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: September 12, 2006.

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 180.579 is amended by adding text and a table to paragraph (b) to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide fenamidone, (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Carrot	0.20	12/31/2009

[FR Doc. 06–7956 Filed 9–21–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0053; FRL–8093–9]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fenbuconazole, α–(2–(4–chlorophenyl)–ethyl)–α–phenyl–3–(1H–1,2,4–triazole)–1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, and RH–9130, trans–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, in or on almond; almond, hulls; apple; apple wet pomace; banana; beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; bushberry subgroup 13B; cattle, meat byproducts; citrus, dried pulp; citrus, oil; cranberry; fruit, citrus, group 10; fruit, stone, group 12; goat, meat byproducts; grain, aspirated fractions; grape; horse, meat byproducts; peanut; pecan; sheep, meat byproducts; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. EPA is also deleting several existing tolerances that are no longer needed as a result of this action. Dow AgroSciences 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 September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0053. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9443; e–mail address: *kish.tony@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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e–CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0053 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 November 21, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0053, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on–line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of July 20, 2005, 70 FR 41718 (FRL–7702–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0E6208, PP 1E6252, PP 1F3989, PP 1F3995, PP 2F4127, PP 2F4135, PP 2F4154, PP 3F4914, PP 4F6879, PP 7F4887, PP 9E5041, and PP 9F6024) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268–1054. The petition requested that 40 CFR 180.480 be amended by establishing tolerances for combined residues of the fungicide fenbuconazole, α–(2–(4–chlorophenyl)–ethyl)–α–phenyl–3–(1H–1,2,4–triazole)–1–propanenitrile, and its metabolites cis–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone and trans–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, in or on almond at 0.05 parts per million (ppm) (PP 3F4194); almond, hulls at 3.0 ppm (PP 3F4194); apple at 0.4 ppm (PP 2F4135); apple, wet pomace at 1.0 ppm (PP 2F4135); banana at 0.3 ppm (PP 2F4154); blueberry at 0.3 ppm (PP 9E5041); cranberry at 1.0 ppm (PP 1E6252); fruit, citrus, group 10 at 1.0 ppm (PPs 7F4900 and 4F6879); fruit, stone, group 12 (except plum, prune) at 2.0 ppm (PP 1F3989); grape at 1.0 ppm (PP 0E6208); pecan at 0.1 ppm (PP 1F3995); plum at 2.0 ppm (PP 1F3989); plum, prune, dried at 7.0 ppm (PP 1F3989); sugar beet, dried pulp at 1.0 ppm (PP 7F4887); sugar beet, molasses at 0.4 ppm (PP 7F4887); sugar beet, roots at 0.2 ppm (PP 7F4887); sugar beet, tops at 9.0 ppm (PP 7F4887); wheat, grain at 0.05 ppm (PP 2F4127); and wheat, straw (PP 2F4127) at 10.0 ppm; establishing tolerances for combined residues of the fungicide fenbuconazole, α–(2–(4–chlorophenyl)–ethyl)–α–phenyl–3–(1H–1,2,4–triazole)–1–propanenitrile, and its metabolite α–(2–(4–chloro–3–(D–glucopyranosyloxy)–phenyl)ethyl)–α–phenyl–1H–1,2,4–triazole–1–propanenitrile, in or on peanut at 0.1 ppm (PP 9F6024) and peanut, hay at 20 ppm (PP 9F6024); by establishing tolerances for combined residues of the fungicide fenbuconazole, α–(2–(4–chlorophenyl)–ethyl)–α–phenyl–3–(1H–1,2,4–triazole)–1–propanenitrile, and its metabolites cis–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, trans–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, and 4–chloro–α–hydroxymethyl–α–phenyl–benzenebutanenitrile in or on fat of cattle, goats, hogs, horses, and sheep at 0.05 ppm (PP 2F4127), and liver of cattle, goats, hogs, horses, and sheep at 0.3 ppm (PP 2F4127). That notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing.

EPA is also deleting several established time–limited tolerances in § 180.480(b) that are no longer needed. These revisions are as follows:

i. Delete the cattle, goat, horse, and sheep meat byproducts tolerances, each for 0.01 ppm and expiring on December 31, 2008. These tolerances are replaced by permanent tolerances of 0.05 ppm for cattle, goat, horse, and sheep meat byproducts, respectively.

ii. Delete the grapefruit tolerance of 0.5 ppm that expires on December 31, 2008. It is replaced by a permanent tolerance of 1.0 ppm for fruit, citrus, group 10.

iii. Delete the grapefruit, dried pulp tolerance of 4.0 ppm that expires on December 31, 2008. It is replaced by a permanent tolerance of 5.0 ppm for citrus, dried pulp.

iv. Delete the grapefruit, oil tolerance of 35 ppm that expires on December 31, 2008. It is replaced by a permanent tolerance of 40.0 ppm for citrus, oil.

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 the

FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA–PEST/1997/November/Day–26/p30948.htm*, *http://www.epa.gov/oppfead1/trac/science*, *http://www.epa.gov/pesticides/factsheets/riskassess.htm*, and *http://www.epa.gov/pesticides/trac/science/aggregate.pdf*.

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 tolerances for combined residues of fenbuconazole, α–(2–(4–chlorophenyl)–ethyl)–α–phenyl–3–(1H–1,2,4–triazole)–1–propanenitrile), and its metabolites RH–9129, cis–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, and RH–9130, trans–5–(4–chlorophenyl)–dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3H–furanone, in or on almond at 0.05 ppm; almond, hulls at 1.0 ppm; apple at 0.4 ppm; apple, wet pomace at 1.0 ppm; banana at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 0.4 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 9.0 ppm; bushberry subgroup 13B at 0.3 ppm; cattle, meat byproducts at 0.05 ppm; citrus, dried pulp at 5.0 ppm; citrus, oil at 40.0 ppm; cranberry at 0.5 ppm; goat, meat byproducts at 0.05 ppm; fruit, citrus, group 10 at 1.0 ppm; fruit, stone, group 12 at 1.0 ppm; grain, aspirated fractions at 6.0 ppm; grape at 1.0 ppm; horse, meat byproducts at 0.05 ppm; peanut at 0.1 ppm; pecan at 0.05 ppm; sheep, meat byproducts at 0.05 ppm; wheat, forage at 4.0 ppm; wheat, grain at 0.1 ppm; wheat, hay at 8.0 ppm; and wheat, straw at 8.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by fenbuconazole as well as the no–observed–adverse–effect–level (NOAEL) and the lowest–observed–adverse–effect–level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov*, Docket Identification (ID) Number EPA–HQ–OPP–2005–0053.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for fenbuconazole used for human risk assessment is shown below in Table 1 of this document.

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

Exposure Scenario	Dose Used in Risk Assessment; Interspecies and Intraspecies and any Traditional UF	Special FQPA Safety Factor (SF); Level of Concern for Risk Assessment	Study; Endpoint and Toxicological Effects
Acute Dietary (Females 13-49 years of age)	NOAEL = 30 mg/kg/day; UF = 100; Acute RfD[1] = 0.3 mg/kg/day	Special FQPA SF = 1; aPAD = acute RfD[1] ÷ Special FQPA SF = 0.3 mg/kg/day	Rat developmental study; Developmental LOAEL = 75 mg/kg/day based on increased resorptions and decreased live fetuses per dam
Acute Dietary (General population including infants and children)	No NOAEL was identified; UF is not applicable; no Acute RfD[1] was calculated.	Special FQPA SF is not applicable; no aPAD[2] was calculated.	No study was selected because no appropriate dose and endpoint could be identified for this population group
Chronic Dietary (All populations)	NOAEL= 3 mg/kg/day; UF = 100; Chronic RfD[1] = 0.03 mg/kg/day.	Special FQPA SF = 1; cPAD[3] = chronic RfD[1] ÷ Special FQPA SF = 0.03 mg/kg/day.	Rat combined chronic toxicity/carcinogenicity study; LOAEL = 30.6 mg/kg/day for males and 43.1 mg/kg/day for females based on decreased body weight gain, increased thyroid weight, and histopathological lesions in the liver and thyroid gland
Incidental Oral (all durations)	No NOAEL was identified; UF is not applicable; no RfD[1] was calculated.	Special FQPA SF is not applicable; no LOC was determined.	No study was selected because no registered uses would result in residential exposure

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

Exposure Scenario	Dose Used in Risk Assessment; Interspecies and Intraspecies and any Traditional UF	Special FQPA Safety Factor (SF); Level of Concern for Risk Assessment	Study; Endpoint and Toxicological Effects
Long-Term Dermal (several months to lifetime)	Oral study NOAEL= 3 mg/kg/day (dermal absorption rate = 4.25%).	Residential LOC for MOE[4] = not applicable;. Occupational LOC for MOE = 100	Rat combined chronic toxicity/carcinogenicity study; LOAEL = 30.6 mg/kg/day for males and 43.1 mg/kg/day for females based on decreased body weight gain, increased thyroid weight, and histopathological lesions in the liver and thyroid gland
Inhalation (all durations)	Oral study NOAEL= 3 mg/kg/day; Absorption factor = 100%).	Residential LOC for MOE[4] = not applicable;. Occupational LOC for MOE = 100	Rat combined chronic toxicity/carcinogenicity study; LOAEL = 30.6 mg/kg/day for males and 43.1 mg/kg/day for females based on decreased body weight gain, increased thyroid weight, and histopathological lesions in the liver and thyroid gland
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 (Q_1*). 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, Q_1* $(mg/kg/day)^{-1}$, is 3.59×10^{-3} in human equivalents.		

[1]RfD means ''Reference Dose''; [2]aPAD means ''acute Population Adjusted Dose''; [3]cPAD means ''chronic Population Adjusted Dose; [4]MOE means ''Margin of Exposure''

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have previously been established (40 CFR 180.480) for the combined residues of fenbuconazole and its metabolites RH-9129 and RH-9130, in or on a variety of raw agricultural commodities. These raw agricultural commodities include fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from fenbuconazole in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure.

The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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 acute exposure assessments: The acute dietary (food plus water) assessment was very conservative — a screening level, Tier 1 assessment. It was based on tolerance-level residues and assumed that 100% of each crop was treated with fenbuconazole. For water exposure the assessment used the estimated maximum peak concentration of fenbuconazole in surface water that was calculated from the requested use pattern for cherries, a worst-case estimate. The only population subgroup that is relevant for this acute assessment is females (13-49 years old).

ii. *Chronic (non-cancer) exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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 exposure assessments: The chronic (non-cancer) dietary assessment included contributions from both food and water. This analysis is more refined than the acute dietary assessment in that it uses average residues from field trials. Due to the manner in which these data were submitted and reviewed, multiple averages were calculated for many of the crops. For these crops the highest average was used in the analysis. The non-cancer chronic dietary analysis assumed 100% crop treated and the annual average estimated surface water concentration from the cherry use.

iii. *Cancer*. The cancer dietary assessment used the same food residue inputs as those of the non-cancer assessment—average residues from field trials and 100% crop treated for all crops. The water component of this assessment used the estimated 30–year average surface water concentration from the cherry use.

iv. *Anticipated residue 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 these tolerances. Anticipated residue data were used in the chronic (non-cancer) and cancer dietary risk analyses but not in the acute dietary risk analysis. The anticipated residues used were the highest per-study-volume average residue from the field trial studies for each crop that were submitted by the registrant.

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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of fenbuconazole for acute exposures are estimated to be 20.3 parts per billion (ppb) for surface water and 0.031 ppb for ground water. The EECs for chronic (non-cancer) and for cancer exposures are estimated to be 16.5 ppb for surface water and 0.031 ppb for ground water.

3. *From non-dietary exposure*. Where the term ''residential exposure'' is used in this document, it refers 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). However, fenbuconazole is not registered for any use that will result in residential exposure.

4. *Cumulative effects from 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.''

Fenbuconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Fenbuconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including fenbuconazole, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenbuconazole. In the prenatal developmental study in rats and rabbits and the 2-generation study in rats, effects in the offspring were observed only at or above those treatment levels which resulted in maternal toxicity.

The degree of concern for infants and children exposed to fenbuconazole *in utero* and/or postnatally is low; there are no residual uncertainties. The toxicology database for fenbuconazole is complete and adequate for risk assessment purposes. Acceptable developmental studies in rats and rabbits and the 2-generation reproduction study in rats did not show evidence of increased susceptibility in offspring exposed to fenbuconazole *in utero* and/or postnatally. A NOAEL for acute effects has been selected for the subpopulation females (13-49 years old) based on developmental effects (increased resorptions and decreased live fetuses per dam) seen at the LOAEL in the developmental rat study. By regulating on the effect of concern for this subpopulation, the risk assessment is protective of potential effects to infants and children. No acute effects of fenbuconazole were identified in any of the other studies.

3. *Conclusion*. There is a complete toxicity data base for fenbuconazole and exposure data are complete or are estimated based on data that reasonably account for potential exposures. The

FQPA safety factor was therefore removed (i.e., reduced to 1x) in assessing the risk posed by fenbuconazole, based on the following considerations:

i. There are no toxicology data gaps for the assessment of the effects of fenbuconazole; a developmental neurotoxicity study is not required.

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

iii. The dietary exposure assessment is based on models and input parameters designed to be protective of human health.

iv. At this time, there are no registered residential uses for fenbuconazole, so this type of exposure to infants and children is not expected.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute exposure to fenbuconazole from dietary (food plus water) consumption was calculated only for the population subgroup females (13-49 years old). It will occupy 3% of the aPAD for this subgroup based on a 95th percentile acute dietary exposure of 0.009014 mg/kg/day. The surface water concentration that was used in this analysis was 20.3 ppb. Because of the toxicology of fenbuconazole, an acute risk analysis is not relevant for the general U.S. population or any other population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has calculated that chronic dietary exposure to fenbuconazole from food plus water will utilize 2% of the cPAD for the general U.S. population, 7% of the cPAD for all infants (less than 1 year old), and 6% of the cPAD for children (1-2 years old). There are no residential uses for fenbuconazole that result in chronic residential exposure to fenbuconazole. The surface water concentration of fenbuconazole that was used for the general U.S. population and each population subgroup in this analysis was 16.5 ppb. EPA does not expect the aggregate exposure to exceed 100% of the cPAD for the general U.S. population or any subgroup of it, as shown below, in Table 2 of this document.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENBUCONAZOLE

Population/ Subgroup	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000666	2
All Infants (>1 Year Old)	0.002016	7
Children (1-2 Years Old)	0.001795	6
Children (3-5 Years Old)	0.001408	5
Children (6-12 Years Old)	0.000783	3
Youth (13-19 Years Old)	0.000419	1
Adults (20-49 Years Old)	0.000525	2
Adults (50+ Years Old)	0.000612	2
Females (13-49 Years Old)	0.000539	2

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposures take 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 site(s) that would result in residential exposure. Therefore, the aggregate risks are the sums of the risks from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Dietary exposure (food plus water) is the only source of exposure to fenbuconazole that is expected to be chronic (cancer exposure is considered to be life-time exposure). The chronic (cancer) aggregate exposure and risk estimates are based on those for the general U.S. population group. In this case the risk is based on a cancer potency (Q_1*) value of 3.59 x 10^{-3} and a dietary exposure to fenbuconazole of 0.000666 mg/kg/day. The dietary exposure is the same as that used for the chronic (non-cancer) assessment. The estimated cancer risk that resulted from this assessment is 2.4 x 10^{-6}. In general, the precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale, e.g., 3.16 x 10^{-7} to 3.16 x 10^{-6}, expressed as 10^{-6}. Risks are generally reported to two significant figures in Agency risk assessments to allow better characterization of changes in risk which might result from potential risk mitigation. This rounding procedure indicates that risks should generally not be assumed to exceed the benchmark level of concern of 1 x 10^{-6} until the calculated risks exceed approximately 3 x 10^{-6}. Therefore, the Agency considers this risk estimate to be negligible because it falls within the range of 1 in 1 million. In addition, the cancer risk estimate for fenbuconazole is overstated due to very conservative exposure assumptions. The exposure estimate used in the cancer risk assessment assumes that 100 percent of crops covered by tolerances are treated and that all crops contain residues at the highest per-study-volume average residue found in crop field trials using maximum, or greater than maximum, permitted application amounts.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

Codex MRL's are established on bananas and pecans at 0.05 ppm, wheat grain at 0.1 ppm, peach at 0.5 ppm, cherries at 1.0 ppm, and wheat straw at 3.0 ppm. Although the residue definitions differ (i.e., Codex does not include the metabolites), the U.S. tolerances for pecans and wheat grain match the Codex limits numerically. The U.S. stone fruit crop group tolerance of 1.0 ppm is consistent with the highest Codex MRL on an individual member (cherries) of that crop group. In the cases of bananas and wheat straw, the levels of total residues in the U.S. tolerance expression (which includes fenbuconazole metabolites) are higher than the Codex MRL (which excludes these metabolites). Therefore, EPA has not harmonized these values.

V. Conclusion

Therefore, tolerances are established for combined residues of fenbuconazole,

α-(2-(4-chlorophenyl)-ethyl)-α-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile and its metabolites cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone, expressed as fenbuconazole, in or on almond at 0.05 ppm; almond, hulls at 1.0 ppm; apple at 0.4 ppm; apple, wet pomace at 1.0 ppm; banana at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 0.4 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 9.0 ppm; bushberry subgroup 13B at 0.3 ppm; cattle, meat byproducts at 0.05 ppm; citrus, dried pulp at 5.0 ppm; citrus, oil at 40.0 ppm; cranberry at 0.5 ppm; fruit, citrus, group 10 at 1.0 ppm; fruit, stone, group 12 at 1.0 ppm; goat, meat byproducts at 0.05 ppm; grain, aspirated fractions at 6.0 ppm; grape at 1.0 ppm; horse, meat byproducts at 0.05 ppm; peanut at 0.1 ppm; pecan at 0.05 ppm; sheep, meat byproducts at 0.05 ppm; wheat, forage at 4.0 ppm; wheat, grain at 0.1 ppm; wheat, hay at 8.0 ppm; and wheat, straw at 8.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerances 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.

VII. 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: September 13, 2006.

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 180.480 is amended in paragraph (a)(1) by revising the table and in paragraph (b), in the table, by removing the commodities cattle, meat byproducts; goat, meat byproducts; grapefruit; grapefruit, dried pulp; grapefruit, oil; horse, meat by products; and sheep, meat byproducts.

The amendment reads as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

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

Commodity	Parts per million
Almond	0.05
Almond, hulls	1.0
Apple	0.4
Apple, wet pomace	1.0

Commodity	Parts per million
Banana	0.3
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	0.4
Beet, sugar, roots	0.3
Beet, sugar, tops	9.0
Bushberry subgroup 13B	0.3
Cattle, meat byproducts	0.05
Citrus, dried pulp	5.0
Citrus, oil	40.0
Cranberry	0.5
Fruit, citrus, group 10	1.0
Fruit, stone, group 12	1.0
Goat, meat byproducts	0.05
Grain, aspirated fractions	6.0
Grape[1]	1.0
Horse, meat byproducts	0.05
Peanut	0.1
Pecan	0.05
Sheep, meat byproducts	0.05
Wheat, forage	4.0
Wheat, grain	0.1
Wheat, hay	8.0
Wheat, straw	8.0

[1]There are no United States registrations for grape as of August 2006.

* * * * *

[FR Doc. 06–7957 Filed 9–21–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0347; FRL–8092–1]

Propiconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes or revises tolerances for combined residues of propiconazole and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent compound in or on various commodities; and inadvertent residues in or on alfalfa, forage and alfalfa, hay. Syngenta Crop Protection, Inc. and Interregional Research Project No. 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 September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0347. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Mary Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0347 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 November 21, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0347, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday,