comment. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

The request for deletion of use on cats and kittens is irrevocable. Therefore, the Agency will not consider requests for withdrawal.

V. Provisions for Disposition of Existing Stocks

The effective date of the amendment will be stated in the notice of amended registration and will be no earlier than October 31, 2005. The Agency has authorized the registrant to sell or distribute product under the previously approved labeling as follows: Products in the United States which have been packaged, labeled, and released for shipment prior to the effective date of the amendment may be sold or distributed by Hartz from its facilities until December 31, 2005, and may be sold, or distributed, by persons other than the registrant until March 31, 2006. After this date, products may not be distributed unless for the purposes of proper disposal or export. The Agency has provided restrictions on existing stocks because the Agency has identified potential risk concerns associated with this registration.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 1, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 05–14066 Filed 7–19–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0053; FRL–7702–7]

Fenbuconazole; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0053, must be received on or before August 19, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Tony Kish, Registration Division (7505C), 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)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0053. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide

a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0053. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2005–0053. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2005–0053.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0053. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 8, 2005.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Dow AgroSciences LLC, and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Dow AgroSciences LLC

PP 0E6208, PP 9F6024, PP 9E5041, PP1E6252, PP 2F4135, PP 7F4887, PP 1F3989, PP 3F4914, PP 2F4127, PP 4F6879, PP 1F3989, PP 1F3995, and PP 2F 4154

EPA has received the following pesticide petitions PP 0E6208, PP 9F6024, PP 9E5041, PP 1E6252, PP 2F4135, PP 7F4887, PP 1F3989, PP 3F4914, PP 2F4127, PP 4F6879, PP 1F3989, PP1F3995, and PP 2F 4154 from Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerance for residues of [fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)- 1-propanenitrile) and its metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone] in or on the raw agricultural commodity grape at 1.0 parts per million (ppm), blueberry at 0.3 ppm, cranberry at 1.0 ppm, fruit, citrus, group 10 at 1.0 ppm, fruit, stone, group 12 (except plum, prune) at 2.0 ppm, pecan at 0.1, banana at 0.3 ppm and [fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile) and its metabolite (alpha-(2-(4-chloro-3-(D-glucopyranosyloxy) -phenyl) ethyl)-alpha-phenyl-1H- 1,2,4-triazole-1-propanenitrile), in or on the raw agricultural commodity peanut at 0.1 ppm, and peanut, hay at 20 ppm.

Previously, EPA had received pesticide petitions PP 2F4135, PP 7F4887, PP 1F3989, PP 3F4914, and PP 2F4127 from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106–2399, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of [fenbuconazole (alpha-(2-(4- chlorophenyl) -ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)- 1-propanenitrile) and its metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone] in or on the raw agricultural commodities apple at 0.4 ppm, apple, wet pomace at 1.0 ppm, sugar beet, roots at 0.2 ppm, sugar beet, tops at 9.0 ppm, sugar beet, dried pulp at 1.0 ppm, sugar beet, molasses at 0.4 ppm, plum at 2.0 ppm, plum, prune, dried at 7.0 ppm, almond at 0.05 ppm, almond, hulls at 3.0 ppm, and wheat, grain at 0.05 ppm, wheat, straw at 10.0 ppm and [fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)- 1-propanenitrile) and its metabolites cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1- ylmethyl)-2-3H-furanone and 4-chloro-alpha(hydroxymethyl)-alpha-phenyl-benzenebutanenitrile] in or on fat of cattle, hogs, horses, goats, and sheep at 0.05 ppm and liver of cattle, hogs, horses, goats, and sheep at 0.3 ppm.

These pending petitions were transferred to Dow AgroSciences on September 21, 2001 and Dow AgroSciences is still interested in pursuing these previously submitted tolerance petitions. Previously these petitions were published in the **Federal Register** for public comment on December 20, 1992, October 21, 1993, February 9, 1994, March 2, 1994, July 13, 1994, August 18, 1994, January 30, 1998, and June 25, 1999.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of fenbuconazole in plants is adequately understood for the purpose of these tolerances. Plant metabolism was evaluated in three diverse crops, wheat, peaches, and peanuts. The route of metabolism is similar in all crop groups and proceeds with three main pathways. Oxidation at the benzylic carbon (pathway 1) led to the ketone and the lactone as metabolites. Oxidation or nucleophilic substitution on the carbon next to the triazole ring (pathway 2) led to triazole alanine (TA) and triazole acetic acid (TAA) presumably through free triazole. Metabolic pathway 3 produced the phenolic metabolite RH–4911, and led to the glucose conjugates found in all crops.

2. *Analytical method.* An adequate enforcement method is available for the established and proposed tolerances. Quantitation of fenbuconazole residues (and metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone) at an analytical sensitivity of 0.01 milligrams/kilogram (mg/kg) is accomplished by soxhlet extraction of samples in methanol, partitioning into methylene chloride, redissolving in toluene, cleanup on silica gel, and gas liquid chromatography using nitrogen specific thermionic detection. Quantitation of fenbuconazole residues (and metabolite alpha-(2-(4-chloro-3-(D-glucopyranosyloxy)-phenyl) ethyl)-alpha-phenyl-1H-1,2,4-triazole-1-propanenitrile) at an analytical sensitivity of 0.03 mg/kg is accomplished by soxhlet extraction of samples in acidic methanol to hydrolyze the glucoside metabolite into the phenol derivative. The analytes are separated by liquid-liquid extractions, cleanup on silica gel, and solid phase extraction. The phenolic derivative and parent are quantified by liquid chromatography/mass spectroscopy.

3. *Magnitude of residues.* The residue data in support of the proposed tolerances was generated from the magnitude of residue studies on grapes, peanuts, blueberry, cranberry, peanut, apple, sugar beet, plum, almond, wheat, citrus (grapefruit, orange, lemon), stone fruit (peaches, cherries, apricots), pecans, and bananas.

i. *Grape.* Fenbuconazole is registered for use on grapes in Latin America and Europe. An import tolerance petition has been submitted (PP 0E6208). Residue studies were conducted in Europe (12 trials) and in Central and South America (5 trials) in support of the import tolerance for grapes. In the Central and South American trials, a suspension concentrate (2F) formulation of fenbuconazole was applied at a single application of 0.3 kg active ingredient/hectare (a.i./ha). Grapes were collected at normal harvest, 61–139 days, after application. In the European trials, fenbuconazole (2F) was applied 3–8 times at a rate of 0.015-0.075 kg a.i./ha per application. Grapes were harvested at 21 days after the last application. The

combined residues, expressed as parent, were < 0.01-0.093 ppm in the Central and South American and 0.046–0.63 ppm in the European trials. Averages were 0.027 ppm in the Central and South American trials and 0.37 ppm in the European trials. Overall average for the 17 trials is 0.27 ppm. An import tolerance of 1.0 ppm is proposed.

ii. *Blueberry.* Eight magnitude of residue studies were conducted on blueberry in field sites located within the major blueberry growing regions in the U.S. recommended by the EPA. A wettable powder (75WP) formulation of fenbuconazole was applied five times at a rate of 0.094 lb active ingredient/Acre (a.i./A) per application. The application rate at one (NJ) of the field trials was 0.047 lb a.i./A per application. Mature fruits were harvested at 25–35 days after the final application. The combined residues, expressed as parent, were 0.013–0.183 ppm. The average residues were 0.069. A tolerance of 0.3 ppm is proposed.

iii. *Cranberry.* Five field trials were conducted in field sites located within the major cranberry growing regions in the U.S. recommended by EPA. Fenbuconazole was applied 5 times as a wettable powder (75WP) formulation at a rate of 0.19 lb/A per application. Mature fruits were harvested at 25-28 days after final application. The combined residues, expressed as parent, ranged from 0.09 ppm to 0.45 ppm with an average of 0.20 ppm. A tolerance of 1.0 ppm is proposed.

iv. *Peanut.* A total of thirteen magnitude of residue studies were conducted in field sites located within the major peanut growing regions in the U.S. recommended by the EPA. A suspension concentrate (2F) formulation of fenbuconazole was applied 6 times at one site and 8 times at the remaining twelve sites at a rate of 0.125 lb a.i./A per application. Peanuts were collected at normal harvest, 14–15 days after the final application. Peanuts were shelled and the nutmeat analyzed. The combined residues, expressed as parent, were non-detected to 0.056 ppm with an average of 0.015 ppm. A tolerance of 0.1 ppm is proposed.

v. *Apples.* Residue studies have been conducted in accordance with the geographic distribution mandated by the EPA for apples. In the apples, the raw agricultural commodity (RAC), the fenbuconazole residues ranged from approximately 0.1 mg/kg to approximately 0.3 mg/kg. Residues were measured in process fractions of apples, apple juice, and apple pomace. Concentration above the residue levels in the RAC occurred only in the pomace at approximately two-fold. Thus, no tolerance for juice is required, but a tolerance for pomace is required.

Seven field trials on apples were carried out in 1990 in six states: PA, WA, NC, MI, VA, and WV. Two application rates were used in each of the studies, the anticipated maximum application rate of 0.14 kg a.i./ha and a 2x exaggerated rate of 0.28 kg a.i./ha. A total of 8–10 applications were made at the normal timing in each trial, and the fruit was harvested at 0, 7, and 13 or 14 days after the final application. All samples were frozen immediately after they were harvested and were kept frozen until analysis, or shipped fresh immediately after harvest and processed and frozen immediately upon receipt and kept frozen until analysis. Samples were analyzed using the residue analytical method for RH-7592 parent and metabolites in stone fruit, and residues were corrected for average fortification recoveries. As would be expected, the residue levels were seen to increase with decreased PHI and increased application rate. The average half-life of residue decline for 6 studies was 11.9–days. The average parent residue at 13–14 PHI at the 0.14 kg a.i./ha rate was 0.086 mg/kg.

Formulation bridging studies were conducted on apples in 1993. Apples grown in WA and PA were treated, in separate plots, with the 2F and 75 WP formulations of fenbuconazole at a rate of 0.14 kg a.i./ha/application. A total of ten or twelve applications were made using an airblast sprayer at the normal timing of each trial, and the fruit was harvested at 14 days after the final application (14–day pre-harvest interval (PHI). Samples were shipped fresh immediately after harvest and frozen immediately upon receipt and kept frozen until processing and subsequent analysis. Samples were analyzed using the residue analytical method for RH-7592 parent and metabolites in stone fruit, but residues were not corrected for average fortification recoveries. Total residues from the two trials were 0.226 and 0.135 mg/kg in the 2F formulation, and 0.184 and 0.162 mg/kg in the 75WP formulation. There were no significant differences in apparent residues found from the use of the two formulations, and residues due to parent compound constituted greater than 85% of the total residues found on the fruit.

Seven field residue trials were conducted on apples in 1995, in CA, CO, MI, NY, OH, OR, and WA. Apples were treated with dilute (0.014 kg active ingredient hectoliter (a.i./hl) and concentrate (0.035 kg a.i./hl) sprays of the 2F formulation of fenbuconazole at a rate of 0.14 kg a.i./ha. A total of 8–10 applications were made using airblast sprayers, with first application at early bud break and subsequent applications on a 10–14 day schedule through bloom and a 14 to 21 day schedule in the cover sprays until harvest. The apples were harvested by hand at a PHI of 14–days. Residue samples were analyzed using the residue analytical method for RH–7592 parent and metabolites in stone fruit, but residues were not corrected for average fortification recoveries. Samples from 3 sites were also analyzed using the residue analytical method for metabolite RH-7905. Metabolite RH-7905 was not detected in any of the samples. The total residues from the concentrate sprays ranged from 0.015 to 0.274 mg/kg and averaged 0.137 mg/kg. The total residues from the dilute sprays ranged from 0.019 to 0.295 mg/kg and averaged 0.139 mg/kg. There is not a significant difference in the magnitude of the residues between dilute and concentrate spray volumes of the 2F formulation of fenbuconazole.

An additional residue study was conducted on apples grown in PA in 1994 and the fruit was used for a processing study. The apples received nine foliar applications of the 2F formulation of fenbuconazole at the normal timing at a rate of 0.14 kg a.i./ha/application. The fruit was harvested 14–days after the last treatment. The raw agricultural commodities (RAC) samples were shipped fresh and either immediately processed or frozen for storage. All RAC and processed samples were analyzed within a less than 30–day period, eliminating the need for generation of storage stability data. The apples were processed at the Food Research Laboratory of Cornell University using methodology simulating commercial apple processing. Briefly, the processing consisted of washing the apples in water, grinding in a hammer mill to apple mash, and pressing of the mash to form both fresh apple juice and wet pomace. The juice was either canned (sampled as unpasteurized juice) or canned and pasteurized (sampled as pasteurized juice). The wet pomace (moisture content 69%) was also sampled. All samples were frozen on generation and stored frozen until analysis. Samples were analyzed using the residue analytical method for RH-7592 and metabolites in stone fruit, and residues were not corrected for average fortification recovery. The average total residues for each component, and its concentration factor, were as follows: Unwashed fruit 0.065 mg/kg NA, washed fruit 0.070 mg/kg NA, wet pomace 0.159 mg/kg 2.46, unpasteurized juice 0.004 mg/kg 0.06,

pasteurized juice 0 mg/kg 0.00. No concentration of residues was seen in the human diet component, i.e., apple juice. Concentration of residues of approximately 2–fold was seen in wet pomace, which is not a component of the human diet.

Feeding studies in the cow, goat, and hen indicated that the only animal commodities which require tolerances are fat and liver. There were no significant residues in eggs or milk at any dose level. Residues in animals declined significantly during the depuration period. In the fat and liver one of the components of the fenbuconazole tolerance expression has a LOQ = 0.05 mg/kg. Because there were detectable residues only in liver, not fat, the LOQ of the least sensitive component drives the fat tolerance. Tolerances of 0.05 ppm in fat and 0.3 ppm in liver were proposed based on the animal data.

vi. *Sugar beets.* Residue studies have been conducted in accordance with the geographic distribution mandated by the EPA for sugar beets. Following full season foliar treatment, the residues of fenbuconazole were higher in the sugar beet tops than in the root. Combined residues in root averaged 0.415 mg/kg. Residues in tops were more variable, and ranged from 0.56–8.89 mg/kg. In a formulation bridging study the residues were higher in the sugar beet tops compared to the root. Total root residues in the 75WP formulation ranged from 0.0061 to 0.268 mg/kg and averaged 0.0616 mg/kg. Total root residues in the 2F formulation ranged from 0.0223 to 0.0523 mg/kg and averaged 0.0328 mg/kg. Total top residues averaged 2.15 mg/kg in the 75WP formulation, and 2.69 mg/kg in the 2F formulation. There was no significant difference in residues between formulations of fenbuconazole. In a processing study the concentration factor for each component was: Root 1.0X, dry pulp 5.39X, molasses 1.82X, and refined sugar 0.1X. Compared to raw roots, a reduction of residues was seen in the human diet component, sugar. Concentration of residues was seen in molasses and dry pulp, neither of which is a component of the human diet.

vii. *Plum.* A total of ten field residue trials were conducted in plums. Six to nine applications were made at the maximum use rate of 0.1 lb active ingredient/Acre (a.i./A) and whole fruit was harvested on the same day as the last application. The highest field residue value in whole fruit was 0.315 ppm; the next highest field residue value was 0.071 ppm. The average field residue value in whole fruit was 0.062 ppm. Residues were measured in dried plums (prunes) in three residue trials. Six applications were made at the maximum use rate of 0.1 lb a.i./A , and whole fruit was harvested on the same day as the last application. Dried plums contained residues of 0.02, 0.04, and 0.014 ppm.

viii. *Almonds.* Residue studies have been conducted in accordance with the geographic distribution mandated by the EPA for almonds. There are no process fractions of almonds. Six field trials in almonds were carried out at 5 sites in CA in 1987. In all of the studies, the anticipated maximum application rate of 0.11 kg a.i./ha and a 2X exaggerated rate of 0.22 kg a.i./ha. A total of three applications were made at the normal timing in all trials, and the almonds were harvested at maturity, 127–200 days after the final application. Samples were shipped fresh or frozen. Hulls were separated from the nuts and processed in a Hobart food processor with dry ice or in a Wiley Mill without dry ice. Nuts were shelled and the nutmeat homogenized in a Waring food processor with dry ice. The processed samples were stored frozen until analysis. Samples were analyzed using the residue analytical method for RH-7592 and metabolites. No residue in any nutmeat sample at the 1x application rate reached 0.01 mg/kg. Residues in the hull at the 1x rate ranged from 0.1 to 1.5 mg/kg. One nutmeat sample treated at the 2x rate had a quantifiable residue of 0.027 mg/kg. The remainder had no detectable residue. Hull sample residues from the 2x rate ranged from 0.5 to 6.6 mg/kg.

Feeding studies in the cow, goat, and hen indicated that the only animal commodities which require tolerances are fat and liver. There were no significant residues in eggs or milk at any dose level. Residues in animals declined significantly during the depuration period. In the fat and liver one of the components of the fenbuconazole tolerance expression has a LOQ = 0.05 mg/kg. Because there were detectable residues only in liver, not fat, the LOQ of the least sensitive component drives the fat tolerance. Tolerances of 0.05 ppm in fat and 0.3 ppm in liver were proposed based on the animal data.

ix. *Wheat.* Residue studies have been conducted in accordance with the geographic distribution mandated by the EPA for wheat. In the wheat grain, the raw agricultural commodity, the fenbuconazole residues ranged from no detectable residue (NDR < LOQ = 0.01 mg/kg) to approximately 0.01 ppm. In wheat straw the fenbuconazole residues ranged from approximately 0.05 ppm to approximately 4.5 ppm. Residues were measured in processed fractions of wheat including cleaned grain, bread, patent flour, flour, red dog, bran, shorts/germ, and middlings. EPA concluded that, no concentration above the residue levels in the RAC occurred so no tolerances for any of these commodities were required. Tolerances of 0.05 ppm in wheat grain and 10 ppm in wheat straw are proposed based on these data.

Feeding studies in the cow, goat, and hen indicated that the only animal commodities which require tolerances are fat and liver. There were no significant residues in eggs or milk at any dose level. In cows there were residues in fat only at the 10x level in one animal at 0.06 mg/kg. Liver contained quantifiable residues in all dose groups and the magnitude of the residue correlated closely with the dose level. At study day 28 the 1 x livers averaged 0.08 mg/kg. Residues declined significantly during the depuration period. In the fat and liver one of the components of the fenbuconazole tolerance expression has a LOQ = 0.05 mg/kg. Because there were detectable residues only in liver, not fat, at the 1x level, the LOQ of the least sensitive component drives the fat tolerance. Tolerances of 0.05 ppm in fat and 0.3 ppm in liver are proposed based on the animal data.

x. *Citrus.* The residue data in support of the proposed tolerance of 1.0 ppm in citrus were generated from the magnitude of residue studies on grapefruits, oranges, and lemons.

a. *Grapefruit.* Magnitude of residue studies were conducted in 1992–1994 at field sites located within the major grapefruit-growing regions in the U.S. recommended by the EPA. A suspension concentrate formulation of fenbuconazole containing 24% a.i. was applied 3 times at a nominal rate of 0.25 lb a.i./A per application. Applications were made using an airblast sprayer and at an interval of 21–28 days in between applications. Mature fruits from control and treated plots were harvested at 0–day after the last application. In some trials, pulp was separated and analyzed. All samples were analyzed for fenbuconazole and its lactone metabolites RH-9129 and RH-9130. Total residues of fenbuconazole and its lactone metabolites (expressed as fenbuconazole) were 0.10–0.494 ppm in whole fruit with an average of 0.21 ppm. Nearly all of the pulp samples showed no detectable residues.

b. *Orange.* Magnitude of residue studies were conducted in 1992–1994 and 1997 at field sites located within the major orange-growing regions in the U.S. recommended by the EPA. A

suspension concentrate formulation of fenbuconazole containing 24% a.i. was applied 3 times at a nominal rate of 0.25 lb a.i./A per application. Applications were made using an airblast sprayer and at an interval of 20–28 days in between applications. Mature fruits from control and treated plots were harvested at 0–day after the last application. In some trials, pulp was separated and analyzed. All samples were analyzed for fenbuconazole and its lactone metabolites RH-9129 and RH-9130. Total residues of fenbuconazole and its lactone metabolites (expressed as fenbuconazole) were 0.126–0.678 ppm in whole fruit with an average of 0.281 ppm. Residues in the pulp are < LOQ (0.01 ppm).

c. *Lemon.* Magnitude of residue studies were conducted in 2,000 at field sites located within the major lemon-growing regions in the U.S. recommended by the EPA. A suspension concentrate formulation of fenbuconazole containing 25% a.i. was applied 3 times at a nominal rate of 0.25 lb a.i./A per application. Applications were made using an airblast sprayer and at an interval of 20–22 days in between applications. Mature fruits from control and treated plots were harvested at 0–day after the last application. A sub-sample of the lemon fruits were also prepared as peeled fruits. All samples were analyzed for fenbuconazole and its lactone metabolites RH-9129 and RH-9130. Total residues of fenbuconazole and its lactone metabolites (expressed as fenbuconazole) were 0.523–0.837 ppm in whole fruit and 0.019–0.173 ppm in the pulp. The average residues were 0.650 ppm in whole fruit and 0.067 ppm in the pulp. The residue data from the lemon trials support the tolerance of 1.0 ppm in citrus.

xi. *Stone fruit*—a. *Peaches.* Ten field trials were conducted on peaches. 7–10 applications were made at the maximum use rate of 0.1 pounds of active ingredient per acre (lb a.i./acre) per application, and fruit was harvested on the last day of application. The highest field residue value was 0.51 ppm, and the average field residue value was 0.36 ppm.

b. *Cherries.* Eleven field trials were conducted on cherries. Five to 6 applications were made at the maximum use rate of 0.1 lb a.i./acre per application, and fruit was harvested on the last day of application. The highest field residue value was 0.63 ppm, and the average field residue value was 0.43 ppm.

c. *Apricots.* Four field trials were conducted on apricots. Six applications were made at the maximum use rate of 0.125 lb a.i./acre per application, and fruit was harvested on the last day of application. The field residue values in four samples measured were 0.17, 0.23, 0.27, and 0.28 ppm.

xiii. *Pecans.* Four field trials were conducted in pecans. Eight to 10 applications were made at the maximum use rate of 0.125 lb a.i./acre per application, and nuts were harvested 28–days after the last application. Field residue values in nutmeat for all four trials were < 0.01 ppm.

xiv. *Bananas.* Eighteen field trials were conducted on bagged bananas, which are typically used in commerce. Eight applications (5 and 7 applications in two trials) were made at the maximum use rate of 0.09 lb a.i./acre per application and bananas were harvested on the last day of application. The highest field residue value in whole fruit or in pulp and peel combined was 0.062 ppm. The average field residue value in whole fruit or in pulp and peel combined was 0.03 ppm.

The results of these studies support the proposed permanent tolerances for fenbuconazole on stone fruit, pecans, and bananas.

B. Toxicological Profile

1. *Acute toxicity.* Fenbuconazole is practically non-toxic after administration by the oral and dermal routes, and was not significantly toxic to rats after a 4 hour inhalation exposure. Fenbuconazole is classified as not irritating to skin and inconsequentially irritating to the eyes. It is not a skin sensitizer.

2. *Genotoxicty.* Fenbuconazole was negative (non-mutagenic) in an Ames assay with and without hepatic enzyme activation. Fenbuconazole was negative in a hypoxanthine guanine phosphoribosyl transferase (HGPRT) gene mutation assay using Chinese hamster ovary (CHO) cells in culture when tested with and without hepatic enzyme activation. In isolated rat hepatocytes, fenbuconazole did not induce unscheduled DNA synthesis (UDS) or repair. Fenbuconazole did not produce chromosome effects in rats *in vivo.* On the basis of the results from this battery of tests, it is concluded that, fenbuconazole is not mutagenic or genotoxic.

3. *Reproductive and developmental toxicity—i. Developmental toxicity in the rat.* In the developmental study in rats, the maternal (systemic) no observed adverse effect level (NOAEL) was 30 mg/kg/day based on decreases in body weight and body weight gain at the lowest observed adverse effect level (LOAEL) of 75 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on an increase in post implantation loss and a significant decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day.

ii. *Developmental toxicity in the rabbit.* In the developmental study in rabbits, the maternal (systemic) NOAEL was 10 mg/kg/day based on decreased body weight gain at the LOAEL of 30 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on increased resorptions at the LOAEL of 60 mg/kg/day.

iii. *Reproductive toxicity.* In the 2-generation reproduction toxicity study in rats, the maternal (systemic) NOAEL was 4 mg/kg/day based on decreased body weight and food consumption, increased number of dams delivering nonviable offspring, and increases in adrenal and thyroid weights at the LOAEL of 40 mg/kg/day. The reproductive (pup) NOAEL was 40 mg/kg/day, the highest dose tested.

4. *Subchronic toxicity—i. Rat 90–day oral study.* A subchronic feeding study in rats conducted for 13–weeks resulted in a NOAEL of 80 parts per million (ppm) (5.1 and 6.3 mg/kg/day in males and females, respectively). The only effect observed at 80 ppm was minimal centrilobular hypertrophy (seen in one male) and hepatocytic centrilobular vacuolation (3 males) with no concomitant increase in liver weight or clinical chemistry correlates and no analogous effects in females. As such, these observations are not considered to be adverse. Increased liver weight, hepatic hypertrophy, thyroid hypertrophy, and decreased body weight were observed at the higher doses of 400 and 1,600 ppm.

ii. *Dog 90–day oral study.* A subchronic feeding study in dogs conducted for 13–weeks resulted in a NOAEL of 100 ppm (3.3 and 3.5 mg/kg/day in males and females, respectively). At the LOAEL of 400 ppm, increased liver weight, clinical chemistry parameters, and liver hypertrophy (males) were observed.

iii. *Rat 4–week dermal study.* In a 21–day dermal toxicity in the rat study, the NOAEL was greater than 1,000 mg/kg/day, with no effects seen at this limit dose.

5. *Chronic toxicity—i. Dog.* A 1–year feeding study in dogs resulted in a NOAEL of 15 ppm (0.62 mg/kg/day) for females and 150 ppm (5.2 mg/kg/day) for males. Decreased body weight, increased liver weight, liver hypertrophy, and pigment in the liver were observed at the LOAEL of 150 and 1,200 ppm in females and males, respectively.

ii. *Mouse.* A 78–week chronic/oncogenicity study was conducted in

male and female mice at 0, 10, 200 (males only), 650, and 1,300 ppm (females only). The NOAEL was 10 ppm (1.4 mg/kg/day), and the LOAEL was 200 ppm (26.3 mg/kg/day) for males and 650 ppm (104.6 mg/kg/day) for females based on increased liver weight and histopathological effects on the liver, which were consistent with chronic enzyme induction. There was no statistically significant increase of any tumor type in males. However, there was a statistically significant increase in combined liver adenomas and carcinomas in females at the high dose only (1,300 ppm; 208.8 mg/kg/day). There were no liver tumors in the control females, and liver tumor incidences in the high-dose females just exceeded the historical control range. In ancillary mode-of-action studies in female mice, the increased tumor incidence was associated with changes in several parameters in mouse liver following high doses of fenbuconazole, including an increase in P450 enzymes (predominately of the CYP 2B type), an increase in cell proliferation, an increase in hepatocyte hypertrophy, and an increase in liver weight. Changes in these liver parameters, as well as the occurrence of the low incidence of liver tumors, were non-linear with respect to dose (i.e., effects were observed only at high dietary doses of fenbuconazole). Similar findings have been shown with several pharmaceuticals, including phenobarbital, which is not carcinogenic in humans. The non-linear dose response relationship observed with respect to liver changes (including the low incidence of tumors) in the mouse indicates that these findings should be carefully considered in deciding the relevance of high-dose animal tumors to human dietary exposure.

iii. *Rat.* A 24–month chronic/oncogenicity study in male and female rats was conducted at 0, 8, 80, and 800 ppm fenbuconazole, and a second 24–month chronic/oncogenicity study was conducted in male rats at 0, 800, and 1,600 ppm. The NOAEL was 80 ppm (3 and 4 mg/kg/day in males and females, respectively), and the LOAEL was 800 ppm (31 and 43 mg/kg/day in males and females, respectively) based on decreased body weight, increased liver and thyroid weights, and liver and thyroid hypertrophy. Fenbuconazole produced a minimal but statistically significant increase in the incidence of combined thyroid follicular cell benign and malignant tumors. These findings occurred only in male rats following life-time ingestion of very high levels (800 and 1,600 ppm in the diet) of fenbuconazole.

iv. *Carcinogenicity.* The Agency has concluded, that the available data provide limited evidence of the carcinogenicity of fenbuconazole in both mice and rats and has classified fenbuconazole as a Group C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** (51 FR 33992, September 24, 1986), and recommended that for the purpose of risk characterization a low-dose extrapolation model applied to the experimental animal tumor data should be used for quantification of human risk (Q1*). EPA's 26 Feb 1998 Hazard Identification Assessment Review Committee (HIARC) report concluded that 0.00359 $(mg/kg/day)^{-1}$ is the appropriate Q* for fenbuconazole; this Q* is based on the fenbuconazole mouse liver tumor data, along with a power surface area scaling factor.

6. *Animal metabolism.* The absorption, distribution, excretion, and metabolism of fenbuconazole in rats, goats, and hens were investigated. Following oral administration, fenbuconazole was completely and rapidly absorbed, extensively metabolized by oxidation/hydroxylation and conjugation, and rapidly and essentially completely excreted, predominately in the feces. Fenbuconazole did not accumulate in tissues.

7. *Metabolite toxicology.* There are no toxicological concerns for fenbuconazole based on differential metabolic pathways in plants and animals. Triazole fungicides are known to produce three common metabolites, 1,2,4-triazole, triazolylalanine and triazole acetic acid. 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. This interim assessment was summarized in the **Federal Register** notice dated August 4, 2004 and titled Propiconazole; Time-Limited Pesticide Tolerances. 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.

8. *Endocrine disruption.* The mammalian endocrine system includes estrogen and androgens as well as other hormonal systems. Fenbuconazole is not known to interfere with reproductive hormones; thus, fenbuconazole should not be considered to be estrogenic or androgenic. There are no known instances of proven or alleged adverse reproductive or developmental effects to people, domestic animals, or wildlife as a result of exposure to fenbuconazole or its residues.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Dietary exposure assessments for fenbuconazole were conducted using the dietary exposure evaluation model (DEEM) software with the food commodity intake data base (DEEM-FCID, version 2) which incorporates food consumption data as reported in the Continuing Survey of Food Intake by Individuals (CSFII) Survey 1994–1996 and 1998. These exposure assessments include all existing uses under section 3 registrations (stone fruit except plums or prunes, pecans and bananas), grape (import, PP 0E6208), peanut (PP 9F6024), blueberry (PP 9E5041), cranberry (1E6252) and all other pending section 3 registrations including apple (PP 2F4135), sugar beet (PP 7F4887), plums and prunes (PP 1F3989), the citrus crop group (PP 7F4900, 7F4901), almond (PP 3F4914, 3H5663), wheat (PP 2F4127) as well as animal commodities. The assessments were performed in 3 levels. In the first assessment, a Tier 1 analysis was conducted with the assumption that 100% of the crops would be treated with fenbuconazole and that residues would be present at the tolerance levels. Also, default processing factors were used except for commodities with tolerances. In the second assessment (Tier 2), similar assumptions were made but the tolerance residues were adjusted with percent crop treated (PCT) from Doane data base available for apricot, cherry, peach, grapefruit, and pecan or from estimated market share for all other commodities. A Tier 3 analysis was used to estimate dietary exposure for the cancer risk assessment. This assessment was refined using available PDP data, average field trial residues adjusted for PCT and available processing factors except for commodities with tolerances.

a. *Acute dietary exposure.* Although, no acute adverse effect was observed as a result of exposure to a single dose, EPA has established an acute reference dose (aRfD) for the purpose of the acute dietary assessment. This aRfD was set at 0.3 mg/kg/day for females 13+ years old, the population sub-group of concern. This was based on the developmental rat toxicity study with a NOAEL of 30 mg/kg/day and an uncertainty factor of 100. The 100-fold safety factor includes intraspecies and interspecies variations. Using the above assumptions for Tier 1 assessment, the food exposure for females 13+ years old at the 95th

percentile was estimated to be 0.0133 mg/kg/day which utilized less that 5% of the acute RfD.

b. *Chronic dietary exposure.* EPA has established a chronic reference dose (cRfD) for fenbuconazole at 0.03 mg/kg/day for all population subgroups. The cRfD is based on the 2–year combined chronic feeding-carcinogenicity study in rats with a NOAEL of 3.03 and 4.02 mg/kg/day in males and females respectively, and an uncertainty factor of 100. The 100-fold safety factor includes intraspecies and interspecies variations. No additional FQPA safety factor is required. The food exposure for the overall U.S. population was estimated for the Tier 1 assessment to be 0.0044 mg/kg/day which utilizes 14.8% of the cRfD. The population subgroup with the highest potential for exposure was children 1–2 years at 62.7% of the cRfD with estimated food exposure of 0.0188 mg/kg/day. For the Tier 2 assessment, the estimated food exposure was reduced to 2.5% of the cRfD for the general population and 9.2% of the cRfD for children 1–2 years.

c. *Cancer dietary exposure.* EPA has classified fenbuconazole as a Group C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals) and has established a Q1* of 0.00359 $(mg/kg/day)^{-1}$ in human equivalents. Using a Tier 3 assessment, the food exposure was estimated to be 0.000074 mg/kg/day with a cancer risk estimate of 2.64×10^{-7}.

ii. *Drinking water.* The estimated drinking water concentration (EDWC) was calculated using the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) which predicts an annual average of 0.22 ppb. These results are considered a conservative assessment of possible concentration of fenbuconazole in drinking water. Using this value of 0.22 parts per billion (ppb), for dietary consumption of water in the DEEM-FCID chronic analysis results in the exposure from drinking water to be insignificant at < 0.1% of the cRfD for all population subgroups. Additionally in a later assessment the Agency used (Generic Estimated Environmental Concentration) GENEEC and (Screening Concentration in Ground Water) SCI-GROW models to estimate the environmental concentrations (EECs) for surface water and ground water. The EECs for fenbuconazole are 6.7 ppb for acute and 3.6 ppb for chronic exposure. Since the EECs in ground water are much lower than the EECs in surface water, conservatively only the surface water EECs were used for comparison with the drinking water levels of comparison (DWLOC). Drinking water levels of comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses. DWLOC is not a regulatory standard for drinking water, but is used as a point of comparison against the estimated potential concentrations in ground water or surface water. It is calculated by subtracting the food dietary exposure (from DEEM analysis) from the RfD and then expressed as µg/L using default body weights (70 kg for adult and 10 kg for infants) and drinking water consumption (2 L/day for adults and 1 L/day for children). The acute DWLOC for females 13 years and older (population sub-group of concern) using Tier 1 assumptions was calculated to be 8602 µg/L. The chronic DWLOC for the general U.S. population and children 1–2 years (population sub-group of concern) was calculated to be 895 µg/L and 112 µg/L, respectively using Tier 1 assumptions. The cancer DWLOC is the concentration in drinking water that results in a negligible cancer risk of 1×10^{-6}. Using the Tier 3 assessment, the estimated chronic food exposure is 0.000074 mg/kg/day for the general U.S. population. Assuming a negligible cancer risk of 1×10^{-6} and the Q1* of 0.00359 $(mg/kg/day)^{-1}$, the maximum allowable water exposure is 0.000205 mg/kg/day resulting in a calculated cancer DWLOC of 7 µg/L. When comparing the EEC to the cancer DWLOC, the Agency policy states that a factor of 3 will be applied to GENEEC modeled values because the estimated environmental concentration is derived from a 56–day average value and not a longer-term average. Applying a factor of 3, the EEC is 1.2 µg/L which is less than the calculated cancer DWLOC of 7 µg/L. The DWLOCs are substantially greater than the estimated residue concentration in ground water or surface water, therefore, exposure to fenbuconazole would not result in unacceptable levels of aggregate human health risk.

2. *Non-dietary exposure.* Fenbuconazole is not currently registered for use on any sites that would result in residential exposure. Thus, the risk from non-dietary exposure would be considered negligible.

D. Cumulative Effects

Fenbuconazole is a member of the triazole class of fungicides. At this time, EPA does not have available data to determine whether fenbuconazole exhibits a common mechanism of toxicity with other triazole fungicides. For purposes of this tolerance action, it is assumed that fenbuconazole does not have a mechanism of toxicity common with other substances and no cumulative risk is required.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions (Tier 1) and taking into account the completeness and reliability of the toxicity data, the chronic dietary food exposure from all section 3 registered and pending uses will utilize 14.8% of the cRfD for the U.S. population. Slight refinement (Tier 2) results in reduced risk estimates of 3% of cRfD for the general U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to fenbuconazole residues from the proposed uses. The acute dietary food exposure at the 95th percentile for females 13+ years, the population sub-group of concern, is approximately 5% of the acute RfD. Therefore, there is no concern for acute exposure because the acute RfD represents the level at or below which a single daily exposure will not pose appreciable risk to human health. Additionally, the potential contribution of fenbuconazole residues in drinking water is expected to be minimal. Using a refined assessment (Tier 3), the cancer risk is 2.65×10^{-7}. Generally the Agency has no concern for exposures that result in a cancer risk estimate below 1×10^{-6}. Including the potential for exposure in drinking water, the cancer risk is not expected to exceed 1×10^{-6} for the U.S. population as a whole.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of fenbuconazole, data from developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of offspring. The completeness and adequacy of the toxicity data base is also considered. No indication of increased susceptibility to infants and children was noted in these

studies for fenbuconazole. EPA has previously determined that no additional safety factor to protect infants and children is necessary for fenbuconazole and that the RfD of 0.03 mg/kg/day is appropriate for assessing risk to infants and children.

Using a conservative Tier 1 assessment, the chronic dietary exposure for fenbuconazole will utilize 62.7% of the cRfD for children 1–2 years old. Slight refinement (Tier 2) reduces the exposure to 9.2% for children 1–2 years old. Even when considering the potential exposure to drinking water, the aggregate exposure is not expected to exceed 100% of the cRfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes with reasonable certainty that no harm will result to infants and children from the aggregate exposure to fenbuconazole from all current and pending uses.

F. International Tolerances

International CODEX values are established for apricot, banana, barley, barley straw and fodder, cattle fat, meat, milk and edible offal, cherries, cucumber, eggs, grapes, melon except watermelon, peach, plum, pome fruits, poultry fat, meat and edible offal, rape seed, rye, summer squash, sunflower, and wheat.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0182; FRL–7722–2]

Alkoxylated Ether Amines; Notice of Filing of a Pesticide Petition to Establish a Tolerance Exemption for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0182, must be received on or before August 19, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Rame Cromwell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9068; e-mail address: *cromwell.rame@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0182. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whther submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.