B. 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 identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period.

1. Electronically

If you submit an electronic comment as prescribed below, 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. EDOCKET. 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 EDOCKET at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, *http://www.epa.gov,* select ''Information Sources,'' ''Dockets,'' and ''EDOCKET.'' Once in the system, select ''search,'' and then key in Docket ID No. ORD–2004–0014. 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 electronic mail (e-mail) to *ORD.Docket@epa.gov,* Attention: Docket ID No. ORD–2004–0014. 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.B.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: U.S. Environmental Protection Agency, ORD Docket, EPA Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention: Docket ID No. ORD–2004–0014.

3. By Hand Delivery or Courier

Deliver your comments to: EPA Docket Center (EPA/DC), Room B102, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention: Docket ID No. ORD–2004–0014. (**Note:** this is not a mailing address.) Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.A.1.

Dated: August 23, 2004.

Jeffery Morris,

Acting Director, Office of Science Policy.

[FR Doc. 04–19612 Filed 8–26–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0292; FRL–7676–9]

Pyraclostrobin; Notice of Filing of Four Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in and 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–2004–0292, must be received on or before September 27, 2004.

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

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–-0001; telephone number: (703) 305–7740; e-mail address: *giles-parker.cynthia@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, pesticide manufacturer, or consume agricultural commodities. Potentially affected entities may include, but are not limited to:

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

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

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

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2004–0292. 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 South Bell St., Arlington, VA.

This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and To Whom Do I Submit Comments?

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

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

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0292. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2004–0292. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0292.

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 South Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0292. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: August 23, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

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

BASF Corporation and Interregional Research Project Number 4 (IR–4)

Pesticide Petitions (PP) 0F6139, 2F6431, 3F6581, and 3E6774

EPA has received three pesticide petitions (PP 0F6139, 2F6431, and 3F6581) from BASF Corporation, Research Triangle Park, NC 27709, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. section 346a (d), to amend 40 CFR part 180.582 by establishing tolerances for the combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its metabolite BF 500–3 (methyl-*N*-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate), expressed as parent compound. The following tolerances are proposed: Bean, succulent 0.5 parts per million (ppm); bean forage 1.0 ppm; bean hay 11.0 ppm; pea, dry 0.5 ppm; pea, field, hay 26 ppm; pea, field, vines 10 ppm; corn, field, grain 0.1 ppm; corn, field, forage 5.0 ppm; corn, field, stover 17 ppm; corn, field, aspirated grain fractions 1.5 ppm; corn, field, refined oil 0.3 ppm); corn, pop 0.1 ppm; corn, sweet, kernel plus cob with husk removed 0.04 ppm; corn, sweet, forage 5.0 ppm; corn, sweet, stover 23 ppm; vegetable, legume, edible-podded, subgroup 6A 0.5 ppm; hop 23 ppm; mango 0.1 ppm; peppermint 8.0 ppm; spearmint 8.0 ppm; papaya 0.1 ppm; pea and bean, succulent shelled, subgroup 6B 0.2 ppm; fruit, pome, group 1.5 ppm; apple, wet pomace 4.0 ppm; sunflower 0.3 ppm; brassica, leafy greens, subgroup 5B 16 ppm; fruit, citrus, group 2 ppm; fruit, citrus, dried pulp 12.5 ppm; citrus, oil 9 ppm; soybean 0.04 ppm; soybean, forage 5 ppm; soybean, hay 7 ppm; and soybean, aspirated grain fractions 0.25 ppm.

EPA has also received a pesticide petition (PP 3E6774) from Interregional Research Project Number 4 (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390, proposing pusuant to section 408(d) of the FFDCA, 21 U.S.C. section 346a (d) to amend 40 CFR part 180.582 by establishing tolerances for the combined residues of the fungicide pyraclostrobin and its metabolite BF 500–3 in or on vegetables, leafy, except brassica, group 4 29 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of these petitions. Additional data may be needed before EPA rules on the petitions. This summary has been prepared by BASF Corporation, Research Triangle Park, NC 27709.

A. Residue Chemistry

1. *Plant and animal metabolism*. Nature of the residue studies (OPPTS 860.1300) were conducted in grape, potato, and wheat as representative crops in order to characterize the fate of pyraclostrobin in all crop matrices. Pyraclostrobin demonstrated a similar pathway and fate in all three crops. In all three crops the pyraclostrobin Residues of Concern (ROC) were characterized as parent (pyraclostrobin) and BAS 500–3 (methyl-*N*[[[1-(4-chlorophenyl) pyrazol-3yl]oxy]o-tolyl] carbamate). In hens the ROC were determined to be parent compound and a hydroxylated metabolite, BAS 500–16. In goats the ROC were determined to be parent and a hydroxylated metabolite BAS 500–10.

2. *Analytical method*. In plants the method of analysis is aqueous organic solvent extraction, column clean up, and quantitation by Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC/MS/MS). In animals the method of analysis involves base hydrolysis, organic extraction, column clean up, and quantitation by LC/MS/MS or derivatization (methylation) followed by quantitation by Gas Chromatography/Mass Spectrometry (GC/MS).

3. *Magnitude of the residue*. Field trials were carried out in order to determine the magnitude of the residue in the following crops: Citrus (reduced Pre-harvest Interval (PHI)), field corn,

sweet corn, edible podded legume vegetables, hops, leafy brassica, mango, mint, papaya, pome fruit, dry peas, soybean, succulent shelled beans, succulent shelled peas, and sunflower. The residue trials in mango and papaya were carried out in Latin America. Field trials for the rest of the crops were conducted in the United States and Canada. Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum PHI 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: Corn, mint, pome fruit, and sunflower. Magnitude of the residue trials were previously carried out in cow and poultry and submitted with PP 0F6139. Field trials were also carried out in order to determine the magnitude of the residue in vegetables, leafy, except brassica, group 4 to satisfy the requirements for a tolerance for pyraclostrobin in this crop group. Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum PHI.

B. Toxicological Profile

1. *Acute toxicology*. Based on available acute toxicity data pyraclostrobin and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical pyraclostrobin in toxicity category IV for acute oral, category III for acute dermal, and category IV for acute inhalation. Pyraclostrobin is category III for both eye and skin irritation, and it is not a dermal sensitizer. Two formulated end use products are registered for use on crops, an Emulsifiable Concentrate (EC) and an Extruded Granule (EG). The EC has an acute oral toxicity category of II, acute dermal category of III, acute inhalation category of IV, eye and skin irritation categories of II, and is not a dermal sensitizer. The EG has acute oral and dermal toxicity categories of III, acute inhalation category of IV, eye irritation category of III, skin irritation category of IV, and is not a dermal sensitizer.

2. *Genotoxicity*. Pyraclostrobin has been tested in a total of 5 genetic toxicology assays consisting of *in vitro* and *in vivo* studies. It can be stated that pyraclostrobin did not show any mutagenic, clastogenic, or other genotoxic activity when tested under the conditions of the studies mentioned in the bulleted list below. Therefore, pyraclostrobin does not pose a genotoxic hazard to humans.

- Ames test (one study of point mutation): Negative.
- *In vitro* Chinese Hamster Ovary (CHO) HGPRT locus mammalian cell mutation assay (one study of point mutation): Negative.
- *In vitro* V79 cells CHO cytogenetic assay (one study of chromosome damage): Negative.
- *In vivo* mouse micronucleus (one study of chromosome damage): Negative.
- *In vitro* rat hepatocyte (one study of DNA damage and repair): Negative.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of pyraclostrobin 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 so the no observable adverse effect level (NOAEL) is the highest dose tested of 300 ppm (32.6 milligrams per kilogram bodyweight per day (mg/kg bw/day)). Parental and pup toxicity in the form of reduced body weight gain were observed at the highest dose tested only. Therefore, the parental systemic and developmental toxicity NOAELs are the same at 75 ppm (8.2 mg/kg bw/day).

No teratogenic effects were noted in either the rat or rabbit developmental studies. In the rat study, maternal toxicity observed at the mid and high dose consisted of decreased food consumption and body weight gain. Developmental changes noted at the high dose were increased incidences of dilated renal pelvis and cervical ribs with no cartilage. The maternal NOAEL was 10 mg/kg bw/day and the developmental NOAEL was 25 mg/kg bw/day. In the rabbit teratology study, maternal toxicity observed at the mid and high doses consisted of decreased food consumption and body weight gain (severe at the high dose). An increased postimplantation loss was also observed at the mid and high doses due to an increase in early resorptions. In rabbits, these types of effects are often observed with significant stress on the mothers (as seen by the body weight gain decrease in this study) and are not indicative of frank developmental toxicity. The NOAEL for both maternal and developmental toxicity was 5 mg/kg bw/day.

4. *Subchronic toxicity*. The subchronic toxicity of pyraclostrobin 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 in feeding studies, general findings in all three species were decreased food consumption and body weight gain and a thickening of the duodenum. Anemia occurred at high dose levels in both rats and mice with accompanying extramedullary hematopoiesis of the spleen in rats. In rats only, a finding of liver cell hypertrophy was indicative of a physiological response to the handling of the chemical. 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 250 mg/kg bw/day. In a 90-day rat neurotoxicity study, a direct neurotoxic effect was not observed.

5. *Chronic toxicity*. Pyraclostrobin was administered to groups of 5 male and 5 female purebred Beagle dogs in the diet at concentrations of 0, 100, 200, and 400 ppm over a period of 12 months. Signs of toxicity were observed at the high dose. Diarrhea was observed throughout the study period for both sexes. High dose males and females initially lost weight and body weight gain was decreased for the entire study period for females. Hematological changes observed were an increase in white blood cells in males and an increase in platelets in both sexes at the high dose. Clinical chemistry demonstrated a decrease in serum total protein, albumin, globulins, and cholesterol in high dose animals of both sexes possibly due to the diarrhea and reduced nutritional status of the animals. The NOAEL was 200 ppm (circa (ca.) 5.5 mg/kg bw/day males; 5.4 mg/kg bw/day females).

In an oncogenicity study, pyraclostrobin was administered to groups of 50 male and 50 female Wistar rats at dietary concentrations of 0, 25, 75, and 200 ppm for 24 months. In a companion chronic toxicity study, 20 rats/sex were used at the same dose levels as in the oncogenicity study. A body weight gain depression of 10–11% in males and 14–22% in females with an accompanying decrease in food efficiency was observed at the high dose. The only other effect observed was a decrease in serum alkaline phosphatase in both sexes at the high dose and decreased alanine aminotransferase in high dose males. There was no evidence that pyraclostrobin produced a carcinogenic effect in rats. The NOAEL for the chronic rat and the cancer rat study is 75 ppm (ca. 3.4 mg/kg bw/day males; 4.6 mg/kg bw/day females).

Pyraclostrobin was administered to groups of 50 male and 50 female B6C3F1 mice at dietary concentrations of 0, 10, 30, 120, and 180 ppm (females

only) for 18 months. Body weights were reduced at the highest doses tested in both males and females. At the high dose, body weight gain decreases of 27% in females and 29% in males with an accompanying decrease in food efficiency were observed. No other signs of toxicity were noted at any dose level. The NOAEL was found to be 120 ppm (ca. 20.5 mg/kg bw/day) for females and 30 ppm (ca. 4.1 mg/kg bw/day) for males. There was no evidence that pyraclostrobin produced a carcinogenic effect in mice.

6. *Animal metabolism*. In a rat metabolism study with pyraclostrobin, 10–13% of the administered dose was excreted in the urine and 74–91% in the feces within 48 hours. Excretion via bile was significant, accounting for 35–38% of the administered dose. By 120 hours after dosing, very little radioactivity remained in tissues. Pyraclostrobin was rapidly and almost completely metabolized. Very little unchanged parent was detected. The phase one biotransformation is characterized by *N*-demethoxylation, various hydroxylations, cleavage of the ether bond and further oxidation of the two resulting molecule parts. Conjugation of the formed hydroxyl groups by glucuronic acid or sulfate also occurred. In summary, pyraclostrobin is extensively metabolized and rapidly eliminated, primarily via the bile, with no evidence of accumulation in tissues.

7. *Metabolite toxicology*. A comparison of the rat metabolism results with the plant metabolism/residue results indicates that toxicology studies performed with the parent pyraclostrobin are sufficient to cover dietary exposure. Plant residues are primarily the parent compound with a fraction (up to 10–20% at most) being the demethoxylated parent. This metabolite is referred to as BF 500–3 in the plant studies and as 500M07 in the rat study. This metabolite in the rat is the first step in the major biotransformation process leading to the majority of the metabolites determined in the major excretion pathway.

8. *Endocrine disruption and endocrine effects*. No specific tests have been conducted with pyraclostrobin 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 pyraclostrobin produces endocrine related effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Assessments were conducted to evaluate the potential risk due to chronic and acute dietary exposure of the U.S. population to residues of pyraclostrobin (BAS 500 F). This fungicide and its desmethoxy metabolite (BAS 500–3) were expressed as the parent compound (BAS 500 F). Tolerance values have previously been established for various cereals, vegetables, fruits, and animal products and are listed in the EPA final rule which published in the **Federal Register** of September 27, 2002 (67 FR 60886) (FRL–7200–7). This analysis includes all currently registered and pending crop uses, from both IR–4 and BASF.

The acute and chronic dietary exposure estimates were based on proposed tolerance values for most crops:

- Measured residue values for vegetables, leafy, except brassica, group 4.
- Percent crop treated.
- Concentration/processing factors.
- Consumption data from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII 1994–1996, 1998) and the EPA Food Commodity Ingredient Database (FCID) using Exponent's Dietary Exposure Evaluation Module (DEEM-FCID, version 2.03) software.

Results of exposure estimates were compared against the pyraclostrobin chronic Population Adjusted Dose (cPAD) and acute Population Adjusted Dose (aPAD) of 0.034 mg/kg bw/day and 0.3 mg/kg bw/day for the general population, respectively. For females of child bearing years (13–49 years old) the aPAD is 0.05 mg/kg bw/day. The EPA determined that the FQPA Safety Factor should not be retained and reduced it to 1X for all exposure scenarios. Therefore, the aPAD and cPAD are the same as the aRfD (acute Reference Dose) and cRfD (chronic Reference Dose), respectively.

Results of the chronic dietary assessments are listed in Table 1. The estimated chronic dietary exposure from pending crops was less than 10% of the cPAD for all subpopulations. Additional refinements such as the use of anticipated residues would further reduce the estimated chronic dietary exposure.

TABLE 1.—CHRONIC DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN CONSIDERING ALL PENDING CROP USES

Population Subgroups	Exposure Estimate (mg/kg bw/day)*	%cPAD**
U.S. population	0.001203	3.5
All infants	0.001291	3.8
1–2 years	0.003066	9.0
3–5 years	0.002570	7.6
1–6 years	0.002644	7.8
6–12 years	0.001571	4.6
13–19 years	0.001093	3.2
Females 13–49 years	0.00984	2.9
Adults 20–49 years	0.000981	2.9
Males 20+ years	0.000981	2.91
Adults 50+ years	0.001001	2.9

* Exposure estimates are based on tolerance values (except measured residue values for vegetables, leafy, except brassica, group 4), default processing factors, and percent crop treated values.

** %cPAD = Percent of chronic Population Adjusted Dose.

As Table 2. shows, the estimated acute dietary exposure was under the aPAD at the 99th and 99.9th percentile. The overall general U.S. population and the most sensitive subpopulation (females 13–49 years) utilized < 5.0% (99th percentile) and 16.1% (99.9th percentile), and < 29.3% (99th percentile) and 93.7% (99.9th percentile) of the aPAD, respectively. Because the FQPA safety factor was reduced to 1X, the aPAD has the same percentage utilization as the aRfD. Additional refinements such as the use of anticipated residues would further reduce the estimated acute dietary exposure.

TABLE 2.—ACUTE DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN CONSIDERING ALL PENDING CROP USES

Population Subgroups	99th Percentile Exposure Estimate (mg/kg bw/day)*	99th Percentile %aPAD**	99.9th Percentile Exposure Estimate (mg/kg bw/day)*	99.9th Percentile %aPAD**
U.S. population	0.014826	4.94	0.048341	16.11
All infants	0.01440	4.80	0.170066	56.69
1–2 years	0.022461	7.49	0.097773	32.59
3 1–5 years	0.021029	7.01	0.067374	22.46
1–6 years	0.021258	7.09	0.074864	24.95
6–12 years	0.013174	4.39	0.043177	14.39
13–19 years	0.009803	3.27	0.034995	11.67
Females 13–49 years	0.014631	29.26	0.046863	93.73
Adults 20 1–49 years	0.013942	4.65	0.045725	15.24
Males 20+ years	0.012556	4.19	0.040721	13.57
Adults 50+ years	0.014673	4.89	0.046918	15.64

* Exposure estimates are based on tolerance values (except measured residue values for vegetables, leafy, except brassica, group 4); default processing factors; and percent crop treated values.
** %aPAD = Percent of acute Population Adjusted Dose.

To ensure that these additional uses on the proposed crops fit within the total risk cup, a dietary exposure assessment (considering tolerance values; anticipated residues for measured residue values for vegetables, leafy, except brassica, group 4; concentration/processing factors; and percent crop treated values) was conducted using all currently registered and proposed crop uses (from both IR–4 and BASF) for pyraclostrobin. This assessment also included the current tolerance values for secondary residues in meat, meat byproducts, liver, and milk. The maximum chronic exposure estimates remained below 25% of the cPAD for the U.S. and all subgroup populations. The acute dietary exposure was 6% (99th percentile) and 16.7% (99.9th percentile) of the aPAD for the general U.S. population. For females (13–49 years), the most sensitive subpopulation, the acute dietary exposure was 31.1% (99th percentile) and 95.9% (99.9th percentile) of the aPAD. Additional refinements with anticipated residues rather than tolerance values would further reduce the estimated dietary exposures.

Results of the chronic (Table 3.) and acute (Table 4.) dietary exposure analysis demonstrate a reasonable certainty that no harm to the general U.S. population or any subpopulation would result from the use of pyraclostrobin on any of the currently registered or pending crops (both IR–4 and BASF uses).

TABLE 3.—CHRONIC DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN (BAS 500 F) CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES

Population Subgroups	Exposure Estimate (mg/kg bw/day)*	%cPAD **
U.S. population	0.004635	13.63
All infants	0.004319	12.70
1–2 years	0.010358	30.46
3–5 years	0.008391	24.68
1–6 years	0.00882	25.94

TABLE 3.—CHRONIC DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN (BAS 500 F) CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES—Continued

Population Subgroups	Exposure Estimate (mg/kg bw/day)*	%cPAD **
6–12 years	0.005745	16.90
13–19 years	0.003896	11.46
Females 13–49 years	0.004116	12.11
Adults 20–49 years	0.004076	11.99
Males 20+ years	0.003926	11.55
Adults 50+ years	0.004076	11.99

* Exposure estimates based on tolerance values for most crops; anticipated residues for vegetables, leafy, except brassica, group 4; actual and default concentration/processing factors; and percent crop treated values.
** %cPAD = Percent of chronic Population Adjusted Dose.

TABLE 4.—ACUTE DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES

Population Subgroups	99th Percentile Exposure Estimate (mg/kg bw/day)*	99th Percentile %aPAD**	99.9th Percentile Exposure Estimate (mg/kg bw/day)*	99.9th Percentile %aPAD **
U.S. population	0.017857	5.95	0.049950	16.65
All infants	0.024342	8.11	0.171591	57.20
1–2 years	0.029415	9.80	0.103802	34.60
3–5 years	0.025813	8.60	0.071777	23.93
1–6 years	0.027509	9.17	0.079941	26.65
6–12 years	0.016407	5.47	0.045736	15.25
13–19 years	0.013536	4.51	0.040675	13.56
Females 13–49 years	0.015546	31.09	0.047942	95.88
Adults 20–49 years	0.014934	4.98	0.046574	15.52
Males 20+ years	0.013838	4.61	0.042017	14.01
Adults 50+ years	0.015641	5.21	0.048111	16.04

* Exposure estimates based on tolerance values for most crops; anticipated residues for vegetables, leafy, except brassica, group 4; actual and default concentration/processing factors; and percent crop treated values.
** %aPAD = Percent of acute Population Adjusted Dose.

ii. *Drinking water.* There are no established maximum contaminant levels or health advisory levels for residues of pyraclostrobin or its metabolite in drinking water. A tier 1 drinking water modeling assessment for pyraclostrobin using the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST) model (for surface water) and Screening Concentration in Groundwater (SCI-GROW) model (for groundwater) produced estimated maximum concentrations of 20.4 parts per billion (ppb) (acute surface water), 0.79 ppb (chronic surface water) and 0.009 ppb (acute and chronic groundwater). These estimated concentrations are less than Drinking Water Levels of Concern (DWLOC), which are the worst-case calculated acceptable levels of pyraclostrobin residues in drinking water based on acute and chronic aggregate exposure for both registered and pending crops (see Tables 5., 6., 7., and 8.).

TABLE 5.—PYRACLOSTROBIN CHRONIC DRINKING WATER EXPOSURE ESTIMATES FOR ALL PENDING CROP USES

Chronic DWLOC	Adults (20–49)	Females (13–49)	Children (1–6 years)	Infants (birth to 1)
No effect level	3.4	3.4	3.4	3.4
Safety factor	100	100	100	100
RfD	0.034	0.034	0.034	0.034
cPAD	0.034	0.034	0.034	0.034
A) Chronic food (mg/kg/day)	0.000981	0.000984	0.002644	0.001291
B) Residential (mg/kg/day)	0	0	0	0
Water cPAD (A + B)	0.0330	0.0330	0.0314	0.0327
Chronic DWLOC (µg/L)	1167.3	1001.7	316.9	328.9
DECs*: FIRST Surface water (µg/L) SCI-GROW Groundwater (µg/L)	 0.79 0.009	 0.79 0.009	 0.79 0.009	 0.79 0.009

* Drinking Water Estimated Concentrations (DECs).

TABLE 6.—PYRACLOSTROBIN ACUTE DRINKING WATER EXPOSURE ESTIMATES FOR ALL PENDING CROP USES

Acute DWLOC	Adults (20–49)	Females (13–49)	Children (1–6 years)	Infants (birth to 1)
No effect level	300	5	300	300
Safety factor	100	100	100	100
RfD	0.3	0.05	0.3	0.3
aPAD	0.3	0.05	0.3	0.3
A) Acute food (mg/kg/day)*	0.045725	0.046863	0.074864	0.170066
B) Residential (mg/kg/day)	0	0	0	0
Water aPAD (A + B)	0.254275	0.003137	0.225136	0.129934
Acute DWLOC (µg/L)	104602.61	1160.64	29673.16	29754.03
DECs: FIRST Surface water (µg/L) SCI-GROW Groundwater (µg/L)	 20.4 0.009	 20.4 0.009	 20.4 0.009	 20.4 0.009

* 99.9th percentile.

TABLE 7.—PYRACLOSTROBIN CHRONIC DRINKING WATER EXPOSURE ESTIMATES CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES

Chronic DWLOC	Adults (20–49)	Females (13–49)	Children (1–6 years)	Infants (birth to 1)
No effect level	3.4	3.4	3.4	34
Safety factor	100	100	100	100
RfD	0.034	0.034	0.034	0.034
cPAD	0.034	0.034	0.034	0.034
A) Chronic food (mg/kg/day)	0.001788	0.001788	0.006654	0.003213
B) Residential (mg/kg/day)	0	0	0	0
Water cPAD (A + B)	0.0322	0.0322	0.0273	0.0308
Chronic DWLOC (µg/L)	1052.6	896.5	251.8	296.8
DECs: FIRST Surface water (µg/L) SCI-GROW Groundwater (µg/L)	 0.79 0.009	 0.79 0.009	 0.79 0.009	 0.79 0.009

TABLE 8.—PYRACLOSTROBIN ACUTE DRINKING WATER EXPOSURE ESTIMATES CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES

Acute DWLOC	Adults (20–49)	Females (13–49)	Children (1–6 years)	Infants (birth to 1)
No effect level	300	5	300	300
Safety factor	100	100	100	100
RfD	0.3	0.05	0.3	0.3
aPAD	0.3	0.05	0.3	0.3
A) Acute food (mg/kg/day)*	0.046574	0.047942	0.079941	0.171591
B) Residential (mg/kg/day)	0	0	0	0
Water aPAD (A + B)	0.253426	0.002058	0.220059	0.128409
Acute DWLOC (µg/L)	104602.61	1160.64	29673.16	29754.03
DECs: FIRST Surface water (µg/L)	 20.4	 20.4	 20.4	 20.4

TABLE 8.—PYRACLOSTROBIN ACUTE DRINKING WATER EXPOSURE ESTIMATES CONSIDERING ALL CROP USES FOR BOTH CURRENT AND PENDING TOLERANCES—Continued

Acute DWLOC	Adults (20–49)	Females (13–49)	Children (1–6 years)	Infants (birth to 1)
SCI-GROW Groundwater (µg/L)	0.009	0.009	0.009	0.009

* 99.9th percentile.

iii. *Food plus water*. The dietary exposure to pyraclostrobin residues is summarized in tables 9. and 10.

TABLE 9.—ESTIMATED DIETARY EXPOSURE TO PYRACLOSTROBIN RESIDUES FROM FOOD AND WATER CONSIDERING ALL PENDING CROP USES

Exposure	Infants (0–1 years)	Children (1–6 years)	Adults (20–49 years)	Females (13–49 years)
Food:				
Acute exposure (mg/kg bw/day)*	0.170066	0.074864	0.045725	0.046863
Chronic exposure (mg/kg bw/day)	0.001291	0.002644	0.000981	0.000984
%aPAD	56.7	24.9	15.24	93.7
%cPAD	3.8	7.8	2.9	2.9
Water:				
Acute exposure (mg/kg bw/day)	0.00204	0.00136	0.000583	0.000648
Chronic exposure (mg/kg bw/day)	0.0000009	0.000001	0	0
%aPAD	0.68	0.45	0.19	1.3
%cPAD	0	0	0	0
Food + Water:				
Acute exposure (mg/kg bw/day)	0.172106	0.076224	0.046308	0.047511
Chronic exposure (mg/kg bw/day)	0.0012919	0.002645	0.000981	0.000984
%aPAD	57.38	25.35	15.43	95
%cPAD	3.8	7.8	2.9	2.9

* 99.9th percentile.

TABLE 10.—ESTIMATED DIETARY EXPOSURE TO PYRACLOSTROBIN RESIDUES FROM FOOD AND WATER CONSIDERING ALL CURRENTLY REGISTERED AND PROPOSED CROP USES

Exposure	Infants (0–1 years)	Children (1–6 years)	Males (20–49 years)	Females (13–49 years)
Food:				
Acute exposure (mg/kg bw/day)	0.171591	0.079941	0.042017	0.047942
Chronic exposure (mg/kg bw/day)	0.003213	0.006654	0.001813	0.001781
%aPAD	57.2	26.6	14	95.9
%cPAD	9.5	19.6	5.3	5.2
Water:				
Acute exposure (mg/kg bw/day)	0.00204	0.00136	0.000583	0.000648
Chronic exposure (mg/kg bw/day)	0.0000009	0.000001	0	0
%aPAD	0.68	0.45	0.19	1.3
%cPAD	0	0	0	0
Food + Water:				
Acute exposure (mg/kg bw/day)	0.173631	0.081301	0.0426	0.04859
Chronic exposure (mg/kg bw/day)	0.0032139	0.006655	0.001813	0.001781
%aPAD	57.88	27.05	14.19	97.2
%cPAD	9.5	19.6	5.3	5.2

These results indicate that dietary exposure to pyraclostrobin (registered and all proposed crop uses), from potential residues in food and water, will not exceed EPA's level of concern (100% of aPAD or cPAD). Overall, we can conclude with reasonable certainty that no harm will occur from either acute or chronic dietary exposure to pyraclostrobin residues.

2. *Non-dietary exposure*. Pyraclostrobin is currently registered for use on golf course turf. The Agency has evaluated the existing toxicological database for pyraclostrobin and has assessed the appropriate toxicological endpoints and the dose levels of concern for this use. Dermal absorption data indicate that absorption is 14%.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA 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.'' Pyraclostrobin is a foliar fungicide which belongs to the new class of strobilurin chemistry. It is a synthetic analog of strobilurin A, a naturally occurring antifungal metabolite of the mushroom Strobillurus tenacellus. The active ingredient acts in the fungal cell through inhibition of electron transport in the mitochondrial respiratory chain at the position of the cytochrome-bc1 complex. The protective effect is due to the resultant death of the fungal cells by disorganization of the fungal membrane system. Pyraclostrobin also acts curatively to prevent the increase and spread of fungal infections by inhibiting mycelial growth and sporulation on the leaf surface. BAS 500 F inhibits spore germination, germ tube growth, and penetration into the host tissues.

EPA is currently developing methodology to perform cumulative risk assessments. At this time, there are no available data to determine whether BAS 500 F has a common mechanism of toxicity with other substances or to show 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, pyraclostrobin does not appear to produce a toxic metabolite that is also produced by other pesticides.

E. Safety Determination

1. *U.S. population*. Adding the proposed uses to those crops that are already on the pyraclostrobin label resulted in aggregate exposure of adults in the U.S. population to pyraclostrobin that utilized at most 67% of the aPAD and 40% of the cPAD. Therefore, no harm to the overall U.S. population would result from the use of pyraclostrobin on the proposed and existing crop uses.

2. *Infants and children*. All subpopulations based on age were considered. The highest potential exposure was predicted for the subgroup children (1–6 years old). Using the FQPA Safety Factor of 3X when appropriate, the addition of the proposed crops to those on the label would use less than 1% of the aPAD and 89% of the cPAD for children (1–6 years old). BASF therefore concludes that there is reasonable certainty that no harm will result to infants or children from aggregate exposure to pyraclostrobin residues on the proposed and existing crop uses.

F. International Tolerances

Maximum Residue Levels (MRLs) have been established for pyraclostrobin in Canada but no MRLs have been established by the Codex Alimentarius Commission.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0271; FRL–7676–7]

Iodine-potassium iodide; 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–2004–0271, must be received on or before September 27, 2004.

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

FOR FURTHER INFORMATION CONTACT: 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 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–2004–0271. 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