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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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 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 an 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

File Symbol: 67979–L. *Applicant*: Syngenta Seeds, Inc., Field Crops-NAFTA, P.O. Box 12257, 3054 Cornwallis Rd., Research Triangle Park, NC 27709–2257. *Product Name*: Event MIR604 Rootworm-Protected Corn. Plant-incorporated protectant. *Active ingredient*: Modified Cry3A protein and the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn SYN-IR604-8.*Proposed classification/Use*: None.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: October 13, 2004.

Phil Hutton,

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

[FR Doc. 04–23691 Filed 10–26–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0273; FRL–7676–1]

BAS 320 I; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2004–0273, must be received on or before November 26, 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: Ann Hanger, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0395; e-mail address: *hanger.ann@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–2004–0273. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment

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

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

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

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

C. How and To Whom Do I Submit Comments?

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

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

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0273. 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–2004–0273. 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–2004–0273.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0273. 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?

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

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: October 19, 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 FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BASF Corporation

Pesticide Petition 4F6839

EPA has received a pesticide petition (PP 4F6839) 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 BAS 320 I, a mixture comprising 4-{(2E)-2-({[4-(trifluoromethoxy)anilino] carbonyl} hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl} benzonitrile and 4-{(2Z)-2-({[4-(trifluoromethoxy)anilino] carbonyl} hydrazono)-2-[3-(trifluoromethyl) phenyl]ethyl} benzonitrile in or on the raw agricultural commodity tuberous and corm vegetables (crop subgroup 1–C) at 0.05 parts per million (ppm), leafy vegetables (crop group 4) at 35 ppm, head and stem brassica (crop subgroup 5–A) at 5 ppm, leafy brassica greens (crop subgroup 5–B) at 25 ppm, fruiting vegetables (crop group 8) at 1.0 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* In three plant metabolism studies (cabbage, tomato and cotton), the major component of the residue was BAS 320 I (E- and Z-isomers). The major degradate was the ketone, M320I04 and an oxidized and cyclized metabolite, M320I23, was present in lesser amounts. These four compounds were defined as the residues of concern and were incorporated into an analytical method. In the confined rotational crop studies plant uptake was very limited and the residues were a mixture of minor and polar components.

2. *Analytical method.* BASF Analytical Method No. 531/0 was developed to determine residues of BAS 320 I (E- and Z-Isomer) and its metabolites M320I04 and M320I23, the residues of concern in plants, in crop matrices. In this method, residues of BAS 320 I are extracted from plant matrices with methanol/water (70:30; v/v) and then partitioned into dichloromethane. For oily matrices, the residues are extracted with a mixture of isohexane/acetonitrile (1:1; v/v). The final determination of BAS 320I and its metabolites is performed by LC/MS/MS.

3. *Magnitude of residues.* Field trials were carried out in order to determine the magnitude of residue in the following crops: Broccoli, cabbage, celery, head lettuce, leaf lettuce, mustard greens, pepper (bell and non-bell), potato, spinach, and tomato. Field trials were conducted in the required regions. Field trials were carried out using the maximum label rate, the maximum number of applications and the minimum preharvest interval. In addition, processing studies were conducted on potatoes and tomatoes to determine the concentration factor during normal processing of the raw agricultural commodities. No animal feeding studies were conducted.

B. Toxicological Profile

1. *Acute toxicity*. Based on the available acute toxicity data BAS 320 I and its formulated product do not pose acute toxicity risks.

FOR TECHNICAL BAS 320 I:

Oral LD50	Rat	Lethal dose $_{50}$ (LD_{50} > 5,000 milligrams/kilogram body weight (mg/kg b.w.)	Category IV

FOR TECHNICAL BAS 320 I:—Continued

Oral LD_{50}	Mouse	LD_{50} > 5,000 mg/kg b.w.	Category IV
Dermal LD_{50}	Rat	LD_{50} > 5,000 mg/kg b.w.	Category IV
Inhalation LC_{50}	Rat	>5.2 mg/liters (L)	Category IV
Eye irritation	Rabbit	Not irritating	Category IV
Skin irritation	Rabbit	Not irritating	Category IV
Skin sensitization (Maximization test)	Guinea pig	Not sensitizing	

FOR THE BAS 320 00 I SC FORMULATION:

Oral LD_{50}	Rat	LD_{50}> 2,000 mg/kg b.w.	Category III
Dermal LD_{50}	Rat	LD_{50}> 4,000 mg/kg b.w.	Category III
Inhalation LC_{50}	Rat	>5.2 mg/L	Category IV
Eye irritation	Rabbit	Slightly irritating	Category III
Skin irritation	Rabbit	Not irritating	Category IV
Skin sensitization (Modified Buehler Method)	Guinea pig	Not sensitizing	

2. *Genotoxicty.* In a battery of three *in vitro* and two *in vivo* mutagenicity assays consisting of all required end-points (point mutation, chromosomal damage, and DNA damage and repair), the weight of the evidence for BAS 320 I indicates a lack of potential genotoxicity.

Specifically, for the battery of three *in vitro* mutagenicity assays with BAS 320 I, no positive responses were observed for increased revertant frequencies with and without metabolic activation bacterial reverse mutation assay or for increased mutant frequencies with and without metabolic activation Hypoxanthine guanine phophoribosyl transferase (HGPRT) locus assay. Although there was a positive result for a statistically increased number of structurally aberrant metaphases in the chromosomes, which indicates clastogenic potential under *in vitro* conditions, this result was only observed without metabolic activation cytogenicity study with V79 cells.

Importantly, the potential biological significance of this apparent chromosome damage observed *in vitro* only without metabolic activation, was evaluated *in vivo* using the mouse micronucleus assay. Testing in the *in vivo* micronucleus study with NMRI mice was conducted at a high dose level (2,000 mg/kg b.w.) that demonstrated clinical symptoms of toxicity, including piloerection and poor general state, in 5 of 5 animals. No significant or dose-related increases in chromosomal damage were observed in this *in vivo* test, indicating that BAS 320 I does not cause chromosomal aberrations in intact animals.

Moreover, it has also been recognized by EPA that more weight should be placed on *in vivo* systems than *in vitro* systems as expressed in the Agency's weight of evidence for genotoxic evaluation of a chemical included in the ''*Guidelines for Mutagenicity Risk Assessment*'' (**Federal Register**, September 24, 1986, Vol. 51: 34006–34012). Thus, the negative *in vivo* results (non-clastogenicity for chromosomal aberrations) observed in the mouse micronucleus assay and the rat hepatocytes assay, should override the positive results obtained in the *in vitro* assay only without metabolic activation. Furthermore, it has been noted that *in vitro* systems may simulate abnormal physiological conditions from prolonged exposure to a chemical in the absence of S–9 metabolic activation (Brusick, D.J. (editor) 1987. *Genotoxicity Produced in Cultured Mammalian Cell Assay by Treatment Conditions.* Mutation Research, Vol. 189, No.1: 1–69 and Sofuni, T. 1993. *Japanese Guidelines for Mutagenicity Testing.* Environmental and Molecular Mutagenesis, Vol. 21, No.1: 2–7). Consequently, based on the weight of the evidence presented above, BAS 320 I does not pose a genotoxic concern.

3. *Reproductive and developmental toxicity.* Potential reproductive toxicity of BAS 320 I was investigated in a 2–generation reproduction toxicity study in Wistar rats by oral gavage administration. Originally, the highest dose tested (HDT) by oral gavage was 75 mg/kg b.w./day, which induced both excessive maternal toxicity (very high incidences of poor general health in females during premating, gestation, and lactation; and statistically decreased food consumption, body weights, and body weight gain) as well as excessive developmental toxicity (statistically impaired pup body weights and body weight gain), which altogether resulted in high pup mortality. Consequently, a meaningful assessment of the potential reproductive toxicity of the test compound at this excessively toxic dose level was not possible. Thereafter, for the next two successive parental generations of rats, which were originally derived from the parents treated at 75 mg/kg b.w./day, the HDT was 50 mg/kg b.w./day.

Subsequently, the no observable adverse effect level (NOAEL) for parental toxicity was 20 mg/kg b.w./day, based on the following effects for females at 50 mg/kg b.w./day (HDT for two consecutive generations) –

increased incidences of poor general health in females during premating, gestation, and lactation; 3 of 25 dams with complete litter losses; and statistically significantly reduced body weights during premating, gestation, and lactation.

The NOAEL for offspring/pup toxicity was 20 mg/kg b.w./day, based on a slight increased incidence of pup mortality at 50 mg/kg b.w./day. Whereas the NOAEL for fertility in this study was 50 mg/kg b.w./day (HDT for two generations), the NOAEL for reproductive performance was considered to be 20 mg/kg b.w./day, based on 3 of 25 dams with complete litter losses, of which 2 of these 3 dams had indications of poor nursing for their first generation of pups. It is noteworthy that because most of the pup mortality was due to poor nursing in only 2 of 25 dams, this finding may be considered to be incidental. Importantly, no comparable impairment of reproductive performance occurred for the succeeding parental generation treated by oral gavage administration at 50 mg/kg b.w./day.

In a developmental (teratology) toxicity study in the Wistar rat, the results indicated that the NOAEL for maternal toxicity was 40 mg/kg b.w./day, based on statistically decreased food consumption and body weight gains at 120 mg/kg b.w./day (HDT). The NOAEL for fetal (prenatal)/developmental toxicity was 120 mg/kg b.w./day (HDT). In addition, there were no indications of any teratogenic effects in the rat fetuses at 120 mg/kg b.w./day (HDT). Therefore, BAS 320 I is considered to be neither a developmental toxicant nor a teratogenic agent in the rat.

In a developmental (teratology) toxicity study in the Himalayan rabbit, the results indicated that the NOAEL for maternal toxicity was 100 mg/kg b.w./day, based on several clinical symptoms of toxicity (including ataxia and poor general state) occurring in 4 of 25 does at 300 mg/kg b.w./day, for which 2 of these 4 does had abortions prior to being sacrificed early, with a third doe at 300 mg/kg b.w./day being sacrificed moribund. Similarly, the NOAEL for fetal (prenatal)/developmental toxicity was 100 mg/kg b.w./day, based on slightly decreased mean fetal body weights as well as an increased rate for a certain skeletal variation, namely incomplete ossification of sternabrae. Because developmental toxicity was only observed at dose levels that were maternally toxic, BAS 320 I is not selectively toxic to the fetal rabbit.

Lastly, in this rabbit developmental toxicity study, there were no indications of any teratogenic effects in the rabbit fetuses at 300 mg/kg b.w./day (HDT). Therefore, BAS 320 I is not teratogenic in the rabbit.

4. *Subchronic toxicity.* In the Sprague-Dawley rat, treatment by oral gavage with BAS 320 I for a subchronic duration (90–day timepoint in the chronic toxicity/carcinogenicity study) resulted in reduced food consumption and/or decreased mean body weight and/or body weight gains in males and females at 300 mg/kg b.w./day and in increased incidences of hepatocellular centrilobular hypertrophy in the livers of males at 300 mg/kg b.w./day. Under the conditions of the study, the NOAEL for oral administration of BAS 320 I for 90 days was 60 mg/kg b.w./day.

In the beagle dog, treatment by oral gavage with BAS 320 I for a subchronic duration (90–day timepoint in the chronic toxicity study) resulted in reduced body weight gain and/or decreased food consumption in several dogs at 30 mg/kg b.w./day and slightly decreased mean cell hemoglobin concentration (MCHC) at 30 mg/kg b.w./day. Under the conditions of the study, the NOAEL for oral administration of BAS 320 I for 90 days was 12 mg/kg b.w./day.

Lastly, in a subchronic (90–day) dermal toxicity study conducted with BAS 320 I technical in Wistar rats, the results support a NOAEL of 100 mg/kg b.w./day, based on decreased food consumption (females) and decreased body weight change in males and females at 300 mg/kg b.w./day, the next HDT.

5. *Chronic toxicity.* In the Sprague-Dawley rat, treatment by oral gavage with BAS 320 I for a 2–year chronic duration resulted in dose-related increased incidences of hepatocellular centrilobular hypertrophy in the livers of males and females at 60 mg/kg b.w./day and at 300/200 mg/kg b.w./day and hepatocellular basophilic alteration in males at 60 and 300 mg/kg b.w./day. (Note: Beginning the first day of Week 3, the dose level of the high-dose females was lowered from 300 to 200 mg/kg b.w./day, due to an adverse effect of –71% decreased body weight gain as compared to controls.)

Therefore, the NOAEL for systemic toxicity following oral administration of BAS 320 I for 24 months to Sprague-Dawley rats was 30 mg/kg b.w./day for males and females. Importantly, treatment with BAS 320 I to rats for 2 years resulted in no test substance-related neoplastic findings, and therefore, the NOAEL for oncogenicity was 300/200 mg/kg b.w./day (HDT).

In the CD–1 mouse, treatment by oral gavage with BAS 320 I for an 18–month chronic duration resulted in a treatment-related increased incidence of increased brown pigment in the spleens of male and female animals administered 1,000 mg/kg b.w./day (HDT), as compared to controls. Under the conditions of the study, the NOAEL for systemic toxicity following oral administration of BAS 320 I for 18 months to CD–1 mice was 250 mg/kg b.w./day (the next HDT) for males and females. Importantly, treatment with BAS 320 I to mice for 18 months resulted in no test substance-related neoplastic findings, and therefore, the NOAEL for oncogenicity was 1,000 mg/kg b.w./day (HDT).

In the beagle dog, treatment via gelatin capsules with BAS 320 I for a 12–month chronic duration resulted in reduced body weight gain and/or decreased food consumption in several dogs at 30 mg/kg b.w./day and slightly decreased mean MCHC at 30 mg/kg b.w./day. Under the conditions of the study, the NOAEL for oral administration of BAS 320 I for 12 months was 12 mg/kg b.w./day.

i. *Threshold effect.* For estimated chronic exposure, the calculation of the chronic reference dose (chronic RfD) is based on the results of the chronic toxicity studies in the rat, mouse, and dog, and the two–generation reproduction study in the rat. For BAS 320 I, the lowest NOAEL for chronic toxic effects is 12 mg/kg b.w./day from the 12–month dog study. A safety factor of 100 is applied to the NOAEL of 12 mg/kg b.w./day, which results in a chronic RfD of 0.12 mg/kg b.w./day.

ii. *Non threshold effect.* Since there were no test substance-related neoplastic findings following long-term treatment with BAS 320 I to mice for 18 months or to rats for 24 months, the NOAEL for oncogenicity in both studies was established at the respective HDT. Therefore, BAS 320 I should be classified as ''not likely to be a human carcinogen.''

6. *Animal metabolism.* In the rat and goat metabolism studies, the majority of the dose was rapidly excreted in the feces. The low levels that were absorbed were distributed throughout various tissues. BAS 320 I was the major component of the extractable residues in all tissues and milk and is the only residue of concern. Metabolism of BAS 320 I occurs by hydroxylation and conjugation on either of the phenyl rings or at the ethylene bridge and are the major routes of detoxification. Cleavage of the semicarbazide bond to yield M320I04 also occurs, usually with accompanying conjugation. The only residue of concern is BAS 320 I.

7. *Metabolite toxicology.* Toxicity of the metabolites of BAS 320 I with potential exposure to humans was concurrently evaluated during toxicity testing of the parent except for the metabolite M320I23 that was not observed in the rat metabolism study. The Z-isomer (M320I02) of BAS 320 I was evaluated in additional toxicity tests to confirm no differences between the minor Z-isomer component and BAS 320 I technical with a 9 to 1 E-isomer to Z-isomer ratio, respectively. The results show no toxicological concerns:

i. *Toxicity studies with the metabolite M320I23*.

• Acute toxicity study with metabolite M 320I023

• The metabolite M 320I023 of BAS 320 I technical demonstrates low acute toxicity via the oral route of exposure in the rat.

• Oral LD_{50} > 2,000 mg/kg b.w. (category III).

ii. *Subchronic toxicity study with metabolite M 320I023*.

In the Sprague-Dawley rat, treatment by oral gavage with metabolite M 320I023 of BAS 320 I technical for a subchronic (90–day) duration resulted in systemic toxicity effects of increased relative liver weights (females) and increased incidences of liver hepatocellular centrilobular hypertrophy in males and females at 1,000 mg/kg b.w./day (HDT), as compared to controls. Under the conditions of the study, the NOAEL for oral administration of the metabolite M 320I023 of BAS 320 I for 90 days was 200 mg/kg b.w./day (next HDT) in males and females.

iii. *Mutagenicity/Genotoxicity studies with metabolite M 320I023*.

In a battery of three *in vitro* and one *in vivo* mutagenicity assays consisting of all required end-points (point mutation, chromosomal damage, and DNA damage and repair), the weight of the evidence for the metabolite M 320I023 (parent ketone) of BAS 320 I technical indicates a lack of potential genotoxicity.

Specifically, for the battery of three *in vitro* mutagenicity assays with metabolite M 320I023 of BAS 320 I technical, no positive responses were observed for increased revertant frequencies with and without metabolic activation bacterial reverse mutation assay or for increased mutant frequencies with and without metabolic activation HGPRT locus assay. Although there was a positive result for a statistically increased number of structurally aberrant metaphases in the chromosomes, which indicates clastogenic potential under *in vitro* conditions, this result was only observed with metabolic activation cytogenicity study with V79 cells.

Importantly, the potential biological significance of this apparent chromosome damage observed *in vitro* only with metabolic activation, was evaluated *in vivo* using the mouse micronucleus assay. Testing in this *in vivo* micronucleus study with NMRI mice was conducted at a high dose level (2,000 mg/kg b.w.), that demonstrated no clinical symptoms of toxicity but which represents the limit dose for this assay. No significant or dose-related increases in *in vivo* chromosomal damage were observed, indicating that the metabolite M 320I023 of BAS 320 I technical does not cause chromosomal aberrations in intact animals.

Moreover, it has also been recognized by U.S. EPA that more weight should be placed on *in vivo* systems than *in vitro* systems as expressed in the Agency's weight of evidence for genotoxic evaluation of a chemical included in the ''Guidelines for Mutagenicity Risk Assessment'' (**Federal Register**, September 24, 1986, Vol. 51: 34006–34012). Thus, the negative *in vivo* results (non-clastogenicity for chromosomal aberrations) observed in the mouse micronucleus assay should override the positive results obtained in the *in vitro* assay only with metabolic activation. Furthermore, it has been noted that *in vitro* systems may simulate abnormal physiological conditions (Brusick, D.J. (editor) 1987. *Genotoxicity Produced in Cultured Mammalian Cell Assay by Treatment Conditions*. Mutation Research, Vol. 189, No.1: 1–69). Additionally, it has been reported in the literature that S–9 metabolic activation does not often have adequate cofactors for activating detoxifying mechanisms found in the whole animal system Ashby, J. 1983. *The Unique Role of Rodents in The Detection of Possible Human Carcinogens and Mutagens*. Mutation Research, Vol. 115: 117–213 Galloway, S.M. 1994. *Chromosome Aberrations Induced In Vitro: Mechanisms. Delayed Expression, and Intriguing Questions*. Environmental and Molecular Mutagenesis, Vol. 23, Supplement 24: 44–53. Consequently, based on the weight of the evidence presented above, the metabolite M 320I023 of BAS 320 I technical does not pose a genotoxic concern.

Therefore, as indicated from the results of the mammalian toxicity studies as well as the mutagenicity assays, metabolite M 320I023 of BAS 320 I does not demonstrate more adverse toxicity when compared to the BAS 320 I.

iv. *Toxicity studies with the Z-Isomer of technical BAS 320 I*.

• Acute toxicity study with Z-Isomer. The Z-isomer of BAS 320 I technical demonstrates low acute toxicity via the oral route of exposure in the rat.

• Oral LD_{50} > 5,000 mg/kg b.w. (category IV).

v. *Subchronic toxicity study with Z-Isomer*. In the Sprague-Dawley rat, treatment by oral gavage with the Z-isomer of BAS 320 I for a subchronic (90–day) duration resulted in impaired body weight gain only in females at the mid-dose (300 mg/kg b.w./day) and the high-dose (1,000 mg/kg b.w./day), as compared to controls. Several microscopic changes were observed in female animals at these two dose levels, but all morphologic changes were regarded to be indirect effects of the impaired body weight gain. Under the conditions of the study, the NOAEL for oral administration of the Z-isomer of BAS 320 I for 90 days was 1,000 mg/kg b.w./day (HDT) in males and 100 mg/kg b.w./day (lowest dose tested) in females.

vi. *Mutagenicity/Genotoxicity study with Z-Isomer.* In an *in vitro* mutagenicity assay with the Z-isomer of BAS 320 I, there were no positive responses observed for increased revertant frequencies with and without metabolic activation bacterial reverse mutation assay.

Therefore, as indicated from the results of the mammalian toxicity studies as well as the mutagenicity assay, the minor isomer of BAS 320 I, namely the Z isomer, does not demonstrate more adverse toxicity when compared to BAS 320 I. 8. Endocrine disruption. Data from the reproduction / developmental toxicity and short- and long-term repeated dose toxicity studies with BAS 320 I in the rat, rabbit, mouse, or dog, do not suggest any endocrine disruption activity. This information is based on the absence of any treatment-related effects from the histopathological examination of reproductive organs as well as a low level of concern for possible effects on fertility, reproductive performance, or any other aspect of reproductive function, or on growth and development of the offspring.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Assessments were conducted to evaluate the potential risk due to acute and chronic dietary exposure of the U.S. population to residues of BAS 320 I. This insecticide and its metabolites (M320I04, M320I23) were expressed as the parent compound (BAS 320 I). The dietary analysis was conducted on all proposed crops which include potatoes, sweet potatoes, yams, leafy greens subgroup, leaf petioles subgroup, head &

stem brassica subroup, leafy brassica greens subgroup, and fruiting vegetables except cucurbits.

Secondary residues from meat, milk, and eggs were not included in this assessment since the proposed crops are only considered for human consumption with the exception of processed potato commodities being potentially utilized in animal feed. Animal feeding studies were not required on potatoes based on results of residues of BAS 320 I and its metabolites (M320I04 and M320I23) in unwashed potatoes. Following an application rate 18 times the proposed seasonal rate, residues in potatoes were at or below the limit of quantitation (LOQ) and thus the proposed tolerance level was set at the LOQ and no feeding studies were needed.

The acute and chronic dietary exposure estimates were based on the proposed tolerance values, 100 percent crop treated values, concentration/processing factors 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 BAS 320 I acute Population Adjusted Dose (aPAD) and chronic Population Adjusted Dose (cPAD) of 20 mg/kg b.w./day and 0.12 mg/kg b.w./day, respectively. Exposure estimates for the BAS 320 I acute dietary assessment were well under 100% of the aPAD at the 99.9th percentile (see table below). The overall U.S. population and the highest exposed subpopulation (all infants) used only 1.16% and 3.26% of the aPAD, respectively. Additional refinements including the use of anticipated residues and predicted percent crop treated would further reduce the acute exposure estimates.

ACUTE DIETARY EXPOSURE ESTIMATES FOR BAS 320 I

Population Subgroups	Exposure Estimate (mg/kg b.w./day)	%aPAD[1]
U.S. population	0.231788	1.16
All infants	0.651674	3.26
1–2 years	0.607989	3.04
3–5 years	0.424105	2.12
1–6 years	0.444105	2.22
6–12 years	0.269403	1.35
13–19 years	0.153397	0.77
Females 13–49 years	0.212264	1.06
Adults 20–49 years	0.210816	1.05
Males 20+ years	0.190737	0.95
Adults 50+ years	0.183849	0.92

[1] 99.9th percentile

Results of the chronic dietary assessments are listed in the table below. The estimated chronic dietary exposure was less than 14.5% of the cPAD for all subpopulations. Additional refinements such as the use of anticipated residues and predicted percent crop treated would further reduce the estimated chronic dietary exposure.

CHRONIC DIETARY EXPOSURE ESTIMATES FOR BAS 320 I

Population subgroups	Exposure Estimate (mg/kg b.w./day)	%cPAD
U.S. population	0.014905	12.4
All infants	0.007363	6.1
1–2 years	0.016032	13.4
3–5 years	0.016745	14.0
1–6 years	0.016241	13.5
6–12 years	0.014179	11.8
13–19 years	0.012417	10.3
Females 13–49 years	0.015466	12.9
Adults 20–49 years	0.015226	12.7
Males 20+ years	0.014347	12.0
Adults 50+ years	0.015557	13.0

ii. *Drinking water*. Drinking water level of comparison (DWLOC) calculation and comparison to surface water and ground water estimations are given in the tables below. The expected environmental concentrations (EEC) for both ground water and surface water are well below the allowable level.

ESTIMATED ACUTE DRINKING WATER VALUES FOR BAS 320 I

DWLOC acute	Adult Males (20–49 years)	Adult Females (13–49 years)	Children (1–6 years)	Children (birth to 1 year)
DWLOC acute (µg/L)	696138.8	596355.81	197403.28	196273.27
DEC's				
PRZM/EXAMS (BASF) Surface water (µg/L)	0.85	0.85	0.85	0.85
Sci-Grow (BASF) Ground water (µg/L)	0.006	0.006	0.006	0.006

ESTIMATED CHRONIC DRINKING WATER VALUES FOR BAS 320 I

DWLOC chronic	Adult Males (20–49 years)	Adult Females (13–49 years)	Children (1–6 years)	Children (birth to 1 year)
DWLOC chronic (µg/L)	3904.9150	3329.5500	1101.1200	1156.8500

ESTIMATED CHRONIC DRINKING WATER VALUES FOR BAS 320 I—Continued

DWLOC chronic	Adult Males (20–49 years)	Adult Females (13–49 years)	Children (1–6 years)	Children (birth to 1 year)
DEC's				
PRZM/EXAMS (BASF) Surface water (μg/L)	0.04	0.04	0.04	0.04
Sci-Grow (BASF) Ground water (μg/L)	0.006	0.006	0.006	0.006

iii. *Aggregate exposure (Diet + Water).* The acute and chronic aggregate exposure of BAS 320 I residues is summarized in the table below.

ESTIMATED AGGREGATE EXPOSURE OF BAS 320 I RESIDUES FROM FOOD AND WATER

Exposure	Infants (0–1 year)	Children (1–6 years)	Males (20–49 years)	Females (13–49 years)
FOOD[1]				
Acute exposure (mg/kg b.w./day)	0.651674	0.444105	0.190737	0.212264
Chronic Exposure (mg/kg b.w./day) %aPAD %cPAD	0.007363 3.26 6.14	0.016241 2.22 13.5	0.014347 0.95 12.0	0.015466 1.06 12.9
WATER				
Acute exposure (mg/kg b.w./day)	0.000085	0.000057	0.000024	0.000027
Chronic exposure (mg/kg b.w./day) %aPAD %cPAD	0.00000400 0.0004 0.0033	0.000003 0.0003 0.0022	0.000001 0.0001 0.0010	0.000001 0.0001 0.0011
AGGREGATE				
Acute exposure (mg/kg b.w./day)	0.651759	0.444162	0.190761	0.212291
Chronic exposure (mg/kg b.w./day) %aPAD %cPAD	0.007367 3.26 6.14	0.016244 2.22 13.5	0.014348 0.95 12.0	0.015467 1.06 12.9

[1] 99.9th percentile

These results indicate the aggregate exposure of BAS 320 I from potential residues in food and water, will not exceed the U.S. EPA's level of concern (100% of PAD). The percent acute and chronic PAD were < 4 and 14% for all subpopulations, respectively. Overall, considering a ''worst-case'' scenario, we can conclude with reasonable certainty that no harm will occur from either acute or chronic aggregate exposure of BAS 320 I residues from the proposed uses.

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.''

The EPA is currently developing methodology to perform cumulative risk assessments. At this time, there is no available data to determine whether BAS 320 I has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment

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 the aggregate exposure to BAS 320 I will utilize less than 2% and 14% of the aPAD and cPAD for the U.S. population, respectively. For the highest exposed age-related subpopulation the maximum aggregate exposure is predicted to be less than 3.5% of the aPAD (infants) and 15% of the cPAD (3–5 years).

2. *Infants and children.* All subpopulations based on age were considered. Infants and children remained below 3.5 and 15% of the aggregate aPAD and cPAD for food and water, respectively. BASF, considering a worst-case situation, concludes with reasonable certainty that no harm will result to infants or children from aggregate exposure to BAS 320 I residues.

No additional FQPA safety factor(s) are considered to be appropriate for BAS 320 I, for the following reasons: There is a complete toxicity database for BAS 320 I and the exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is no evidence of susceptibility following in utero exposure to rats and there is a low level of concern for any uncertainties in the developmental toxicity study in rabbits or the 2–generation reproduction study,

after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment. Based on these data and conclusions, a FQPA safety factor of 1X appears to be appropriate for BAS 320 I.

F. International Tolerances

No Maximum residue levels (MRLs) have been established for BAS 320 I by the Codex Alimentarius Commision (CODEX) or in Canada and Mexico.

[FR Doc. 04–24039 Filed 10–26–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0224; FRL–7370–1]

Modified Cry3A Protein mCry3A and the Genetic Material Necessary for its Production in Corn; 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, entified by docket identification (ID) number OPP–2004–0224, must be received on or before November 26, 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: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@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–2004–0224. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

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

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

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are