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–2003–0100. 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–2003–0100. 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–2003–0100.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0100. 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.

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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 registration activity.
7. Make sure to submit your comments by the deadline in this notice.
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. Registration Applications

EPA received an application as follows to register a pesticide product containing a new active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

Product Containing an Active Ingredient Not Included in Any Previously Registered Product

1. *File Symbol:* 67979–U. *Applicant*: Syngenta Seeds, 3054 Cornwallis Road, Research Triangle Park, NC 27709. *Product name*: VIP3A. *Type of product:* Plant-incorporated protect. *Active ingredient*: *Bacillus thuringiensis* VIP3A control protein as expressed in Event COT102 cotton plants. *Proposed classification/Use*: None. For insect control on plants.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: May 29, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Division, Office of Pesticide Programs.

[FR Doc. 03–14326 Filed 6–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0194; FRL–7310–4]

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 ID number OPP–2003–0194, must be received on or before July 11, 2003.

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

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division

(7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@epamail.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 categories and entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in 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. *EPA Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0194. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and to Whom Do I Submit Comments?

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

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

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2. Describe any assumptions that you used.

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

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

5. Provide specific examples to illustrate your concerns.

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

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

II. What Action is the Agency Taking?

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

List of Subjects

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

May 28, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

BASF Corporation

PP 3F6568

EPA has received a pesticide petition (PP 3F6568) from BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of (3-(4,5-dihydro-isoxazol-3-yl)-4-methanesulfonyl-2-methylphenyl)-(5-hydroxyl-1-methyl-1H-pyrazol-4-yl)methanone in or on the raw agricultural commodities: Corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernal plus cob with husks removed; corn, sweet, stover; cattle, kidney; cattle, liver; goat, kidney; goat, liver; hog, kidney; hog, liver; horse, kidney; horse, liver; sheep, kidney; and sheep, liver at 0.05; 0.01; 0.05; 0.01; 0.05; 0.05; 0.01; 0.05; 0.02; 0.70; 0.20; 0.70; 0.20; 0.70; 0.20; 0.70; 0.20; and 0.70 parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of BAS 670 H (3-(4,5-dihydro-isoxazol-3-yl)-4-methanesulfonyl-2-methylphenyl)-(5-hydroxyl-1-methyl-1H-pyrazol-4-yl)methanone) was determined in corn forage, stover and grain using 14_C labeled materials applied to young corn plants at an exaggerated application rate of 0.134 lb active ingredient/acre. BAS 670 H and

one significant metabolite, M670H05, were found in low levels in the plant matrices with the majority of the radioactive residues incorporated into natural products. M670H05 resulted from oxidation of the carbonyl bridge to a carboxylic acid with concomitant loss and breakdown of the pyrazole ring. The significant metabolite M670H05 was found in the rat metabolism study.

2. *Analytical method*. Suitable independently validated analytical methods (for crop and animal matrices) are submitted for detecting and measuring BAS 670 H levels in or on food with a limit of detection that is satisfactory for enforcing the requested tolerances. Residues are first extracted from the matrices by aqueous solvent then cleaned up by acid partitioning into organic solvent, then base partitioned, and quantified with application to high performance liquid chromatography with dual mass selective detectors (LC/MS/MS).

3. *Magnitude of residues*. Field studies were conducted at 30 sites over 2 years with sites selected to fulfill both EPA and Canadian Pest Management Regulatory Agency (PMRA) requirements. The end product, BAS 670 00H, was applied broadcast over corn plants in two applications at 25 g active ingredient/ha (0.022 lb a.i./acre) + 75 g a.i./ha (0.067 lb a.i./acre) for a total of 100 g a.i./ha (0.089 lb a.i./acre) with the final application targeted for 45 days before milk stage. Samples of field corn were harvested at the milk stage to cover sweet corn harvest timing. All matrices were analyzed for parent and M670H05 with the limit of quantitation (LOQ) setting the proposed tolerances. No residues were detected above the LOQ in any of the corn RAC samples analyzed (fresh corn, forage, grain, and stover). To determine the fate of any BAS 670 residues in processed grain, the field study incorporated an exaggerated 5x application rate. No residues above LOQ were detected in the 5x treated grain samples; therefore, the analyses of the grain processed fractions was not required. The cow feeding study at three dosing levels show that food tolerances for parent in only kidney and liver matrices are necessary (and not for any other matrices such as meat, fat, and milk).

B. Toxicological Profile

1. *Acute toxicity—i.* Oral (rat): $(LD)_{50}$ = >2,000 milligrams/kilogram body weight (mg/kg bwt) (male/female) = Category III.

ii. Dermal (rat): $(LD)_{50}$ = >2,000 mg/kg bwt (male/female) = Category III.

iii. Inhalation (rat): $(LC)_{50}$ = >5.8 milligrams/per liter (mg/L) (male/female) = Category IV.

iv. Primary eye irritation (rabbit): Slightly irritating = Category III.

v. Primary dermal irritation (rabbit): Slightly irritating = Category III.

vi. Dermal sensitization (guinea pig): Not a sensitizer.

vii. Oral neurotoxicity (rat): NOAEL = 2,000 mg/kg bwt (male/female).

2. *Genotoxicty*. BAS 670 H was tested for its genotoxic potential in a battery of five *in vitro* or *in vivo* studies covering all required end-points (gene mutations, chromosomal and chromosome aberrations, and DNA damage and repair). Several batches of BAS 670 H have been tested over the time, from early laboratory produced material to current manufacturing process material. BAS 670 H did not demonstrate any genotoxic effects *in vivo*. *In vitro*, either batches tested for chromosomal aberrations caused a slight, significant clastogenic effect in the presence of S-9 mix, but the *in vivo* test for the equivalent end-point was negative. Three of the four batches tested in the bacterial reverse mutation assay were not mutagenic, but, the batch with the least purity displayed a weak mutagenic effect at the highest dose in *Salmonella typhimurium* TA98 in the absence of S-9 mix, most likely caused by impurities, which are not present in the current production batch. Overall, the weight of the evidence is that BAS 670 H is not genotoxic.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of BAS 670 H was investigated in a 2-generation rat reproduction study as well as in rat, mouse and several rabbit teratology studies (with different batches of BAS 670 H) and a rat developmental neurotoxicity study.

There were no adverse effects on fertility of both genders and no effect on the reproductive performance of males in the two-generation study at any dose tested. There was, however, a high litter loss in F_0 and F_1 associated with insufficient maternal care at higher dose levels with clear maternal toxicity. General parental toxicity included eye and kidney effects, caused by elevated tyrosine levels due to hydroxyphenylpyruvate dioxygenase (HPPD) inhibition. The same organs were affected in subchronic and chronic feeding studies with rats. Pup effects were observed in the F_1 and F_2 generation including perinatal pup mortality and impaired body weight gain, the lower body weight effects were considered to lead to brain and spleen weight changes and delays in preputial separation. As observed in the parental animals, effects on eyes and kidneys were observed in the pups. Renal pelvis dilation was observed at lower doses, although, there was no overt maternal toxicity, significantly elevated tyrosine levels were observed in the dams and pups. The no observed adverse effect level (NOAEL) for fertility (F_0 and F_1, both genders) was 4,000 ppm (about 450 mg/kg bwt/day); the NOAEL for reproductive performance was 40 ppm (about 4 mg/kg body weight/day) for the F_1 females. The NOAEL for general toxicity was 4 ppm (about 0.4 mg/kg bwt/day). The NOAEL for developmental toxicity (growth and development of the offspring) was 4 ppm (about 0.4 mg/kg body weight/day) for the F_1 pups, but was lower than 4 ppm for the F_2 pups due to renal pelvis dilations at all dose levels.

Developmental neurotoxicity was not observed at any dose in the developmental neurotoxicity study. At all dose levels, eye effects due to elevated tyrosine levels were found in dams and pups. Additionally, there were decreased body weights in the dams at the high and mid dose, but there were no indications of adverse effects on reproductive performance of the parental females. In pups of both genders, decreased preweaning and postweaning body weight gains and body weights were observed at the low dose level and above. This is an indicator of a retardation of the general physical development, which is considered to be responsible for a slight delay of maturation. The NOAEL for developmental neurotoxicity was 800 mg/kg bwt/day (highest dose tested). There is no NOAEL for the eye lesions and reduced body weight gain of the pups. NOAELs for these effects were determined in prenatal development studies in rats, rabbits and mice.

No developmental toxicity was noted in the mouse prenatal development study. In the prenatal development study in rats no teratogenic effect was observed, but there was maternal toxicity together with skeletal variations in the pups. The same skeletal variation (i.e. supernumerary ribs) was also found in rabbit prenatal development studies. This effect is associated with the family of HPPD inhibiting substances. In addition, several rabbits had pups with a soft tissue malformation: unilateral kidney agenesis. The NOAEL for the skeletal variations and the kidney agenesis was 0.5 mg/kg bwt/day, the NOAEL for overt maternal toxicity was 50 mg/kg bwt/day. The developmental effects in rabbits occurred at dose-levels below overt maternal toxicity; however, measured tyrosine blood levels in the

dams were substantially elevated at these dose levels. Elevated tyrosine levels are known to cause kidney toxicity.

4. *Subchronic toxicity.* The subchronic toxicity of BAS 670 H was investigated in 90–day feeding studies in rats, mice and dogs, and in a 28–day dermal administration study in rats. Several supplemental short-term mechanistic studies in rats and mice were performed to elucidate the mode of action. Generally, very mild toxicity was observed in mice and dogs at high doses. In a combined neurotoxicity 90–day feeding study in rats, no signs of neurotoxicity were observed. Effects were seen in the pancreas, eye, kidney, liver, and thyroid gland. The target organs are identical with those in the chronic feeding studies with rats.

Two modes of action have been elucidated for BAS 670 H by short-term mechanistic studies, one leading to effects on eyes, kidney and liver, and a second leading to effects at the thyroid: BAS 670 H causes elevated tyrosine levels by HPPD inhibition accounting for effects on eye, liver and kidney. The mouse is the accepted model for this tyrosine level elevations, and a NOAEL of 1.2 mg/kg bwt/day was established for tyrosine elevation in mice. Other mechanistic studies demonstrated an impairment of pituitary-thyroid hormone levels by enhancing the hepatic clearance of thyroid hormones. The NOAEL for interference with thyroid hormones was 0.4 mg/kg bwt/day. The NOAEL for effects on the exocrine pancreas in rats was 1.1 mg/kg/bwt/day. Similar effects were seen in the 28–day dermal study with rats; the NOAEL was 100 mg/kg bwt/day.

5. *Chronic toxicity.* The chronic toxicity and oncogenicity studies with BAS 670 H include two 12–month feeding studies with dogs, an 18–month mouse feeding study, a 12–month rat chronic feeding study and a 24–month rat oncogenicity study. In the chronic dog study, mild reductions of the body weight were observed at high doses. The NOAEL was 100 ppm (2.9 and 3.1 mg/kg bwt/day in males and females respectively).

In the 18–month chronic feeding study in mice, increased liver weights were seen at high doses. The NOAEL was 80 ppm (19 and 26 mg/kg bwt/day in males and females respectively). BAS 670 H was not carcinogenic to mice. In the chronic feeding studies in rats, the main target organs were eye, liver, kidney, thyroid gland, and pancreas. The same organs were affected in the subchronic studies. Short-term mechanistic studies demonstrated that BAS 670 H causes elevated tyrosine levels by HPPD inhibition accounting for effects on the eye, liver and kidney. The mouse is the accepted model for this tyrosine level elevation, and a NOAEL of 1.2 mg/kg bwt/day was established for tyrosine elevation in mice. The NOAEL for effects on the exocrine pancreas in rats 6 ppm in both genders (0.4 and 0.5 mg/kg bwt/day in males and females respectively). At the end of the 24–month oncogenicity study, there was a slight but significant increase in benign thyroid adenomas in both genders. The thyroid was the only organ affected and the increase of the adenomas was significant only at the highest dose tested, while considerable general toxicity was already seen at 20–times lower doses. The mechanism of thyroid tumor formation by BAS 670 H was thoroughly investigated in short-term mechanistic studies. An enhanced hepatic clearance of thyroid hormones impairs pituitary-thyroid hormone levels leading to hypertrophy, hyperplasia and ultimately neoplasia. There is general agreement, that this mechanism is well understood in rodents and is of minor relevance to humans. A clear NOAEL of 0.4 mg/kg bwt/day was demonstrated for effects on thyroid hormone levels. A threshold (non-linear) cancer assessment is proposed and a cancer classification as ''not likely to be a human carcinogen.''

6. *Animal metabolism.* In the rat metabolism studies, the majority of the residue was excreted within 48 hours from both males and females. In all matrices investigated unchanged parent is the main component. Degradation starts with hydroxylation of the oxazole ring. The identified metabolites from both pyrazole ring label and phenyl ring label studies are reported. Goat and hen metabolism studies were conducted with feeding levels of about 10 ppm. In the goat, the majority of the applied dose was excreted. Non-metabolized BAS 670H was the major radioactive residue, and M670H02, formed from hydroxylation at the 4-position of the isoxazole ring, was the only significant metabolite formed. In poultry BAS 670 F was also rapidly excreted. Residues in liver consisted mainly of BAS 670H, and the only significant metabolite in poultry was again M670H02. The significant metabolite M670H02 was found in the rat metabolism study.

7. *Metabolite toxicology.* Toxicity of the metabolites of BAS 670 H with potential exposure to humans was concurrently evaluated during toxicity testing of the parent, because both plant and animal metabolites are formed during the course of toxicity testing. Both plant and animal metabolites are considered not of toxicological concern. Some testing was conducted on the anaerobic aquatic metabolite, 670M10. The results as given below show no toxicological concern:

- Bacterial reverse mutation test (Ames): No effect = negative.
- Mammalian somatic cell gene mutation test (MNT): No effect = negative.
- Cytogenetic study *in vivo* (mouse HPRT): No effect = negative.
- 28–Day feeding study (rat): NOAEL 1,197 mg/kg bwt/day and 1,304 mg/kg bwt/day (male and female, respectively).

8. *Endocrine disruption.* BAS 670 H has been shown to alter thyroid hormone levels in rats as also observed with other 4-hydroxyphenylpyruvate dioxygenase enzyme inhibitor active ingredients. However, there have been no effects noted on sexual or other hormones in numerous subchronic and chronic toxicity studies with multiple species.

C. Aggregate Exposure

1. *Dietary exposure.* A chronic population adjusted dose (cPAD) of 0.00044 mg/kg/day is proposed. This cPAD is based on a lowest observed adverse effect level (LOAEL) of 0.4 mg/kg/day for pup renal pelvis dilation in the 2-generation rat reproduction study with an extra 3X uncertainty factor for using the LOAEL (rather than a NOAEL) plus a 3X Food Quality Protection Act (FQPA) factor on top of the standard 100X uncertainty factor. So the total uncertainty factor is 900 (3 x 3 x 100), and the cPAD is calculated as 0.4/900 = 0.00044.

An acute dietary population adjusted dose (aPAD) is proposed as 0.0013 mg/kg/day. This aPAD is based upon a NOAEL of 0.4 mg/kg/day obtained in the rat thyroid hormone study and a 3X FQPA uncertainty factor on top of the standard 100 (0.4/300 = 0.0013).

BAS 670 H has been shown to be non-carcinogenic in mice, but was associated with an increase in thyroid follicular cell tumors at high doses in the rat. These tumors have been shown to develop by a non-genotoxic mode of action, in fact they were the consequence of induced changes of thyroid hormone levels. Therefore BAS 670 H should be classified as ''not likely to be a human carcinogen.''

i. *Food.* Exposure estimates were compared against the cPAD and aPAD of 0.0013 mg/kg bwt/day and 0.004 mg/kg bwt/day, respectively. Results of the chronic dietary exposure assessments demonstrated that even with the worst-case assumptions (residues at tolerance level and 100% crop treated), the estimated chronic dietary exposure was

less than 12.5% of the cPAD for the total U.S. population and all the subpopulations. The greatest exposure occurred in infants and children. Exposure estimates for the acute dietary assessment were well under 100% of the acute population adjusted dose (aPAD) at the 99th percentile. The overall U.S. population and the highest exposed subpopulation (infants <1 year) utilized only 5.3% and less than 21%, respectively.

ii. *Drinking water.* There are no established maximum contaminant levels or health advisory levels for residues of BAS 670 H or its metabolites in drinking water. A tier 1 drinking water modeling assessment for BAS 670 H using the FIRST model (for surface water) and SCI-GROW (for ground water) produced estimated maximum concentrations of 0.22 parts per billion (ppb) (chronic) for surface water and 0.20 ppb for ground water. These estimated concentrations are less than a worst case calculated acceptable level of 3.95 ppb children chronic drinking water levels of concern (DWLOC) for residues in drinking water based on chronic aggregate exposure. Therefore, taking into account all uses and exposures one concludes, with reasonable certainty that residues of BAS 670 H in drinking water will not result in unacceptable levels of aggregate human health risk at this time.

2. *Non-dietary exposure.* There are no registered or proposed residential uses for BAS 670 H.

D. Cumulative Effects

At this time, there is no available information to indicate that BAS 670 H or its metabolites have a common mechanism of toxicity with other substances. Therefore, there is no reason to include this pesticide or its metabolites in a cumulative risk assessment. For the purposes of this tolerance action, EPA has not assumed that BAS 670 H and its metabolites have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Aggregate exposure to the overall U.S. population utilized only 8.7% of the aPAD and 12.7% of the cPAD, respectively. Therefore, no harm to the overall U.S. population would result from the use of BAS 670 H on field, sweet, or pop corn.

2. *Infants and children.* There is a complete toxicity base for BAS 670 H and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Taking into account the completeness of the data base, BASF Corporation concludes that the FQPA safety factor should be retained but reduced to 3X. This is based on the occurrence of kidney malformations in rabbits and skeletal variations in rabbits and rats, all occurring at doses, which caused either maternal tyrosine elevations or other evidence of maternal toxicity. The full toxicological data base that has been developed for BAS 670 H includes many additional mechanistic studies, revealing consistency and the mode of action of these effects. The kidney was a target organ in all repeated dose studies and these effects were caused by elevated tyrosine levels due to inhibition of the HPPD enzyme. Using the standard worst case exposure assumptions (residues at tolerance level and 100% crop treated), aggregate exposure to BAS 670 H from food and water will utilize 33% and less than 24% of the aPAD and cPAD, respectively for infants and children. EPA generally has no concern for exposures below 100% of the PAD because it represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. BASF Corporation concludes that there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to BAS 670 H residues with the approval of this tolerance petition.

F. International Tolerances

No maximum residue levels (MRLs) have been established for BAS 670 H by the CODEX Alimentarius Commission or in Mexico.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0177; FRL–7308–7]

Acetic Acid; Notice of Filing a Pesticide Petition to Establish an Exemption from the Requirements of 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 ID number OPP–2003–0177, must be received on or before July 11, 2003.

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

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address:*benmhend.driss@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–2003–0177. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket