including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, Arlington, VA (703) 305–5805. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 1200 Pennsylvania Ave., NW., Washington, DC 20460. Such requests should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

II. Did EPA Approve the Application?

The Agency approved the application after considering all required data on risks associated with the proposed use of chlorfenapyr (4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile), and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of chlorfenapyr (4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile) when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

III. Approved Registrations

1. EPA issued a notice, published in the **Federal Register** of November 19, 1999 (64 FR 63316) (FRL 6392–7), which announced that American Cyanamid (now BASF) P.O. Box 400 Princeton, NJ 08543–0400, had submitted an application to register the pesticide product, Alert, miticide-insecticide (EPA File Symbol 241–GTU), containing chlorfenapyr (4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile) at 21.4%. This product was not previously registered.

The application was approved on January 19, 2001, as Pylon miticide-insecticide (EPA Registration Number 241–374) for use on pests of ornamentals grown in greenhouses.

2. EPA issued a notice, published in the **Federal Register** of December 2, 1998 (63 FR 66534) (FRL FRL 6046–6), which announced that American Cyanamid (now BASF) P.O. Box 400 Princeton, NJ 08543–0400, had submitted an application to register the pesticide product, AC 303,630 Technical, a technical product (EPA File Symbol 241–GAA), containing chlorfenapyr (4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile) at 93%. This product was not previously registered.

The application was approved on January 19, 2001, as Chlorfenapyr Technical (EPA Registration Number 241–366) containing chlorfenapyr at 96.2% for formulating into pesticide products used on ornamentals in greenhouses.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: February 16, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 01–6729 Filed 3–16–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1002; FRL–6771–2]

Notice of Filing Pesticide Petitions 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 pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1002, must be received on or before April 18, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1002 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1002. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1002 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: ''opp-docket@epa.gov'', or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1002. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: March 5, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petitions 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.

Interregional Research/Bayer Corporation

PP 9E6045, 9E6046, 9E6048, 0E6103, 0E6117, 0E6153, 0E6158, 0E6212, 7F4895, 0F6086, and 0F6091

EPA has received pesticide petitions (PP 9E6045, 9E6046, 9E6048, 0E6103, 0E6117, 0E6153, 0E6158, and 0E6212) from the Interregional Research Project Number 4 (IR-4), State Agricultural Experimentation, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. EPA has also received pesticide petitions (7F4895, 0F6086, and 0F6091) from Bayer Corporation, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120–0013. The petitions propose, 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 tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]alpha-(1,1-dimethylethyl)-1*H*-1,2,4] in or on the raw agricultural commodities as follows:

1. PP 9E6045. Proposes the establishment of tolerances in or on turnip, tops at 8.0 parts per million (ppm) and turnip, roots at 0.4 ppm.

2. PP 9E6046. Proposes the establishment of a tolerance in or on hop at 5.0 ppm.

3. PP 9E6048. Proposes the establishment of a tolerance in or on vegetable, cucurbit, group at 0.1 ppm.

4. PP 0E6103. Proposes the establishment of a tolerance in or on mango (postharvest) at 0.2 ppm.

5. PP 0E6117. Proposes the establishment of a tolerance in or on plum (postharvest) at 1.0 ppm.

6. PP 0E6153. Proposes the establishment of tolerances in or on sunflower, seed at 0.05 ppm, sunflower, refined oil at 0.2 ppm, and sunflower, meal at 0.2 ppm.

7. PP 0E6158. Proposes the establishment of a tolerance in or on okra at 1.0 ppm.

8. PP 0E6212. Proposes the establishment of a tolerance in or on lychee at 1.5 ppm.

9. PP 7F4895. Proposes the establishment of tolerances for nut, tree, group at 0.05 ppm, almond, hulls at 5.0 ppm, pistachio at 0.05, wheat, forage at 3.0 ppm, wheat, hay at 6.0 ppm, and wheat, straw at 1.4 ppm.

10. PP 0F6086. Proposes the establishment of tolerances in or on bean, succulent at 0.1 ppm, bean, seed at 0.1 ppm, cotton, undelinted seed at 2.0 ppm, and cotton, gin byproducts at 16.0 ppm.

11. PP 0F6091. Proposes the establishment of tolerances in or on asparagus at 0.01 ppm, coffee, green bean at 0.1 ppm, coffee, roasted bean at 0.2 ppm, garlic, bulb at 0.1 ppm, and onion, dry bulb at 0.1 ppm.

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

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residue in plants and animals is adequately understood. The residue of concern is the parent compound only, as specified in 40 CFR 180.474.

2. *Analytical method.* An enforcement method for plant commodities has been validated on various commodities. It has undergone successful EPA validation and has been submitted for inclusion in Pesticide Analytical Method II (PAM). The animal method has also been approved as an adequate enforcement method.

3. *Magnitude of residues*—i. *Wheat.* Nineteen residue crop field trial studies were conducted to evaluate the quantity of tebuconazole residue in wheat following a foliar application of Folicur 3.6 F. These trials were conducted in EPA Regions II, IV, V, VI, VII, VIII, and X. Residues of tebuconazole were quantitated by gas chromatography using a thermionic specific detector. The limit of quantitation (LOQ) for green forage, hay, and straw was 0.1 ppm. The LOQ for grain was 0.05 ppm. The highest average field trial (HAFT) was 2.51 ppm for green forage, 5.31 ppm for wheat hay, and 1.27 ppm for wheat straw. The residues of tebuconazole in wheat grain were less than the LOQ of 0.05 ppm. Data from a 5x processing study also showed residues of tebuconazole in wheat grain less than the LOQ of 0.05 ppm.

ii. *Pecans.* Five residue crop field trial studies were conducted to evaluate the quantity of tebuconazole residue in pecan nutmeat following treatment of pecan trees with Folicur 3.6 F. These five trials were conducted in Regions II, IV, VI, and VIII as required in EPA's June 1994 guidance on number and location of trials. Residues of tebuconazole were quantitated using gas chromatography. Residues in all nutmeat samples were less than or equal to the LOQ of 0.05 ppm. Therefore, a tolerance of 0.05 ppm is being proposed.

iii. *Almonds.* Six residue crop field trial studies were conducted in EPA's Region X to evaluate the quantity of tebuconazole residue in almond nutmeat and almond hulls following treatment with Elite 45 DF. Tebuconazole residues were quantitated by gas chromatography using a thermionic specific detector. The LOQ for tebuconazole was 0.05 ppm for almond nutmeat and 0.1 ppm for almond hulls. Residues in all nutmeat samples were less than or equal to the LOQ. The HAFT residue value for almond hulls was 4.13 ppm. Therefore, tolerances of 0.05 and 5.0 ppm are being proposed for almond nutmeat and hulls, respectively.

iv. *Turnips.* Five field trials were conducted in order to provide information on the magnitude of tebuconazole residues on turnip tops and roots following foliar applications of Folicur 3.6 F. Trials were conducted in Georgia, New Jersey, Ohio, Tennessee, and Texas. Residue levels ranged from 0.75 ppm to 5.62 ppm for turnip tops and <0.05 ppm to 0.234 ppm for turnip roots. A tolerance of 8.0 ppm for turnip tops and 0.4 ppm for turnip roots is being proposed by IR-4.

v. *Hops.* Three field trials were conducted in order to provide information on the magnitude of tebuconazole residues on hops following foliar applications of Folicur 3.6 F. One trial was conducted in Oregon and two trials in Washington. Residue levels ranged from 0.579 ppm to 3.418 ppm. A tolerance of 5.0 ppm is being proposed by IR-4.

vi. *Cucurbits.* Data from summer squash, cucumber and cantaloupe residue crop field trials were used to evaluate the quantity of tebuconazole residue in cucurbits. Data on summer squash were collected from California, Florida, Georgia, New York, and Ohio. Data on cucumbers were collected from Florida, Georgia, Michigan, North Carolina, Ohio, and Texas. Cantaloupe trials were conducted in California, Georgia, Ohio, and Texas. Residue levels from all cucurbits ranged from 0.02 to 0.076 ppm. A tolerance of 0.1 ppm is being proposed by IR-4.

vii. *Bean (succulent).* Studies were conducted to evaluate the quantity of tebuconazole residue on fresh bean pods and dry bean seed following treatments with Folicur 3.6 F. Twelve field trials were conducted on fresh beans, and 14 field trials were conducted on dry beans. Tebuconazole residues were quantitated by gas chromatography using a thermionic specific detector. The LOQ for tebuconazole was 0.05 ppm. The highest residue of tebuconazole was 0.06 ppm in fresh beans. The highest residue in dry beans was 0.08 ppm. Therefore, tolerances are

being proposed at 0.1 ppm for both succulent and seed beans.

viii. *Cotton*. Studies were conducted to evaluate the quantity of tebuconazole residue in undelinted cotton seed and cotton gin byproducts (gin trash) following treatment of cotton plants with Folicur 3.6 F. Tebuconazole residues in undelinted cotton seed were quantitated by gas chromatography. The LOQ was 0.05 ppm in undelinted cotton seed and 0.2 ppm in gin trash. The highest measured residue in undelinted cotton seed was 1.89 ppm and 15.2 ppm in cotton gin trash at a 29–day PHI. Therefore, tolerances are being proposed at 2.0 ppm for undelinted cotton seed and 16.0 ppm for cotton gin trash.

A cotton processing study was conducted with Folicur 3.6 F at 5 times the maximum season proposed label use rate. Processing was performed using procedures which simulate commercial processing practices. The undelinted seed, meal, hull, and refined oil were evaluated for the residue of tebuconazole by gas chromatography. The LOQ in undelinted seed was 0.02 ppm. The LOQ in the processed products of meal, hull and refined oil was 0.04 ppm. Residue of tebuconazole in cotton undelinted seed was 0.04 ppm, while residue in the processed commodities were <0.04 ppm. Therefore, no tolerances are being requested for processed products.

ix. *Asparagus*. Three field trials were conducted in Peru to evaluate the quantity of tebuconazole residue in or on asparagus spears following four foliar applications of Folicur 3.6 F to asparagus ferns. Tebuconazole residues were quantitated by gas chromatography using a nitrogen phosphorus detector. The LOQ for tebuconazole was 0.01 ppm. Since the residue of tebuconazole was <0.01 ppm in all treated asparagus samples, a tolerance on 0.01 ppm is being proposed.

x. *Coffee*. Four field trials were conducted in Brazil and four field trials were conducted in Guatemala to evaluate the quantity of tebuconazole residue in or on dried green coffee beans following applications of Folicur 3.6 F to coffee trees. Tebuconazole residues were quantitated by gas chromatography. The LOQ was 0.01 ppm. The maximum residue value was 0.07 with the majority of the residue values being below the LOQ. Therefore, a tolerance of 0.1 ppm is being requested for green beans.

A processing study was conducted on dried green coffee beans from a field trial in Guatemala. Tebuconazole residues in dried green coffee beans, roasted coffee beans, and instant coffee were quantitated by gas chromatography. The LOQ for tebuconazole was 0.01 in green coffee beans, 0.8 ppm in roasted coffee beans, and 0.04 ppm in instant coffee. The highest average residue found in this study was 0.04 ppm in dried green coffee beans, 0.08 ppm in roasted coffee and 0.03 ppm in instant coffee. The data show that there is no concentration of residues as a result of processing into instant coffee and a slight concentration from dry beans (0.04 ppm) to roasted beans (0.08) ppm. A 0.2 ppm tolerance is being proposed for roasted coffee beans.

xi. *Garlic*. Three field trials were conducted in Mexico to evaluate the quantity of tebuconazole residue in or on garlic bulbs after a seed (clove) treatment of Folicur 3.6 F. Tebuconazole residues were quantitated by gas chromatography. The LOQ for tebuconazole was 0.10 ppm. Since all average validated tebuconazole residues were at or below the LOQ, a tolerance of 0.1 ppm is being proposed.

xii. *Onion*. Three field trials were conducted in Mexico to evaluate the quantity of tebuconazole residue in or on onion bulbs following foliar applications of Folicur 3.6 F. Tebuconazole residues were quantitated by gas chromatography. The LOQ for tebuconazole was 0.10 ppm. Since the HAFT was below the LOQ, a tolerance of 0.1 ppm is being proposed.

xiii. *Mango*. Three trials were conducted at a tropical fruit packing facility in order to provide information on the magnitude of tebuconazole residues on mango (post-harvest). Tebuconazole residues were quantitated by gas chromatography. All residue values were <0.05. A tolerance of 0.2 ppm is being proposed by IR-4.

xiv. *Plums*. Two trials were conducted in California in a fruit packing facility in order to provide information on the magnitude of tebuconazole residues on plums (post-harvest). The highest tebuconazole residue detected in plums was 0.44 ppm. Therefore, a tolerance of 1.0 ppm is being proposed by IR-4.

xv. *Sunflower*. IR-4 received requests from Kansas and North Dakota for the use of tebuconazole on sunflowers. To support these requests, magnitude of residue data were collected from seven field trials located in EPA Region V. Three of the trials were conducted in Kansas; the remaining four trials were located in North Dakota. Since all residues in the 1X field trails are less than the LOQ of 0.04 ppm, a tolerance of 0.05 ppm is being proposed for sunflower seed. Based on a processing study on peanuts completed by Bayer Corporation, a processing study was deemed not necessary and tolerances of 0.2 ppm are being requested for sunflower oil and sunflower meal.

xvi. *Lychee*. Three magnitude of residue field trials were conducted in Homestead, Florida. Residues from treated samples ranged from 0.4 ppm to 0.98 ppm. Tebuconazole residues were quantitated by gas chromatography. A tolerance of 1.5 ppm is requested by IR-4 for tebuconazole residues in or on lychee.

xvii. *Okra*. Magnitude of residue data were collected from six field trials located in EPA Region II (three trials), Region III (one trial), and Region VI (two trials). Residues ranged from 0.0863 ppm to 0.590 ppm tebuconazole in the treated samples. Tebuconazole residues were quantitated by gas chromatography. A tolerance of 1.0 ppm is requested by IR-4 for tebuconazole residues in or on okra.

B. Toxicological Profile

1. *Acute toxicity*. Tebuconazole exhibits moderate toxicity. The rat acute oral LD_{50} = 3,933 milligram/kilogram (mg/kg) (category III); the rabbit acute dermal LD_{50} >5,000 mg/kg (category IV); and the rat acute inhalation LC_{50} >0.371 milligram/Liter (mg/L) (category II). Technical tebuconazole was slightly irritating to the eye (category III) and was not a skin irritant (category IV) in rabbits. Tebuconazole was not a dermal sensitizer.

2. *Genotoxicity*. An Ames test with *Salmonella sp.*, a mouse micronucleus assay, a sister chromatid exchange assay with Chinese hamster ovary cells, and an unscheduled DNA synthesis assay with rat hepatocytes provided no evidence of mutagenicity.

3. *Reproductive and developmental toxicity*—i. In a developmental toxicity study, pregnant female rats were gavaged with technical tebuconazole at levels of 0, 30, 60, or 120 mg/kg/day between days 6 and 15 of gestation. The maternal no observed adverse effect level (NOAEL) was 30 mg/kg/day and the maternal lowest observed adverse effect level (LOAEL) was 60 mg/kg/day based on increased absolute and relative liver weights. The developmental NOAEL was 30 mg/kg/day and the developmental LOAEL was 60 mg/kg/day based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum and limbs plus an increase in supernumerary ribs.

ii. In a developmental toxicity study, pregnant female rabbits were gavaged with technical tebuconazole at levels of 0, 10, 30, or 100 mg/kg/day between days 6 and 18 of gestation. The maternal NOAEL was 30 mg/kg/day and the maternal LOAEL was 100 mg/kg/day

based on minimal depression of body weight gains and food consumption. The developmental NOAEL was 30 mg/kg/day and the developmental LOAEL was 100 mg/kg/day based on increased postimplantation losses, malformations in eight fetuses out of five litters (including peromelia in five fetuses/four litters; palatoschisis in one fetus/one litter), hydrocephalus and delayed ossification.

iii. In a developmental toxicity study, pregnant female mice were gavaged with technical tebuconazole at levels of 0, 10, 30, or 100 mg/kg/day between days 6 and 15 of gestation (part 1 of study) or at levels of 0, 10, 20, 30, or 100 mg/kg/day between days 6 and 15 of gestation (part 2 of study). The maternal NOAEL was 10 mg/kg/day and the maternal LOAEL was 20 mg/kg/day. Maternal toxicity (hepatocellular vacuolation and elevations in AST, ALP and alkaline phosphatase) occurred at all dose levels but was minimal at 10 mg/kg/day. Reduction in mean corpuscular volume in parallel with reduced hematocrit occurred at doses greater than or equal to 20 mg/kg/day. The liver was the target organ. The developmental NOAEL was 10 mg/kg/day and the developmental LOAEL was 30 mg/kg/day based on an increase in the number of runts.

iv. In a developmental toxicity study, pregnant female mice were administered dermal doses of technical tebuconazole applied at levels of 0, 100, 300, or 1,000 mg/kg/day between days 6 and 15 of gestation. Equivocal maternal toxicity was observed 1,000 mg/kg/day. The maternal NOAEL was nearly equal to 1,000 mg/kg/day. The developmental NOAEL was 1,000 mg/kg/day.

v. In a 2–generation reproduction study, rats were fed technical tebuconazole at levels of 0, 100, 300, or 1,000 ppm, (0, 5, 15, or 50 mg/kg/day, males and females). The parental maternal NOAEL was 15 mg/kg/day and the parental LOAEL was 50 mg/kg/day based on depressed body weights, increased spleen hemosiderosis and decreased liver and kidney weights. The reproductive NOAEL was 15 mg/kg/day and the reproductive LOAEL of 50 mg/kg/day based on decreased pup body weights from birth through 3–4 weeks.

vi. In a developmental neurotoxicity study, pregnant female rats were fed a nominal concentration of 0, 100, 300 or 1,000 ppm of tebuconazole in the diet. The NOAEL for maternal toxicity in this study was 300 ppm (based on mortality, body weight and feed consumption reductions, and prolonged gestation in the 1,000 ppm dosage group). The 1,000 ppm dose level was considered to be excessively toxic for the F_1 offspring, based on mortality, marked reductions in pup body weight and body weight gain, reduction in pup absolute brain weight (at postpartum day (PD) 12 and adult), a developmental delay in vaginal patency, and decreased cerebellar thickness. The effects on brain weight and morphology are considered to represent incomplete compensation for the marked decrease in body weight gain during development. By approximately day 80 postpartum, the body weight had completely recovered in the females but was still reduced (89% of the control group value) in the males. The brain weights had shown an incomplete recovery (90% to 93% of the control group values) in both sexes. The NOAEL for the F_1-generation rats was 300 ppm. Technical grade tebuconazole did not cause any specific neurobehavioral effects in the offspring when administered to the dams during gestation and lactation at dietary concentrations up to and including 1,000 ppm. The overall NOAEL in this study for the F_1 offspring was 300 ppm.

4. *Subchronic toxicity*—i. In a 90–day oral feeding study, rats were administered technical tebuconazole at levels of 0, 100, 400, or 1,600 ppm (0, 8, 34.8, or 171.7 mg/kg/day for males or 0, 10.8, 46.5, or 235.2 mg/kg/day for females). In males, the NOAEL was 34.8 mg/kg/day and the LOAEL was 171.7 mg/kg/day based on decreased body weight and decreased body weight gain, adrenal vacuolation and spleen hemosiderosis. In females, the NOAEL was 10.8 mg/kg/day and the LOAEL of 46.5 mg/kg/day was based on adrenal vacuolation.

ii. In a 90–day oral feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 200, 1,000, or 5,000 ppm (0, 74, 368, or 1,749 mg/kg/day for males or 0, 73, 352, or 1,725 mg/kg/day for females). In females, the NOAEL was 73 mg/kg/day and the LOAEL was 352 mg/kg/day based on decreased body weight and decreased body weight gain, decreased food consumption and increased liver *N*-demethylase activity. At the highest dose tested (HDT), lens opacity was seen in all males and in one female and cataracts were seen in three females.

iii. In a 21–day dermal toxicity study, rabbits were exposed dermally to technical tebuconazole 5 days a week at doses of 0, 50, 250, or 1,000 mg/kg/day. No significant systemic effects were seen. The systemic NOAEL >1,000 mg/kg/day.

iv. In a 21–day inhalation toxicity study, rats were exposed to technical tebuconazole (15 exposures - 6 hours/day for 3 weeks) at airborne concentrations of 0, 0.0012, 0.0106, or 0.1558 mg/L/day. The NOAEL was 0.0106 mg/L/day and the LOAEL was 0.1558 mg/L/day based on piloerection and induction of liver *N*-demethylase.

5. *Chronic toxicity*—i. In a 2–year combined chronic feeding/carcinogenicity study, rats were administered technical tebuconazole at levels of 0, 100, 300, or 1,000 ppm (0, 5.3, 15.9, or 55 mg/kg/day for males or 0, 7.4, 22.8, or 86.3 mg/kg/day for females). In males, the NOAEL was 5.3 mg/kg/day and the LOAEL was 15.9 mg/kg/day based on C-cell hyperplasia in the thyroid gland. In females, the NOAEL was 7.4 mg/kg/day and the LOAEL was 22.8 mg/kg/day based on body weight depression, decreased hemoglobin, hematocrit, mean corpuscular volume and mean corpuscular hemoglobin concentration and increased liver microsomal enzymes. No evidence of carcinogenicity was found at the levels tested.

ii. In a 1–year chronic feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 40, 200, or 1,000 (weeks 1-39) and 2,000 ppm (weeks 40-52) (0, 1, 5 or 25/50 mg/kg/day for males and females). The NOAEL was 1 mg/kg/day and the LOAEL was 5 mg/kg/day based on ocular lesions (lenticular and corneal opacity) and hepatic toxicity (changes in the appearance of the liver and increased siderosis).

iii. In a 1–year chronic feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 100, or 150 ppm (0, 3.0, or 4.4 mg/kg/day for males or 0, 3.0 or 4.5 mg/kg/day for females). The NOAEL was 3.0 mg/kg/day and the LOAEL was 4.4 mg/kg/day based on adrenal affects in both sexes. In males there was hypertrophy of adrenal zona fasciculata cells amounting to 4/4 at 150 ppm and to 0/4 at 100 ppm and in controls. Other adrenal findings in males included fatty changes in the zona glomerulosa (3/4) and lipid hyperplasia in the cortex (2/4) at 150 ppm vs. (1/4) for both effects at 100 ppm and control dogs. In females there was hypertrophy of zona fasciculata cells of the adrenal amounting to 4/4 at 150 ppm and to 0/4 at 100 ppm and 1/4 in controls. Fatty changes in the zona glomerulosa of the female adrenal amounted to 2/4 at 150 ppm and to 1/4 at 100 ppm and in controls.

iv. In a 91–week carcinogenicity study, mice were administered technical tebuconazole at levels of 0, 500, or 1,500 ppm (0, 84.9, or 279 mg/kg/day for males or 0, 103.1, or 365.5 mg/kg/day for females). Neoplastic histopathology

consisted of statistically significant increased incidences of hepatocellular neoplasms; adenomas (35.4%) and carcinomas (20.8%) at 1,500 ppm in males and carcinomas (26.1%) at 1,500 ppm in females. Statistically significant decreased body weights and increased food consumption were reported that were consistent with decreased food efficiency at 500 and 1,500 ppm in males and at 1,500 ppm in females. Clinical chemistry values (dose-dependent increases in plasma GOT, GPT and alkaline phosphatase) for both sexes were consistent with hepatotoxic effects at both 500 and 1,500 ppm. Relative liver weight increases reached statistical significance at both 500 and 1,500 ppm in males and at 1,500 ppm in females. Non-neoplastic histopathology included dose-dependent increases in hepatic pancinar fine fatty vacuolation, statistically significant at 500 and 1,500 ppm in males and at 1,500 ppm in females. Other histopathology included significant oval cell proliferation in both sexes and dose-dependent ovarian atrophy that was statistically significant at 500 and 1,500 ppm. The Maximum Tolerated Dose (MTD) was achieved at or around 500 ppm.

6. *Animal metabolism*. Rats were gavaged with 1 or 20 mg/kg radio-labeled technical tebuconazole, 98.1% of the oral dose was absorbed. Within 72 hours of dosing, over 87% of the dose was excreted in urine and feces. At sacrifice (72 hours post dosing), total residue gastrointestinal (GI tract) amounted to 0.63% of the dose. A total of 10 compounds were identified in the excreta. A large fraction of the identified metabolites corresponded to successive oxidations steps of a methyl group of the test material. At 20 mg/kg, changes in detoxication patterns may be occurring.

7. *Endocrine disruption*. No special studies investigating potential estrogenic or endocrine effects of tebuconazole have been conducted. However, the standard battery of required studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects but no such effects were noted in any of the studies with either tebuconazole or its metabolites.

C. Aggregate Exposure

1. *Dietary exposure*. An aggregate risk assessment was conducted for residues of tebuconazole. For purposes of assessing the potential acute and chronic dietary exposure, Bayer has estimated acute and chronic exposure for all registered crops; section 18 uses on filberts, garlic, sunflowers, wheat and barley; petitions and uses pending with the EPA on wheat, beans (succulent and dry), cotton, coffee, asparagus, garlic, onions and the tree nut crop group; and proposed IR-4 uses on the cucurbit vegetables crop group, turnips (roots and tops), hops, plums (post-harvest), mangoes (post-harvest), and sunflowers.

Novigen Sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM), which is licensed to Bayer, was used to estimate the chronic and acute dietary exposure. This software used the food consumption data for the 1994-1996 USDA Continuing Surveys of Food Intake by Individuals (CSFII 1994-1996). To assess acute dietary risk, EPA used an endpoint of 10 mg/kg/day NOAEL from the developmental toxicity study in mice (64 FR 1132, January 8, 1999) (FRL–6050–5). This endpoint was based on an increased incidence of runts observed at the LOAEL of 30 mg/kg/day. The population adjusted dose for acute dietary (aPAD) was determined by dividing the NOAEL by an uncertainty factor of 1,000 (10X for interspecies differences, 10X for intraspecies variability and 10X for FQPA safety factor): aPAD = 10/(1,000) = 0.01 mg/kg/day. To assess the chronic dietary risk, EPA (64 FR 1132) used the NOAEL of 3.0 mg/kg/day from a 1-year dog feeding study. This endpoint was due to histopathological changes in the adrenal gland. The population adjusted dose for chronic dietary cPAD was determined by dividing the NOAEL by an uncertainty factor of 100 (10X for interspecies differences and 10X for intraspecies variability): cPAD = 3/100 = 0.03 mg/kg bw/day. This cPAD applies to all population subgroups.

Results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of tebuconazole on currently registered and pending uses.

i. *Food*— a. *Acute*. The acute dietary (food) risk assessment was conducted using a Monte Carlo analysis (Tier 3). The anticipated residue values used were determined from field trial data reflecting maximum application rates and minimum preharvest intervals. Field trial residue distributions were used in the Monte Carlo simulation for those foods identified as single-serving commodities. For those foods considered to be blended or processed, mean field trial residues were calculated. The dietary exposure assessment estimated percent of the aPAD and corresponding margins of exposure (MOE) for the overall U.S. population (all seasons) and subpopulations. For the overall U.S. population the %aPAD = 36.49%. The most highly exposed population subgroup, children (1-6 years), had an exposure equal to 70.20% of the aPAD. These exposure estimates are within EPA's criteria of acceptability at the 99.9th percentile.

b. *Chronic*. In the analysis for the chronic dietary (food only) risk assessment the anticipated residue values used were determined from field trail data conducted at maximum application rates and minimum preharvest intervals. Mean anticipated residues values were calculated substituting half of the LOQ for those samples for which residues were reported below the LOQ. The chronic dietary analysis estimated the cPAD for the overall U. S. population (all seasons) and subpopulations. For the overall U.S. population the %cPAD = 0.1%. For the most highly exposed population subgroup, children (1 to 6 years), the exposure was estimated to be 0.3% of the cPAD.

ii. *Drinking water*. EPA has determined (64 FR 1132) that there are no monitoring data for residues of tebuconazole in ground water. In addition, they have established no health advisory levels or Maximum Contaminant Levels for residues of tebuconazole in drinking water. EPA has determined that tebuconazole is persistent and relatively immobile in water. EPA has used the Screening Concentration in Ground Water (SCI-GROW) screening model to determine the Estimated Environmental Concentration (EEC) of 0.3 µg/L of tebuconazole in ground water for both chronic and acute analysis.

a. *Acute*. EPA has determined that the acute drinking water levels of concern (DWLOC) is 200 µg/L for females (13+ years old) and 14 µg/L for infants/children. The EECs for acute analysis of water are 0.3 µg/L (ground water) and 14 µg/L (surface water). EPA does not expect the acute aggregate exposure to exceed 10% of the acute RfD. Therefore, EPA has concluded with reasonable certainty that no harm will result to the subpopulations of concern, females (13+ years old), or infants and children from aggregate exposure to residues of tebuconazole.

b. *Chronic*. EPA has determined that the chronic DWLOC is 910 µg/L for the U.S. population, 720 µg/L for females (13+ years, nursing), and 190 µg/L for

infants/children. The EECs for chronic analysis of water are 0.3 µg/L (ground water) and 10 µg/L (surface water). EPA does not expect the chronic aggregate exposure to exceed 100% of the chronic RfD. Therefore, EPA has concluded with reasonable certainty that no harm will result from chronic (non-cancer) aggregate exposure to tebuconazole residues.

2. *Non-dietary exposure.* Tebuconazole is currently registered for use on the following residential non-food sites: the formulation of wood-based composite products, wood products for in-ground contact, plastics, exterior paints, glues and adhesives. EPA has determined (64 FR 1132) that exposure via incidental ingestion (by children) and inhalation are not a concern for these products which are used outdoors. No paints or other end-use products containing tebuconazole are available for interior use. Therefore, EPA has determined that no risk is expected for residential nonfood sites.

D. Cumulative Effects

Tebuconazole is a member of the triazole class of systemic fungicides which included other triazoles such as bitertanol, cyproconazole, diclobutrazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, myclobutanil, penconazole, propiconazole, tetraconazole, triadimefon, and triadimenol. At this time, the EPA has not made a determination that tebuconazole and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for these tolerance petitions, it is assumed that tebuconazole does not have a common mechanism of toxicity with other substances and only the potential risks of tebuconazole in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population.* Based on the exposure assessments described above under Unit C. Aggregate Exposure and on the completeness and reliability of the toxicity data, it can be concluded that aggregate exposure estimates from all label and pending uses of tebuconazole are 36.49% of the aPAD and 0.1% of the cPAD for dietary exposures. Since EPA found no concern from drinking water or non-dietary exposure (64 FR 1132), it can be concluded with reasonable certainty that the potential risks to the overall U.S. population would not exceed the Agency's level of concern.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of tebuconazole, data from developmental toxicity studies in mice, rats, 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 maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Using the conservative exposure assumptions described above under Unit C. Aggregate Exposure, it can be concluded that the aggregate dietary exposure estimates from the proposed uses of tebuconazole would not exceed 70.20% of the aPAD and 0.3% of the cPAD for the most sensitive population subgroup children (1-6 years). Since EPA found no concern from drinking water or non-dietary exposure (64 FR 1132), it can be concluded with reasonable certainty that the potential risks to infants and children would not exceed the Agency's level of concern.

F. International Tolerances

There are no established Codex or Canadian Maximum Residue Levels (MRLs) for tebuconazole. A Mexican MRL has been established on barley for tebuconazole.

[FR Doc. 01–6711 Filed 3–16–01; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–997; FRL–6766–7]

Notice of Filing Pesticide Petitions to Establish Tolerances for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–000, must be received on or before April 18, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–000 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Tavano, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6411; e-mail address: tavano.joseph@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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/*. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person.* The Agency has established an official record for this