

proposed uses will utilize at most 15% of the aRfD and 1% of the cRfD even for the most highly exposed population subgroups (non-nursing infants). Therefore, there is a reasonable certainty that no harm will result to infants and children from the currently proposed uses of thiacloprid.

#### F. International Tolerances

No CODEX Maximum Residue Levels (MRL's) have been established for residues of thiacloprid on any crops at this time.

[FR Doc. 03-11200 Filed 5-6-03; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0156; FRL-7305-7]

### Cyazofamid; 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-2003-0156, must be received on or before June 6, 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:** Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6742; e-mail address: [mcneilly.dennis@epa.gov](mailto:mcneilly.dennis@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. *EPA Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0156. 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 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 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.

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-2003-0156. 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](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2003-0156. 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-2003-0156.

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-2003-0156. 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: April 23, 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 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.

**ISK Biosciences Corporation**

PP 1F6305

EPA has received a pesticide petition [1F6305] from ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord OH 44077, 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 the fungicide cyazofamid, 4-chloro-2-cyano-N, N-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide (CA), in or on the raw agricultural commodity (RAC) potatoes at 0.01 parts per million (ppm) and cucurbits at 0.1 ppm and the fungicide cyazofamid and the metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile (CA) in or on the RAC tomatoes at 0.2 ppm and wine grapes 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

**A. Residue Chemistry**

1. *Plant metabolism.* The plant metabolism studies in potatoes and tomatoes, together with the magnitude of the residue studies in potatoes, tomatoes and cucurbits, suggest that the tolerance for potatoes, tomatoes, and cucurbits should be based only on parent cyazofamid. However, magnitude of the residue studies on processed tomatoes indicate that both cyazofamid and CCIM are identifiable residues in tomato puree and paste. The nature and magnitude of the residue studies for potatoes showed that there were no detectable residues of cyazofamid or any of its metabolites in the RACs or processed commodities. Similar studies on fresh tomatoes indicated that the major identifiable and quantifiable residue is cyazofamid. Magnitude of the residue studies conducted on cucurbits (cucumber, summer squash and melon) also confirmed that the major residue is cyazofamid. Nature of the residue studies showed that no single identifiable residue represents more than about 7% of the total radioactive residue. The nature and magnitude of the residue studies on grapes showed that cyazofamid was the major identifiable residue with low levels of CCIM. The residue in wine made from cyazofamid treated grapes is CCIM. The tolerance expression for potatoes and cucurbits will include parent

cyazofamid only. The tolerance expression for wine grapes and tomatoes will include parent, cyazofamid, and the metabolite CCIM.

2. *Analytical method.* An analytical enforcement method is available for determining cyazofamid plant residues in or on potatoes, cucurbits, tomatoes and wine grapes. Samples are chopped in a food chopper and a 20-g sub-sample is removed for extraction with 100 milliliter (mL) of acetonitrile (twice). The combined extracts are partitioned with hexane and then are reduced to 10 mL with a rotary evaporator. The sample is then partitioned between 100 mL of 2% aqueous sodium sulfate solution and 50 mL of methylene chloride (twice). The residue is dissolved and passed through a 2 gram (g) Florisil column followed by quantification by ultraviolet-high performance liquid chromatography (UV-HPLC).

3. *Magnitude of residues.* Residue data from 31 field trails (0- and 7-day pre-harvest intervals (PHIs)) on cucurbits [11 sites for cucumbers, 11 sites for muskmelons and 9 sites for summer squash] conducted from 1999-2001 showed that mean cyazofamid residues were 0.02 ppm for 0-day PHI and <0.01 ppm for 7-day PHI on the RAC commodities. The highest mean cyazofamid residue was 0.07 ppm at 0-day PHI on muskmelon. The highest 7-day PHI cyazofamid residue was 0.04 ppm on cucumbers. At both PHI's CCIM residues were <0.01 ppm except for 3 samples (2 sites, both 0-day PHI) which were at the 0.01 ppm LOQ. The sample with the highest total residue had 0.08 ppm (0.07 ppm cyazofamid + 0.01 ppm CCIM). The studies had a target of 6 applications of 0.071 lb. of active ingredient per acre (0.42 lb acre (a.i./acre) total) of the Cyazofamid 400SC formulation each at 7-day intervals.

Data from 18 field trials in potatoes conducted in 1999-2000 showed that no residues of cyazofamid or CCIM were observed in any of the RAC commodity at any location (7-day PHI). There were up to 10 applications of 0.071 lb. of active ingredient per acre (0.70 lb a.i./acre total) of the Cyazofamid 400SC formulation at 7-day intervals. The PHI for most trials was 7-days; however, residue dissipation studies with PHIs of 0-, 1-, 3- and 7-days were run at 2 locations. Maximum residues of 0.01 ppm of cyazofamid were seen at 0- and 1-day PHIs at one location and no residues were found at the other location. The results of a processing study in which the final application was at a 3X application rate showed that for samples taken with a 3-day PHI no detectable residues of cyazofamid or

CCIM were found in potato flakes, chips or wet peels. Therefore, no concentration of residues occurred during processing.

For tomatoes, residues of cyazofamid were determined in the treated samples from 35 RAC trials (0- and 7-day PHI) conducted from 1999-2001. The mean per site residues ranged from non-detected (<0.01 ppm) to 0.15 ppm cyazofamid. CCIM residues of 0.01-0.02 ppm were found in samples from four of the sites. The sample with the maximum residue had 0.16 ppm cyazofamid and no detectable CCIM. The studies had a target of six applications of 0.071 lb of active ingredient per acre (0.42 lb a.i./acre total) of the Cyazofamid 400SC formulation each at 7-day intervals.

The results of a tomato processing study in which the final application was at a 3X application rate showed that for samples taken with a 3-day PHI, cyazofamid was <0.01 ppm in both tomato paste and puree. Tomato paste had 0.02 ppm CCIM and tomato puree had 0.01 ppm CCIM. Therefore, there is no concentration of residues during tomato processing.

Data from 15 field trials in grapes conducted from 1999-2001 in the United States, Argentina, Mexico and Europe showed that mean cyazofamid residues ranged from <0.01 to 0.34 ppm and mean CCIM residues ranged from <0.01 to 0.02 ppm in the RAC commodity (21-day PHI) following eight applications of 0.081 to 0.089 lb. of active ingredient per acre (0.65 to 0.71 lb a.i./acre total) of the Cyazofamid 25SC formulation each at 10- to 16-day intervals.

Grapes from six of the sites were processed into must and wine. Most samples had cyazofamid residues ranging from 0.01 to 0.09 ppm. The CCIM residues in must ranged from <0.01 to 0.01 ppm. Cyazofamid residues in wine were all <0.01 ppm. CCIM residues in wine ranged from <0.01 ppm to 0.02 ppm.

**B. Toxicological Profile**

1. *Acute toxicity.* Results from a battery of acute toxicity studies place technical cyazofamid in Toxicity Category IV for oral LD<sub>50</sub>, inhalation LC<sub>50</sub> and dermal and eye irritation, and Category III for dermal LD<sub>50</sub>. Technical cyazofamid is not a dermal sensitizer. In an acute neurotoxicity study, no treatment related effects were observed at any dose. The no observed effect level (NOEL) was 2,000 milligrams/kilogram (mg/kg) bodyweight (bw).

2. *Genotoxicity.* A battery of five tests has been conducted to assess the genotoxic potential of technical

cyazofamid. Assays conducted included *in vitro* reverse gene mutation tests in bacteria and an *in vitro* forward gene mutation test in a mammalian cell system, a chromosomal damage test in mammalian cells, a DNA repair test in bacteria, and an *in vivo* micronucleus test in mice. Cyazofamid did not elicit a genotoxic response in any of the studies conducted.

3. *Reproductive and developmental toxicity.* In a two-generation reproductive toxicity study, the only effects observed were body weight effects which were observed at 20,000 ppm in dams during gestation and lactation and in weanling pups. No reproductive effects were observed. The NOEL for reproductive effects was 20,000 ppm (1,338 mg/kg bwt/day). The NOEL for parental toxicity was 2,000 ppm (134 mg/kg bwt/day). In a rat developmental study, cyazofamid was dosed by gavage from Days 0 to 19 of gestation. There were no treatment-related effects observed in the study. The NOEL for maternal and developmental effects was 1,000 mg/kg bwt/day. In a rabbit developmental study, pregnant rabbits were dosed with cyazofamid by gavage on Days 4 to 28 of gestation. There were no treatment-related effects observed in the study. The NOEL for maternal and developmental effects was 1,000 mg/kg bwt/day. The developmental studies (prenatal developmental studies in rat and rabbit and the two generation reproduction study in rat) provided no indication of increased sensitivity of rats or rabbits from *in utero* or postnatal exposure to cyazofamid. Cyazofamid is not a developmental or reproductive toxicant.

4. *Subchronic toxicity.* The oral toxicity of cyazofamid was investigated in rats and dogs in 13-week studies. The exposure was by dietary administration for the rats and by capsule for the dogs. There were no treatment-related effects observed in dogs up to 1,000 mg/kg bwt/day which was the highest dose tested. In rats, treated at 5,000 ppm there was a treatment related increase in kidney and liver weights and increased observation of *basophilic tubules*. The latter was observed only in males. The NOEL was 500 ppm which was equivalent to a dosage of 29.9 mg/kg bwt/day to males and 33.3 mg/kg bwt/day to females.

5. *Chronic toxicity.* A combined chronic and oncogenicity study was conducted in rats. Cyazofamid was administered continuously for a period of 104 weeks to male and female Fischer rats. Cyazofamid was not carcinogenic in this study. The NOEL for chronic effects was 500 ppm (17 mg/kg bwt/day)

based on kidney and liver weight differences and increases in urine volume and chloride levels at 5,000 ppm. In a long-term feeding study, mice were dosed with cyazofamid in the diet for 78 weeks. No treatment related effects were observed and it was concluded, that cyazofamid was not carcinogenic. The NOEL was 7,000 ppm (985 and 1,203 mg/kg bwt/day for males and females, respectively). In a chronic dog study, four groups of six dogs/sex/group received the test material via capsule for 52 weeks. No treatment related effects were observed. The NOEL was 1,000 mg/kg bwt/day.

6. *Animal metabolism.* Studies on the metabolism of cyazofamid in animals using radioactive test material have been conducted with cyazofamid, labeled with <sup>14</sup>C in two positions, the benzene [<sup>14</sup>C-Bz]- or imidazole [<sup>14</sup>C-Im] position. Absorption is rapid, but the percentage of cyazofamid absorbed after an oral dosage decreases as the dosage is increased. All absorbed radiocarbon is rapidly eliminated with urinary and biliary elimination of radiocarbon nearly complete within 24 hours. The metabolic pathway of cyazofamid includes the rapid hydrolysis of the dimethylsulfonamide group and the oxidation of the benzyl methyl group.

7. *Metabolite toxicology.* Comparison of the metabolism of cyazofamid by plants and in animals indicates that a number of the identified metabolites are common to both plants and animals but metabolism in plants is more extensive than in animals. The data indicate that the final products of the metabolism of cyazofamid in animals and plants represent differences in the extent of metabolism. Several of the metabolites resulting from cyazofamid are similar in plants and animals and, therefore, have already been evaluated toxicologically.

8. *Endocrine disruption.* An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects was reported in subchronic, chronic or reproductive toxicology. There was no observed pathological finding of the endocrine organs in these studies, and there were no reproductive effects at the maximum dose tested of 20,000 ppm. There is no evidence at this time that cyazofamid causes endocrine effects.

### C. Aggregate Exposure

1. *Dietary exposure.* A reference dose (RfD) of 0.17 mg/kg bwt/day is proposed for humans, based on the NOEL from the 2 year rat study (17 mg/kg bwt/day) and dividing by an uncertainty factor of 100. The acute NOEL of 100 mg/kg bwt is from the acute neurotoxicity study

adjusted for oral absorption of 5%. No treatment related effects were observed at any dose level.

i. *Food.* Tier 1 chronic and acute dietary exposure analyses were conducted for cyazofamid in/on cucurbits, potatoes, tomatoes and wine grapes to determine the exposure contribution of these commodities to the diet and to ascertain the chronic and acute risk potential. The estimates were based on proposed tolerance level residues for all crops, potato and tomato processing studies, market share assumptions of 100% crop treated, and consumption data from the 1994 through 1996 United States Department of Agriculture (USDA) continuing survey of food intake.

Even using all of the worst case exposure scenarios listed above, the Tier 1 chronic dietary exposure estimates resulted in an estimated exposure for the U.S. population of 0.000594 mg/kg bwt/day. This exposure corresponds to 0.3% of the RfD of 0.17 mg/kg bwt/day. The highest exposure estimate was calculated for the children 1–6 years population subgroup. This exposure was determined to be 0.000939 mg/kg bwt/day (0.6% of the RfD).

The Tier 1 acute assessment for the U.S. population resulted in a margin of exposure (MOE) of 35,789 at the 95<sup>th</sup> percentile. This corresponded to an estimated exposure of 0.002793 mg/kg bwt/day. The highest acute exposure estimate (95<sup>th</sup> percentile) was observed in children 1–3 years subpopulation: 0.004580 mg/kg bwt/day. This correlates to an MOE of 21,833. It can be concluded that acute or long-term dietary exposure to cyazofamid through residues on treated cucurbits, potatoes, tomatoes and imported wine grapes should not be of cause for concern.

ii. *Drinking water.* Since cyazofamid is intended for application outdoors to field grown potato, tomato and cucurbits crops, the potential exists for parent and or metabolites to reach ground or surface water that may be used for drinking water. The calculated drinking water levels of comparison (DWLOCs) for chronic exposure for adult males, adult females and toddlers were estimated to be 5,929 parts per billion (ppb), 5,083 ppb, and 1,691 ppb, respectively. The calculated DWLOCs for acute exposure for all adults, adult females and toddlers were estimated to be 34,902 ppb, 29,923 ppb, and 9,954 ppb, respectively. The chronic and acute DWLOC values are well above the modeled chronic and acute drinking water estimated concentrations (DWECs) of 0.023 ppb (generic expected estimated concentration (GENEEC) 56–day) and 1.38 ppb (GENEEC

instantaneous value), respectively. Therefore, there is comfortable certainty that no harm will result from combined dietary food and water, exposure due to the use of cyazofamid on cucurbits, potatoes and tomatoes.

2. *Non-dietary exposure.* No petition for registration of cyazofamid is being made for either indoor or outdoor residential use. Non-occupational exposure of cyazofamid to the general population is, therefore, not expected and is not considered in aggregate exposure estimates.

#### D. Cumulative Effects

Cyazofamid is a cyanoimidazole fungicide. Since there are no other members of this class of fungicides, it is considered unlikely that cyazofamid would have a common mechanism of toxicity with any other pesticide in use at this time.

#### E. Safety Determination

1. *U.S. population.* Dietary and occupational exposure will be the major routes of exposure to the U.S. population. Ample margins of safety have been demonstrated for both situations. For the U.S. population, the chronic dietary exposure to cyazofamid is 0.000594 mg/kg bwt/day, which utilizes 0.3% of the RfD for the overall U.S. population, assuming 100% of the crops are treated. The acute dietary exposure to the U.S. population is 0.002793 mg/kg bwt/day (95<sup>th</sup> percentile) resulting in a MOE of 35,789.

Using only pesticide handlers exposure data base (PHED) data levels A and B (those with a high level of confidence), MOE for occupational exposure is 5,195 for mixer/loaders, and 5,884 for aerial applicators. Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is a reasonable certainty that no harm will result from the aggregate exposure of residues of cyazofamid including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* Chronic dietary exposure of the most highly exposed subgroup in the population, children 1–6, is 0.000939 mg/kg bwt/day or 0.6% of the RfD. The acute dietary exposure of the most exposed subgroup, children 1–3, is 0.00458 mg/kg bwt/day. This correlates to an MOE of 21,833.

There are no residential uses of cyazofamid. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication of greater sensitivity of children, and the conservative exposure

assessment; there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to residues of cyazofamid from all anticipated sources of dietary and non-occupational exposure.

Accordingly, there is no need to apply an additional safety factor for infants and children.

#### F. International Tolerances

There are presently no Codex maximum residue limits established for residues of cyazofamid on any crop. [FR Doc. 03–11198 Filed 5–6–03; 8:45 am]

BILLING CODE 6560–50–S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0111; FRL–7305–1]

#### Folpet; 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–2003–0111 must be received on or before June 6, 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:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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. 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. 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. *EPA Docket.* EPA has established an official public docket for this action under docket ID number OPP–2003–0111. 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