conducted via oral gavage in rabbits with dosages of 0, 100, 300, and 1,000 mg/kg bwt/day. The NOAEL for maternal toxicity was 100 mg/kg bwt/day and was 1,000 mg/kg/day for developmental toxicity. As noted above this NOAEL is based on fecal alterations and an abortion in a single dam at the next highest dose of 300 mg/kg/day. The dam which displayed the fecal alterations and abortion also displayed decreased body weight, body weight gain and food consumption - compared to the group mean - during gestation. These decreases occurred even prior to compound administration. These decreases in body weight, body weight gain, and food consumption, prior to compound administration, all indicate an animal in poor health and this poor state of health, rather than compound exposure, was likely the reason for the fecal alterations and abortion. No teratogenic effects were observed at any dose level.

4. *Reproductive toxicity*. A 2–generation reproduction study in rats was conducted with dosages of 0, 12, 118, and 1,183 mg/kg bwt/day. No impairment of reproductive function was noted at any dose. The parental and developmental NOAEL are both 12 mg/kg/day. Mild effects in both the parents and pups were noted at 118 mg/kg/day and consisted of an increased incidence of hepatic centrilobular hypertrophy in parents and, in the pups, slightly decreased body weight and body weight gain (7%) in F2 generation only, and only in males. At 1,183 mg/kg/day paternal effects included decreased body weights and food consumption, increased liver weights and increased incidence of hepatic centrilobular hypertrophy and degeneration. Pup effects at this dose were an increase in pup mortality in the F2 only and a decreased body weight in F1 and F2.

5. *Reference dose*. In all reproductive studies, the NOAELs for developmental effects were either equal to or higher than those for the parents. Therefore, BAS 510 F shows no selective toxicity for the young. In addition, there were no direct neurotoxicity effects noted in either the acute or subchronic neurotoxicity studies.

Based on these results, no additional safety factors to protect children are warranted. Since the reproductive studies NOAELs are higher than the RfD calculated from the chronic rat study, BASF believes the RfD of 0.05 mg/kg/day is also appropriate to measure safety for infants and children. Therefore, the chronic population adjusted dose is also 0.05 mg/kg bwt/day.

F. International Tolerances

A maximum residue level has not been established for BAS 510 F in any crop by the Codex Alimentarius Commission.

[FR Doc. 03–3694 Filed 2–13–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0007; FRL–7289–1]

Pyrimethanil; 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 pyrimethanil in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0007, must be received on or before March 17, 2003.

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: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 identification (ID) number OPP–2003–0007. 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, 1921 Jefferson Davis Hwy., 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–2003–0007. 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–2003–0007. 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–2003–0007.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0007. 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: February 3, 2003.

Debra Edwards,

Acting 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.

Janssen Pharmaceutica Inc.

PP 2F6480

EPA has received a pesticide petition (2F6480) from Janssen Pharmaceutica Inc., Plant and Material Protection Division, 1125 Trenton-Harbourton Road, Titusville, NJ 08560 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 by establishing tolerances for residues of the fungicide, pyrimethanil (4,6-dimethyl-*N*-phenyl-2-pyrimidinamine) in or on the raw agricultural commodities citrus fruits (calamondin, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, sour and sweet oranges, pummelo and Satsuma mandarin) at 6 parts per million (ppm), pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) wet pomace at 12 ppm, and pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) at 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolic profile of pyrimethanil has been investigated following application to five different crops (apple, carrots, grapes, lettuce and tomatoes) and is well understood. In plants, pyrimethanil is the only significant residue ranging from essentially all of the Total Radioactive Residues (TRR) in carrots and tomatoes to 44% in lettuce. Limited metabolism of pyrimethanil occurs with minor amounts (less than 10%) of the phenyl and pyrimidyl hydroxylated metabolites (AE C614276, AE C614277, AE C614278, and AE C621312) being released after acid hydrolysis. Analysis of the foliage from apples and carrots confirmed that the metabolism of pyrimethanil in plants proceeded primarily via hydroxylation of the aromatic ring structures as well as the methyl groups.

2. *Analytical method*. The plant metabolism studies indicated that analysis for the parent compound, pyrimethanil was sufficient to enable the assessment of the relevant residues in crop commodities. For citrus, the pyrimethanil was extracted with acetone, the extract acidified and washed with isohexane and basified to enable solvent partition. After solvent exchange to ethyl acetate, the residue is determined using GC-MS. For pome fruits, the pyrimethanil was extracted directly with ethyl acetate/isohexane (1:1), dried, and analyzed for residues with GC-MS. The limit of quantitation is 0.05 ppm. These methods allow detection and measurement of residues in or on agricultural commodities at or above the proposed tolerance level.

3. *Magnitude of residues*. Magnitude of residue trials were conducted for pyrimethanil on apples, pears, and citrus (lemons, oranges (navels and valencias), tangerines, tangelos, and grapefruit). Trials were conducted in the major producing states which together represent 97%, 70%, and 75% of the citrus, apple and pear domestic production, respectively. Samples were collected according to good agricultural practices at harvest and/or following a postharvest treatment. The pre-harvest interval (PHI) for pome fruit was 7 days following application of the fungicide at the proposed label rate, to approximate maximum field residues. The proposed PHI for pome fruit is 72 days. Samples were harvested at maturity and analyzed with a method having an level of quantitation (LOQ) of 0.05 ppm pyrimethanil. Residues in the raw agricultural commodity (RAC) samples (range, maximum and average) are discussed per crop grouping below.

i. *Citrus fruits (calamondin, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, sour and sweet oranges, pummelo and Satsuma mandarin)*. Nine trials were conducted on citrus during 2001. An end use formulation containing 400 gram/liter or 3.34 lbs/active ingredient/gallon of pyrimethanil was applied by drench, dip and/or line spray in water, storage wax or shipping wax. Multiple treatments (single, double and triple applications) were investigated. A maximum of ten different multiple treatment scenarios were investigated for lemons, seven for oranges, and five for grapefruit. Fruit were washed between treatments only when this was typical of commercial packinghouse operations. The maximum rates applied were 1,000 ppm in drench and dip tanks, and 2,000 ppm in any type of line spray. The maximum proposed use recommendations are for a 4 minute drench at 500 ppm, 2 minute dip at 1,000 ppm, and/or 2,000 ppm line spray for water or storage and shipping wax, with a maximum of three applications. Whole fruit and edible pulp were analyzed separately for pyrimethanil residues. In the whole fruit samples, maximum residues were 6.0 ppm for the proposed applications, and 0.76 ppm for edible pulp. Mean pyrimethanil residues ranged from 1.1 ppm for an single aqueous line spray applied with a 20,000 ppm treating solution to 5.45 ppm for a triple treatment that included a drench (1,000 ppm), dip (1,000 ppm), and 2,000 ppm wax line spray. A single orange trial was established in Florida as a processing study. Pyrimethanil was

applied as a dual application at rates of 2,000 and 4,000 ppm active ingredient (a.i.) in aqueous and wax line sprays, respectively. This rate is the maximum for the aqueous treatment and two times the proposed label rate for wax incorporation. Mean pyrimethanil residue levels found in/on the samples were: Whole citrus fruits 7.46 ppm, dried pulp 2.93, orange juice 0.05 ppm and citrus oil 131 ppm. No pyrimethanil-derived residue concentrated from the whole fruit into the orange juice or dried pulp. However, the pyrimethanil residues concentrated from the whole oranges into the citrus oil by a factor of 17.5. Citrus oil is not considered as a ready-to-eat food commodity and since none of the of the processed food products are likely to contain pyrimethanil residues above the proposed citrus tolerance of 6.0 ppm in the raw agricultural commodity of whole fruit utilizing dilution factors, tolerances are not necessary for citrus oil.

ii. *Pome fruit (apples, pears, Oriental pears, crabapples, loquats, mayhew, and quince)*. Ten trials were established for this study, four in Washington, four in California, and two in New York. Of the 10 trials, 4 were conducted on pears and 6 on apples. A pre-harvest formulation of pyrimethanil was applied to the apple or pear trees during a single application, at a nominal rate of 0.40 lb of a.i., 7 days prior to harvest. Mean pyrimethanil residue levels found in or on the apple fruit following both preharvest and postharvest applications ranged from 0.49 ppm for a single aqueous line spray at 1,000 ppm a.i. to 1.44 ppm for the dual treatment consisting of a drench (1,000 ppm) followed by an aqueous line spray (1,000 ppm). Individual sample residues ranged from a low of 0.11 ppm for the 1,000 ppm aqueous line spray to 2.84 ppm for the dual treatment of a 1,000 ppm drench followed by a 2,000 ppm wax application. The limit of quantitation of the analytical method was 0.05 ppm. A single trial was established in Washington as a processing study. Pyrimethanil was applied to apple trees four times prior to harvest. Applications were made at a nominal rate of 2.0 lb a.i./Acre, with 7 days between applications. This rate is approximately five times the proposed label application rate. Mean pyrimethanil residue levels found in or on the samples were: Whole apple fruit 0.17 ppm, wet pomace 0.69 ppm, and juice 0.06 ppm. No pyrimethanil-derived residue concentrated from the whole fruit into the apple juice. However, the pyrimethanil residues concentrated from the whole apples into the wet pomace by a factor of 4.

B. Toxicological Profile

1. *Acute toxicity*. Pyrimethanil is of low acute toxicity placing the active ingredient in Toxicity Category II, III and IV. Pyrimethanil is non-irritating to the eyes and skin and is not a skin sensitizer.

Acute neurotoxicity. Groups of 10 rats/sex/group were dosed once by oral gavage at dose levels of 0, 30, 100, 1,000 milligrams/kilogram (mg/kg) of pyrimethanil bodyweight. On the day of dosing, high dose animals experienced transient behavioral effects attributable to receipt of a substantial bolus dose of test substance. No histopathological lesions accompanied these transient behavioral changes. The no observed adverse effect level (NOAEL) was 100 mg/kg due to reduced body temperature for males. The NOAEL was 30 mg/kg.

2. *Genotoxicity*. Pyrimethanil is not mutagenic or genotoxic in any assay in either the presence or absence of metabolic activation.

3. *Reproductive and developmental toxicity*. Pyrimethanil is not a developmental or reproductive toxicant.

i. *Teratology - rat*. Thirty Sprague Dawley rats/group received doses of 0, 7, 85, 1,000 mg/kg of pyrimethanil by gavage from gestation days (GD) 6-15. At the highest dose tested, reduced maternal body weight gain was observed during GD6-15, along with a slight but statistically significant decrease in food consumption, hair loss, hunched posture, slight emaciation, and slightly reduced mean fetal body weight. The maternal and developmental NOAEL was 85 mg/kg.

ii. *Teratology - rabbit*. Groups of at least 18 time-mated New Zealand White rabbits received oral gavage doses of 0, 7, 45, or 300 mg/kg/day pyrimethanil over gestation days (GD) 7-19. At the highest dose tested, there was a decrease in body weight gain, production of feces and food consumption. Three females were euthanized due to severe emaciation. The highest dose, 300 mg/kg/day exceeded the maternal maximum tolerated dose (MTD). The maternal NOAEL was 45 mg/kg/day due to reduced fecal production in 1/3 of the animals. The high dose resulted in reduced mean fetal body weight, increased incidence of runts, delayed skeletal ossification and incidence of fetuses with 13 thoracic vertebrae and ribs. The maternal NOAEL was 7 mg/kg/day. The developmental NOAEL was 45 mg/kg/day.

iii. *Two-generation reproduction - rat*. Three groups of 30 Sprague-Dawley rats per sex received dietary exposure to pyrimethanil at levels of 0, 1.7, 20.9, or 266.7 mg/kg/day. In the parental generation at the highest dose tested there was a statistically significant decrease in mean body weight gain in both sexes. Mean pup weights, observed on PND1 through weaning, were reduced, though were within the range of historical controls. In the F1 generation at the highest dose tested, mean body weights and mean food consumption were reduced. Though the mean score for the combined sexes was the same as the controls, a marginally different air-righting reflex at PND11 associated with reduced body weight was seen in high dose male pups. The NOAEL for maternal and developmental toxicity was 20.9 mg/kg/day. The reproductive NOAEL was 266.7 mg/kg/day.

4. *Subchronic toxicity*—i. *28–Day dietary rat*. Five Sprague-Dawley rats/sex/group received dietary exposure to pyrimethanil for 28 days at 0, 844, 1,161, 1,500, and 2,710 mg/kg/day. All doses exceeded the maximum tolerated dose. Severe emaciation was observed at all dose levels. Body weight gains and food consumption were reduced. Liver and thyroid histopathology were observed, along with reduced hemoglobin, MCV and MCH. Kidney, adrenal and liver weights were altered. No NOEL or NOAEL was achieved.

ii. *90–Day dietary rat*. Ten Sprague-Dawley rats/sex/group received pyrimethanil in the diet at dose levels of 0, 5.4-6.8, 54.5-66.7, and 545-667 mg/kg/day (males and females, respectively). High dose animals had reduced body weight gain and food consumption, increased urinary protein in males, colored urine (not blood or bilirubin) and minimal hepatocellular hypertrophy. The NOAEL in males was 54.5-66.7 (males and females, respectively) due to colored urine and a low incidence of minimal centrilobular hepatocellular hypertrophy. The NOAEL was 5.4 mg/kg/day (males) -6.8 mg/kg/day (females).

iii. *28-Day dietary-mouse*. Five CD-1 mice/sex/group received dietary doses of 0, 167-236, 567-667, 1960-2357 mg/kg/day, males and females respectively, for 28 days (all the mice in one additional high dose group, 30,000 ppm, died within the first week of the study). At 1960-2357 mg/kg/day, animals experienced: body weight loss (females), decreased body weight gain during the first 2 weeks (males), a statistically significant decrease in cholesterol, statistically significant decreases in relative liver weights (females), pigmentation of thyroid follicles, urolithiasis, moderate urothelial hyperplasia in urinary bladder, and

slight kidney tubular degeneration (females). The NOAEL was 167-236 mg/kg/day.

iv. *90–Day dietary-mouse*. Twenty CD-1 mice/sex/group received pyrimethanil diet exposure at dose levels of 0, 12-18, 139-203, 1,864-2,545 mg/kg/day males-females for 90 days. At the high dose, animals had decreased body weight and increased food consumption, cholesterol and total bilirubin. High dose females had increased relative liver weights. Histopathology in the high dose animals was found in the kidneys, liver, thyroid, and urinary bladder. High dose males had slight urinary tract tubular dilation and slight to moderate hyperplasia of bladder epithelium. The NOAEL was determined to be 12 mg/kg/day (males) -18 mg/kg/day (females). Based on mild hepatic glycogen depletion, the NOAEL was 139-203 mg/kg/day (males and females, respectively).

v. *90–Day dietary-dog*. Four beagle dogs/sex/group received pyrimethanil by gavage for 90 days at doses of 0, 6, 80, 1,000 mg/kg/day. The high dose was lowered to 800 mg/kg/day on day 7 due to frequent and consistent vomiting. Decreased body weight, food, and water consumption were observed. Males had a significant reduction in phosphate, while females experienced a slight reduction in sodium, anion gap and total protein. At 80 mg/kg/day, infrequent vomiting after dosing and decreased water consumption were observed. After 4 weeks of dosing at 80 mg/kg/day, males had significantly reduced phosphate. The NOAEL was 80 mg/kg/day. The NOEL was 6 mg/kg/day.

vi. *Subchronic neurotoxicity*. Groups of 12 Sprague-Dawley rats per sex were treated for 13 weeks with pyrimethanil via the diet at 0, 4, 38.7-44.3, 391.9-429.9 mg/kg/day (males and females, respectively). There were no treatment-related findings in behavioral assessments, neuropathology or brain morphometrics. The NOAEL for this study is 38.7-44.3 mg/kg/day (males and females, respectively) based upon decreased body weight and food consumption in the high dose group.

vii. *Dermal toxicity evaluation*. No dermal studies have been conducted for pyrimethanil.

5. *Chronic toxicity*—i. *Chronic toxicity - dog*. Four beagle dogs/sex/group received pyrimethanil by gavage at levels of 0, 2, 30, or 250 mg/kg/day for 12 months. The high dose was reduced from 400 to 250 mg/kg/day on day 8 of treatment due to excessive vomiting during the first week of treatment. At the high dose, there was a decrease in mean body weight gain and mean consumption of food and water. The NOAEL for the study was 30 mg/kg/day, with the high dose of 250 mg/kg/day being the NOAEL.

ii. *Combined chronic toxicity/oncogenicity - rat*. Seventy Sprague-Dawley rats/sex/group received pyrimethanil by diet at levels of 0, 1.3-1.8, 17-22, and 221-291 mg/kg/day (males and females, respectively) for 2 years. At the highest dose tested, body weight gain and food consumption were decreased. Absolute liver weights were increased. Histopathology revealed centrilobular hepatocyte hypertrophy, increased incidence of eosinophilic foci (males), thyroid follicular hyperplasia, hypertrophy and colloid depletion, and the presence of a brown pigment, identified as lipofuscin in thyroid follicular cell epithelium. There was a statistically significant, dose-dependent increase in the incidence of benign thyroid follicular cell adenomas. There was no increased incidence in any malignant tumor or increase in tumor multiplicity as a result of daily dietary ingestion of pyrimethanil at any dose level. The results of special studies, discussed below, demonstrate that the benign thyroid tumors are likely a secondary result of a disruption of thyroid-pituitary homeostasis, a well-known, threshold-mediated mechanism. The NOAEL was 17 mg/kg/day (males) and 22 mg/kg/day (females).

iii. *Oncogenicity - mouse*. Fifty-one CD-1 mice/sex/group received pyrimethanil by diet at 0, 16, 160, and 1,600 ppm (corresponding to 0, 2-2.5, 20-24.9, and 210.9-253.8 mg/kg/day in males and females, respectively). There was an increase in the number of high dose male deaths caused by urogenital tract lesions. Urinary bladder histopathology on those dying during the course of the study indicates an increase in the incidence of male urinary bladder distension, cystitis, urothelial hyperplasia and inflammation of the penis. These findings are consistent with the findings of both the 28- and 90-day studies indicating that high dose administration of pyrimethanil resulted in urolith formation leading to irritation, distension and hyperplasia of the urinary bladder and urinary tract. Chronic dietary treatment with pyrimethanil produced no increased incidence of tumor-bearing mice nor of any specific tumor type suggestive of a carcinogenic effect. The NOAEL for both sexes was 20-24.9 mg/kg/day (males and females, respectively).

iv. *Special studies*. Since rodent thyroid tumors are fairly common, and since the EPA has established that five lines of evidence are required to prove the thyroid-pituitary disruption mode of action for rodent thyroid tumors, special studies were undertaken

a. *Thyroid mechanistic study (14-Day)*. Sprague Dawley rats received 378.5 mg/kg/day of pyrimethanil for 14 days to study the effects of pyrimethanil on the thyroid and liver microsomal enzymes. An increase in the levels of UDPGT and a corresponding statistically significant increase in liver weight were observed. Thyroid hormones T4 and T3 were decreased, while TSH levels were significantly increased. All effects were shown to be reversible.

b. *Dietary thyroid function test using perchlorate discharge (7-Day)*. Sprague Dawley rats received 509 mg/kg/day pyrimethanil or 177 mg/kg/day propylthiouracil, or 109 mg/kg/day phenobarbital in order to study the function of the thyroid gland. The animals fed pyrimethanil had 43% decreased body weight gain, 21% decreased food consumption and a 150% increase in uptake of iodine-125. There was no significant discharge of radioactive iodine from the thyroid after administration of perchlorate.

The required five lines of evidence to support the threshold mode of action for thyroid pituitary disruption and rat thyroid tumors are satisfied in the pyrimethanil studies.

EPA's final rule establishing a tolerance for pyrimethanil in wine stated that ''The Agency's Carcinogenicity Peer Review Committee (CPRC) chose a non-linear approach Margin of Exposure (MOE) based on a NOAEL of 17 mg/kg/day for increased incidences of thyroid tumors in rats. The MOE methodology was selected because of thyroid tumors associated with administration of pyrimethanil in the rat, which may be due to a disruption in the thyroid-pituitary status. This chemical has been classified as a Group C chemical (possible human carcinogen) and a non-linear methodology (MOE) was applied for the estimation of human cancer risk. The estimated MOE does not exceed the Agency's level of concern and therefore, EPA has a reasonable certainty that no harm will result from exposures to residues of pyrimethanil.''

6. *Animal metabolism*. Pyrimethanil is rapidly metabolized and excreted from lactating dairy cows. The observed total radioactive residues in edible tissues and milk were as follows: Milk - maximum residue of 0.069 ppm; liver - 0.363 ppm; kidney 0.249 ppm and muscle 0.017 ppm. The metabolic pathway is similar to that of plants involving hydroxylation of the phenyl and pyrimidine rings as well as hydroxylation of the methyl

substituents. Further metabolic reactions occur including cleavage of the phenyl ring to produce substituted pyrimidines. The major metabolite was AE C614276 (46% of the kidney residues, 63% of the milk residues) resulting from hydroxylation of the phenyl ring. Hydroxylation of the pyrimidinyl ring of pyrimethanil resulted in formation of minor amounts of AE C614277. Hydroxylation of the methyl groups of pyrimethanil resulted in formation of minor amounts of AE C614278. Hydroxylation of the methyl groups of AE C614276 resulted in formation of minor amounts of AE C614800.

7. *Metabolite toxicology*. The primary residue of concern in both crop and animal commodities is pyrimethanil. In the animal metabolism, since major metabolites are produced following the oral administration of pyrimethanil, toxicology data for metabolites are completely supported by data obtained for pyrimethanil.

8. *Endocrine disruption*. Chronic, life span, and multi-generational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal endocrine effects. Any endocrine related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of pyrimethanil is negligible.

C. Aggregate Exposure

1. *Dietary exposure*. Tolerances are proposed under 40 CFR part 180 for pyrimethanil in or on citrus fruits and pome fruits following postharvest application. An import tolerance for wine grapes has been approved by the EPA. A petition for registration of pyrimethanil on bananas is pending at EPA. In March 2002, registration applications and tolerance petitions were filed for tree nuts, bulb vegetables, grapes, stone fruits (except cherries), pome fruit (preharvest application), tuberous and corm vegetables, strawberries, and tomatoes. There are no residential uses proposed for pyrimethanil. Therefore, potential human risk scenarios cover aggregate exposure from food residues and drinking water.

i. *Food*. Refined estimates of acute dietary exposure from potential pyrimethanil residues with the addition of postharvest uses on citrus and pome fruits are all well under 100% of the acute reference dose (RfD) at the 99.9th percentile. The most highly exposed sub population of non-nursing infants utilizes 13.35% of the RfD, while the U.S. population utilizes 6.1%. These potential dietary exposures were estimated in a Tier 3 Monte Carlo risk assessment using the Dietary Exposure Evaluation Model (DEEM) software (Novigen 2001). The 1994–96, 1998 Continuing Surveys of Food Intake by Individuals (CSFII) consumption data from USDA was used which includes the Supplemental Children's Survey (1998). Residue values included in the assessment were distributions of the field trail values incorporating percent crop treated (PCT) as zeroes for all non-blended and partially blended items. Blended items were included as the average residue and adjusted for PCT. These PCT values are the anticipated market share of pyrimethanil for the crops at market maturity (5 years). Concentration factors derived from processing studies were included where appropriate. Secondary residues for meat and milk were included in the assessment. These were calculated using theoretical dietary burdens from sensible diets for beef and dairy cattle and tissue to feed ratios from the ruminant feeding study.

Refined chronic dietary exposure estimates resulting from the proposed uses of pyrimethanil are well within acceptable limits for all population subgroups examined. The most highly exposed group of non-nursing infants utilized 0.9% of the reference dose with the U.S. population utilizing 0.2% of the reference dose. A Tier 3 chronic analysis was done using the DEEM software, (Novigen 2001). The 1994–96, 1998 CSFII consumption data from USDA were used. Average anticipated residue values were calculated from the appropriate field trial studies conducted for pyrimethanil. The average residue values were adjusted by the projected PCT at product maturity. Concentration factors derived from processing studies were included where appropriate. Secondary residues were calculated using theoretical dietary burdens derived from sensible diets for beef and dairy cattle and tissue to feed ratios from the ruminant feeding study.

ii. *Drinking water*. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was followed to perform the Tier One drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessments, including water models such as Screening Concentrations in Ground Water (SCI-GROW), First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZMS/EXAMS), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface and ground water and the highest levels (whether ground or surface) are assumed to be the drinking water residue. In the case of pyrimethanil, monitoring data are not available. SCI-GROW and FIRST were used to estimate a drinking water residue. Calculation of the Drinking Water Estimated Concentration (DWEC) for surface water for the worst case pyrimethnail use scenario results in a acute DWEC of 122 ppb and a chronic DWEC of 37 ppb. Drinking Water Levels of Comparison (DWLOCs) calculated based on the acute and chronic risk assessments described above are many fold higher than these conservative DWECs. The adult acute and chronic DWLOCs are 9,860 ppb and 5,936 ppb respectively. Children's acute and chronic DWLOCs are 2,641ppb and 1,686 ppb respectively.

2. *Non-dietary exposure*. Pyrimethanil products are not labeled for residential uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational exposure.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' There are no available data to determine whether pyrimethanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyrimethanil does not appear to form a toxic metabolite produced by other substances. For the purposes of the tolerance petition, it has been assumed that pyrimethanil does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. Using the assumptions and data described above, based on the completeness and reliability of the toxicity data, it is concluded that dietary risk from the proposed uses of pyrimethanil are acceptable for all populations examined. Chronic exposure for the U.S. population utilizes 0.2% (0.000392 mg/kg bw/day) of the chronic reference dose. Acute exposure for the U.S. population utilizes 6.1% (0.018287 mg/kg bw/day) of the acute reference dose. The most highly exposed population of non-nursing infants utilizes only 0.9% of the chronic reference dose and

13.35% of the acute reference dose. The actual exposures are likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD (acute or chronic), because the RfD represents the level at or below which exposure will not pose appreciable risk to human health. DWLOC for adults both acute (9,860 ppb) and chronic (5,936 ppb) are several orders of magnitude above the conservative DWEC for acute (122 ppb) and chronic (37 ppb) worst case scenarios. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to residues of pyrimethanil.

2. *Infants and children*. The relevant toxicity studies as discussed in the toxicology section above show no extra sensitivity of infants and children to pyrimethanil, therefore, the FQPA safety factor can be removed. Using the assumptions and data described in the exposure section above, it is concluded that dietary risk from the proposed uses of pyrimethanil are acceptable for all infant and children sub-populations examined. The most highly exposed sub-population was non-nursing infants for both the chronic and acute analyses. The sub-population non-nursing infants utilizes 0.9% (0.001563 mg/kg bw/day) of the chronic reference dose and 13.35% (0.040040 mg/kg bw/day) of the acute reference dose. All other infant and children populations have less exposure. The chronic and acute drinking water levels of concern for children (1,684 ppb and 2,600 ppb respectively) are well above the conservative drinking water estimated concentrations for chronic and acute scenarios. The chronic DWEC is 37 ppb and the acute DWEC is 122 ppb. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of pyrimethanil.

F. International Tolerances

Maximum Residue Limits for pyrimethanil have not been established by the Codex Alimentarius Commission.

[FR Doc. 03–3695 Filed 2–13–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0020; FRL–7289–9]

Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent 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 microbial agent in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0020, must be received on or before March 17, 2003.

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: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: bacchus.shanaz@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 categories and entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. 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 identification (ID) number OPP–2003–0020. 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, 1921 Jefferson Davis Hwy., 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