

In reviewing delegation requests, EPA's role is to approve state capabilities, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a delegation request for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a delegation request, to use VCS in place of a delegation request that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This information notice granting delegation of the Federal PSD program to Allegheny County issued under the authority of sections 101, 110, and 301 of the Clean Air Act, as amended (42 U.S.C. 7401, 7410, 7601).

Dated: March 18, 2003.

**Thomas C. Voltaggio,**

*Acting Regional Administrator, Region III.*

[FR Doc. 03-7241 Filed 3-25-03; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0070; FRL-7295-8]

### Buprofezin; Notice of Filing Pesticide Petitions to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket ID number OPP-2003-0070, must be received on or before April 25, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** 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

32532)

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

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0070. 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-2003-0070. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or

other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2003-0070. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2003-0070.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0070. 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 13, 2003.

**Debra Edwards,**

*Acting 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 was prepared by the petitioner and represent the views 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 (IR-4)

*PP 2E6369, 2E6455, and 2E6493*

EPA has received pesticide petitions (2E6369, 2E6455, and 2E6493) from the Interregional Research Project Number (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.511 by establishing tolerances for residues of buprofezin in or on the following raw agricultural commodities: Lychee, logan, spanish lime, rambutan, and pulasan at 0.3 parts per million (ppm) (2E6369); bean, snap, succulent at 0.02 ppm (2E6455); and pistachio at 0.05 ppm (2E6493). 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 the petitions. This summary has been prepared by Nichino American, Inc., Wilmington, DE 19808, the registrant.

#### 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 tomatoes, lettuce, and cotton unchanged buprofezin was the only significant residue. In citrus, besides buprofezin, the principal polar residue is a hexose conjugate of BF4 (buprofezin hydroxylated in the t-butyl group), which was resistant to enzyme hydrolysis. With acid hydrolysis of the polar fraction, BF26 was released, with minor amounts of BF9 and BF12. The same compounds were observed following acid hydrolysis of a standard of BF4, which clearly indicates that BF4 is the conjugated metabolite existing in

citrus. Although only limited metabolism was observed in lettuce and cotton, trace levels of BF4/BF26, BF9, and BF12 were observed indicating that the metabolic pathway does not differ with plant species.

2. *Analytical method.* Metabolism studies on lettuce and tomatoes have shown that the only significant residue in these crops is buprofezin. Development of the analytical method took place in parallel with the metabolism studies and the method was designed to quantify two metabolites (BF9 and BF12) in addition to the parent compound. This method was used for analysis of samples from the field trials on all crops except citrus, but for tolerance enforcement only the parent compound is considered.

3. *Magnitude of residues.* The magnitude of residues is adequately understood and supports the proposed tolerances.

#### B. Toxicological Profile

1. *Acute toxicity.* An assessment of toxic effects caused by buprofezin is discussed in Unit III.A. and Unit III.B. of the **Federal Register** dated September 5, 2001 (66 FR 46382) (FRL-6796-6).

2. *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. The proposed metabolic pathway was provided in the tolerance petition, PP 0F6087. For convenience, degradates are referred to by an internal code: BF 1 through 13. Corresponding chemical structures were provided in the tolerance petition, PP 0F6087.

3. *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 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 versus 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—i. Food.* Chronic dietary exposure was estimated using Dietary Exposure Evaluation Model (DEEM™) tolerance levels, and 100% crop treated, except for tomatoes with 40% of the crop treated. The chronic dietary exposure to the U.S. population (total) was estimated as 0.001229 milligrams/kilogram/body weight/day (mg/kg bwt/day), and was 37% of the estimated reference dose (RfD). Exposure to children ages 1 to 6, the highest exposed population subgroup, was 0.002393 mg/kg bwt/day (73% of the estimated RfD).

ii. *Drinking water.* The residue of concern in drinking water was determined to be buprofezin. The potential exposure of buprofezin in drinking water abstracted from surface water was assessed using a Tier 2, modeling approach. EPA's Pesticide Root Zone Model (PRZM) was used to generate potential runoff loads from a standardized agricultural field (10-hectare (ha)) to a standardized aquatic system (1-ha 2-meters (m) deep pond) following application of buprofezin to citrus (the maximum proposed use rate for all crops). Exposure Analysis Modeling Systems (EXAMS) was used to estimate the exposure concentration in surface water. The "once-in-10-year" exceedance probability corresponded to a concentration at 0.52 part per billion (ppb). This value refers to the 56-day average estimated concentration in a farm pond draining agricultural land and must be considered a gross overestimate of concentrations of buprofezin

at the point of drinking water abstraction.

2. *Non-dietary exposure.* Food uses described in these petitions are strictly agricultural and will not add to any residential non-dietary exposure that may exist.

#### 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 residue 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 will occupy 4% of the aPAD for females 13 years and older (no endpoint was identified for the general population including infants and children). In addition, there is potential for acute dietary exposure to buprofezin in drinking water. After calculating drinking water levels of concern (DWLOCs) and comparing them to the estimated environmental concentrations (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, chronic dietary exposure to the U.S. population (total) was 37% of the RfD. Exposure to potential residues in drinking water is expected to be negligible, as DWLOCs are substantially higher than modeled acute and long-term EECs. The margin of exposure (MOE) from the limited potential for short-term exposure from residential uses was >1,000. 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.

iii. *Aggregate cancer risk for the U.S. population.* In accordance with EPA Guidelines for Carcinogen Risk Assessment (proposed July 1999), the Agency's Cancer Assessment Review Committee has classified buprofezin as having suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential, and further recommended that no quantification of cancer risk is required.

2. *Infants and children.* The chronic dietary exposure was 29% of the RfD for infants and 72% of the RfD for children ages 1 to 6. Exposure to potential residues in drinking water is expected to be negligible, as DWLOCs are substantially higher than modeled acute and long-term EECs. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to infants and children from exposure to buprofezin. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to buprofezin residues.

#### F. International Tolerances

Permanent CODEX maximum residue levels have been established for residues of buprofezin in cucumbers at 1.0 ppm, tomatoes at 1.0 ppm, and citrus at 0.5 ppm.

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0106; FRL-7299-3]

### Azoxystrobin; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket ID number OPP-2003-0106, must be received on or before April 25, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** 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:

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- 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**.