procedural policies. As such, all public meetings will be announced in the **Federal Register** at least 15 days prior to their scheduled times.

Background: The U.S. Navy and the State of Florida are planning to deploy the ex-Oriskany, a World War II era aircraft carrier, as an artificial reef in the Gulf of Mexico. In accordance with the Toxic Substances Control Act (TSCA) and its Federal PCB regulations (40 CFR part 761), the U.S. Navy has applied for and must obtain a risk-based PCB disposal approval prior to sinking the vessel with non-liquid PCBs onboard. The EPA may approve such an application if it finds the disposal action will not pose an unreasonable risk of injury to human health or the environment. To evaluate the potential transfer of non-liquid PCBs to the marine environment and the subsequent risk that they might pose to human and ecological receptors using the artificial reef, the Navy performed leaching studies of different on-board PCB containing materials followed by fate and transport modeling of the leaching results to evaluate how released chemicals might behave in the near-reef marine environment. The U.S. Navy has also developed a fate and transport model known as the Prospective Risk Assessment Model (PRAM). EPA Region 4 has requested that the SAB conduct a consultation followed by an advisory on the U.S. Navy's assessment of potential human health and environmental risks from PCBs released from the ex-Oriskany following deployment as an artificial reef. The focus of the SAB consultation and advisory includes the leaching studies, the PRAM, and characterization of potential risks.

Procedures for Providing Public Comment: The EPA SAB Staff Office will accept written public comments of any length for the SAB Panel's consideration, and accommodate oral public comments whenever possible. The EPA SAB Staff Office expects that public statements presented at this meeting will not repeat previously submitted oral or written statements to this Panel. Oral Comments: Requests to provide oral comments must be in writing (e-mail, fax or mail) and received by Dr. Shallal no later than five business days prior to the teleconference or meeting to reserve time on the meeting agenda. For teleconferences, opportunities for oral comment will usually be limited to no more than three minutes per speaker or organization and no more than fifteen minutes total. Written Comments: Written comments should be received in the SAB Staff Office at least five business days prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the DFO at the address/contact information noted above in the following formats: one hard copy with original signature and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 98/2000/XP format).

Dated: June 28, 2005.

Anthony F. Maciorowski,

Acting Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–13278 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0145; FRL–7721–5]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2005–0145, must be received on or before August 5, 2005.

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

FOR FURTHER INFORMATION CONTACT: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address:*mcneilly.dennis@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2005–0145. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

Certain types of information will not be placed in the EPA Dockets.

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

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

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

C. How and to Whom Do I Submit Comments?

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

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

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0145. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov,* Attention: Docket ID number OPP–2005–0145. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2005–0145.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0145. 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: June 27, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's 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 BASF Corporation, 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.

BASF CORPORATION

PP 4F6875, 3E6791, 5E6933

EPA has received pesticide petitions PP 4F6875, 3E6791, 5E6933 from BASF Corporation, Research Triangle Park, NC 27709 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 boscalid (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro(1,1'-biphenyl)-2-yl) in or on the raw agricultural commodity almond, hulls at 15 parts per million (ppm), vegetable, leafy, except brassica, group 4 at 50 ppm, and banana at 0.5 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*. Nature of the residue studies (OPPTS Harmonized Guideline 860.1300) were conducted in grapes, lettuce and beans as representative crops in order to characterize the fate of boscalid (BAS 510F) in all crop matrices. In all three crops the boscalid BAS 510F Residues of Concern (ROC) were characterized as parent boscalid (BAS 510F). A confined rotational crop study also determined that parent was the residue of concern in the representative crops of radish, lettuce and wheat.

2. *Analytical method*. In plants, the parent residue is extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up. Quantitation is by gas chromatography using mass spectrometry (GC/MS). In livestock, the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by liquid/liquid partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column clean-up. The parent and acetylated metabolite are quantitated by gas chromatography with electron capture detection.

3. *Magnitude of residues*. Field trials were carried out in order to determine the magnitude of the residue in/on almond hulls, leafy vegetables (celery and spinach), and banana. Field trials were conducted in the United States in the required regions for almonds and leafy vegetables. A total of 12 trials were conducted on bananas during the growing season in the principal banana growing regions represented by the countries of Costa Rica, Colombia, Ecuador, Guatemala, Honduras, Martinique, and Mexico. The number and locations of field trials are in accordance with (OPPTS Harmonized Guideline 860.1500). Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum pre-harvest interval for each crop or crop group.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data, BAS 510F and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical Boscalid (BAS 510F) in toxicity category IV for acute oral; category III for acute dermal and category IV for acute inhalation. BAS 510F is category IV for both eye and skin irritation, and it is not a dermal sensitizer. For almonds, the formulated end use product proposed is as follows: A water dispersible granule (WG) termed Pristine (BAS 516 02/04F) containing a 2:1 mixture of boscalid (BAS 510F) and pyraclostrobin (BAS 500F). BAS 516 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

For leafy vegetables (except brassica vegetables), crop group 4, two formulated end use products are proposed as follows: a water dispersible granule (WG) termed Endura (BAS 510 02/04F) containing 70% boscalid (BAS 510F) and a water dispersible granule (WG) termed Pristine (BAS 516 02/04F) containing a 2:1 mixture of boscalid (BAS 510F) and pyraclostrobin (BAS 500F). BAS 510 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer. BAS 516 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

For banana, the formulated end use product used in the studies is a water dispersible granule (WG) with various proposed trade names such as Cantus, banastar, etc. containing 50% Boscalid

(BAS 510F). BAS 510F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

2. *Genotoxicity*. Ames test 1 study; gene point mutation: Negative; *in vitro* CHO/HGPRT Locus Mammalian Cell Mutation Assay (1 study; point gene mutation): Negative; *in vitro* V79 Cell cytogenetic assay 1 study; chromosome damage: Negative; *in vivo* mouse micronucleus (1 study; chromosome damage): Negative; *in vitro* rat hepatocyte (1 study; DNA damage and repair): Negative. BAS 510F has been tested in a total of 5 genetic toxicology assays consisting of *in vitro* and *in vivo* studies. It can be stated that BAS 510F did not show any mutagenic, clastogenic or other genotoxic activity when tested under the conditions of the studies mentioned above. Therefore, BAS 510F does not pose a genotoxic hazard to humans.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of BAS 510F was investigated in a 2-generation rat reproduction study as well as in rat and rabbit teratology studies.

There were no adverse effects on reproduction in the 2-generation study at any dose tested. The reproductive no observed adverse effect level (NOAEL) is 10,000 ppm 1,165 and 1,181 milligrams/kilogram/body weight/day (mg/kg/bwt/day) for males and females, respectively), the highest dose tested (HDT). Pup effects were observed, at the HDT. In males of the F1 generation, reduced body weight and reduced body weight gain were observed at 10,000 ppm. Additionally, hepatocyte degeneration was observed in males in animals of both the F0 and F1 generations at 10,000 ppm. The parental systemic NOAEL is 1,000 and 10,000 113 and 1,181 mg/kg bwt/day) for males and females, respectively. Toxicity to the offspring was seen at 1,000 ppm in the form of decreased pup weights in the F2 males, and at 10,000 ppm in the form of decreased pup weights for both males and females of both the F1 and F2 generations. The offspring NOAEL is 100 and 1,000 ppm (12 and 116 mg/kg bwt/day) for males and females, respectively.

The Agency concluded that there are no residual uncertainties for prenatal and postnatal toxicity as the degree of concern is low for the susceptibility seen in the above studies, and the dose and endpoints selected for the overall risk assessments will address the concerns for the body weight effects seen in the offspring. Although, the dose selected for overall risk assessments (21.8 mg/kg bwt/day) is higher than the NOAELs in the 2-generation reproduction study (10.1 mg/kg bwt/day) and the developmental neurotoxicity study (14 mg/kg bwt/day), these differences are considered to be an artifact of the dose selection process in these studies. For example, there is a 10-fold difference between the lowest observed adverse effect level (LOAEL). (106.8 mg/kg bwt/day) and the NOAEL (10.1 mg/kg bwt/day) in the 2-generation reproduction study. A similar pattern was seen with regard to the developmental neurotoxicity study, where there is also a 10-fold difference between the LOAEL (147 mg/kg bwt/day) and the NOAEL (14 mg/kg bwt/day). There is only a 2–3-fold difference between the LOAEL (57 mg/kg bwt/day) and the NOAEL (21.8 mg/kg bwt/day) in the critical study used for risk assessment. Because the gap between the NOAEL and LOAEL in the 2-generation reproduction and developmental neurotoxicity studies was large and the effects at the LOAELs were minimal, the true no observed adverse effect level was probably considerably higher. Therefore, the selection of the NOAEL of 21.8 mg/kg bwt/day from the 1–year dog study is conservative and appropriate for the overall risk assessments. In addition, the endpoints for risk assessment are based on thyroid effects seen in multiple species (mice, rats and dogs) and after various exposure durations (subchronic and chronic exposures) which were not observed at the LOAELs in either the 2-generation reproduction or the developmental neurotoxicity studies. Based on these data, the Agency concluded that there are no residual uncertainties for prenatal and postnatal toxicity.

No teratogenic effects were noted in either the rat or rabbit developmental studies. In the rat study, evidence of maternal or developmental toxicity was not observed at any dose (highest dose tested of 1,000 mg/kg bwt/day). Neither a maternal nor developmental LOAEL were found since the highest dose tested was the NOAEL in both studies. In the rabbit teratology study, maternal toxicity observed at the mid dose of 300 mg/kg bwt/day consisted of discolored/reduced feces in one dam and an abortion in one dam. This finding is not necessarily indicative of a definitive test substance related adverse effect. The dam which displayed the fecal alterations and abortion also displayed decreased body weight and body weight gain, compared to the group mean during gestation. These decreases occurred even prior to compound administration. Food consumption was also dramatically decreased in this dam compared to the other animals in the group. Every day from gestation day (GD) 1–12, this dam had food consumption values which were less than half the mean for the group (compound administration began on GD 7). From GD 13 to 26 (when the animal aborted and was sacrificed) this dam ate essentially nothing (food consumption during this time period was less than or equal to 1.5 grams food/day). 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.

At the high dose of 1,000 mg/kg bwt/day a maternal body weight gain decrease compared to controls of 81% was observed during the treatment period. Reduced food consumption, reduced body weight and abortions in three dams, were also seen at 1,000 mg/kg bwt/day. Evidence of developmental toxicity was not seen at any dose tested. Developmental neurotoxicity was not observed at any dose in the developmental neurotoxicity study. No maternal toxic effects were noted at any dose in this study. No developmental toxicity was seen at the low dose of 12 mg/kg bwt/day parts per million (100 ppm). Reduced body weights and body weight gains were seen at 118 mg/kg bwt/day 1,000 ppm during post natal day (PND) 1 4. Reduced body weights and body weight gains were seen at 1,183 mg/kg bwt/day (10,000 ppm) as well as decreased absolute pup brain weight at day PND 11 (both sexes) and decreased brain length (males only) at PND. The reduced pup brain weights and decreased brain length go hand-in-hand and both are due to the decreased pup weights seen at this dose. In this respect, it should be noted that pup brain weights relative to body weight at PND 11 were not significantly different from controls at this dose. Though no maternal toxicity was seen in this study, other studies using similar doses of BAS 510F resulted in maternal toxicity. A dose of 118 mg/kg bwt/day in female rats of the same strain in the multigeneration study, resulted in an increased incidence of hepatic centrilobular hypertrophy, a parameter which could not have been detected in the developmental neurotoxicity (DNT) study as liver histopathology on parental animals was not performed in the DNT study.

4. *Subchronic toxicity.* The subchronic toxicity of BAS 510F was

investigated in a 90 day feeding studies with rats, mice and dogs, and in a 28 day dermal administration study in rats. Additonally a 90 day neurotoxicity study in rats was performed. Generally, mild toxicity was observed. At high dose levels (doses above the LOAELs) in feeding studies, all three species displayed alterations in various clinical chemistry parameters. These clinical chemistry alterations were likely secondary to general toxicity. Statistically significant increased absolute and relative thyroid weights were observed in male rats only at doses at and above the LOAEL. Increased absolute and relative liver weights were observed in both sexes at doses above the LOAEL in rats and dogs. Increased absolute and relative liver weights were seen in both sexes of the mouse at lower doses. However, the increases in liver weights at these lower doses in the mouse were not deemed to be compound related due to the unusually low concurrent control liver weight values. At doses above the LOAELs, liver weight increases were supported by histopathology alterations in the rat and mouse, but not in the dog. Overall, only mild toxicity was observed in oral subchronic testing.

In the 28 day repeat dose dermal study, no systemic effects were noted up to the HDT of 1,000 mg/kg bwt/day. In a 90 day rat neurotoxicity study, there was no mortality, signs of clinical toxicity, or adverse effects on food consumption or body weight at any dose level in either sex. No signs of neurotoxicity were observed during clinical observations, functional observation batteries, motor activity measurements of neuropathology. Therefore, there were no selective neurotoxic effects. Adverse effects were not seen even at the highest dose level tested. A LOAEL was not found and the NOAEL is the highest tested of 15,000 ppm (1,050 mg/kg bwt/day in males; 1,272 mg/kg bwt/day in females).

5. *Chronic toxicity*. Based on review of the available data, the Reference Dose (RfD) for BAS 510F will be based on a 1–year feeding study in dogs with a NOAEL of 21.8 mg/kg bwt/day. Using an uncertainty factor of 100, the RfD is calculated to be 0.218 mg/kg bwt/day. The following are summaries of chronic toxicity studies submitted to EPA.

The chronic toxicity/oncogenicity studies with BAS 510F include a 12–month feeding study with Beagle dogs, an 18–month B63CF1 mouse feeding study, a 24 month Wistar rat chronic feeding study and a 24– month Wistar rat oncogenicity study.

At the HDT in dogs, effects observed consisted primarily of increased liver and thyroid weights and some serum clinical chemistry changes. The NOAEL was 800 ppm (21.8 mg/kg bwt/day males; 22.1 mg/kg bwt/day females.)

Decreased body weights were seen in males in the mouse chronic study at doses of 8,000 ppm (1,804 mg/kg bwt/day) and above. Decreased female body weight was seen at doses of 2,000 ppm (331 mg/kg bwt/day) and above. The target organ in this study was the liver. The NOAEL was 65 and 443 mg/kg bwt/day 8,000 and 2,000 ppm for male and female mice, respectively. In both the rat chronic and oncogenicity studies, the HDT of 15,000 ppm exceeded a maximum tolerated dose (MTD) and was discontinued after 17 months. Effects observed at the next highest dose of 2,500 ppm primarily centered around the thyroid and liver. The NOAEL was 23 and 30 mg/kg bwt/day 2,500 ppm for male and female rats, respectively.

Overall, mild toxicity was observed with chronic exposure to BAS 510F. No evidence of treatment-induced oncogenicity was observed in the mouse or dog studies. A slight increase in thyroid follicular cell adenomas was seen in both sexes at the high dose when the data from both rat bioassays are combined.

A mode of action (MOA) for the thyroid follicular cell adenomas has been proposed. This MOA is based on the EPA publication ''Assessment of Thyroid Follicular Cell Tumors,'' March 1998, EPA/630/R 97/002. This document describes the criteria which must be met in order for a compound to be considered under the MOA described in that publication. BASF Corporation believes that BAS 510F has met the cited criteria.

Threshold effects. Based on a review of the available chronic toxicity data, BASF believes EPA will establish the RfD for BAS 510F at 0.218 mg/kg bwt/day. This RfD for BAS 510F is based on the 2 year chronic and 2–year oncogenicity studies in rats and the 1–year dog study with the lowest threshold NOAEL of 21.8 mg/kg bwt/day for males. Using an uncertainty factor of 100, the RfD is calculated to be 0.218 mg/kg bwt/day. Based on the acute toxicity data, BASF believes that BAS 510F does not pose any acute dietary risks.

BAS 510F was shown to be noncarcinogenic in mice and dogs. There was a slight increase in thyroid follicular cell ademonas at the high dose in both sexes in the rat. A threshold based MOA for these tumors based on the EPA publication ''Assessment of thyroid follicular cell tumors'' (EPA/630/R 97/002, March, 1998), has been proposed. BASF believes the data to support this proposed mode of action are strong, and that the thyroid tumors seen in the rat following BAS 510F exposure have a threshold. In addition, a battery of genotoxicity studies demonstrated that BAS 510F has no genotoxic or clastogenic potential. Therefore, BASF believes that the threshold approach to regulating BAS 510F is appropriate. Also, it should be noted that, while the Agency has in the past considered tumors of this type to be potential human carcinogens, the European Union has published a policy which considers these tumor types, when they occur at low incidence rates in the rat, to not be relevant to man. The publication: European Commission, European Chemicals Bureau, ECBI/49/99 Add. 1 Rev. 2; ''Draft Summary Record, commission group of specialized experts in the fields of carcinogenicity, mutagenicity and reprotoxicity,'' meeting at Arona, September 1–2 1999), Therefore, BASF believes that these tumors are not likely relevant to humans and, if these tumors are to be considered relevant to humans, the threshold approach to cancer risk assessment is appropriate.

6. *Animal metabolism*. In the rat, the predominant route of excretion of BAS 510F is fecal with urinary excretion being minor. The half-life of BAS 510F is less than 24 hours. Saturation of absorption appears to be occurring at the high dose level. BAS 510F is rapidly and intensively metabolized to a large number of biotransformation products. The hydroxylation of the diphenyl moiety was the quantitatively most important pathway. Second most important was the substitution of the Cl of the 2-chloropyridine part against SH by conjugation with glutathione. No major differences were observed. In hens and goats the residues of concern were determined to be parent, the hydroxylated metabolite M510 F01 (2-chloro-N-(4'chloro-5-hydroxy-biphenyl-2-yl)nicotinamide), and the glucuronic acid of the metabolite M510 F02.

7. *Metabolite toxicology*. No additional studies were required for metabolite toxicology.

8. *Endocrine disruption*. No specific tests have been conducted with BAS 510F to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity studies (i.e., subchronic and chronic toxicity, teratology and multi-generation reproductive studies) which would suggest that BAS 510F produces endocrine related effects.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* An assessment was conducted to evaluate the potential risk due to chronic dietary exposure of the U.S. population and sub-populations to residues of BAS 510F (Boscalid). Tolerance values have previously been established and are listed in U.S. 40 CFR 180.589. This analysis included all crops with established tolerance values, crops pending tolerance assignment (vegetable, leafy crop group 4 at 50 ppm, almond hulls at 15 ppm and an import tolerance for banana pulp of 0.5 ppm).

a. *Acute dietary exposure assessment.* An acute assessment was not needed since EPA Toxicological Endpoint Selection (TES) Committees had previously evaluated the boscalid toxicity data and determined there was no toxic effect attributable to a single dose. Therefore, a quantitative acute dietary exposure and risk assessment were not required.

b. *Chronic dietary exposure assessment.* A Tier 1 chronic dietary exposure assessment was conducted assuming tolerance level residues in all crops and 100% crop treated for all registered, pending, and proposed crops. Default processing factors were also used in the assessment. EPA Food Commodity Ingredient Data Base (FCID) was also used in Exponent's Dietary Exposure Evaluation Module (DEEM-FCID) software. Residues in animal commodities (i.e. meat, meat byproducts, milk, eggs) were included at the tolerance levels currently established and listed in 40 CFR 180.589.

Dietary exposure estimates were compared against the established boscalid chronic population adjusted dose (cPAD) of 0.218 mg/kg bwt/day for all populations. Results of the chronic dietary assessments are listed in the Table 1. The estimated chronic dietary exposure from all crops and animal commodities was less than 33% of the cPAD for all sub-populations. Additional refinements such as the use of anticipated residues and adjusted crop treated factors would further reduce the estimated chronic dietary exposure. The results in the table below demonstrate that there are no safety concerns for any sub-population based on established and new uses, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

TABLE 1.–SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR BAS 510F (BOSCALID).

Population Subgroup	Exposure Estimate (mg/kg bwt/day)	%cPAD
U.S. population	0.028430	13.0
All Infants	0.040972	18.8
Children 1–2 years old	0.069725	32.0
Children 3–5 years old	0.053362	24.5
Children 6–12 years old	0.032094	14.7
Youth 13–19 years old	0.02535	11.6
Females 13–49 years old	0.021689	9.9
Adults 20–49 years old	0.024906	11.4
Adults 50+ years old	0.025333	11.6

%cPAD = percent of chronic population adjusted dose Exposure estimates based on tolerance values, percent crop treated values for established crop tolerances, 100% CT for crops with proposed tolerances

ii. *Drinking water.* Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as %PAD. Instead, drinking water levels of concern (DWLOCs) are calculated and used as points of comparison against the model estimates of a pesticide's concentration in water. A DWLOC is the theoretical upper allowable limit of a pesticide's concentration in drinking water and is calculated with consideration of the aggregate exposure to a pesticide from food and residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses.

Different populations will have different DWLOCs. If the DWLOC is greater than the model water concentrations, the EPA concludes that exposure from drinking water is not a risk issue. The modeled water concentration is obtained from the FIRST model for surface water and the SCIGROW model for ground water. The values used for comparison to the DWLOC are the maximum concentrations for any use. When the EEC's are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water would not result in unacceptable levels of aggregate human health risk.

a. *Acute aggregate exposure and risk (food and water).* Since EPA Toxicological Endpoint Selection (TES) Committees has evaluated the boscalid toxicity data and determined there was no toxicologic endpoints for acute dietary exposure, the determination of an acute aggregate exposure and risk evaluation was not required.

b. *Chronic aggregate exposure and risk (food and water).* Table 2. summarizes the aggregate exposure and risk.

TABLE 2.–AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BAS 510F (BOSCALID)

Population Subgroup	Chronic Food Exposure (mg/kg bwt/day	cPAD[1]	Maximum Allowable Water Exposure (mg/kg/bwt/day)	DWLOC (µg/L)	Sci-Grow ground water (µg/L)	FIRST surface water (µg/L)
Infants (0–1 year)	0.040972	0.218	0.177028	1770		
Children (1–2 years)[1]	0.069725	0.218	0.148275	1,483	0.63	26.0
Adult females (13–49)	0.021689	0.218	0.196311	5,889		
U.S population	0.028430	0.218	0.189570	6,634		

[1]Inter/intra species safety factor = 100 FQPA safety factor = 1, NOAEL = 21.8 mg/kg bwt/day

The results in the summary table of chronic DWLOCs demonstrate that there are no safety concerns for any subpopulation based on established and new uses, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

In summary, we can conclude with reasonable certainty that no harm will occur from chronic aggregate exposure of boscalid.

Short-term and intermediate term aggregate exposure and Risk (food, water and residential exposure)

Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure from food and water. Residential exposure is used to refer to non-occupational and non-dietary exposure. No new residential uses are currently being registered for boscalid that would increase non-dietary exposure. The residential exposure value used in this risk assessment was previously determined by the EPA (July 30, 2003, 68 FR 44640) (FRL–7319–6) and considers dermal exposure to adults from the golf course use. The MOE and DWLOC presented in the table below are considered to be representative for youth playing golf because youth and adults possess similar body surface area to weight ratios and because the dietary exposure for youth (13–19 years old) is less than that of the general U.S. population. The aggregate risk for short-term exposure is summarized in Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BAS 510F (BOSCALID)

Pop	Short-Term Scenario									
	NOAEL(mg/kg/day)	Target MOE[1]	Max Exp[2] (mg/kg/day)	Avg. food exp (mg/kg/day)	Residential Exp[3] (mg/kg/day)	Aggregate MOE[4] (food and residential)	Max water Exp[5] (mg/kg/day)	Ground water EEC[6] (µg/L)	Surface water EEC[6] (µg/L)	Short-term DWLOC (µg/L)[7]
U.S.	21.8	100	0.218	0.028	0	746	0.189	0.63	26	5,663

[1]Target MOE is 100.
[2]Maximum Exposure (mg/kg/day) = NOAEL Target MOE.
[3]Residential Exposure = Exposure to adult while playing golf.
[4]Aggregate MOE = (NOAEL (Avg. Food + residential Exposure).
[5]Maximum Water Exposure (mg/kg/day) = Target Max Exposure (Food Exposure + Residential Exposure).
[6]Crop producing the highest EEC values were used for comparison.
[7]The DWLOC (µg/L) = maximum water exposure (mg.kg/day) x body weight (kg) water consumption (L) x 0.001 mg/ug. Adult female weight was used to calculate, which covers adult male risk. The dietary exposure for the U.S. population is higher than that of groups having residential golf exposure (i.e., adults, youth 13–19).

2. *Non-dietary exposure.* No new residential uses are currently being registered for boscalid that would increase non-dietary exposure. A non-occupational dermal post-application exposure/risk assessment for individuals golfing and harvesting fruit at ''U-Pick'' farms and orchards was previously conducted by EPA, (July 30, 2003, 68 FR 44640) (FRL–7319–6). Because U-Pick is a one-time event (duration <1 day) and the EPA found that the oral studies indicated there were no endpoints appropriate to quantify acute risk.

Therefore, only the golfing scenario was evaluated with respect to non-occupational, non-dietary exposure. The dermal MOE's for adults playing golf were 27,000 to 74,000. Although, specific MOE's were not calculated for youths playing golf, the adult MOEs are considered representative since the body surface area to weight ratios for adolescents do not vary significantly from those of adults.

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.'' BAS 510F is a foliar fungicide chemically belonging to the carboxin class of fungicides. BAS 510F acts in the fungal cell by inhibiting mitochondrial respiration through inhibition of the succinate-ubiquinone oxidase reductase system in Complex II of the mitochondrial electron transport chain. BAS 510F shares this mode of action with only one other currently registered U.S. pesticide - carboxin.

EPA is currently developing methodology to perform cumulative risk assessments. At this time, there is no available data to determine whether BAS 510F 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, BAS 510F does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that dietary exposure to BAS 510F will utilize 13.0% of the cPAD for the U.S. population. The aggregate exposure including food, water, and residential golf exposure has shown that there is no concern from the exposure from drinking water. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of BAS 510F, including anticipated dietary and drinking water exposures and non-occupational exposures.

2. *Infants and children*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that dietary exposure to BAS 510F will utilize 32% of the cPAD for most highly exposure infant and children subgroup (children 1–2 years of age). The aggregate exposure including food, water, and residential golf exposure has shown that there is no concern to any subpopulation from the exposure from drinking water. BASF concludes that there is a reasonable certainty that no harm to infants or children will result from the aggregate exposure to residues of BAS 510F, including anticipated dietary and drinking water exposures and non-occupational exposures.

F. International Tolerances

A maximum residue level (MRL) has not been established for boscalid BAS 510F in any crop by the codex Alimentarius Commission.

[FR Doc. 05–13175 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0058; FRL–7719–3]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2005–0058, must be received on or before August 5, 2005.

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

FOR FURTHER INFORMATION CONTACT: Bryant Crowe, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: *crowe.bryant@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0058. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public