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–2003–0161. 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–2003–0161. 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–2003–0161.

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–2003–0161. 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. 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: 72431–R. *Applicant*: Jeneil Biosurfactant Company, 400 N. Dekora Woods Boulevard, Saukville, WI 53080. *Product name*: Zonix Biofungicide. *Type of product*: Biochemical fungicide. *Active ingredient*: Rhamnolipid biosurfactant (decanoic acid, 3-[[6-deoxy-2-*O*-(6-deoxy-alpha-*L*-mannopyranosyl)-alpha-*L*-mannopyranosyl]oxy]-, 1-(carboxymethyl)octyl ester, mixture with 1-(carboxymethyl)octyl 3-[(6-deoxy-alpha-*L*-mannopyranosyl)oxy]decanoate). *Proposed classification/Use*: None. For horticultural and agricultural use to control zoosporic plant pathogenic fungi.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: April 24, 2003.

Sheryl K. Reilly,

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

[FR Doc. 03–11003 Filed 5–6–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0139; FRL–7303–7]

Thiacloprid; 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–2003–0139, 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: Marilyn Mautz, Registration Division (7505C), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6785; e-mail address: *mautz.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0139. 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.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 submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

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

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2. *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–2003–0139.

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

5. Provide specific examples to illustrate your concerns.

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

7. To ensure proper receipt by EPA, be sure to identify the docket 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 (PP) 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 22, 2003.

Debra Edwards,

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.

Bayer CropScience and IR-4

PP# 9F6060 and PP# 3E6546

EPA has received PP# 9F6060 from Bayer CropScience (formerly, Bayer Corporation, 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120), P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709, and PP# 3E6546 from Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the insecticide thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]cyanamide (CAS No. 111988–49–9)) in or on the raw agricultural commodities:

Bayer Petition (PP# 9F6060) proposes to establish tolerances for:

Apple, wet pomace at 0.6 parts per million (ppm).
Cattle, meat at 0.2 ppm.
Cattle, meat byproducts at 0.2 ppm.
Cotton, gin byproducts at 11.0 ppm.
Cotton, undelinted seed at 1.0 ppm.
Fruit, pomace, group 11 at 0.3 ppm.
Milk at 0.1 ppm.

IR-4 Petition (PP# 3E6546) proposes to establish tolerances for:

Fruit, stone, group 12 at 0.5 ppm.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of 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 plants, the metabolism of thiacloprid is adequately understood for the purposes of

establishing these proposed tolerances. Unchanged parent thiacloprid accounted for 70% or greater of the residues in all plant metabolism studies (cotton, tomato, and apple), with the exception of the material identified in cotton seed. In cotton seed, the main component was the 6-chloronicotinic acid metabolite, accounting for 45.8%. All residues contained the 6-chloro-pyridinyl moiety. In animals, parent thiacloprid was the major component in all edible tissues, milk, and eggs. All residues and metabolites in the animal tissues contained the 6-chloro-pyridinyl moiety, same as in the plant tissues. Therefore, the residues of concern are the combined residues of thiacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all calculated as thiacloprid.

2. *Analytical method*. The analytical method for determining residues in pome fruit and cotton samples is a common moiety method for thiacloprid and its metabolites containing the 6-chloro-pyridinyl moiety. This method utilizes oxidation, derivatization, and analysis by capillary gas chromatography with a mass-selective (MS) detector. There is a confirmatory method specific for thiacloprid and several metabolites utilizing high performance liquid chromatography (HPLC) with Electrospray MS/MS-detection. This HPLC/MS-MS method was used for analysis of the stone fruit samples. Thiacloprid and its metabolites are stable in cotton and pome fruit commodities for at least 24 months and in stone fruit commodities for at least 10 months when the commodities are frozen.

3. *Magnitude of residues—Cotton*—Field trials were conducted with cotton in 12 different locations, representing 6 different EPA regions. Three foliar applications were made to mature cotton plants at a rate of 0.1 lb active ingredient/acre (a.i./A) with 3 to 11 days between applications. The pre-harvest interval (PHI) ranged from 12 to 20 days. The highest average field trial was 0.73 ppm in undelinted cotton seed. For gin trash, the HAFT residue was 10.10 ppm. The processing study, conducted with cottonseed, indicated no concentration in any cottonseed processed commodities.

Pome fruit (apple/pear)—A total of 18 field trials (12 apple and 6 pear) were conducted in 6 different EPA regions. Applications were made as ground-based foliar sprays at 0.25 lb ai/A with 6- to 8-day intervals. The highest residue at 30-day PHI was 0.277 ppm, in apples. The highest residue at a 45-day PHI was 0.258 ppm, occurring in pears. Although residues in pome fruit did not consistently decline in relation to sampling intervals, residues were generally lower at the longer PHI (45 days) in harvest experiments. In the apple processing study, residues concentrated in the wet pomace (1.8X) but did not concentrate in the apple juice. A home processing study indicated significant reduction in residues.

Stone fruits (sweet cherry/peach/plum)—A total of 24 field trials (7 sweet cherry, 11 peach, and 6 plum) were conducted in different EPA regions (3 for sweet cherry, 7 for peach, and 3 for plum). Applications were made as ground-based foliar sprays at 0.25 lb ai/A with 6- to 8-day intervals. The highest residue at the 14-day PHI was 0.423 ppm, in peaches. The highest residue at a 28-day PHI was 0.359 ppm, occurring in peaches. Residues in stone fruit raw agricultural commodities (RACs) consistently declined in relation to sampling intervals, with lower residues at the longer PHI (28 days).

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} values for thiacloprid technical ranged from 444 (female) to 836 (male) milligram/kilogram (mg/kg) in the rat. The acute dermal LD_{50} was greater than 2,000 mg/kg in rats. The 4-hour rat inhalation LD_{50} ranged from 1,223 (female) to >2,535 (male) mg/meter cubed (m^3) air (aerosol). Thiacloprid was not irritating to rabbit skin or eyes. Thiacloprid did not cause skin sensitization in guinea pigs.

2. *Genotoxicty*. Extensive mutagenicity studies conducted to investigate point and gene mutations, DNA damage and chromosomal aberration show thiacloprid to be non-genotoxic.

3.*Reproductive and developmental toxicity*. In a 2-generation reproduction study, Sprague-Dawley rats were administered dietary levels of thiacloprid at levels of 0, 50, 300, and 600 ppm. The no-observed-adverse-effect-levels (NOAELs) for reproductive parameters was established at 50 ppm, based on increased liver and thyroid weight gains in the parental and F1 generations. A developmental toxicity study was conducted with Wistar rats gavaged at 0, 2, 10, and 50 mg/kg. The following NOAELs were determined: Maternal toxicity, 10 mg/kg/day and developmental toxicity, 10 mg/kg/day. A developmental toxicity study was conducted with rabbits treated orally by gavage at 0, 2, 10, and 45 mg/kg. The following NOAELs were determined: Maternal toxicity, 2 mg/kg/body weight (bwt)/day and developmental toxicity, 2 mg/kg/day. From the developmental toxicity studies in rats and rabbits, no primary developmental toxic potential could be derived. Additionally, a developmental neurotoxicity study was conducted at dietary doses of 0, 50, 300, or 500 ppm in the female Sprague-Dawley rat. The targeted concentration of 50 ppm was considered a NOAEL for maternal toxicity and the F1 offspring. No specific neurobehavioral effects in the offspring were identified up to and including the highest dose tested of 500 ppm.

4. *Subchronic toxicity*. 90-day feeding studies were conducted in rats, mice, and dogs. In the subchronic rat and dog studies, the demonstrated NOAELs were 25 ppm and 1,000 ppm, respectively. The subchronic mouse study did not demonstrate a NOAEL at the lowest level (50 ppm) tested.

5.*Chronic toxicity*. A 2-year rat chronic toxicity/oncogenicity study demonstrated a NOAEL of 25 ppm. Liver enzyme induction occurred at doses of > 50 ppm. A 2-year mice oncogenicity demonstrated a NOAEL at the lowest dose of 30 ppm. A 1-year chronic toxicity study in dogs demonstrated a NOAEL of 250 ppm, with slight prostatic weight increases in some of the 1,000 ppm animals (possibly due to different maturation in the animals) being the only treatment-related findings. There is significant evidence that thiacloprid is not acting through a genetic mechanism (all genotoxicity studies are negative). Thiacloprid should be managed using a margin-of-exposure extrapolation. The dose response to thiacloprid shows the following pattern: First, at lower dose levels, thiacloprid induces liver enzymes. At moderate dose levels in animals, it increases liver enzymes and aromatase is induced. At the highest dose levels, repeated administration of thiacloprid induces liver enzymes, including aromatase, which leads to hormonal effects such as elevated estrogen levels, which indirectly cause uterine tumors in rats and ovarian luteomas in mice. High-dose thyroid tumors seen in the chronic rat study were determined to be related to thyroid hormone imbalance and not a direct effect of thiacloprid.

6. *Animal metabolism*. In animals, parent thiacloprid was the major component in all edible tissues, milk, and eggs. All residues and metabolites in the animal tissues contained the 6-chloro-pyridinyl moiety, same as in the plant tissues. Therefore, the residues of concern are the combined residues of thiacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all calculated as thiacloprid.

7. *Metabolite toxicology*. Two specific metabolites, KKO 2254 and WAK 6999, were examined toxicologically. In addition to negative Ames tests, the acute toxicological potential for both sexes, as measured by LD_{50}, was determined to be >2,000 mg/kg for both metabolites. In light of these findings no special toxicological concerns, exceeding that of thiacloprid, would be expected from the metabolites of the parent compound

8. *Endocrine disruption*. The toxicology database for thiacloprid is current and complete. Studies in this database include evaluation of the potential effects on reproduction and development and an evaluation of the pathology of the endocrine organs following short- or long-term exposure.

C. Aggregate Exposure

1. *Dietary exposure*. Acute and chronic dietary analyses were conducted to estimate exposure to potential thiacloprid residues in/on the following crops: Fruit, pome, group; fruit, stone, group; and cotton using the DEEM^T software (Version 7.76) from Exponent, Inc. The 94–94,98 CSFII consumption database was used along with anticipated residues and processing factors where available. Projected percent crop treated values were incorporated into both the acute and chronic dietary exposure analyses at 20%, 10%, and 5% for pome fruit, stone fruit, and cotton, respectively. Exposure estimates to water were made based upon modeling. The acute reference dose (aRfD) (aRfD = 0.031 mg/kg/bwt/day) was based upon an acute NOEL of 3.1 mg/kg/bwt/day from the acute oral neurotoxicity study in rats and an uncertainty factor of 100. The chronic reference dose (cRfd) (cRfD = 0.012 mg/kg/bwt/day) was based upon a chronic NOEL of 1.2 mg/kg/bwt/day and an uncertainty factor of 100.

i. *Food*. The acute dietary exposure estimates at the 99.9th percentile for the U.S. population was calculated to be approximately 7% of the aRfD. The population subgroup with the highest exposure was non-nursing infants (<1year old) at approximately 15% of the aRfD. Chronic dietary exposure estimates from residues of thiacloprid for the U.S. population was 0.2% of the cRfD. The population subgroup with the highest exposure was non-nursing infants with 1% of the cRfD utilized.

ii. *Drinking water*. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water analysis for thiacloprid. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as SCI-GROW, FIRST, GENEEC, PRZM/EXAMS, and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water. In the case of thiacloprid, monitoring data do not exist, therefore, FIRST and SCIGROW models were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for acute and chronic exposures for all adults and children greatly exceed the modeled thiacloprid drinking water estimated concentrations (DWEC). The acute DWLOC values are 1013 parts per billion (ppb) for adults (U. S. population) and 267 ppb for children. The worst case DWEC for acute scenarios is calculated to be 10.95 ppb using the FIRST surface water model. The chronic DWLOC values are 430 ppb for adults and 122 ppb for children. The DWEC for the worst case chronic scenario is 0.62 ppb (FIRST).

2. *Non-dietary exposure*. There are no current plans to support thiacloprid uses on turf or ornamental plants, including homeowner uses.

D. Cumulative Effects

Thiacloprid is thought to be part of a class of chemistry called the chloro-nicotinyls. For this class of chemistry and it's registered compounds EPA has not yet conducted a detailed review of common mechanisms to determine whether it is appropriate, or how to include these chemicals in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thiacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance actions; therefore, EPA has not assumed that thiacloprid has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described in Unit C. of this petition and based on the completeness of the toxicity data, it can be concluded that acute dietary exposure to residues of thiacloprid from all proposed uses will utilize less than 7% of the aRfD for the U.S. population and 15% of the aRfD for the most highly exposed subpopulation (non-nursing infants). EPA generally has no concerns for exposures below 100% of the reference dose (RfD), because the RfD represents the level at or below which exposure will not pose any appreciable risk to human health. Additionally, the acute DWLOC was calculated to be nearly 100 time greater than thiacloprid residues in water predicted by conservative models. The chronic dietary exposure occupies 0.2% of the cRfD for the U.S. population and 1% of the cRfD for the most highly exposed subpopulation (non-nursing infants). EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. The chronic DWLOC was calculated to be nearly 700 and 200 times greater than the thiacloprid residues in water predicted by conservative models. Therefore, there is a reasonable certainty that no harm will result to the general U.S. population from aggregate acute or chronic exposure to thiacloprid residues from proposed uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of thiacloprid, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in rats have been considered. The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through 2 generations, as well as any observed systemic toxicity.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for thiacloprid relative to pre- and post-natal effects is complete. Further for thiacloprid, the NOEL of 1.2 mg/kg/bwt/day from the 2-year chronic toxicity/carcinogenicity study, which was used to calculate the cRfD (discussed in Unit C.1. of this petition), is already lower than the NOELs from the developmental studies in rats (10 mg/kg/bwt/day) and rabbits (2 mg/kg/bwt/day) and lower than the NOEL from the 2-year reproductive toxicity study in rats (50 mg/kg/bwt/day). Since a 100-fold uncertainty factor is already used to calculate the RfD, an additional safety factor for infants and children is not warranted.

Using the conservative exposure assumptions described in Unit C. of this petition, Bayer CropScience has concluded that the total aggregate exposure to thiacloprid from all

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.

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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*.

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