5. If there is relevance to your project, briefly describe the Tribal and non-Tribal populations of surrounding counties/States, and surrounding land use.

6. How many people (Tribal/non-Tribal) are employed by the Tribal Government (e.g., in government services, including health care, police and fire protection).

7. How many are employed on the reservation in other areas that use pesticides or may be impacted by their use (e.g., agriculture, animal husbandry, fisheries/fishing, forestry, construction, casinos/resorts/golf course maintenance)?

8. If you are concerned about pesticide pollution that may originate within reservation boundaries, what are the potential sources and what chemicals might be involved?

9. If you are concerned with pollution migration from off-reservation sources, what are those potential sources, and what chemicals are of specific concern?

10. Is the Tribe concerned about water quality issues? If so, please describe the nature of these concerns.

11. Does the Tribe currently have any pesticide policy in place?

Selection criteria

Total possible points: 100

Technical Qualifications, Overall Management Plan, Past Performance (30 Points)

Does the person(s) designated to lead the project have the technical expertise he or she will need to successfully complete it? Does the project leader have experience in grant and project management? Proposals should provide complete information on the education, skills, training and relevant experience of the project leader. As appropriate, please cite technical qualifications and specific examples of prior, relevant experience. If this project will develop new Tribal capacity, describe how the project leader and/or staff will gain necessary training and expertise.

To whom does the project leader report? What systems of accountability and management oversight are in place to ensure this project stays on track?

Has the Tribe or Tribal consortium received past funding from EPA's Office of Pesticide Programs, other EPA programs, or other sources? If so, please identify the funding source and activities/deliverables it supported.

If previously performed work directly impacts this project, briefly describe the connection. If a directly relevant project is currently ongoing, what progress has been made?

If this new project builds upon earlier efforts, how will you use the knowledge, data, and experience of grant outputs from previous projects to shape this new proposed activity?

Justification for Need of the Project, Soundness of Technical Approach (35 Points)

Why is this project important to the Tribe or the Tribal consortium? What environmental issues(s) will it address and how serious and/or pervasive are these issues? What is the expected outcome of the project? What benefits will this project provide to the Tribe, human health, and the environment?

Has the Tribe identified a need to coordinate or consult with other parties (Tribal and/or non-Tribal) to ensure the success of this project? If so, who are they? How does the Tribe plan to involve these parties? How will they be affected by the outcome of the project?

What are the key outputs of this project? How do you propose to quantify and measure progress? Have interim milestones for this project been established? If so, what are they? How will you evaluate the success of the project in terms of measurable environmental results? Please describe the steps you will take to ensure successful completion of the project and provide a time line and description of interim and final results and deliverables.

Does your budget request accurately reflect the work you propose? Please provide a clear correlation between expenses and project objectives. Will EPA funding for this project be supplemented with funding from other source(s)? If so, please identify them.

Benefits, Sustainability, Transferable Results (35 Points)

What ecological or human health benefits does this project provide? What quality of life issues does the project address?

Does the project have limited or broad application to address risks related to pesticides?

Will the results from this project continue to provide benefits to the Tribe or other Tribes after the period of performance has expired and this funding is no longer available? How are the benefits of this effort expected to be sustained over time?

Does the applicant understand/acknowledge the need for coordination between Tribal agencies and outside communities, and/or Federal, State or local agencies? Will the project help build Tribal infrastructure or capacity? How?

Can the project results be incorporated into existing and/or future pesticide-related Tribal environmental activities? Are any of the deliverables, experiences, products, or outcomes resulting from the project transferable to other communities? Might this project readily be implemented by another Tribe?

VII. Post Selection Activity

Selected applicants must formally apply for funds through the appropriate EPA regional office. In addition, selected applicants must negotiate a final work plan, including reporting requirements, with the designated EPA regional project officer. For more general information on post award requirements and the evaluation of grantee performance, see 40 CFR part 31.

VIII. Submission to Congress and the Comptroller General

Grant solicitations such as this are considered rules for the purpose of the Congressional Review Act (CRA). The CRA, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

Environmental protection, Pesticides, Tribes.

Dated: January 30, 2003.

Stephen L. Johnson,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 03–3582 Filed 2–13–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0341; FRL–7289–5]

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 boscalid in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0341, must be received on or before March 17, 2003.

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

FOR FURTHER INFORMATION CONTACT: Richard Keigwin, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7618; e-mail address: keigwin.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0341. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and To Whom Do I Submit Comments?

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

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

EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2002–0341. 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–2002–0341. 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–2002–0341.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0341. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

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

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

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: February 3, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of a Petition

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

BASF Corporation

PP 1F6313

EPA has received a pesticide petition (1F6313) from BASF Corporation, P.O. Box 13528, 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 a tolerance for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro(1,1'-biphenyl)-2-yl)]] in or on the following primary raw agricultural commodities and processed commodities: Root vegetables (crop group 1-B) 1.0 parts per million (ppm), tuberous and corm vegetables (crop group 1-C) 0.05 ppm, bulb vegetables (crop group 3) 3.0 ppm, leafy vegetables (crop group 4) 11.0 ppm, head and stem brassica (sub crop group 5-A) 3.0 ppm, legume vegetables (crop group 6) 2.2 ppm, fruiting vegetables (crop group 8) 1.0 ppm, cucurbit vegetables (crop group 9) 1.5 ppm, stonefruit (crop group 12) 1.7 ppm, berries (crop group 13) 3.5 ppm, tree nuts (crop group 14) 0.25 ppm, almond hulls 3.0 ppm, pistachios 0.65 ppm, mint 30.0 ppm, grapes 3.5 ppm, raisins 8.5 ppm, strawberries 1.2 ppm, peanut 0.05 ppm, peanut meal 0.15 ppm, peanut oil 0.15 ppm, canola 3.5 ppm, sunflower seed 3.5 ppm.

BASF Corporation also proposes to amend 40 CFR part 180 by establishing tolerances for residues of 3-pyridinecarboxamide, 2-chloro-*N*-(4'-

chloro(1,1'-biphenyl)-2-yl) in or on the following raw agricultural and processed commodities of rotational crops: Beet root 1.0 ppm, root vegetables (crop group 1-B) 1.0 ppm, leaves of root and tuber vegetables (crop group 2) 1.0 ppm, head and stem brassica (sub crop group 5-A) 3.0 ppm, leafy brassica greens (sub crop group 5-B) 18.0 ppm, legume vegetables - peas (crop group 6) 2.2 ppm, foliage of legume vegetables (crop group 7): forage 1.5 ppm, hay 2.0 ppm, vines 0.05 ppm, cucurbit vegetables (crop group 9) 1.5 ppm, cereal grains (crop group 15) 0.20 ppm, forage fodder and straw of cereal grains (crop group 16) forage 2.0 ppm, straw 3.0 ppm, fodder 1.5 ppm, grass forage fodder and hay (crop group 17) forage 2.0 ppm, hay 8.0 ppm, straw 0.3 ppm, seed 0.2 ppm, non-grass animal feeds (crop group 18) forage 1.0 ppm, hay 2.0 ppm, seed 0.2 ppm, mint 30.0 ppm, cotton seed 0.05 ppm, cotton gin by-products 0.3 ppm, soybean seed 0.1 ppm, soybean hulls 0.2 ppm, flax seed 3.5 ppm, sunflower seed 3.5 ppm, and rice hulls 0.5 ppm.

BASF Corporation is also proposing to amend 40 CFR part 180 by establishing tolerances for the combined residues of 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro (1,1'-biphenyl)-2-yl and its metabolite 2-chloro-*N*-(4'chloro-5-hydroxy-biphenyl-2-yl)nicotinamide expressed in parent equivalents in the following animal commodities: Cow milk 0.10 ppm, cow muscle 0.10 ppm, cow fat 0.30 ppm, cow meat by-products 0.35 ppm, eggs 0.02 ppm, poultry muscle 0.05 ppm, poultry fat 0.05 ppm, and poultry meat by-products 0.05 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 860.1300) were conducted in grapes, lettuce, and beans as representative crops in order to characterize the fate of boscalid, also known as BAS 510 F, in all crop matrices. In all three crops, the BAS 510 F Residues of Concern (ROC) were characterized as parent (BAS 510 F). 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 cleanup. Quantitation is by gas chromatography/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 cleanup. The parent and acetylated metabolite are quantitated by gas chromatography/electron capture detection (GC/ECD).

3. *Magnitude of residues*. Field trials were carried out in order to determine the magnitude of the residue in the following crops: Almonds, beans (dry and succulent), edible peas (dry and succulent), canola, carrot, cucurbits, grape, lettuce, leafy vegetables (brassica and non-brassica), onion (dry bulb and green), peanut, pecan, pepper (bell and chili), pistachio, potato, berries (crop group), stonefruit (cherries, peaches, plums), strawberry, tomato, mint, and sunflower. Field trials were conducted in the United States and Canada in the required regions. Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum preharvest interval for each crop or crop group. In addition, processing studies were conducted on the following crops to determine concentration factors during normal processing of the raw agricultural commodity into the processed commodities: Canola, grape, peanut, plum, tomato, sunflower, and mint. Magnitude of the residue studies were also carried out in dairy cows and hens. Tier III field rotational crop studies were conducted to support rotational crop tolerances for beet roots, beet tops, cotton, foliage of legume vegetables, soybeans, cereals, grass and non-grass animal feeds. Processing studies were conducted on soybeans and rice to determine concentration factors.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data BAS 510 F and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical BAS 510 F in toxicity category IV for acute oral; category III for acute dermal and category IV for acute inhalation. BAS 510 F is category IV for both eye and skin irritation, and it is not a dermal sensitizer. Two formulated end use products are proposed, a Water Dispersible Granule (WG) termed BAS 510 02 F containing 70% BAS 510 F and a Water Dispersible Granule (WG) termed BAS 516 02 F containing a 2:1 mixture of BAS 510 F and BAS 500 F. BAS 510 02 F has an acute oral toxicity category of III, acute dermal of III, acute inhalation of IV, eye irritation of III, skin irritation of IV, and is not a dermal sensitizer. BAS 516 02 F has an acute oral toxicity category of III, acute dermal of III, acute inhalation of IV, eye irritation of III, skin irritation of IV, and is not a dermal sensitizer.

2. *Genotoxicity*. Ames Test (one study; point mutation): Negative; *In Vitro* CHO/HGPRT Locus Mammalian Cell Mutation Assay (one study; point mutation): Negative; *In Vitro* V79 Cell Cytogenetic Assay (one study; chromosome damage): Negative; *In Vivo* Mouse Micronucleus (one study; chromosome damage): Negative; *In Vitro* Rat Hepatocyte (one study; DNA damage and repair): Negative. BAS 510 F has been tested in a total of five genetic toxicology assays consisting of *in vitro* and *in vivo* studies. It can be stated that BAS 510 F did not show any mutagenic, clastogenic or other genotoxic activity when tested under the conditions of the studies mentioned above. Therefore, BAS 510 F does not pose a genotoxic hazard to humans.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of BAS 510 F 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. Pup effects were observed, with parental toxicity, at the highest dose tested only. In both parental generations, reduced food consumption and reduced body weight (bwt) gain were observed at 10,000 ppm. Both absolute and relative liver weights were increased 21% in F1 generation parental females at the high dose of 10,000 ppm only. Hepatocellular centrilobular hypertrophy (usually slight) was observed in many animals of both sexes in both the F0 and F1 generations at 1,000 ppm, and in all animals of both sexes at 10,000 ppm. Additionally, some of the parental male rats at 10,000 ppm, in both generations, displayed centrilobular liver cell degeneration. Developmental toxicity 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 weight for both males and females of both the F1 and F2 generations. The parental systemic and developmental toxicity no observed adverse effect levels (NOAEL) are both 100 ppm (12 milligrams/kilogram/day (mg/kg/day).

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/day). Neither a maternal nor developmental lowest observed adverse effect level (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 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 ≤ 1.5 grams/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 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/day. Evidence of developmental toxicity was not seen at any dose tested.

Developmental neurotoxicity (DNT) 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/day (100 ppm). Reduced body weights and body weight gains were seen at 118 mg/kg/day (1,000 ppm) during postnatal day (PND) 1–4. Reduced body weights and body weight gains were seen at 1,183 mg/kg/day (10,000 ppm) as well as decreased absolute pup brain weight at day 11 post partum (p.p.) (both sexes) and decreased brain length (males only) at day 11 p.p. 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 p.p. 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 510 resulted in maternal toxicity. A dose of 118 mg/kg/day in female rats of the same strain in the multi-generation study, resulted in an increased incidence of hepatic centrilobular hypertrophy a parameter which could not have been detected in the DNT study as liver histopathology on parental animals was not performed in the DNT study.

4. *Subchronic toxicity.* The subchronic toxicity of BAS 510 F was investigated in 90–day feeding studies with rats, mice and dogs, and in a 28–day dermal administration study in rats. A 90–day neurotoxicity study in rats was also 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 highest dose tested of 1,000 mg/kg/day.

In a 90–day rat neurotoxicity study, there was no mortality, signs of clinical toxicity, 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/day in males; 1,272 mg/kg/day in females).

5.*Chronic toxicity.* Based on review of the available data, the Reference Dose (RfD) for BAS 510 F will be based on a 24–month feeding study in rats with a threshold no observed effect level (NOEL) of 5 mg/kg/day. Using an uncertainty factor of 100, the RfD is calculated to be 0.05 mg/kg/day. The following are summaries of chronic toxicity studies submitted to EPA. The chronic toxicity/oncogenicity studies with BAS 510 F 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 highest dose tested 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 males; 22.1 mg/kg bwt females).

Decreased body weights were seen in males in the mouse chronic study at doses of 400 ppm and above. Decreased female body weight was seen at doses of 2,000 ppm and above. The target organ in this study was the liver. In both the rat chronic and oncogenicity studies, the highest dose tested 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.

Overall, mild toxicity was observed with chronic exposure to BAS 510 F. 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 510 F has met the cited criteria.

Threshold effects. Based on a review of the available chronic toxicity data, BASF believes EPA will establish the Reference Dose (RfD) for BAS 510 F at 0.05 mg/kg/day. This RfD for BAS 510 F is based on the 2–year chronic and 2–year oncogenicity studies in rats with a threshold average NOAEL of 5 mg/kg/

day for males and females. Using an uncertainty factor of 100, the RfD is calculated to be 0.05 mg/kg/day. Based on the acute toxicity data, BASF believes that BAS 510 F does not pose any acute dietary risks.

BAS 510 F was shown to be non-carcinogenic in mice and dogs. There was a slight increase in thyroid follicular cell adenomas at the high dose in both sexes in the rat. A threshold-based mode of action 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 510 F exposure have a threshold. In addition, a battery of genotoxicity studies demonstrated that BAS 510 F has no genotoxic or clastogenic potential. Therefore, BASF believes that the threshold approach to regulating BAS 510 F 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, 12 September 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 510 F is fecal with urinary excretion being minor. The half-life of BAS 510 F is less than 24 hours. Saturation of absorption appears to be occurring at the high dose level. BAS 510 F is rapidly and intensively metabolised 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 with regard to label, sex, and dose level. In hens and goats the residues of concern were determined to be parent, the hydroxylated metabolite M510F01 (2-chloro-*N*-(4'chloro-5-hydroxy-biphenyl-2-yl)nicotinamide), and the glucuronic acid of the metabolite M510F02.

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

8. *Endocrine disruption*. No specific tests have been conducted with BAS 510 F 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 510 F produces endocrine-related effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. A chronic dietary exposure analysis was conducted for BAS 510 F including crops which are target uses as well as inadvertent residues in rotational crops. The analysis assumed 100% of the crops were treated, default processing factors (even though much lower experimentally-derived processing factors are available), and used the tolerance value for residues. Even with these worst-case assumptions, it was determined that the Theoretical Maximum Residue Contribution (TMRC) was only 30.1% of the RfD dose for the U.S. population and 62.5% for children 1–6 years (the highest exposed age-related subpopulation). Based on the toxicology results, an acute dietary risk assessment for BAS 510 F is most likely not required, but if so only for children 1–6 years. For dietary exposure estimation, 100% crop treated and tolerance values for residues were used. The resulting acute exposure prediction for children 1–6 years (the highest exposed age-related subpopulation) resulted in an acceptable 8.8% of the acute reference dose at the 95th percentile. If a more realistic scenario were used assuming percent crop treated and the range of residues, a much lower exposure would be obtained.

ii. *Drinking water*. Estimates of ground water and surface water levels were determined using Screening Concentrations in Ground Water (SCI-GROW) and First Index Reservoir Screening Tools (FIRST) models, respectively. Using SCI-GROW to estimate chronic exposure to BAS 510 F from drinking water, drinking water consumption utilizes 0.15% of the RfD for the U.S. population and 0.044% for children ages 1–6. Using FIRST to estimate chronic exposure to BAS 510 F from drinking water, drinking water consumption utilizes 0.08% of the RfD for the U.S. population and 0.24% of the RfD for children ages 1–6.

2. *Non-dietary exposure*. BAS 510 F is not currently planned for residential uses. Thus, residential exposure is not aggregated into the risk assessment.

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 510 F is a foliar fungicide chemically belonging to the carboxin class of fungicides. BAS 510 F acts in the fungal cell by inhibiting of mitochondrial respiration through inhibition of the succinate-ubiquinone oxidase reductase system in Complex II of the mitochondrial electron transport chain. BAS 510 F 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 510 F 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 510 F 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 aggregate exposure to BAS 510 F will utilize 30.2% of the RfD for the US population. For the highest exposed age-related subpopulation (children 1-6 years), the maximum aggregate exposure is predicted to be 62.8% of the reference dose. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of BAS 510 F, including anticipated dietary and drinking water exposures and non-occupational exposures.

2. *Developmental toxicity in the rat*. A developmental study was conducted via oral gavage in rats with dosages of 0, 100, 300, and 1,000 mg/kg bwt/day with a maternal and developmental no observed adverse effect level (NOAEL) of 1,000 mg/kg. No evidence of developmental toxicity was observed up to the highest dose tested.

3. *Developmental toxicity in the rabbit*. A developmental study was

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

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

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

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

F. International Tolerances

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0007; FRL–7289–1]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0007. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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