- Yeasts / g: < 10 CFU
- Molds / g: < 10 CFU
- Coliforms / g most probable number (MPN): < 3 CFU
- *E. coli* / g (MPN): < 3 CFU
- *Staphylococcus aureus* / 10 g: < 10 CFU
- *Salmonella* / 25 g: absent

The recommended usage level of the red cabbage color as a visual pH indicator is less than 1%. The color value of a 1% solution of the red cabbage color is 16 absorbency units (determined by spectrophotometry at 535 nm after dilution in McIlvaine buffer at pH 3.0). Here, the color principles (and other red cabbage components) are less than those which are typically contained in an unprocessed red cabbage juice.

At a 1% usage level of the red cabbage color concentrate, the level of solvents and citric acid that are contained in the color concentrate are in line with current good manufacturing practice (cGMP) for foods. In particular, propylene glycol is at a level or 0.18%, *i.e.*, more than 10-fold lower than the level set by cGMP for foods other than alcoholic beverages, confectionery and frostings, seasoning and flavouring, nuts and nut products for which higher levels are permitted.

[FR Doc. 04–25502 Filed 11–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0357; FRL–7686–6]

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 extending time-limited tolerances for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0357, must be received on or before December 17, 2004.

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: J. R. Tomerlin, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0598; e-mail address: *tomerlin.bob@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 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–2004–0357. 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 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.

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–2004–0357. 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–2004–0357. 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–2004–0357.

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–2004–0357. 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 a pesticide petition 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 this petition contains 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 petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: November 3, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner 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 1F3989, 1F3995, and 2F4154.

EPA has received pesticide petitions (1F3989, 1F3995, and 2F4154) from Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.480 by extending the time-limited tolerances for the combined 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 fruit, stone, group 12 (except plum, prune) at 2.0 parts per million (ppm); pecan at 0.1 ppm; banana at 0.3 ppm. EPA has determined that the petition contains 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

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 lactones RH-9129 and RH-9130) 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.

3. *Magnitude of residues*—i. *Stone fruit-peaches.* Ten field trials were conducted on peaches. Seven to 10 applications were made at the maximum use rate of 0.1 pounds of active ingredient per acre (lb ai/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.

ii. *Stone fruit-cherries*. Eleven field trials were conducted on cherries. Five to 6 applications were made at the maximum use rate of 0.1 lb ai/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.

iii. *Stone fruit-apricots*. Four field trials were conducted on apricots. Six applications were made at the maximum use rate of 0.125 lb ai/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.

iv. *Pecans*. Four field trials were conducted in pecans. Eight to 10 applications were made at the maximum use rate of 0.125 lb ai/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.

v. *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 ai/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 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 26Feb98 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 of August 4, 2004 (69 FR 47005) (FRL–7352–1) 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 Database (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) and section 18 registrations (grapefruit, blueberry, and meat and meat by-products resulting from grapefruit pulp as animal feedstuff). The assessments were performed in two levels. In the first assessment (Level 1), 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. In the second assessment (Level 2), residues at tolerance levels were still assumed but the percent crop treated (PCT) was adjusted using the 4 or 5 year average for chronic assessment and the highest PCT for acute assessment. PCT values were based on data available for apricot, cherry, peach, grapefruit and pecan from the Doane database. Additionally, the default processing factors were used for all processed commodities except citrus oil. The tolerance of 35 ppm was used for citrus oil based on the residue data in grapefruit.

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 Level 1 assessment, the food exposure for females 13+ years old at the 95th percentile was estimated to be less than 0.005 mg/kg/day which utilized less that 2% of the aRfD. For the level 2 assessment, the estimated food exposure at the 99.99*th* percentile was less than 0.003 mg/kg/day which utilizes less than 1.0% of the 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 to be 0.000552 mg/kg/day which utilizes less then 2% of the cRfD. The population subgroup with the highest potential for exposure was non-nursing infants at 10.6% of the cRfD with estimated food exposure of 0.003185 mg/kg/day. For the level 2 assessment, the estimated food exposure drops to 0.6% of the cRfD for the general population and 2.8% of the cRfD for non-nursing infants.

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 the above assumptions for Level 1 assessment, the food exposure was estimated to be 0.00552 mg/kg/day with a cancer risk estimate of 1.98×10^{-6}. Using the refinements of PCT in the Level 2 assessment results in a more realistic cancer risk assessment of 6.9×10^{-7} and a food exposure of 0.000191 mg/kg/day.

ii. *Drinking water*. The estimated drinking water concentration was calculated using the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) which predicts and 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 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). 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 groundwater 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) was calculated to be 8,915 µg/L. The chronic DWLOC for the general U.S. population and non-nursing infants (population sub-group of concern) was calculated to be 1,043 µg/L and 292 µg/L, respectively. The cancer DWLOC is the concentration in drinking water that results in a negligible cancer risk of 1×10^{-6}. Using the Level 2 assessment, the estimated chronic food exposure is 0.000191 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 0.00009 mg/kg/day resulting in a calculated cancer DWLOC of 3 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 3 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 (Level 1/Tier 1) and taking into account the completeness and reliability of the toxicity data, the chronic dietary food exposure from all supported section 3 and section 18 registered uses will utilize 1.8% of the cRfD for the U.S. population. The major identifiable sub-group with the highest chronic food exposure is non-nursing infants at 10.6% of the cRfD. 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 <2% of the aRfD. 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 slight refinement for PCT, the cancer risk assessment is 6.9 x 10^{-7}. Generally the Agency has no concern for exposures that result in a cancer risk estimate below 1 x 10^{-6}. Including the potential for exposure in drinking water, the cancer risk is not expected to exceed 1x 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 database 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.

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.

[FR Doc. 04–25501 Filed 11–16–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority.

November 9, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Pub. L. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction (PRA) comments should be submitted on or before January 18, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Cathy Williams, Federal Communications Commission, Room 1-C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at 202–418–2918 or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0216.

Title: Section 73.3538, Application to Make Changes in an Existing Station.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 50.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 50 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: On February 14, 2001, the Commission adopted a *Report and Order,* In the Matter of An Inquiry Into the Commission's Policies and Rules Regarding AM Radio Service Directional Antenna Performance Verification, MM Docket No. 93–177. This *Report and Order* relaxed the technical requirements for AM stations using directional antennas. Among other things, this *Report and Order* eliminated the need to file an informal application to specify new AM station directional antenna field monitoring points. 47 CFR Section 73.3538(b) requires a broadcast station to file an informal application to modify or discontinue the obstruction marking or lighting of an antenna supporting structure. The requirement to file an informal application to relocate the main studio outside the principal community contour has approval under 47 CFR Section 73.1125 (3060–0171). The data is used by FCC staff to ensure that the modification or discontinuance of the obstruction marking or lighting will not cause a menace to air navigation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–25518 Filed 11–16–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) being Reviewed by the Federal Communications Commission, Comments Requested

November 9, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Pub. L. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control