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

Section 408(b)(2)(D)(v) requires that the Agency must consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Available information in this context include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

At the present time, there are insufficient data available to allow Nichino America, Inc. to properly evaluate the potential for cumulative effects with other pesticides to which an individual may be exposed. For the purposes of this assessment, therefore, Nichino America, Inc. has assumed that buprofezin does not have a common mechanism of toxicity with any other registered pesticides. Therefore, only exposure from buprofezin is being addressed at this time.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. To estimate acute aggregate exposure risk, the Agency combined the high-end value from food and water, and compared it to the acute population adjusted dose (aPAD). Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to buprofezin for females 13–49 years (no endpoint was identified for the general population including infants and children). The acute dietary exposure from buprofezin will occupy 1.54% of the aPAD. In addition, there is potential for acute dietary exposure to buprofezin in drinking water. Acute Drinking Water Levels of Comparison (DWLOC) were calculated based on an aPAD of 2.0 milligrams/ kilogram/day. For the acute assessment, the females (13–49 years) subpopulation generated an acute DWLOC of approximately 59,076 ppb. After calculating DWLOCs and comparing them to the EECs for surface 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 0.001464 mg/kg bwt/day, and was 14.6 % of the estimated chronic population adjusted dose (cPAD). Exposure to potential residues in drinking water is expected to be negligible, as DWLOCs of 299 ppb are substantially higher than modeled acute and long-term EECs. Based on these assessments, it can be concluded that there is reasonable 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 0.005444 mg/kg bwt/day (54.4 % of the estimated cPAD). Exposure to potential residues in drinking water is expected to be negligible, as DWLOCs are substantially higher than modeled acute and long-term EECs. 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. The acute EEC of 102 ppb is considerably less than 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 34 ppb.

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. 04–5513 Filed 3–16–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0046; FRL–7347–3]

Fludioxonil; 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 pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0046, must be received on or before April 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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–2004–0046. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and To Whom Do I Submit Comments?

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

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

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0046. 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–2004–0046. 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–2004–0046.

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–2004–0046. 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: March 4, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

Interregional Research Project Number 4 (IR-4)

3E6551, 3E6639, 3E6701, and 3E6803

EPA has received pesticide petitions (3E6551, 3E6639, 3E6701, and 3E6803) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.516 by establishing tolerances for residues of fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-H-pyrrole-3-carbonitrile in or on the following raw agricultural commodities:

1. PP 3E6551 proposes a tolerance for kiwifruit at 20 parts per million (ppm).

2. PP 3E6639 proposes a tolerance for leafy greens subgroup 4A, except spinach at 30 ppm.

3. PP 3E6701 proposes tolerances bean, dry and bean, succulent at 0.4 ppm.

4. PP 3E6742 proposes tolerances for fruit, pome, group 11 at 5.0 ppm, yam at 8.0 ppm, and melon subgroup 9A at 0.03 ppm.

5. PP 3E6803 proposes tolerances for citrus, crop group 10 at 10 ppm; citrus, dried pulp at 20 ppm, citrus, oil at 500 ppm, and pomegranate at 2.0 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of petitions prepared by Syngenta Crop Protection, Inc., Greensboro, NC 27409.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of fludioxonil is adequately understood for the purpose of the proposed tolerances.

2. *Analytical method*. Syngenta has developed and validated analytical methodology for enforcement purposes. This method (Syngenta Crop Protection Method AG-597B) has passed an Agency petition method validation for several commodities, and is currently the enforcement method for fludioxonil. This method has also been forwarded to the Food and Drug Administration for inclusion into PAM II. An extensive database of method validation data using this method on various crop commodities is available.

3. *Magnitude of residues*. Complete residue data for the crops requested in this filing have been submitted. The requested tolerances are adequately supported.

B. Toxicological Profile

An assessment of toxic effects caused by fludioxonil is discussed in Unit III. A. and Unit III. B. of the **Federal Register** dated August 2, 2002 (67 FR 50354) (FRL–7188–7).

1. *Animal metabolism*. The metabolism of fludioxonil in rats is adequately understood.

2. *Metabolite toxicology*. The residues of concern for tolerance setting purposes is the parent compound. Consequently, there is no additional concern for toxicity of metabolites.

3. *Endocrine disruption*. Fludioxonil does not belong to a class of chemicals known for having adverse effects on the endocrine system. No estrogenic effects have been observed in the various short- and long-term studies conducted with various mammalian species.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Tier III acute and chronic dietary exposure evaluations were made using the Dietary Exposure Evaluation Model (DEEM™), version 7.87 from Exponent. Empirically derived processing factors for apple juice (0.09X), apple pomace (6.77X) and grape juice (0.36X) were used in these assessments. The apple juice processing factor was used as a surrogate for pear juice. All other processing factors used

the DEEM™ defaults. All consumption data for these assessments was taken from the USDA's Continuing Survey of Food Intake by individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII children's survey (1998) consumption database. These exposure assessments included all registered uses and pending uses on leafy greens subgroup 4A, except spinach, beans, dry and succulent, kiwi fruit, citrus crop group, citrus, dried pulp, citrus, oil, pomegranate, pome fruit group 11, yam, and melon subgroup 9A. Secondary residues in animal commodities were estimated based on theoretical worst-case, yet nutritionally adequate animal diets and transfer information from feeding studies.

ii. *Drinking water*. Fludioxonil rapidly degrades via photolysis on the soil surface and in water. The half-lives are 1 day and 10 days, respectively. This potential for rapid degradation reduces the potential for ground water or surface water exposure. Fludioxonil K_{ocs} range from 991 to 2,440 indicating a relatively high affinity for binding to soil. Estimated Environmental Concentrations (EECs) of fludioxonil in drinking water were determined for the highest use rate of fludioxonil (turfgrass use). Screening Concentration in Ground Water (SCI-GROW) (Version 2.2) was used to determine acute and chronic EECs in ground water and Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST) (Version 1.0) was used to determine acute and chronic EECs in surface water. Based on the model outputs, the ground water EECs for fludioxonil are 0.174 parts per billion (ppb) for acute and chronic exposure. The surface water EECs were 70 ppb and 26 ppb for acute and chronic exposure, respectively.

2. *Non-dietary exposure*. There is a potential residential post-application exposure to adults and children entering residential areas treated with fludioxonil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected.

D. Cumulative Effects

Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity''. EPA does not have, at this time, available data to determine whether fludioxonil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, EPA has not assumed that fludioxonil has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*—i. *Acute*: For the purpose of the aggregate risk assessment, the exposure value was expressed in terms of margin of exposure (MOE), which was calculated by dividing the no observable adverse effect level (NOAEL) by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the acute reference dose (%aRfD). Acute exposure to the females 13–50 years subpopulation resulted in a MOE of 1,919 (5.2% of the acute RfD of 1.0 milligrams/kilograms - bodyweight/day (mg/kg-bw/day)). Since the benchmark MOE for this assessment was 100 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses for fludioxonil.

Acute drinking water levels of comparison (DWLOC) were calculated based on an acute populated adjusted dose (aPAD) of 1 mg/kg/day. The females (13–50 years) subpopulation generated an acute DWLOC of approximately 28,440 ppb. The acute EEC of 70 ppb is considerably less than 28,440 ppb. The chronic and aggregate risk from fludioxonil residues in food and drinking water would; therefore, not be expected to exceed the EPA's level of concern.

ii. *Chronic*: The chronic exposure to the most exposed sub-population (children 1 and 2 years old) resulted in a MOE of 753 (13.3% of the chronic RfD of 0.033 mg/kg-bw/day). The chronic dietary exposure analysis (food only) indicated that exposure from all established and proposed fludioxonil uses would be 13.3% of the chronic RfD of 0.033 mg/kg-bw/day for the most sensitive subpopulation, children 1 and 2 years old.

Estimated concentrations of fludioxonil residues in surface and ground water were below the calculated acute DWLOC. The children 1 and 2 years old subpopulation had the lowest chronic DWLOC of approximately 286 ppb, which is considerably higher than the chronic EEC of 26 ppb.

Based on the completeness and reliability of the toxicity data supporting these petitions, and the results of the above exposure calculations, Syngenta believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues arising from all current and proposed fludioxonil uses, including anticipated dietary exposure from food, water, and all other types of non-occupational exposures.

2. *Infants and children*. No additional FQPA safety factor was applied. Syngenta has considered the potential aggregate exposure from food, water and non-occupational exposure routes and concluded that aggregate exposure is not expected to exceed 100% of the chronic reference dose and that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to fludioxonil.

[FR Doc. 04–5514 Filed 3–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0047; FRL–7346–8]

Flumioxazin; 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 pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0047, must be received on or before April 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION: