 fenbuconazole 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 fenbuconazole 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 fenbuconazole.

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

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

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 comparisons (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 fenbuconaozle, they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated EECs of fenbuconazole for acute exposures are estimated to be 14.1 parts per billion (ppb) for surface water and 0.005 ppb for ground water. The EECs for chronic exposures are estimated to be 7.3 ppb (peak annual) and 5.9 ppb (30–year average) for surface water and 0.005 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).

Fenbuconazole is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fenbuconazole 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 fenbuconazole 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) (FRL–5754–7).

However, the Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid, metabolites common to most of the triazole fungicides. To support the extension of existing parent triazole-derivative fungicide tolerances, EPA conducted an interim human health assessment for aggregate exposure to 1,2,4-triazole. The exposure and risk estimates presented in this assessment are overestimates of actual likely exposures and therefore, should be considered to be highly conservative. Based on this assessment, EPA concluded that for all exposure durations and population subgroups, aggregate exposures to 1,2,4-triazole are not expected to exceed its level of concern. This assessment should be considered interim due to the ongoing series of studies being conducted by the U.S. Triazole Task Force (USTTF). Those studies are designed to provide the Agency with more complete toxicological and residue information for free triazole and are expected to be submitted to the Agency in late 2004 and early 2005. Upon completion of review of these data, EPA will prepare a more sophisticated assessment based on the revised toxicological and exposure data bases.

i. *Toxicology*. The toxicological data base for 1,2,4-triazole is incomplete. Preliminary summary data presented by the USTTF to EPA indicate that the most conservative endpoint currently available for use in a risk assessment for 1,2,4-triazole is a LOAEL of 15 mg/kg/day, based on body weight decreases in male rats in the reproductive toxicity study (currently underway). This endpoint, with an uncertainty factor of 1,000 was used for both acute and chronic dietary risk, resulting in an RfD of 0.015 mg/kg/day. The uncertainty factor of 1,000 includes an additional 10X safety factor for the protection of infants and children. The resulting PAD is 0.015 mg/kg/day.

ii. *Dietary exposure*. The USTTF conducted an acute dietary exposure assessment based on the highest triazole-derivative fungicide tolerance level combined with worst-case molecular weight and plant/livestock metabolic conversion factors. This approach provides a conservative estimate of all sources for 1,2,4-triazole except the *in vivo* conversion of parent compounds to free-triazole following dietary exposure. The degree of animal *in vivo* conversion is dependent on the identity of the parent fungicide. In rats, this conversion ranges from 0% to 77%, the*in vivo* conversion for fenbuconaozle is 2.5%. For purposes of this interim assessment, EPA used the dietary exposure estimates provided by the USTTF adjusted based on the highest rate of conversion observed for any of the parent triazole-derivative fungicides to account for this metabolic conversion. The assessment includes residue estimates for all food commodities with either existing or pending triazole-derivative fungicide registrations. The resulting acute dietary exposure estimates are extremely conservative and range from 0.0032 mg/kg/day for males 20+ years old to 0.014 mg/kg/day for children 1 to 6 years old. Estimated risks range from 22% to 93% of the PAD. In order to estimate chronic exposures via food, EPA used the 70th percentile of exposures from the acute assessment. The 70th percentile is a common statistic used to estimate central tendency from a distribution and its use to estimate chronic exposures is appropriate. Estimated risks range from 10% to 47% of the PAD. It is emphasized that the use of both highest tolerance level residues and the highest *in vivo* conversion factor results in dietary risk estimates that far exceed the likely actual risk.

iii. *Non-dietary exposure*. Triazole-derivative fungicides are registered for use on turf, resulting in the potential for residues of free triazole in grass and/or soil. Thus dermal and incidental oral exposures to children may occur. It is believed that residues of free triazole occur within the plant matrices and are not available as surface residues. Therefore, direct dermal exposure to 1,2,4-triazole due to contact with plants is not likely to occur. However, dermal exposure to parent fungicide and subsequent *in vivo* conversion to 1,2,4-triazole may occur. In order to account for this indirect exposure to free triazole, EPA used a conversion factor of 10%, which is the highest rate of *in vivo* conversion observed in rats for any of the triazole-derivative fungicides with registrations on turf. Incidental oral exposure may occur by direct and indirect routes. To assess direct exposure, EPA used a conversion factor of 17%, which is the highest rate of conversion to free triazole observed in any of the plant metabolism studies. As with indirect dermal exposure, EPA used a conversion factor of 10% in its assessment of indirect oral exposure. Based on residential exposure values estimated for propiconazole (0.0005 mg/kg/day via the dermal route and 0.03 mg/kg/day via the oral route) and the conversion factors described above, combined direct and indirect dermal exposures are estimated to be less than 0.0001 mg/kg/day and combined oral exposures are estimated to be less than 0.0019 mg/kg/day. The overall residential exposure is likely to be less than 0.0020 mg/kg/day. Relative to the 15 mg/kg/day point of departure, this gives an MOE of approximately 7,500 for children. Based on the current set of uncertainty factors, the target MOE is 1,000, indicating that the risk associated with residential exposure to 1,2,4-triazole for children is below EPA's level of concern. The adult dermal exposure estimate is slightly less than that of children. Incidental oral exposure is not expected to occur with adults.

iv. *Drinking water*. Modeled estimates of 1,2,4-triazole residues in surface water and ground water, as reported by the USTTF, and the DWLOC approach were used to address exposure to free triazole in drinking water. EECs of free triazole in ground water were obtained from the SCI-GROW model and range from 0.0 to 0.026 ppb, with the higher concentrations associated with uses on turf. Surface water EECs were obtained using the FIRST model. Acute surface water EECs ranged from 0.29 to 4.64 ppb for agricultural uses and up to 32.1 ppb from use on golf course turf. EPA notes that ground water monitoring studies in New Jersey and California showed maximum residues of 16.7 and 0.46 ppb, respectively, which exceed the SCI-GROW estimates significantly. Contrariwise, preliminary monitoring data from USDA's Pesticide Data Program for 2004 show no detectable residues of 1,2,4-triazole in any drinking water samples, either treated or untreated (maximum LOD = 0.73 ppb, n = 40 each).

v. *Aggregate exposure*. In estimating aggregate exposure, EPA combined potential dietary and non-dietary sources of 1,2,4-triazole. To account for the drinking water component of dietary exposure, EPA used the DWLOC approach, as noted above. The DWLOC represents a maximum concentration of a chemical in drinking water at or below which aggregate exposure will not exceed EPA's level of concern. In considering non-dietary exposure, EPA used the residential exposure estimate for children and applied it to all population subgroups. As previously noted, this estimate is considered to be highly conservative for children. Since adults are not expected to have non-dietary oral exposure to 1,2,4-triazole and that pathway makes up the majority of the residential exposure estimate for

children, application of that exposure estimate to adults is considered to be extremely conservative. Residential exposure is expected to occur for short-term and/or intermediate-term durations, and therefore is not a component in the acute or chronic aggregate exposure assessment. In order to assess aggregate short-term and intermediate-term exposure, EPA combined the residential exposure estimate and the background level of exposure to free triazole via food. Less than 1% of lawns in the U.S. are expected to be treated with triazole fungicides, so the likelihood of co-occurring dietary and residential exposures is very low.

With the exception of the acute DWLOCs for infants and children 1–6 years, all DWLOCs are greater than the largest EEC (surface water estimate from use on turf), indicating that aggregate exposures are not likely to exceed EPA's level of concern. Although the acute DWLOCs for infants and children 1–6 years indicate that aggregate exposure may exceed the aPAD of 0.015 mg/kg/day, EPA does not believe this to be the case due to the extremely conservative nature of the overall assessment (highest-tolerance level residues, 100% crop treated, 77% *in vivo* conversion factor). Furthermore, the drinking water monitoring data from the Pesticide Data Program found no detectable residues of either free triazole or parent triazole-derivative fungicide in its preliminary 2004 dataset, indicating that neither parent compounds nor 1,2,4-triazole are likely to occur in drinking water. For all exposure durations and population subgroups, EPA does not expect aggregate exposures to 1,2,4-triazole to exceed its level of concern.

The Agency is planning to conduct a more sophisticated human health assessment in early 2005 following submission and review of the ongoing toxicology and residue chemistry studies for 1,2,4-triazole.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There are no data gaps for the assessment of the effects of fenbuconazole following *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenbuconazole.

3. *Conclusion*. There is a complete toxicity data base for fenbuconazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor (SF) could be removed (i.e., reduced to 1X) in assessing the risk posed by fenbuconazole for several reasons:

(i) There are no data gaps for the assessment of the effects of fenbuconazole following *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required.

(ii) There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenbuconazole.

(iii) The dietary food exposure assessment utilizes conservative assumptions (tolerance level residues) with respect to residues in food. Although some %CT information was used for the chronic dietary food exposure assessment, 100% CT was assumed for the acute assessment. Together, these assumptions result in high-end estimates of dietary exposure and risk.

(iv) The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations;

(v) At this time, there are no registered residential uses for fenbuconazole; therefore, this type of exposure to infants and children is not expected.

E. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and 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 fenbuconazole will occupy 0.9% of the aPAD for females 13 years and older, the only population subgroup for which an acute endpoint was identified. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13 - 49 years old	0.3	0.9	14.1	0.005	8,900

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenbuconazole from food will utilize 0.3% of the cPAD for the U.S. population, 1.3% of the cPAD for all infants, and 1.0% of the cPAD for children 1 to 2 years old. There are no residential uses for fenbuconazole that result in chronic residential exposure to fenbuconazole. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.03	0.3	7.3	0.005	1,000
All infants	0.03	1.3	7.3	0.005	300
Children 1 - 2 years old	0.03	1.0	7.3	0.005	300

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).

Fenbuconazole 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 level of concern.

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

Fenbuconazole 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 level of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, DWLOC for cancer risk were calculated. To calculate the DWLOC, the chronic dietary food exposure for the overall U.S. population was subtracted from the exposure required to achieve a one in one million cancer risk (1×10^{-6}). Under FFDCA section 408, pesticides posing a negligible cancer risk can qualify as meeting section 408's reasonable certainty of no harm safety standard. EPA has traditionally interpreted a negligible cancer risk as a cancer risk in the range of a one in one million risk. Risks as high as three in one million have been regarded as in the range of one in one million. A value of 1×10^{-6} was used in calculating the DWLOC for fenbuconazole as a conservative, first-tier cancer risk assessment. The exposure required to achieve negligible risk is calculatedas $1 \times 10^{-6} \div Q1^*$ $0.00359\ (mg/kg/day)^{-1}$. For cancer risk exposure, based on an adult body weight of 70 kg and 2L consumption of water per day, the estimated cancer DWLOC is 6.3 ppb for the U.S. population. EFED's 30–year average EEC of 5.9 ppb is lower than the cancer DWLOCs for the U.S. population. Therefore, the Agency concludes with reasonable certainty that, the aggregate cancer risk for fenbuconazole does not exceed the negligible risk standard (i.e., will not result in a cancer risk of greater than the range of 1×10^{-6}). The process is illustrated in Table 5.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (CANCER) EXPOSURE TO FENBUCONAZOLE

Population Subgroup	Negligible Exposure mg/kg/day	%PAD (Food)	Surface Water EEC (ppb)	Chronic Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.000279	0.3	5.9	0.005	6.3

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

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method for fenbuconazole in or on plants was submitted for inclusion in the Pesticide Analytical Manual Vol. 2 (PAM II).

B. International Residue Limits

There are Codex maximum residues levels (MRLs) expressed as fenbuconazole (fat-soluble) in milk, cattle meat, liver, kidney, and fat, all at 0.05 ppm (limit of quantitation, LOQ). Since the MRLs levels are based on different residue definitions and LOQs

than that of U.S. registrations, international harmonization is not feasible.

C. Response to Comments

A commenter raised several objections to the extension of time-limited tolerances for fenbuconzaole: (1) Complete data should be in before any approval is given by EPA; further, the Agency should not rely on limited evidence; (2) a 4–hour toxicity test is not a fair amount of time to test anything; (3) testing conducted on animals has absolutely no validity and is cruel to the test animals; and (4) the DEEM™ software is not suitable for evaluating risk.

These points will be addressed in turn.

1. *Missing data/limited evidence*. The commenter's mention of limited evidence appears to be a reference to the cancer potential for febuconazole. The carcinogenicity testing performed on fenbuconazole is complete and meets Agency scientific standards; however, the results of these tests are limited in that fenbuconazole does not appear to be a strong carcinogen. This evidence was taken into account in EPA's risk assessment and in making the safety determination. To the extent the commenter is concerned with the fact that there is limited information regarding 1,2,4-triazole, EPA would note that it more than compensated for the data limitations with regard to that chemical by making extremely conservative (i.e., health-protective) assumptions in assessing its risk.

2. *4–Hour toxicity test*. The Agency does not agree that the toxicity of pesticides can be judged by some undefined 4–hour toxicity test. Testing requirements for pesticides have been developed over many years following extensive review by the FIFRA Science Advisory Panel and many other scientific experts and groups, as well as exhaustive notice and comment rulemaking procedures. This comment is frivolous.

3. *Animal testing*. This commenter's objections to animal testing have been addressed in prior rulemaking documents. See 69 FR 63083, October 29, 2004.

4. *DEEM™ software*. The commenter provides no basis for claiming that the DEEM™ is unsuitable for risk assessment. For this reason alone, the comment is insignificant. EPA would note, however, that the DEEM™ software has been thoroughly tested by the Agency and has been reviewed by an independent body of technical experts, the FIFRA Scientific Advisory Panel, and found to be suitable for evaluating risks to pesticide residues on food. The results of that review may be found at*http://www.epa.gov/scipoly/sap/2000/ february/ partialfinalreport06292000.pdf*.

D. Conditions

Time-limited tolerances were originally proposed for fenbuconazole because of several conditions of registration, namely the submission of the following items. Five additional studies had to be submitted: (1) Fish life cycle, (2) growth and reproduction of aquatic plants, (3) droplet size spectrum, (4) drift field evaluation, and (5) 49–month storage stability study. Several corrections to the labels were required. Mitigation measures to address chronic non-target organism toxicity concerns had to be identified and submitted. Production of the Indar 75 WSP product could not exceed 38,000 lb (28,500 lb active ingredient) for each year of conditional registration and information on its production had to be submitted for the first federal fiscal year during which fenbuconazole was registered for use on stone fruits and pecans. Production information had to be submitted for the Enable 2F product (EPA Registration Number 62719–416) for the first federal fiscal year during which this product was registered for use on pecans. The company has subsequently submitted studies, information, and corrected labels, and participated in task forces, intended to satisfy all these condition-of-registration requirements. All such submissions that have been reviewed have been found to satisfy the appropriate registration condition. However, the establishment of permanent tolerances for fenbuconazole depends upon the resolution of recent questions the Agency has raised regarding the toxicity of 1,2,4-triazole, triazolylalanine, and triazolyl acetic acid, metabolites common to the triazole class of fungicides. New data to address the Agency's questions about these compounds is being generated and will be reviewed by the Agency. However, the Agency has decided to extend the time-limited tolerances until such data are reviewed and the questions about 1,2,4-triazole, triazolylalanine, and triazolyl acetic acid have been resolved.

V. Conclusion

Therefore, the tolerance is established 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-*3H*-furanone, in or on banana (whole fruit) at 0.3 ppm; fruit, stone, group 12 (except plum, prune) at 2.0 ppm; pecan at 0.1 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0410 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 St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0410, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated:February 18, 2005

Betty Shackleford,

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), 346a and 371.

■ 2. Section 180.480 is amended by revising the table in paragraph (a)(1) to read as follows:

§ 180.480 Fenbuconaozle; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million	Expiration/ revocation date
Banana (whole fruit)	0.3	12/31/08
Fruit, stone, group 12, except plums and prunes	2.0	12/31/08
Pecans	0.1	12/31/08

* * * * *

FR Doc. 05–4474 Filed 3–8–05; 8:45 am

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Chapter 3

Acquisition Regulation

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: The Department of Health and Human Services is correcting a direct final rule that appeared in the **Federal Register** on January 3, 2005 amending its acquisition regulation (HHSAR). Significant adverse comments were not received and the direct final rule became effective on March 4, 2005. The final rule is being corrected to address non-adverse comments received in response to the direct final rule.

DATE: *Effective Date:* Effective on March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Tracey Mock, Office of Acquisition Management and Policy, telephone (202) 205–4430, e-mail: *Tracey.Mock@hhs.gov*.

SUPPLEMENTARY INFORMATION:

A. Background

The Department of Health and Human Services issued a direct final rule on January 3, 2005 amending its acquisition regulation (HHSAR) and comments were due by February 2, 2005. Comments were received requesting (1) that contracts covered by the Service Contract Act not be excluded from the authority to write service contracts for a period of up to 10 years, (2) that the assignment of order numbers be up to seventeen digits, rather than requiring that all orders be comprised of seventeen digits, and (3) the redesignation of paragraphs pertaining to numbering acquisitions. The direct final rule, which became a final rule on March 4, 2005, is being corrected to reflect these comments.

List of Subjects in 48 CFR, Parts 304, 317, and 352.

Government procurement.

Dated: March 3, 2005.

Ed Sontag,

Assistant Secretary for Administration and Management.

■ Accordingly, 48 CFR chapter 3, parts 304, 317, and 352 are corrected as follows:

■ 1. The authority citation for 48 CFR chapter 3, parts 304, 317, and 352 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

PART 304—ADMINISTRATIVE MATTERS

304.7001 Numbering Acquisitions. [Amended]

■ 2. Redesignate paragraph 304.7001(d) as paragraph 304.7001(e).

■ 3. Redesignate paragraph 304.7001(c) as paragraph 304.7001(d).

■ 4. Revise paragraph (a) introductory text and add paragraph (c) of Section 304.7001 to read as follows:

304.7001 Numbering acquisitions.

a. *Acquisitions which require numbering.* The following acquisitions shall be numbered in accordance with the system prescribed in paragraphs (b), (c), and (d) of this section:

b. * * *

c. *Numbering system for orders.* Order numbers will be assigned to contracts with orders. The order number shall be up to a seventeen digit number consisting of the following:

(1) The three digit identification code of the Department (HHS);

(2) A one digit numeric identification code of the servicing agency:

O Office of the Secretary
P Program Support Center
M Centers for Medicare & Medicaid Services
F Food and Drug Administration
D Centers for Disease Control and Prevention
I Indian Health Service
S Substance Abuse and Mental Health Administration
N National Institutes of Health
H Health Resources and Services Administration
A Agency for Health Care Research and Quality;

(3) The three digit numeric identification code assigned by the Office of Acquisition Management and Policy (OAMP) to the contracting office within the servicing agency;

(4) An alphanumeric tracking number, up to ten characters, the content of which is determined by the contracting office within the servicing agency.

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PART 317—SPECIAL CONTRACTING METHODS

■ 5. Correct section to read as follows:

317.204 Contracts

The total of the basic and option periods shall not exceed 10 years in the case of services and the total of the basic and option quantities shall not exceed the requirement for 5 years in the case of supplies. These limitations do not apply to information technology contracts. However, statutes applicable to various classes of contracts may place additional restrictions on the length of contracts.

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

352.224–70 [Amended]

■ 6. In 352.224–70 amend paragraph (g) by removing ''The provisions of paragraph (e) of this clause shall not apply when the information is subject to conflicting or overlapping provisions in other Federal, State, or local laws'' and adding ''The provisions of paragraph (d) of this clause shall not apply when the information is subject to conflicting or overlapping provisions in other Federal, State, or local laws'' in its place.

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