accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Such requests should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161.

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.

II. Did EPA Conditionally Approve the Application?

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest. The Agency has considered the available data on the risks associated with the proposed use of *Chondrostereum purpureum* strain PFC 2139, Oil of Black Pepper, Piperine, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *Chondrostereum purpureum* strain PFC 2139, Oil of Black Pepper, and Piperine, during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

Consistent with section 3(c)(7)(C) of FIFRA, the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

III. Conditionally Approved Registrations

1. EPA issued a notice, published in the **Federal Register** of December 31, 2001 (66 FR 67520) (FRL–6813–7), which announced that MycoLogic Inc., Department of Biology, University of Victoria, P.O. Box 3020, Victoria, BC, Canada V8W 3N5, submitted applications to register the pesticide products, CP-PFC 2139, a manufacturing use product, for the formulation of an end-use product (EPA File Symbol 74200–R) and Chontrol Paste (a biological herbicide) (EPA File Symbol 74200–E), containing the active ingredient *Chondrostereum purpureum* isolate PFC 2139, at 1.68% and 0.67%, respectively. These products have not previously been registered.

The applications were conditionally approved on September 23, 2004, containing the active ingredient *Chondrostereum purpureum* strain PFC 2139 for the manufacturing use product CP-PFC 2139 (EPA Registration Number 74200–1) and for the end-use product Chontrol Paste (EPA Registration Number 74200–2), for control of alders, aspen, and other hardwoods in rights-of-way and forests.

2. EPA issued a notice, published in the **Federal Register** of December 24, 2003 (68 FR 74576) (FRL–7338–2), which announced that Woodstream Corporation, 69 N. Locust Street, Lititz, PA 17543, had submitted an application to conditionally register the pesticide product, Animal Repellent Granular, animal repellent (EPA File Symbol 50932–RN), containing the active ingredients Oil of Black Pepper at 0.48% and Piperine at 0.185% as active ingredients not included in any previously registered product.

The application was conditionally approved on March 18, 2004 for the end-use product as Animal Repellent Granular (EPA Registration Number 50932–10) for use as an animal repellent.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: December 10, 2004.

Janet L. Andersen,

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

[FR Doc. 04–27888 Filed 12–21–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0399; FRL–7689–4]

Buprofezin; Notice of Filing an Amended Pesticide Petition to Increase Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2004–0399, must be received on or before January 21, 2005.

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: Richard J. Gebken, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6701; e-mail address:*gebken.richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be

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

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

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0399. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and to Whom Do I Submit Comments?

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

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

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at*http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0399. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0399. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid

the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0399.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0399. 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: December 9, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

Nichino America, Inc.

PP 4F6873

EPA has received a petition (PP 4F6873) from Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808 (the registrant) by revising a previous pesticide petition (PP 0F6087) that was submitted by Aventis Crop Science (formerly AgrEVO USA Co, that published in the **Federal Register** of June 21, 2000 (65 FR 38543) (FRL–6557–3). Nichino America, Inc. is proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.511 by establishing increased tolerances for residues of buprofezin (2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one) in or on the following raw agricultural commodities: Fruit, citrus, Group 10 at 2.5 parts per million (ppm), citrus, dried pulp at 7.5 ppm, and citrus, oil at 80 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 metabolic profile of buprofezin has been elucidated in a wide range of crops, including tomatoes, lettuce, cotton, and citrus. In citrus, although buprofezin was a major component of the residue, a chromatographically well-defined region of radioactivity, clearly associated with polar conjugates, was observed. Mass spectrometry identified the principal polar residue as a hexose conjugate of BF4 (buprofezin hydroxylated in the t-butyl group). Although the conjugate was resistant to enzyme hydrolysis, acid hydrolysis of the polar fraction released predominantly BF26 with minor amounts of BF9 and BF12. The same compounds were observed following acid hydrolysis of a standard of BF4 clearly indicating that BF4 is the conjugated metabolite existing in citrus. Although only limited metabolism was observed in lettuce and cotton, trace levels of similar metabolites, including the conjugate BF4 were observed indicating that the metabolic pathway does not differ with plant species.

2. *Analytical method*. The proposed analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography using nitrogen phosphorous detection.

3. *Magnitude of residues*. Nineteen field trials were conducted on oranges with buprofezin, the principal residue of concern, in Regions 3, 6, and 10 at the maximum rate and minimum application and the minimum preharvest interval (PHI) of 3 days. In addition, decline data were generated that confirmed that residues of buprofezin decreased as the PHI

increased from 1 to 30 days. The highest average residue value for oranges treated with buprofezin (HAFT) at a 3–day PHI was 1.80 ppm. Results from a previous processing study indicate that the concentration in citrus oil was 42.7X and in citrus dried pulp 2.5X. The requested tolerances are adequately supported.

B. Toxicological Profile

An extensive battery of toxicology studies has been conducted with buprofezin. EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk The nature of the toxic effects caused by buprofezin is discussed in Unit III.A. of the final rule on Buprofezin Pesticide Tolerance published in the **Federal Register** on September 5, 2001 (66 FR 46381) (FRL–6796–6). An assessment of toxic effects caused by buprofezin, including the toxicological endpoints of concern, is also discussed in Unit III.A. and Unit III.B. of the June 25, 2003 **Federal Register** (68 FR 37765) (FRL–7310–7).

1. *Animal metabolism*. The metabolism of buprofezin has been extensively studied in various species of animals and fish. Buprofezin has several groups that can metabolize in a variety of ways thus potentially producing a very large number of metabolites. Extensive metabolism to many minor metabolites was observed in all the animal species. Metabolism in fish was, however, much more limited and clearly defined. Although not all metabolic intermediates have been detected in all the species, the major routes of metabolism have been identified in animals and fish and a consistent pattern is observed throughout these species. The proposed metabolic pathway was provided in the tolerance petition, PP 0F6087. For convenience, degradates are referred to by an internal code: BF1 through 13. Corresponding chemical structures were provided in the tolerance petition, PP 0F6087.

i. *Metabolism in rats*. The major metabolite found in rat excreta was parent buprofezin in addition to several compounds formed after extensive metabolism. Whereas plant metabolism appeared restricted mainly to oxidation of the tertiary butyl group, oxidation of the butyl group and hydroxylation of the phenyl ring were both observed in rats. Oxidation of the t-butyl group proceeded beyond an alcohol to an acid and was accompanied by ring opening. The most extensively metabolized compound identified in rats was BF23 (acetylated p-aminophenol).

ii. *Metabolism in ruminants and hens*. Residue levels were low (0.05 ppm) in all ruminant and poultry tissues and commodities, following treatment at exaggerated rates (approximately 20X and 7,500X the anticipated dietary burden, respectively). The only exceptions were cow liver (1.21 ppm), cow kidney (0.41 ppm), hen liver (0.15 ppm), and egg yolk (0.11 ppm). Extensive metabolism was observed in both species with a large number of minor metabolites being produced. The principal metabolites identified in the cow were BF2 and BF23, indicating that the major pathway of degradation in ruminants is hydroxylation of the phenyl ring followed by opening and degradation of the heterocyclic ring. The identification of trace levels of BF13 confirms this pathway. As in rats, BF23 was the most extensively metabolized compound identified. Trace levels of BF12 were also detected. This indicates that the parallel pathway of heterocyclic ring opening without hydroxylation of the phenyl ring is also in operation. Similarly in hens, the identified metabolites were derived from degradation of the heterocyclic ring either with (BF13) or without (BF9 and BF12) phenyl ring hydroxylation. No single unidentified compound accounted for more than 6% of the total residue in any animal tissue or commodity, with the exception of a component comprising 8.7% of egg white. The total residue in egg white was, however, only 0.02 ppm even at this highly exaggerated dose rate.

iii. *Metabolism in fish*. Analysis of fish tissues, following a bioaccumulation study, found a much simpler metabolic profile. Buprofezin was present in both edible and non-edible tissues, but the principle metabolites were polar conjugates of BF4. Trace levels of BF12 were also detected.

2. *Endocrine disruption*. No special studies have been conducted to investigate the potential of buprofezin to induce estrogenic or other endocrine effects. The standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects. The only effect noted on endocrine organs was an increased incidence of follicular cell hypertrophy and C-cell hyperplasia of the thyroid gland in rats administered buprofezin. Buprofezin also caused mild to moderate hepatotoxic effects at this dietary concentration. The effect on the thyroid is consistent with an increased turnover of T3/T4 in the liver with a resultant rise in TSH secretion (due to the hepatotoxicity). The rat is known to be much more susceptible than humans to these effects due to the very rapid turnover of thyroxine in the blood in rats (12 hours vs. about 5 to 9 days in humans). Therefore, the thyroid pathological changes which have been noted following administration of high doses of buprofezin are considered to be of minimal relevance to human risk assessment, particularly considering the low levels of buprofezin to which humans are likely to be exposed.

C. Aggregate Exposure

1. *Dietary exposure*. Acute and chronic dietary risk analyses were conducted to estimate the potential buprofezin residues in/on the following crops: Avocado, banana, canistel, cotton, grape, grape raisin, longan, lychee, mango, papaya, mamey sapote, Spanish lime, head lettuce, leaf lettuce, snap bean, tomato, curcurbit vegetables, citrus oil, citrus orange, citrus grapefruit, citrus lemon, pome fruit, apples, pome fruit pear, peach, almond, and pistachio using the Dietary Exposure Evaluation Model (DEEM-FCID, ver. 1.30) software. Exposure estimates to water were based on modeling and on percent crop treated.

2. *Food*. The acute dietary exposure was based on the following assumptions: Residues at tolerance levels, 100% crop treated, and DEEM (ver. 7.76) default processing factors for all registered/proposed commodities (Tier 1). The Hazard Identification Assessment Review Committee (HIARC) met on February 15, 2000, and determined the endpoint selection for buprofezin (HED Doc. No. 014093) and subsequently on October 22, 2002, to evaluate the potential for increased susceptibility of infants and children from exposure to buprofezin. Based on toxicological considerations, the special FQPA safety factor was set at 1X when assessing acute and chronic dietary exposures. The acute dietary aPAD (acute Population Adjusted Dose) was set at 2.0 milligrams/kilogram/day (mg/kg/day) for females aged 13–50 years old based on a developmental toxicity study in rats that had an oral no observed adverse effect level (NOAEL) of 200 mg/kg/day. The chronic dietary cPAD (chronic Population Adjusted Dose) was determined to be 0.01 mg/kg/day for the general population based on a oral NOAEL of 1.0 mg/kg/day in the 2–year rat chronic/oncogenicity study. The

uncertainty factor of 100 was used to account for interspecies and intraspecies variations. Since the only evidence of carcinogenicity was ''suggestive,'' this endpoint was not deemed relevant to this assessment.

The resulting food exposure estimate for females 13–49 years old was less than 5.4% of the Population Adjusted Dose (aPAD). No acute endpoint was identified for the remaining population subgroups. The chronic dietary exposure was based on the following assumptions: Percent crop treated, average field trial residues at maximum label rates, and minimum PHIs with no reduction factors for common washing, cooking, or preparation practices. The food exposure estimates from residues of buprofezin for the U.S. population was 38% of the cPAD. The subpopulation with the highest exposure was children 1–2 years old with < 81% of the cPAD used. These are considered conservative values.

3. *Drinking water*. The residue of concern in drinking water was determined to be buprofezin. There are no established maximum contaminant levels or health advisory levels for residues of buprofezin in drinking water.

In the absence of comprehensive water monitoring data, the Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index resevoir. The Screen Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

The estimated drinking water concentrations (EDWCs) in surface water were determined using the Tier II PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling Stystem (PE4-PL, version 01). PRZM is used to simulate pesticide transport as a result of runoff and erosion and spray drift from an agricultural field and EXAMS estimates environmental fate and transport of pesticides in surface water. The long-term average-estimated environmental concentrations (EEC) was 3.5 parts per billion (ppb). The acute EDWCs are 19.2 ppb, and for chronic 4.5 ppb. In ground water, using Tier I SCI-GROW, the acute level is 0.1 ppb and chronic is 0.1 ppb.

4. *Non-dietary exposure*. The term residential exposure is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Buprofezin is not registered for use on any sites that would result in residential exposure.

D. Cumulative Effects

A determination has not been made that buprofezin has a common mechanism of toxicity with other substances. Buprofezin does not appear to produce a common toxic metabolite with other substances. A cumulative risk assessment was, therefore, not performed for this analysis. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to buprofezin and any other substances and buprofezin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that buprofezin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/ pesticides/ cumulative/*.

E. Safety Determination

1. U.S. population—i. *Acute risk*. Using the conservative assumptions discussed above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to the proposed uses of buprofezin will utilize at most 5.4% of the acute reference dose of females (13–49 years) and is likely to be much less, as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the aPAD Drinking Water Levels of Comparison (DWLOC) were calculated based on an aPAD of 2.0 mg/kg/day. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

ii. *Chronic risk*. Based on the toxicology data base and available information on anticipated residues, the chronic dietary exposure to the U.S. population (total) was estimated as 0.003769 mg/kg/day and was 38% of the estimated cPAD. Exposure to potential residues in drinking water are expected to be negligible. Based on these assessments, it can be concluded that there is reasonably certainty of no harm to the U.S. population or any population subgroup from exposure to buprofezin.

2. *Infants and children*. Chronic exposure to children ages 1–2, the highest exposed population subgroup, was 0.008116 mg/kg/day (81% of the cPAD). Exposure to potential residues in drinking water is expected to be negligible. EPA has determined that reliable data support using the standard margin of exposure (MOE) and uncertainty factor (100 for combined interspecies and intraspecies variability) for buprofezin and that an additional safety factor of 10 is not necessary to be protective of infants and children. EPA generally has no concern for exposures below 100% of the cPAD. The acute EEC of 19 ppb is considerably less than the DWLOC of 59,076 ppb. For the chronic assessment, the children 1–2 years old subpopulation generated the lowest chronic DWLOC of approximately 46 ppb. Thus, the chronic DWLOC of 46 ppb is higher than the chronic EEC of 4.5 ppb. The Agency has considered the potential aggregate exposure from food, water and non-occupational exposure routes and has concluded aggregate exposure is not expected to exceed 100% of the chronic reference dose, and consequently, has determined there is a reasonable

certainty that no harm will occur to infants and children from aggregate exposure to residues of buprofezin.

F. International Tolerances

Canada, Codex, and Mexico do not have maximum residue limits for residues of buprofezin in/on the proposed crops. Therefore, harmonization is not an issue.

[FR Doc. 04–27772 Filed 12–21–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0403; FRL–7689–6]

Pyriproxyfen: Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2004–0403, must be received on or before January 21, 2005.

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: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6411; e-mail address: *tavano.joseph@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0403. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and to Whom Do I Submit Comments?

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