F. Safety Determination

1. *U.S. population*. The use of products containing yeast extract hydrolysate, which lacks toxicity and is used in such low concentrations, is compatible with EPA's objectives to register reduced risk pesticides. Based on its lack of toxicity and the fact that yeast extracts are already present in the diet, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to residues of yeast extract hydrolysate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Yeast extract hydrolysate is applied at low rates and with its lack of toxicity and its history of safe use, it does not pose a safety concern.

2. *Infants and children*. Based on the lack of toxicity of yeast extract hydrolysate, there is a reasonable certainty that no harm to children or adults will result from aggregate exposure to yeast hydrolysate. Exempting yeast extract hydrolysate from the requirement of a tolerance should pose no significant risk to humans.

G. Effects on the Immune and Endocrine Systems

Yeast extract hydrolysate is a naturally occurring biochemical. To date there is no evidence to suggest that yeast extract hydrolysate functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

H. Existing Tolerances

There are no existing tolerances for yeast extract hydrolysate in the United States.

I. International Tolerances

There are no known approved Codex maximum residue levels established for residues of yeast extract hydrolysate.

[FR Doc. 03–19916 Filed 8–5–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0240; FRL–7319–3]

Cyromazine; Notice of Filing of Pesticide Petitions 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 pesticide petitions 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–2003–0240, must be received on or before September 5, 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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:

- Industry (NAICS 111, 112, 311, 32532), e.g., Crop production, Animal production, Food manufacturing, and 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 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–2003–0240. 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 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–2003–0240. 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–2003–0240. 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–2003–0240.

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–2003–0240. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

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

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

5. Provide specific examples to illustrate your concerns.

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

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

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding 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: July 28, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions were 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.

Interregional Research Project Number 4 (IR-4)

PP 2E6507 and PP 2E6510

EPA has received pesticide petitions (PP 2E6507 and PP 2E6510) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.414 by establishing tolerances for residues of cyromazine, (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on the following raw agricultural commodities: Leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 parts per million (ppm) (2E6507), garlic, bulb; garlic great-headed, bulb; onion, dry bulb; rakkyo, bulb; and shallot, bulb at 0.2 ppm (2E6507), vegetable brassica, leafy, group 5, except broccoli at 10 ppm (2E6510), broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10 ppm, and kidney of cattle, goats, hogs, horses, and sheep at 0.2 ppm, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm (2E6510). IR-4 also proposed that tolerances for residues of cyromazine in or on dry bulb onion at 2.0 ppm and green onion at 0.1 ppm established under 40 CFR 180.414(a) and Chinese cabbage and Chinese mustard at 3.0 ppm established under 40 CFR 180.414(c) be deleted when the proposed tolerances are established. Chinese cabbage and Chinese mustard are included in the Brassica leafy vegetable group. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This summary has been prepared by the Syngenta Crop Protection Incorporated.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of cyromazine in plants is adequately understood for the purposes of these tolerances.

2. *Analytical method*. Methods AG-408 and AG-417 as listed in the Food and Drug Administration's Pesticide Analytical Manual (PAM), Vol-II are adequate to enforce the proposed tolerances.

3. *Magnitude of residues*. Residue field tests were conducted in typical growing regions for Brassica and bulb vegetables and turnip tops. The data collected support the proposed tolerances of 10.0 ppm for Brassica leafy vegetables, 10.0 ppm for turnip tops and 3.0 ppm for bulb vegetables.

B. Toxicological Profile

1. *Acute*. A rat acute oral toxicity study with a lethal dose $(LD)_{50}$ of approximately 3,387 milligrams/kilogram (mg/kg) (toxicity category III; moderately toxic). A rat acute dermal toxicity study with a LD_{50} greater than 3,100 mg/kg (toxicity category III; moderately toxic). A rat acute inhalation study with a lethal concentration $(LC)_{50}$ greater than 2.9 mg/kg (toxicity category IV; slightly toxic). A primary eye irritation study in the rabbit that showed no eye irritation. A primary dermal irritation study in the rabbit that showed mild irritation (toxicity category; IV). A dermal sensitization study in the guinea pig that showed no sensitization.

2. *Genotoxicity*. Studies on gene mutation and other genotoxic effects showed no evidence of point mutation in an Ames test; no indication of mutagenic effects in a dominant lethal test; and no evidence of mutagenic effects in a nucleus anomaly test in Chinese hamsters.

3. *Reproductive and developmental toxicity*. In a rat developmental toxicity study, the maternal no observed adverse effect level (NOAEL) was 100 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) was 300 mg/kg based on decreased body weight gain and clinical observations. The developmental NOAEL was 300 ppm. The developmental LOAEL was 600 mg/kg based upon an increase of minor skeletal variation.

In a rabbit developmental toxicity study, the maternal NOAEL was 10 mg/kg. The maternal LOAEL was 30 mg/kg based upon decreased body weight gain and food consumption. The developmental NOAEL/LOAEL was greater than or equal to 60 mg/kg.

In a multi-generation study in rats, the systemic NOAEL was 30 ppm (1.5 mg/kg). The systemic LOAEL was 1,000 ppm (50 mg/kg) based upon decreased body weights associated with decreased food consumption. The developmental/offspring systemic NOAEL was 1,000 ppm. The developmental/offspring systemic LOAEL was 3,000 ppm (150 mg/kg) based upon decreased body weight at birth through weaning. There were no effects on reproductive parameters at the highest dose tested (HDT) (3,000 ppm).

4. *Subchronic toxicity*. In a 6–month feeding study in dogs, the NOAEL was 30 ppm (0.75 mg/kg). The LOAEL was 300 ppm (7.5 mg/kg) based upon decreased hematocrit and decreased hemoglobin. Groups of male and female beagle dogs (4/sex/dose) were fed diets containing cyromazine at 0, 30, 300, or 3,000 ppm (0, 0.75, 7.5, or 75 mg/kg/day, respectively) for 6–months. No treatment-related effects were observed in survival, clinical signs or body weight parameters. Pronounced effects on hematologic parameters were manifested as decreases in hematocrit and hemoglobin levels at 300 and 3,000 ppm.

5. *Chronic toxicity*. In a 24–month feeding study in rats the NOAEL for the study was 30 ppm (1.5 mg/kg/day). The LOAEL was 300 ppm (15.0 mg/kg) based on decreased body weight. In a 24–month mouse chronic feeding carcinogenicity study the NOAEL was 50 ppm (7.5 mg/kg/day). The LOAEL was 1,000 ppm (150.0 mg/kg) based upon decreased body weight. There was no evidence of carcinogenicity at 3,000 ppm (450 mg/kg). In a 24–month rat chronic feeding carcinogenicity study the NOAEL was greater than 3,000 ppm (150 mg/kg) (HDT). There was no evidence of carcinogenicity at 3,000 ppm.

Cancer Peer Review Committee determined that there is no evidence of carcinogenicity in studies in either the mouse or rat. Based upon this determination it can be concluded that cyromazine does not pose a cancer risk.

6. *Animal metabolism*. The metabolism of cyromazine has been adequately characterized in the rat, goat, and chicken.

7. *Metabolite toxicology*. EPA has removed melamine, a metabolite of cyromazine, from the tolerance expression as a residue of toxicological concern. For more information on melamine, see the **Federal Register** of September 15, 1999 (64 FR 50043) (FRL–6098–7).

8. *Endocrine disruption*. Cyromazine does not belong to a class of chemicals proven to have adverse effects on the endocrine system. There is no evidence that cyromazine has any effect on endocrine function in developmental or reproduction studies.

C. Aggregate Exposure

1. *Dietary exposure—Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established.

i. *Acute*. There were no toxicological effects attributed to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic*. The cyromazine chronic dietary exposure assessment utilized the Dietary Exposure Evaluation Model (DEEM®), version 7.76 from Exponent. All consumption data from this assessment were taken from the USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII children's survey (1998) consumption database.

The cyromazine Tier III chronic dietary exposure assessment was based upon residue field trial results, and tolerance residues for crops when no field trial data were available. Anticipated residue estimates were used for milk, meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep; and for all other commodities tolerance level residues were assumed. The maximum percent crop treated values for cyromazine were obtained from the Doane's Market Survey Database (1999–2001) and used for lima beans (0.8%), cantaloupe (3.9%), peppers (8.6%), tomatoes (2.9%), celery (68.9%), lettuce (9.7%), spinach (19.5%), and onions (0.2%). For all other registered or proposed crop uses, it was assumed that 100% of these crops were treated.

2. *Drinking water*. EPA uses the FQPA Index Reservoir Screening Tool (FIRST) to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW) to estimate pesticide concentrations in ground water. FIRST incorporates an index reservoir environment and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact that processing (mixing, dilution, or treatment) would have on the removal of pesticides from the water source. The primary use of these models by EPA is to provide a Tier I assessment to estimate the concentration of pesticides in drinking water.

Estimated Environmental Concentrations (EECs) of cyromazine in drinking water were determined for the highest use rate of cyromazine. Based on the model outputs, the EECs of cyromazine are 1.8 parts per billion (ppb) for chronic exposure to ground water and 10 ppb for chronic exposure to surface water.

3. *Non-dietary exposure*. Cyromazine is currently registered for commercial outdoor use on landscape ornamentals and commercial interiorscapes. There are no lawn or indoor residential uses and significant residential exposure is not expected.

D. Cumulative Effects

When considering whether to establish, modify, or revoke a tolerance, section 408(b)(2)(D)(v) requires that the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residue and ''other substances that have a common mechanism of toxicity.'' Neither Syngenta nor EPA has at this time, data available to determine whether cyromazine has a common mechanism of toxicity with other substances or the methodology 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, cyromazine does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination.

1. *Acute risk*. There were no toxicological effects observed in oral toxicity studies, including the developmental toxicity studies in rats and rabbits, that could be attributed to a single exposure (dose). Since there is a reasonable certainty of no harm from acute dietary exposure, an acute aggregate risk assessment was not performed for cyromazine.

2. *Chronic risk*. The chronic dietary exposure risk analysis (food only) showed that exposure from all established and these proposed tolerances would be 2.9% of the chronic reference dose (cRfD) for the most exposed subpopulation, children 1 to 2 years old. EPA has determined that reliable data support using the standard margin of exposure and uncertainty factor (100 for combined interspecies and intraspecies variability) for cyromazine and an additional safety factor of 10X is not necessary to protect infants and children.

3. *Drinking water*. The chronic drinking water level of concern (DWLOC) for the most exposed subpopulation (children 1–6 years) is 728 ppb. Based upon the SCI-GROW and FIRST model outputs, the EECs of cyromazine in surface water and ground water are below the chronic DWLOC; therefore, EPA should not have a concern regarding cyromazine in drinking water.

4. *Non-dietary exposure*. Due to the nature of the non-dietary use, the commercial use of cyromazine on landscape ornamentals will not result in any significant residential exposure.

Syngenta has considered the potential aggregate exposure from food, water, and non-occupational exposure routes and concluded that aggregate exposure is not expected to exceed 100% of the cRfD. Therefore, Syngenta has concluded that there is reasonable certainty that no harm will result from aggregate exposure to cyromazine residues.

F. International Tolerances.

The U.S. tolerances and Codex Maximum Residue Levels (MRLs) are compatible for ruminant tissue, bell pepper, and tomato. Codex MRLs and U.S. tolerances are incompatible for milk, celery, cucumber, lettuce, melon, and mushroom.

[FR Doc. 03–20014 Filed 8–5–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0234; FRL–7317–6]

Benoxacor; 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.