would be for applications to agricultural commodities at rates less than those used as an herbicide or crop desiccant.

Based on the following five considerations, EPA concluded that nonanoic acid is unlikely to pose a risk under all reasonable exposure scenarios:

i. Fatty acids such as nonanoic acid are processed by known metabolic pathways within the body and contribute to normal physiological function.

ii. Nonanoic acid is naturally present at levels up to 224 ppb in apples, 385 ppm in the skin of grapes, and 143 ppm in grape pulp. It is present in a number of other foods as well. An average serving of grapes containing 385 ppm of nonanoic acid in the grape skins would result in exposure to nonanoic acid to an average consumer of 164 µg/kg/day. In comparison, a worst case estimate of dietary exposure to nonanoic acid as a result of its use as sanitizer is 9.7 µg/kg/day for a 70 kg adult and 45 µg/kg/day for a 15 kg child.

iii. The Food and Drug Administration has cleared nonanoic acid as a synthetic food flavoring agent and adjuvant (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1% nonanoic acid) (21 CFR 173.315). Nonanoic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with GAP. It is also exempt from a tolerance when used as a herbicide on all plant food commodities provided that allocations are not made directly to the food commodity except when used as a harvest aid or desiccant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159).

iv. Dietary toxicity testing evidenced adverse reactions only at doses that were at or above limit doses. Dermal toxicity testing showed no significant systemic reaction.

v. The estimated exposures to nonanoic acid and other fatty acids from direct or indirect addition to food as well as sanitizer uses are well below the doses administered in animal studies that are required to elicit an adverse effect. Accordingly, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to nonanoic acid (68 FR 7931).

Nonanoic acid has an estimated 1–day half-life in soil (RED: Soap Salts; EPA–738–R–92–015) and the estimated half-life in the atmosphere is about 1.6 days. Volatilization half-life of nonanoic acid from a river was estimated to be 29 days from a model river and 210 days from a model lake. Nonanoic acid is also inactivated in water by the formation of calcium and magnesium salts which are insoluble precipitates and non-reactive. In summary, nonanoic acid is highly unlikely to accumulate in the environment due to rapid metabolism in soils and neutralization as insoluble salts.

2. *Infants and children.* As previously discussed the dietary safety factor for nonanoic acid is approximately 10,000 fold; therefore, risk to children and infants, with primary exposure thru ingestion, would be of minimal concern.

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Based on the numerous considerations, EPA concluded that pelargonic acid was sufficiently non-toxic that a margin of safety analysis was not appropriate. For the same reasons, EPA has not applied an additional margin of safety for the protection of infants and children (68 FR 7931).

F. International Tolerances

Codex maximum residue levels have not been established for nonanoic acid (68 FR 7931).

G. References

1. Suryanarayanan, S. and W. B. McConnell. 1964. The metabolism of pelargonate-1-C14 by wheat stem rust uredospores. Report: NRC8214. National Research Council of Canada, Saskatoon (Saskatchewan) Prairie Regional Lab., May 8, 1964 (Abstract).

2. Haque, Z. U. and K. J. Aryana. 2002. Volatiles in lowfat chedder cheese containing commercial fat replacers. Food Sci. Tech. Res. 8(2): 188–190 (Abstract).

3. Reiche, L., C. Willis, J. Wilkison, S. Shaw and O. de Lacharriere. 1998. Clinical morphology of sodium lauryl sulfate and nonanoic acid irritant patch test reactions at 48h and 96h in 152 subjects. Contact Dermatitis 39(5): 240–243 (Abstract).

4. Wahlberg, J. E. and H. I. Maibach. 1980. Nonanoic acid irritation - A positive control at routing patch testing? Contact Dermatitis 6(2): 128–130 (Abstract).

5. Willlis, C. M., C. J. M. Stephens and J. D. Wilkinson. 1988. Experimentally-induced irritant contact dermatitis. Determination of optimum irritant concentrations. Contact Dermatitis 18(1): 20–24 (Abstract).

6. Wahlberg, J. E., K. Wrangsjo and A. Hietasalo. 1985. Skin irritancy from nonanoic acid. Contact Dermatitis 13(4): 266–269 (Abstract).

[FR Doc. E4–553 Filed 3–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0044; FRL–7347–1]

Buprofezin; 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–2004–0044, 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 32523)

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–2004–0044. 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–2004–0044. 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–2004–0044. 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–2004–0044.

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–2004–0044. 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 assignedto this action in the subject line on the first page of your response. You may also provide thename, 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 theelements 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 Petitions

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

Interregional Research Project Number 4 (IR-4)

PP 3E6636, 3E6741, and 3E6747

EPA has received pesticide petitions (3E6636, 3E6741, and 3E6747) from IR-4, 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.511 by establishing tolerances for residues of the insecticide, buprofezin, (2-tert-butylimino-3- isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one) in or on the raw agricultural commodities: Fruit, pome, group 11, except apple and apple, pomace at 4.0 parts per million (ppm) (PP 3E6636), apple at 1.2 ppm (PP 3E6636), apple, pomace at 2.5 ppm (PP 3E6636), peach, apricot, and nectarine at 3.0 ppm (PP 3E6741), and avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.30 ppm (PP 3E6747). EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on these petitions. This notice includes a summary of the petitions prepared by Nichino America, Incorporated, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808.

A. Residue Chemistry

1. *Plant metabolism.* The plant metabolism of buprofezin is adequately understood for the pupose of the proposed tolerances.

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.* Residue data has been submitted for fruit, pome, group 11, except apple and apple, pomace; apple; apple, pomace; peach, apricot, and nectarine; and avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, guava, feijoa, jaboticaba, wax jambu, starfruit,

passionfruit, and acerola. The requested tolerances are adequately supported.

B. Toxicological Profile

An assessment of the toxic effects caused by buprofezin is discussed in Unit III. A. and Unit III. B. of the **Federal Register** dated June 25, 2003 (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. Indeed, 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.

2. *Metabolite toxicology*—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.

3. *Endocrine disruption*. 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 at dietary concentrations of 2,000 ppm for 24 months. Buprofezin also caused mild to moderate hepatotoxic effects at this dietary concentration. Nichino America, Inc. believes that the effect on the thyroid most likely resulted from 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 5-9 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*. Tolerances have been established (40 CFR 180.511) for the residues of buprofezin, in or on, the following raw agricultural commodities: Almond; banana; bean, snap, succulent; cattle, fat; cattle, meat byproducts; cattle, liver; citrus, oil; citrus, dried pulp; fruit, citrus; goat, fat; goat, meat byproducts; goat, liver; grape; grape, raisin; hog, fat; hog, meat byproducts; hog, liver; horse, fat; horse, meat byproducts; horse, liver; logan; lychee; milk; pistachio; pulasan; rambutan; sheep, fat; sheep, meat byproducts; sheep, liver; and spanish lime. There are also time-limited tolerances established for lettuce, head; lettuce, leaf; and vegetable, cucurbit. These tolerances are set to expire on 12/31/04. Other additional time-limited tolerances include banana; cotton, gin byproducts; cotton, undelinted seed; and tomato. The expiration date for these tolerances is 12/31/05.

i. *Food*—a. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994-1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. As a result, the following assumptions were made for the acute exposure assessments: The acute dietary analysis assumed tolerance level residues, DEEM (ver. 7) default processing factors, and 100% crop treated for all registered and proposed commodities (Tier I).

b. *Chronic exposure*. Chronic dietary exposure was estimated using the 1994-98 CSFII and DEEM[7]. For all crops, 100% crop-treated was used. Tolerance level residues and default processing factors were used for meat and milk, succulent bean, cucurbit, almond, acerola, avocado, carambola, cherimoya, cotton, genip, guava, longan fruit, lychee, mango, papaya, passion fruit, pistachio, sapodilla, soursop, and sugar apple. Average field trial data and experimental processing factors (when available) were used for banana (including plantains), grape, lettuce, citrus, pome fruit, and peaches (including apricots and nectarines). For tomato, tolerance level residues and experimental processing factors, were used.

ii. *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. Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of buprofezin for acute exposures are estimated to be 102 parts per billion (ppb) for surface water and 0.08 ppb for ground water. The EECs for chronic surface water and ground water exposures are estimated to be 34 ppb, and 0.08 ppb, respectively.

2. *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

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)