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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. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. 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. Background

A. What Action is the Agency Taking?

The Agency has issued the Reregistration Eligibility Decision (RED) for the herbicide active ingredient oxadiazon. Oxadiazon is registered for pre-emergent herbicide treatment of turf and ornamentals. The oxadiazon risk mitigation included rate reductions and packaging requirements. In addition, aerial applications have been eliminated.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1988, EPA is conducting an accelerated reregistration program to reevaluate existing pesticides to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of the chemical listed in this document is substantially complete, and the pesticide's risks have been mitigated so that it will not pose unreasonable risks to people or the environment when used according to its approved labeling.

All registrants of pesticide products containing the active ingredient listed in this document will be sent the RED, and must respond to labeling requirements and product-specific data requirements (if applicable) within 8 months of receipt. Products also containing other pesticide active ingredients will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing this RED as a final document with a 60–day comment period. Although, the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. If any comment significantly affects the RED, EPA will amend the RED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for the RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: August 14, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–19711 Filed 8–27–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0291; FRL–7676–8]

Pyraclostrobin; Notice of Filing a Pesticide Petition to Increase 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–2004–0291, must be received on or before September 29, 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, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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

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

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0291. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

For public commentors, 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–2004–0291. 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–2004–0291. 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–2004–0291.

3. *By hand delivery or courier*. Deliver your comments to: Public Information

and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0291. 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 theelements 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.

List of Subjects

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

Dated: August 24, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. 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 4F6850

EPA has received a pesticide petition (4F6850) from BASF Corporation, Research Triangle Park, NC, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C 346a (d), to amend 40 CFR 180.582 by increasing the tolerance 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, in strawberry to 1.5 parts per million (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 this petition. Additional data may be needed before EPA rules on the petition.

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 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 GC/MS.

3. *Magnitude of the residue*. Field trials were carried out in order to determine the magnitude of the residue in strawberry using the maximum label rate, the maximum number of applications, and the minimum pre-harvest interval.

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 proposed, an Emulsifiable Concentrate (EC) and an Extruded Granule (EG). The EC has an acute oral toxicity category of II, acute dermal of III, acute inhalation 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 of IV, eye irritation of

III, skin irritation of IV, and is not a dermal sensitizer.

2. *Genotoxicity*—i. Ames Test (one study of point mutation): Negative;

ii. *In vitro* CHO/HGPRT locus mammalian cell mutation assay (one study of point mutation): Negative;

iii. *In vitro* V79 cells CHO cytogenetic assay (one study of chromosome damage): Negative;

iv. *In vivo* mouse micronucleus (one study of chromosome damage): negative; and

v. *In vitro* rat hepatocyte (one study of DNA damage and repair): Negative. 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 above. Therefore, pyraclostrobin does not pose a genotoxic hazard to humans.

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 NOAEL is the highest dose tested (HDT) of 300 ppm (32.6 mg/kg bw/day (milligrams per kilogram bodyweight per day)). Parental and pup toxicity in the form of reduced bodyweight gain were observed at the HDT only. Therefore, the parental systemic and developmental toxicity NOAEL's 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 doses 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 (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 multigeneration 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 U.S. EPA final rule published in the **Federal Register** of September 27, 2002 (67 FR 60886; FRL–7200–7). This analysis included the current registered crops at the approved tolerance values with strawberry at the proposed tolerance of 1.5 ppm.

The acute and chronic dietary exposure estimates were based on established tolerance values (with strawberry at 1.5 ppm), default processing factors, 100% crop treated values, and consumption data from the 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) software.

Result 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 be removed-that is, reduced to 1X for all exposure scenarios. Therefore, the acute Population Adjusted Dose (aPAD) and the chronic Population Adjusted Dose (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. below. The estimated chronic dietary exposure from current registered crops plus strawberry at 1.5 ppm was less than 57% of the cPAD for all subpopulations. Additional refinements such as the use of anticipated residues, processing factors, and percent crop treated values would further reduce the estimated chronic dietary exposure.

TABLE 1.—CHRONIC DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN (BAS 500 F) CONSIDERING ALL CURRENTLY REGISTERED CROP USES AT THE APPROVED TOLERANCE VALUES AND STRAWBERRY AT THE PROPOSED TOLERANCE OF 1.5 PPM

Population Subgroups	Exposure Estimate[1] (mg/kg bw/day)	%cPAD[2]
U.S. Population	0.005574	16.4
All Infants	0.006406	18.8
1-2 years	0.01924	56.6
3-5 years	0.014254	41.9
1-6 years	0.015337	45.1
6-12 years	0.008168	24.0
13-19 years	0.004577	13.5
Females 13-49 years	0.004116	12.1
Adults 20-49 years	0.004086	12.0
Males 20+ years	0.00411	12.1
Adults 50+ years	0.004197	12.3

[1]Exposure estimates are based on tolerance values, default processing factors, and 100% crop treated values

[2]%cPAD = percent of chronic Population Adjusted Dose

The estimated acute dietary exposure (see Table 2.) for all currently registered crops, using the approved tolerance values, plus strawberry at the proposed tolerance of 1.5 ppm, was well below the Agency's level of concern (100% aPAD). The overall general population and the most sensitive subpopulation (females 13-49 years old) utilized <6 and <25% of the aPAD at the 95th percentile, 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, processing factors, and percent crop treated values would further reduce the estimated acute dietary exposure.

TABLE 2.—ACUTE DIETARY EXPOSURE ASSESSMENT FOR PYRACLOSTROBIN (BAS 500 F) CONSIDERING ALL CURRENTLY REGISTERED CROP USES AT THE APPROVED TOLERANCE VALUES AND STRAWBERRY AT THE PROPOSED TOLERANCE OF 1.5 PPM

Population Subgroups	95th Percentile Exposure Estimate[1] (mg/kg bw/day)	% aPAD[2]
U.S. Population	0.017127	5.7
All Infants	0.025157	8.4
1-2 years	0.051777	17.3
3-5 years	0.038115	12.7
1-6 years	0.04298	14.3
7-12 years	0.019884	6.6
13-19 years	0.013618	4.5
Females 13-49 years	0.012147	24.3
Adults 20-49 years	0.011916	4.0
Males 20+ years	0.011594	3.9
Adults 50+ years	0.011803	3.9

[1]Exposure estimates are based on tolerance values, default processing factors, and 100% crop treated values

[2]%aPAD = percent of chronic Population Adjusted Dose

ii. *Drinking water*. There are no established maximum contaminant levels or health advisory levels for residues of pyraclostrobin (BAS 500 F) or its metabolite in drinking water. A tier 1 drinking water modeling assessment for pyraclostrobin using the FIRST model (for surface water) and SCI-GROW model (for groundwater) produced estimated maximum concentrations of 20.4 ppb (acute surface water), 0.79 ppb (chronic surface water), and 0.009 ppb (acute and chronic groundwater). These estimated concentrations are less than worst-case calculated acceptable levels (DWLOC) of pyraclostrobin residues in drinking water based on acute and chronic aggregate exposure. Chronic and acute drinking water exposure estimates and DWLOCs for pyraclostrobin are presented in Tables 3. and 4., respectively.

TABLE 3.—PYRACLOSTROBIN (BAS 500 F) CHRONIC DRINKING WATER EXPOSURE ESTIMATES FOR ALL CURRENTLY REGISTERED 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)	0.004086	0.004116	0.015337	0.006406
B: Residential (mg/kg/day)	0	0	0	0
Water cPAD (A + B)	0.029914	0.029884	0.018663	0.027594
Chronic DWLOC (μg/L)	1.0×10^3	9.0×10^2	3.0×10^2	3.0×10^2
DECs:				
FIRST (EFED) Surface water (μg/L)	0.79	0.79	0.79	0.79
SCI-GROW (EFED) Ground-water (μg/L)	0.009	0.009	0.009	0.009

TABLE 4.—PYRACLOSTROBIN (BAS 500 F) ACUTE DRINKING WATER EXPOSURE ESTIMATES FOR ALL CURRENTLY REGISTERED 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	3	0.05	3	3
aPAD	3	0.05	3	3
A: Acute Food[1] (mg/kg/day)	0.011916	0.012147	0.04298	0.025157
B: Residential (mg/kg/day)	0	0	0	0
Water aPAD (A + B)	2.988084	0.037853	2.95702	2.974843
Acute DWLOC (μg/L)	1.0×10^5	2.0×10^2	3.0×10^4	3.0×10^4
DECs:				
FIRST (EFED) Surface water (μg/L)	20.4	20.4	20.4	20.4
SCI-GROW (EFED) Ground-water (μg/L)	0.009	0.009	0.009	0.009

[1]95th percentile

iii. *Food plus water*. The food plus water exposure to pyraclostrobin residues is summarized in Table 5.

TABLE 5.— ESTIMATED DIETARY EXPOSURE TO PYRACLOSTROBIN RESIDUES FROM FOOD AND WATER CONSIDERING ALL CURRENTLY REGISTERED CROP USES AND FOOD RESIDUES AT THE APPROVED TOLERANCES AND STRAWBERRY AT THE PROPOSED TOLERANCE OF 1.5 PPM

Exposure	Infants (0-1 years)	Children (1-6 years)	Adults (20-49 years)	Females (13-49 years)
Food:				
Acute Exposure (mg/kg bw/day) ..	0.025157	0.04298	0.011916	0.012147
Chronic Exposure (mg/kg bw/day)	0.006406	0.015337	0.004086	0.004116
%aPAD	8.4	14.3	4.0	24.3
%cPAD	18.8	45.1	12.0	12.1
Water:				
Acute Exposure (mg/kg bw/day) ..	0.00204	0.001360	0.000583	0.000648
Chronic Exposure (mg/kg bw/day)	0.0000009	0.000001	0.000000	0.000000
%aPAD	0.680	0.453	0.194	1.295
%cPAD	0.003	0.002	0.001	0.001

TABLE 5.— ESTIMATED DIETARY EXPOSURE TO PYRACLOSTROBIN RESIDUES FROM FOOD AND WATER CONSIDERING ALL CURRENTLY REGISTERED CROP USES AND FOOD RESIDUES AT THE APPROVED TOLERANCES AND STRAWBERRY AT THE PROPOSED TOLERANCE OF 1.5 PPM—Continued

Exposure	Infants (0-1 years)	Children (1-6 years)	Adults (20-49 years)	Females (13-49 years)
Food + Water:				
Acute Exposure (mg/kg bw/day) ..	0.027197	0.044340	0.012499	0.012795
Chronic Exposure (mg/kg bw/day)	0.0064069	0.015338	0.004086	0.004116
%aPAD	9.07	14.78	4.17	25.59
%cPAD	18.84	45.11	12.02	12.11

These results indicate that dietary exposure to pyraclostrobin from potential residues in food and water will not exceed the U.S. EPA's level of concern (100% of PAD). 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) 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 500F inhibits spore germination, germ tube growth, and penetration into the host tissues.

The EPA is currently developing methodology to perform cumulative risk assessments. At this time, there are no available data to determine whether BAS 500F 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 produced by other pesticides.

E. Safety Determination

1. *U.S. population.* Adding the proposed tolerance increase in strawberry to those crops already on the pyraclostrobin label, aggregate exposure to adults in the U.S. population 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 in or on the existing label crops, including with the tolerance increase in strawberry.

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

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

[OPPT–2004–0110; FRL–7676–5]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSC, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from July 13, 2004 to August 6, 2004, consists of the PMNs, pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the docket ID number OPPT–2004–0110 and the specific PMN number or TME number, must be received on or before September 29, 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: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–