C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–34226A in the subject line on the first page of your response.

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

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

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–34226A. Electronic comments may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

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

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

5. Provide specific examples to illustrate your concerns.

6. 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 control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued a RED for the pesticide active ingredient listed in this document. 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 included 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. In addition, EPA is reevaluating existing pesticides and reassessing tolerances under the Food Quality Protection Act (FQPA) of 1996. The pesticide included in this notice also has been found to meet the FQPA safety standard.

All registrants of pesticide products containing the active ingredient triallate have been sent the appropriate 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. All comments will be carefully considered by the Agency. If any comment significantly affects a 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 this 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, Pesticides.

Dated: May 4, 2001.

Lois Rossi,

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

[FR Doc. 01–12903 Filed 5–22–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1020; FRL–6780–7]

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 control number PF–1020, must be received on or before June 22, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1020 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

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

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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

2. *In person*. The Agency has established an official record for this action under docket control number PF–1020. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

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

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

5. Provide specific examples to illustrate your concerns.

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

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the

name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received 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 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: May 3, 2001.

James Jones,

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 petitioners. EPA is publishing the petition summary verbatim without editing it in any way. 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, Agricultural Products

PP 0F6139

EPA has received pesticide petition number 0F6139 from BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709–3528 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for combined residues of BAS 500 F or pyraclostrobin (methyl-N-(((1-(4-chlorophenyl)pyrazol-3-yl)oxy, o-tolyl)N-methoxycarbamate) and its metabolite BF 500-3 (methyl-N-(((1-(4-chlorophenyl pyrazol-3-yl)oxy)o-tolyl)carbamate); expressed as parent compound in or on the raw agricultural commodities almond hulls at 1.6 ppm, banana at 0.04 parts per million (ppm), barley (grain) at 0.4 ppm, barley (hay) at 25 ppm, barley (straw) at 6.0 ppm, berries (crop group) at 1.0 ppm, bulb vegetables (crop group) at 0.7 ppm, citrus fruits (crop group) at 0.7 ppm, cucurbits (crop group) at 0.5 ppm, fruiting vegetables (crop group) at 1.0 ppm, grape at 2.0 ppm, grass seed (seed screenings) at 27 ppm, grass seed (straw) at 14.0 ppm, grass seed (forage) at 10.0 ppm, grass seed (hay) at 4.5 ppm, lentil at 0.5 ppm, orange oil at 4.2 ppm, orange pulp (dry) at 6.3 ppm, peanut at 0.05 ppm, peanut oil at 0.1 ppm, pea (dry, seed) at 0.4 ppm, radish tops at 16.0 ppm, raisin at 6.0 ppm, root vegetables (crop subgroup 1-B) at 0.4 ppm, rye (grain) at 0.04 ppm, rye (straw) at 0.5 ppm), stone fruits (crop group) at 0.7 ppm, strawberry at 0.4 ppm, sugar beet (dry pulp) at 1.6 ppm, sugar beet (root) at 0.2 ppm, sugar beet (top) at 8.0 ppm, tomato paste at 2.0 ppm, tree nuts (crop group) at 0.04 ppm, tuberous and corm vegetables (crop subgroup 1-C) at 0.04 ppm, wheat (grain) at 0.2 ppm, wheat (hay) at 6.0 ppm, wheat (straw) at 6.0 ppm, cattle (fat) at 0.1 ppm, cattle (kidney) at 0.1 ppm, cattle (liver) at 0.6 ppm, cattle (milk) at 0.03 ppm, cattle (muscle) at 0.1 ppm, poultry (egg) at 0.1 ppm, poultry (muscle) at 0.1 ppm, poultry (liver) at 0.1 ppm, poultry (fat) at 0.1 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 sufficency 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 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 BAS 500 F in all crop matrices. BAS 500 F demonstrated a similar pathway and fate in all three crops. In all three crops the BAS 500 F residues of concern were characterized as parent (BAS 500 F) and BAS 500–3.

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 residues*. Field trials were carried out in order to determine the magnitude of the residue in the following crops: almond, banana, barley, carrot, citrus, cucurbits (crop group), peas (dry, field), grape, grass grown for seed, lentil, onions (dry bulb and green), peanut, pecan, peppers (bell and chili), pistachio, potato, radish, berries (crop group), rye, stone fruits, strawberry, sugar beet, tomato and wheat. The residue trials in bananas 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 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: citrus, grape, peanut, potato, stone fruits, sugar beet, tomato, and wheat. Magnitude of the residue trials were also carried out in cow and poultry.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data BAS 500 F and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical BAS 500 F in toxicity category IV for acute oral, category III for acute dermal, and category II for acute inhalation. BAS 500 F is category III for both eye and skin irritation and 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 III, and is not a dermal sensitizer. The WG 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.

TABLE 1.—ACUTE TOXICITY OF TECHNICAL BAS 500 F

Study Type	Species	Results	Toxicity Category
Oral LD_{50}	Rat	LD_{50}*> 5,000 mg/kg bwt	IV

TABLE 1.—ACUTE TOXICITY OF TECHNICAL BAS 500 F—Continued

Study Type	Species	Results	Toxicity Category
Dermal LD_{50}	Rat	LD_{50} > 2,000 mg/kg bwt	III
Inhalation LC_{50}	Rat	0.31 < LC_{50}**< 1.07 mg/L	II
Eye irritation	Rabbit	Slight irritation	III
Skin irritation	Rabbit	Moderate irritation	III
Skin sensitization	Guinea pig	Non-sensitizing	
Acute oral neurotoxicity (0, 100, 300, and 1,000 mg/kg bwt)	Rat	No neurotoxic effects at doses up to 1,000 mg/kg	

*Lethal Dose 50%
**Lethal Concentration 50%

TABLE 2.—ACUTE TOXICITY OF FORMULATED END-USE PRODUCT, BAS 500 00F (HEADLINE EC FUNGICIDE)

Study Type	Species	Results	Toxicity Category
Oral LD_{50}	Rat	LD_{50} > 500 mg/kg bwt (males); 260 mg/kg (200–500 mg/kg) bwt (females)	II
Dermal LD_{50}	Rat	LD_{50} > 4,000 mg/kg bwt	III
Inhalation LC_{50}	Rat	LC_{50} = 3.51 mg/L	IV
Eye irritation	Rabbit	Moderate irritation	III
Skin irritation	Rabbit	Moderate irritation	III
Skin sensitization	Guinea pig	Non-sensitizing	

TABLE 3.—ACUTE TOXICITY OF FORMULATED END-USE PRODUCT, BAS500 02F (CABRIO EG AND INSIGNIA FUNGICIDES)

Study Type	Species	Results	Toxicity Category
Oral LD_{50}	Rat	LD_{50} > 2,000 mg/kg bwt	III

TABLE 3.—ACUTE TOXICITY OF FORMULATED END-USE PRODUCT, BAS500 02F (CABRIO EG AND INSIGNIA FUNGICIDES)—Continued

Study Type	Species	Results	Toxicity Category
Dermal LD_{50}	Rat	LD_{50} > 2,000 mg/kg bwt	III
Inhalation LC_{50}	Rat	LC_{50} = 4.7 mg/L	IV
Eye irritation	Rabbit	Slight irritation	III
Skin irritation	Rabbit	Slight irritation	IV
Skin sensitization	Guinea pig	Non-sensitizing	

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 Cells CHO 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 500 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 500 F did not show any mutagenic, clastogenic or other genotoxic activity when tested under the conditions of the studies mentioned above. Therefore, BAS 500 F does not pose a genotoxic hazard to humans.

TABLE 4.—SUMMARY OF GENOTOXICITY STUDIES ON BAS 500 F

Study	Test Organism	Concentration Range	Results
Gene mutation: Ames reverse mutation assay	*S. typhimurium* strains TA 1535, TA 100, TA 1537 and TA 98; *E. Coli* strain WP2 uvrA; with and without metabolic activation.	20 to 5,000 μg per plate	Negative with and without metabolic activation
Gene mutation: *in vitro* Chinese Hamster Ovary*in vitro* cell study (HGPRT locus)	HGPRT locus of Chinese Hamster Ovary cells, with and without metabolic activation	0.625 to 20 μg/mL*	Negative with and without activation
Chromosomal aberration:*in vitro* cytogenicity	Chinese hamster V79 cells, with and without metabolic activation	0.005 to 25 μg/mL	Negative with and without metabolic activation
Unscheduled DNA synthesis:*in vitro* assay with primary rat hepatocytes	Primary hepatocytes from Wistar rats	0.004 to 1.0 μg/mL	Negative

TABLE 4.—SUMMARY OF GENOTOXICITY STUDIES ON BAS 500 F—Continued

Study	Test Organism	Concentration Range	Results
Cytogenetic study *in vivo*: mousemicronucleus test	NMRI mice	0, 75, 150 and 300 mg/kg bwt	Negative

*micrograms per milliliter

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of BAS 500 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 so the no observed adverse effect level (NOAEL) is the highest dose tested of 300 parts per million (ppm) (32.6 milligrams per kilogram body weight per day (mg/kg bwt/day)). Parental toxicity in the form of reduced body weight gain and pup effects were observed at the highest dose tested only. Pup effects consisted primarily of reduced body weight gain. Most likely due to the small pup size, reduced organ weights were observed in the thymus, spleen and brain of F2 pups, and a slight delay in vaginal opening time was observed in some F1 female pups. Therefore, the parental systemic and developmental toxicity NOAELs are the same at 75 ppm (8.2 mg/kg bwt).

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. There were no treatment-related developmental effects. The maternal NOAEL was 10 mg/kg bwt and the developmental NOAEL was the highest dose tested of 50 mg/kg bwt.

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 not indicative of frank developmental toxicity. The NOAEL for both maternal and developmental toxicity was 5 mg/kg bwt.

TABLE 5.—SUMMARY OF REPRODUCTIVE AND DEVELOPMENTAL STUDIES ON BAS 500 F

Study	NOAEL	LOAEL *	Effects at LOAEL or Higher
Multigeneration rat reproduction: 0, 25, 75, and 300 ppm (0, 2.7, 8.2, and 32.6 mg/kg bwt)	Reproductive function: 32.6 mg/kg bwt (300 ppm); systemic toxicity: 8.2 mg/kg bwt (75 ppm); developmental toxicity: 8.2 mg/kg bwt (75 ppm)	Reproductive function: >32.6 mg/kg bwt (> 300 ppm); systemic toxicity: 32.6 mg/kg bwt (> 300 ppm); developmental toxicity: 32.6 mg/kg bwt (> 300 ppm)	No impairment of reproductive function at any of the dose levels tested. 300 ppm: parental - reduced body weight and food consumption; pups - reduced body weight during lactation with corresponding organ weight changes (F2) and slightly delayed vaginal opening (F1 only)
Rat teratology: 0, 10, 25, and 50 mg/kg bwt	Maternal toxicity: 10 mg/kg bwt; developmental toxicity: 50 mg/kg bwt	Maternal toxicity: 25 mg/kg bwt; developmental toxicity: > 50 mg/kg bwt	No teratogenic effects. 25 mg/kg bwt: maternal effects were decreased body weight gain and decreased food consumption. 50 mg/kg bwt: maternal effects were a severe decrease in body weight gain, and reduced food consumption.
Rabbit teratology: 0, 5, 10, and 20 mg/kg bwt	Maternal: 5 mg/kg bwt; developmental toxicity: 5 mg/kg bwt	Maternal: 10 mg/kg bwt; developmental toxicity: 10 mg/kg bwt	No teratogenic effects. 10 mg/kg bwt: maternal effects were decreased body weight gain and food consumption, and decreased mean gravid uterus weight; developmental effects were increased post-implantation loss due to early resorptions, with subsequent decrease in mean live fetuses per rabbit. 20 mg/kg bwt: maternal effects were severely decreased body weight gain, decreased food consumption, and decreased gravid uterus weight; developmental effects were increased postimplantation loss due primarily to early resorptions.

*Lowest observed adverse effect level

4. *Subchronic toxicity*. The subchronic toxicity of BAS 500 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 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.

In a 90–day rat neurotoxicity study, a direct neurotoxic effect was not observed. The grip strength of forelimbs was statistically significantly decreased in high dose females at the end of the study. This was assessed as being related to the significant body weight impairment at this dose level. This is confirmed by the fact that functional observational batteries and motor activity measurement did not reveal any other signs indicative for neurotoxicity. Moreover, comprehensive microscopic investigation of the central and peripheral nervous system did not reveal any substance-dependent changes. This is outlined in the table.

TABLE 6.—SUMMARY OF SUBCHRONIC STUDIES FOR BAS 500 F

emsp;	NOAEL	LOAEL	Effects at LOAEL or Higher
4–Week dermal rat: 0, 40, 100, and 250 mg/kg bwt	250 mg/kg bwt (systemic)	> 250 mg/kg bwt	Skin irritation at application site; no systemic effects related to treatment
90-Day rat feeding study: 0, 50, 150, 500, 1000 and 1,500 ppm (0, 3.5, 10.7, 34.7, 68.8 and 105.8 mg/kg bwt for males; 0, 4.2, 12.6, 40.8, 79.7,and 118.9 mg/kg bwt for females).	3.5 mg/kg bwt males; 4.2 mg/kg bwt females (equivalent to 50 ppm both sexes)	10.7 mg/kg bwt males; 12.6 mg/kg bwt females (equivalent to 150 ppm both sexes)	Generally mild toxicity at high doses. 150 ppm (LOAEL): decreased absolute liver weight males; increased extramedullary hematopoiesis. ≥ 500 ppm: decreased food consumption and body weight change; leukocytosis; hemolytic anemia males; mild anemia females; decreased serum liver enzymes; increased relative weights of spleen and adrenal gland (both sexes), kidney, testes, brain (males), and liver and ovaries (females); mucosal hyperplasia of duodenum; increased extramedullary hematopoiesis of spleen; hepatocellular hypertrophy.
90-Day mouse feeding study: 0, 50, 150, 500, 1,000, and 1,500 ppm (0, 9.2, 30.4, 119.4, 274.4, and 475.5 mg/kg bwt for males; 0, 12.9, 40.4, 162, 374.1, and 634.8 mg/kg bwt for females)	9.2 mg/kg bwt males; 12.9 mg/kg bwt females (equivalent to 50 ppm for both sexes)	30.4 mg/kg bwt males; 40.4 mg/kg bwt females (equivalent to 150 ppm both sexes)	Generally mild toxicity at high doses. 150 ppm (LOAEL): decreased body weight gain and hematocrit (males); decreased triglycerides and thickening of the duodenum (females). ≥ 500 ppm: decreased body weight change; mild leukopenia; mild hypochromic microcytic anemia; decreased serum protein, globulins, and triglycerides; thickening of the duodenal mucosa.
90–Day Beagle dog feeding study: 0, 100, 200 and 450 ppm (0, 2.8, 5.8, and 12.9 mg/kg bwt males; 0, 3.1, 6.2, 13.6 mg/kg bwt females)	5.8 mg/kg bwt males; 6.2 mg/kg bwt females (equivalent to 200 ppm for both sexes)	12.9 mg/kg bwt males; 13.6 mg/kg bwt females (equivalent to 450 ppm both sexes)	Generally mild toxicity at high doses. 450 ppm (LOAEL): Decreased food consumption (females); slight body weight loss and diarrhea; decreased serum protein, albumin, and globulins; increased platelets (females); hypertrophy in duodenum.
90-Day rat feeding neurotoxicity study 0, 50, 250, 750 - males, 0, 50, 250 and 1500 ppm - females (0, 3.5, 16.9, 49.9 mg/kg bwt - males; 0, 4.0, 20.4, 49.9 and 119.9 mg/kg bwt - females)	Systemic: 3.5 mg/kg bwt (50 pm) - males; 20.4 mg/kg bwt (250 ppm)- females	Systemic: 16.9 mg/kg bwt (250 ppm) - males; 49.9 mg/kg bwt (750 ppm) - females	250 ppm (males): Reduced food and water consumption.

5. *Chronic toxicity*. The following are summaries of chronic toxicity studies submitted to EPA.

BAS 500 F was administered to groups of five male and five 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 bwt/day males; 5.4 mg/kg bwt/day females).

For the chronic toxicity portion of the rat study, BAS 500 F was administered to groups of 20 male and 20 female Wistar rats at dietary concentrations of 0, 25, 75, and 200 ppm for 24 months. For the carcinogenicity portion of the rat study, BAS 500 F 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. The results of a 2–year chronic toxicity study and a 2–year carcinogenicity study in rats indicate that a maximum tolerated dose was clearly met at the high dose of 200 ppm (ca. 9 mg/kg bwt males and 12 mg/kg bwt females). This is demonstrated by a body weight gain depression of 10–11% in males and 14–22% in females. 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 BAS 500 F 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 bwt/day males; 4.6 mg/kg bwt/day females).

BAS 500 F 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. The high dose body weight gain decreases of 27% in females and 29% in males exceeded that required for a maximum tolerated dose. No other signs of toxicity were noted at any dose level. The NOAEL was found to be 120 ppm (ca. 20.5 mg/kg bwt/day) for females and 30 ppm (ca. 4.1 mg/kg bwt/day) for males. There was no evidence that BAS 500 F produced a carcinogenic effect in mice.

6. *Carcinogenicity*. There were no tumors associated with treatment observed in either a 2–year rat oncogenicity study or in an 18–month mouse oncogenicity study. Based on EPA Proposed Guidelines For Carcinogen Risk Assessment, BASF believes that BAS 500 F will be classified as ''not likely'' to be carcinogenic to humans. Under the current assessment method, BASF believes that EPA will classify BAS 500 F as Group E '(evidence of noncarcinogenicity to humans).

TABLE 7.—SUMMARY OF CHRONIC TOXICITY/ONCOGENICITY STUDIES ON BAS 500 F

Study	NOAEL	LOAEL	Comments
12–Month beagle dog feeding study: 0, 100, 200 and 400 ppm (0, 2.8, 5.5 and 10.8 mg/kg bwt males; 2.7, 5.4, 11.2 mg/kg bwt females)	5.5 mg/kg bwt males; 5.4 mg/kg bwt females (200 ppm both sexes)	10.8 mg/kg bwt males; 11.2 mg/kg bwt females (400 ppm both sexes)	Generally mild toxicity. 400 ppm: decreased body weight gain (initially in males and throughout study in females); decreased food consumption (females); diarrhea; decreased serum total protein, albumin, globulins, and cholesterol; increased platelets; increased white blood cells (males).
18-Month mouse oncogenicity study: 0, 10, 30, and 120 ppm males (1.4, 4.1, and 17.2 mg/kg bwt); 0, 10, 30, 120 and 180 ppm females (1.6, 4.8, 20.5, 32.8 mg/kg bwt)	4.1 mg/kg bwt males (30 ppm); 20.5 mg/kg bwt females (120 ppm)	17.2 mg/kg bwt males (120 ppm); 32.8 mg/kg bwt females (180 ppm)	Generally mild toxicity. No treatment-related tumors. 120 ppm: decreased body weight and body weight change (males). 180 ppm (females only): Decreased body weight and body weight change.
24-Month chronic toxicity study in Rats: 0, 25, 75, and 200 ppm (0, 1.1, 3.4, and 9.0 mg/kg bwt males; 0, 1.5, .4.6 and 12.3 mg/kg bwt females)	3.4 mg/kg bwt males; 4.6 mg/kg bw females (75 ppm both sexes)	9.0 mg/kg bwt males; 12.3 mg/kg bwt females (200 ppm both sexes)	Generally mild toxicity. 200 ppm: decreased body weight and body weight change; decreased serum alkaline phosphatase (both sexes) and alanine aminotransferase (males)
24-month carcinogenicity study in rats: 0, 25, 75 and 200 ppm (0, 1.2, 3.4, and 9.2 mg/kg bwt males; 0, 1.5, 4.7, and 12.6 mg/kg bw females)	3.4 mg/kg bwt males; 4.7 mg/kg bwt females (75 ppm both sexes).	9.2 mg/kg bwt males; 12.6 mg/kg bwt females (200 ppm both sexes)	Generally mild toxicity. No treatment-related tumors. 200 ppm: decreased body weight gain (both sexes); decreased food consumption (males); increased liver cell necrosis.

7. *Animal metabolism*. In hens the residues of concern were determined to be parent compound and a hydroxlated metabolite, BAS 500–16. In goats the residues of concern were determined to be parent and a hydroxylated metabolite BAS 500–10.

8. *Metabolite toxicology*. A comparison of the rat metabolism results with the plant metabolism/residue results indicate that toxicology studies performed with the parent compound are sufficient to cover dietary exposure. Therefore, no specific toxicity studies were conducted on metabolites of this compound.

9. *Endocrine disruption*. No specific tests have been conducted with BAS 500 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 multigeneration reproductive studies) which would suggest that BAS 500 F produces endocrine-related effects.

10. *Threshold effects*. Based on a review of the available chronic toxicity data, BASF believes EPA will establish the Reference Dose (RfD) for BAS 500 F at 0.04 mg/kg/day. This RfD for BAS 500 F is based on the 2–year chronic and 2–year oncogenicity studies in rats with a threshold average NOAEL of 4 mg/kg/day for males and females. Using an uncertainty factor of 100, the RfD is calculated to be 0.04 mg/kg/day. Based on the acute toxicity data, BASF believes that 500 F does not pose any dietary risks.

11. *Non-threshold effects*. There were no tumors associated with treatment observed in either a 2–year rat oncogenicity study or in an 18–month mouse oncogenicity study. Based on

EPA Proposed Guidelines For Carcinogen Risk Assessment, BASF believes that BAS 500 F will be classified as ''not likely'' to be carcinogenic to humans. Under the current assessment method, BASF believes that EPA will classify BAS 500 F as Group E (evidence of noncarcinogenicity to humans).

C. Aggregate Exposure

BASF believes that pyraclostrobin does not pose any acute dietary risks, so an acute exposure analysis is not necessary. Based on a review of the available chronic toxicity data, BASF believes EPA will base the chronic RfD for pyraclostrobin on the 2–year chronic and 2–year oncogenicity studies in rats, which had an average threshold NOAEL of 4 mg/kg/day for males and females. BASF further believes that EPA will use an uncertainty factor of 100 and establish the RfD at 0.04 mg/kg/day. The following table expresses the results of the chronic aggregate analysis of exposure to pyraclostrobin. This analysis is discussed further below.

TABLE 8.—SUMMARY OF CHRONIC AGGREGATE EXPOSURE TO BAS 500 F

	U.S. Population (% of RfD)	Children 1–6 (% of RfD)
Chronic dietary exposure	5%	10%
Residential exposure*	2.5%	12.5%
Total RfD used by diet and residential exposure	7.5%	22.5%
Remainder of RfD available for water (%) (Drinking Water Level of Concern)	92.5%	77.5%
SCIGROW modelground water estimation**	<1%	<1%
GENEEC model (56 d) surface water estimation**	<1%	<1%
Total of RfD used by diet, water and residential	7.5%	77.5%

*Acute values used as worst case
**Used highest values predicted from the model for all agricultural uses; assumes 2 liters/day consumed and 60 kg bwt for adults and 1 liter/day and 10 kg bwt for children

1.*Dietary exposure*— i. *Food*. For purposes of assessing the potential dietary exposure, BASF has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from the proposed tolerances for BAS 500 F.

A Tier 1 worst case estimate of dietary exposure was conducted assuming that 100% of all crops for which tolerances are established are treated and that pesticide residues are always found at the tolerance levels. The TMRC from the proposed uses of BAS 500 F on all crops is 0.002 mg/kg bwt/day and utilizes 5% of the RfD for the overall U.S. population. The exposure of the most highly exposed subgroup in the population, children (1–6 years old), is 0.004 mg/kg bwt/day and utilizes 10% of the RfD.

The following table summarizes the mean dietary exposures and the percents of RfD occupied by these exposures.

TABLE 9.—SUMMARY OF CHRONIC DIETARY EXPOSURE TO BAS 500 F—(DRES (DIETARY RISK EVALUATION SYSTEM))

Group	µg/kg body weight/day	%RfD
U.S. population	2.004	5
All infants (<1 year old)	2.260	6
Children 1–6 years old	4.144	10
Children 7–12 years old	2.092	5
Females 13–50 years old	1.338	3

ii. *Drinking water*. Estimates of ground water levels and surface water levels were determined using the Screening Concentration in Groundwater (SCIGROW) and Generic Estimated Environmental Concentration (GENEEC) models, respectively. The drinking water levels of concern (DWLOCs) for chronic exposure are obtained by subtracting the chronic dietary food exposures and residential exposures from the RfD, as outlined in Table 10.

TABLE 10.—PERCENTAGES OF REFERENCE DOSE FOR CHRONIC WATER EXPOSURE TO BAS 500 F

	U.S. Population (% of RfD)	Children 1–6 (% of RfD)
Chronic dietary exposure	5%	10%
Residential exposure*	2.5%	12.5%
Total RfD used by diet and residential	7.5%	22.5%
Remainder of RfD available for water (%) (Drinking Water Level of Concern)	92.5%	77.5%
SCIGROW ground water estimation**	<1%	<1%
GENEEC (56 d) surface water estimation**	<1%	<1%

TABLE 10.—PERCENTAGES OF REFERENCE DOSE FOR CHRONIC WATER EXPOSURE TO BAS 500 F—Continued

	U.S. Population (% of RfD)	Children 1–6 (% of RfD)
Total of RfD used by diet, water and residential	7.5%	77.5%

*Acute values used as worst case

** Used highest values predicted from the model for all agricultural uses; Assumes 2 liters/day consumed and 60 kg bwt for adult and 1 liter/day and 10 kg bwt for child

The SCIGROW and GENEEC estimates of ground and surface water levels for BAS 500 F are well below the DWLOC. Overall, using worst-case parameters the predicted aggregate exposure by all potential routes for both adults and children is less than the chronic referencedose.

2. *Non-dietary exposure.* BAS 500 F is planned for use on residential lawns. Acute exposure was estimated using data from a BAS 500 F turf transferable residue (TTR) study, a dermal penetration of 2.6% and default values from the EPA Standard Operating Procedures for residential exposure. For adults, the exposure estimate of 0.001 mg/kg bwt/day is equivalent to only 2.5% of the chronic reference dose. Estimation of exposure of children includes dermal contact on the lawn plus oral ingestion via fingers in the mouth, grass and dirt. Using the worst-case EPA defaults, the acute exposure result is estimated to be 0.005 mg/kg bwt/day which is 12.5% of the chronic Reference Dose.

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 500 F 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* (Anke et. al., 1977). 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. BAS 500 F 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 is no available data to determine whether BAS 500F 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 500 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 500 F will utilize 5% of the RfD for the U.S. population. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to BAS 500 F, including anticipated dietary exposure and non-occupational exposures.

2. *Infants and children.* A developmental study was conducted via oral gavage in rats with dosages of 0, 10, 25, and 50 mg/kg bwt/day with a maternal NOAEL of 10 mg/kg bwt/day and a developmental NOAEL of 50 mg/kg bwt/day. No evidence of developmental toxicity was observed up to the highest dose tested. These NOAELs are higher than the NOAEL of 4 mg/kg bwt/day from the chronic rat study used to establish the RfD.

A developmental study was conducted via oral gavage in rabbits with dosages of 0, 5, 10, and 20 mg/kg bwt/day. The NOAEL for both maternal and developmental toxicity was 5 mg/kg bwt/day. No teratogenic effects were observed at any dose level, and the only developmental effect observed was an increase in postimplantation loss at doses which produced maternal toxicity. These NOAELs are higher than the NOAEL of 4 mg/kg bwt/day from the chronic ratstudy used to establish the RfD.

A 2–generation reproduction study in rats was conducted with dosages of 0, 2.7, 82, and 32.6 mg/kg bwt/day. The NOAELs are 32.6 mg/kg bwt/day (highest dose tested) for reproductive function and 8.2 mg/kg bwt/day for parental and developmental toxicity. No impairment of reproductive function was noted at any dose level. At the high dose reduced parental body weight gains were accompanied by reduced pup weights and corresponding reduced pup organ weights (F2 only) and slightly delayed vaginal opening (F1 only). The slight delay in vaginal opening was most likely due to the smaller pups and corresponding delay in physical development. These NOAELs are higher than the NOAEL of 4 mg/kg bwt/day from the chronic rat study used to establish the RfD.

Based on these results, no additional safety factors to protect children are warranted. Since developmental and reproductive toxicity occurs at levels above the levels shown to exhibit parental toxicity and since these levels are higher than those used to calculate the RfD, BASF believes the RfD of 0.04 mg/kg/day (4 mg/kg/day and an Uncertainty Factor of 100) is an appropriate measure of safety for infants and children.

Dietary exposure of the most highly exposed subgroup in the population, children (1–6 years old) is 0.004 mg/kg bwt/day. This accounts for 10% of the RfD. Worst case default predictions indicate that residential uses of BAS 500 F will amount to 12.5% of the RfD and that contamination of drinking water is extremely small and amounts to <1% of the reference dose. Aggregate exposure of children (1–6 years old) amounts to 22.5% of the RfD. In addition, there were no significant findings in relevant toxicity studies (i.e., subchronic and chronic toxicity, teratology, and multi-generation reproductive studies) which would suggest that BAS 500 F produces endocrine-related effects.

Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to BAS 500 F, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Tolerances

A maximum residue level (MRL) has not been established for BAS 500 F in any crop by the Codex Alimentarius Commission.

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