

infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose no observed effect level (NOEL). Results for each potential exposed subpopulation (adults, children 1–6 years, and infants <1 year) were compared to the systemic absorbed dose NOEL for cyfluthrin to provide estimates of margins of exposure (MOE). The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,700, and 2,500 for adults, children 1–6 years, and infants (<1 year), respectively. The aggregate MOE for adults is approximately 3,700 and the MOEs for infants and children exceed 2,400. The non-dietary methods used in the analyses can be characterized as highly conservative due to the conservatism inherent in the calculation procedures and input assumptions. An example of this is the conservatism inherent in the jazzercise methodology's over-representation of residential post-application exposures. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the Food Quality Protection Act of 1996 for the current label uses. The additional use of cyfluthrin on the proposed new uses will have no impact on the analysis for non-dietary exposure.

#### D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL–5734–6) and other EPA publications pursuant to FQPA.

#### E. Safety Determination

1. *U.S. population.* Using the assumptions and data described above, based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure to the proposed uses of cyfluthrin will utilize at most 1.5% of the chronic PAD for the U.S. population. The acute dietary exposure to cyfluthrin will utilize at most 34.8% of the acute PAD. The actual exposure both acute and chronic 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 PAD because the PAD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. Drinking water levels of comparison based on the dietary and aggregate exposures are much greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the PAD, if they occur at all. Large margins of safety exist for the non-dietary and aggregate exposure. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food, drinking water, and non-dietary) to residues of cyfluthrin.

2. *Infants and children.* The relevant toxicity studies as discussed in the toxicology section above show no extra sensitivity of infants and children to cyfluthrin; therefore, the FQPA safety factor can be removed. Using the assumptions and data described in the exposure section above, the percent of the chronic PAD that will be used for exposure to residues of cyfluthrin in food for children 1–2 years (the most highly exposed sub-population) is 5.4%. Infants utilize 1.2% (0.000056 mg/kg bwt/day) of the chronic PAD. For the acute assessment, children 1–2 years utilize 52.1% of the acute PAD and infants utilize 34.5% of the acute PAD. As in the adult situation, drinking water levels of comparison are higher than the worst case drinking water estimated concentrations and are expected to use well below 100% of the PAD, if they occur at all. As with adults, large margins of safety exist for the non-dietary and aggregate exposure for infants and children. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of cyfluthrin.

#### F. International Tolerances

There are no Codex maximum residue levels established for cyfluthrin on the

commodities proposed in these petitions.

[FR Doc. 04–1240 Filed 1–27–04; 8:45 am]

BILLING CODE 6560–50–S

#### ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0372; FRL–7335–9]

#### Tebufenozide; 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–2003–0372, must be received on or before February 27, 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:** Joseph M. 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](mailto: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 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-2003-0372. 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 on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

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

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment 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-2003-0372. 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-2003-0372. 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-2003-0372.

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-2003-0372. 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: January 5, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

### **Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Dow AgroSciences 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.

### **Dow AgroSciences**

*PP 7F4824*

EPA has received a pesticide petition (PP 7F4824) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268 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 part 180, to reestablish the time-limited tolerance for indirect or inadvertent residues of tebufenozide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-

dimethylethyl)-2-4-(hydroxyethyl) benzoyl benzoyl in or on the raw agricultural commodity foliage of legume vegetables at 0.1 parts per million (ppm), forage, fodder, hay and straw of cereal grains at 0.5 ppm, grass forage, fodder and hay at 0.5 ppm, and forage, fodder, straw and hay of nongrass animals feeds at 0.5 ppm. Rohm and Haas Company requested these tolerances under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. A Notice of Filing was submitted and published in the **Federal Register** of July 2, 1999 (64 FR 35999) (FRL-6085-6). Based on the data submitted by Rohm and Haas Company, the Agency determined that only time-limited tolerances for these residues could be established. The final rule was published on October 21, 1999 (64 FR 56690; FRL-6382-6) with the time-limited tolerances expiring on September 30, 2003. To establish permanent tolerances, 12 additional trials were requested to establish the requested tolerances in cereal grains and legumes for a 30-day plantback interval. Rohm and Haas committed to fulfill these data gaps. The data were submitted to the Agency on March 25, 2003. An extension of the tolerance which expired September 30, 2003 is needed to allow for Agency review of the additional rotational crop data. 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 qualitative nature of tebufenozide residues in plants and animals is adequately understood and was previously published in the **Federal Register** of October 21, 1999 (64 FR 56690) (FRL-6382-6).

2. *Analytical method.* Adequate enforcement methods are available for determination of tebufenozide in rotational crops. The available Analytical Enforcement Methodology was previously reviewed in the **Federal Register** of October 21, 1999 (FR 64 56690). Dow AgroSciences has also submitted method validation/concurrent recovery studies for a proposed enforcement method. The high performance liquid chromatography/mass spectroscopy (HPLC/MS) method (GRM 02.20) is to be

used for determining residues of tebufenozide in/on rotated crops.

3. *Magnitude of residues.* Twelve field rotation crops residue trials were conducted and residues of tebufenozide and its metabolite were measured. The requested tolerances are adequately supported.

#### B. Toxicological Profile

The toxicological profile and endpoints for tebufenozide which supports this petition to reestablish time-limited tolerances were previously published in the **Federal Register** of October 21, 1999 (64 FR 56690).

#### C. Aggregate Exposure

1. *Dietary exposure.* Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U.S. population subgroups to residues of tebufenozide. These analysis cover all registered crops, as well as, uses pending with the Agency, active and proposed Section 18 uses, and proposed IR-4 minor uses. There are no registered residential nonfood uses of tebufenozide.

i. *Food.—a. Acute exposure and risk.* 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. Neither neurotoxicity nor systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 milligrams/kilogram (mg/kg). No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day limit-dose during gestation to pregnant rabbits. This risk is considered to be negligible.

b. *Chronic exposure and risk.* In conducting a chronic dietary risk assessment, reference is made to the conservative assumptions made by EPA: tebufenozide time-limited tolerances (64 FR 56690, October 21, 1999), tolerance level residues, and some percent crop tested (Tier 2). The analysis was determined using Dietary Exposure Evaluation Model (DEEM) software and the U.S. Department of Agriculture (USDA) Nationwide Continuing Surveys of Food Intake by Individuals (SCFII) that was conducted from 1989 through 1992.

ii. *Drinking water.—a. Acute exposure and risk.* Because no acute dietary endpoint was determined, Dow AgroSciences concludes that there is a

reasonable certainty of no harm from acute exposure from drinking water.

b. *Chronic exposure and risk.* The Agency calculated the Tier I Estimated Environmental Concentrations (EECs) for tebufenozide using generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCI-GROW) (ground water) models for use in the human health risk assessment. For chronic exposure, the worst case EECs for surface water and ground water were 16.5 parts per billion (ppb) and 1.04 ppb, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water. These modeling data were compared to the chronic drinking water levels of comparison (DWLOC) for tebufenozide in ground water, and surface water.

For purposes of chronic risk assessment, the estimated maximum concentration for tebufenozide in surface water and ground waters (16.5 ppb) was compared to the back-calculated human health DWLOCs for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized below in Table:

TABLE—DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE TO TEBUFENOZIDE<sup>1</sup>

| Population Category <sup>2</sup>       | Chronic RfD (mg/kg/day) | Food exposure (mg/kg/day) | Exposure max. water (mg/kg/day) <sup>3</sup> | (DWLOC) µg/L <sup>4, 5, 6</sup> | EEC <sup>7</sup> calc. max. µg/L (in percent) |
|----------------------------------------|-------------------------|---------------------------|----------------------------------------------|---------------------------------|-----------------------------------------------|
| U.S. population (48 contiguous states) | 0.018                   | 0.0038                    | 0.0142                                       | 497                             | 16.5                                          |
| Females (13 + years)                   | 0.018                   | 0.0043                    | 0.0137                                       | 411                             | 16.5                                          |
| Children (1–6 years)                   | 0.018                   | 0.0092                    | 0.0088                                       | 88                              | 16.5                                          |

<sup>1</sup> Values are expressed to two significant figures.

<sup>2</sup> Within each of these categories, the subgroup with the highest food exposure was selected.

<sup>3</sup> Maximum water exposure chronic milligrams/kilogram/day (mg/kg/day) = Chronic PAD mg/kg/day.

<sup>4</sup> Drinking water levels of concern (DWLOC) µg/L = Max. water exposure mg/kg/day x bodyweight kg divided by 10<sup>-3</sup> mg/µg x water consumed daily (L/day).

<sup>5</sup> HED default body weights are: General U.S. population, 70 kg; females (13+ years old), 60 kg; other adult populations, 70 kg; and, all infants/children, 10 kg.

<sup>6</sup> HED default daily drinking rates are 2 liter/day (L/day) for adults and 1 L/day for children.

<sup>7</sup> Estimates Environmental Concentration (EEC). Chronic 56-day value.

2. *Non-dietary exposure.* There is a potential for occupational exposure to tebufenozide during mixing, loading and application activities. However, the Agency did not identify dermal or inhalation endpoints for tebufenozide and determined that risks from these routes of exposure are negligible.

#### 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 tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of

this tolerance petition, Dow AgroSciences has not assumed that tebufenozide has a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population.* Using the exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, Dow AgroSciences has concluded that dietary (food only) exposure to tebufenozide will utilize 21% of the chronic population adjusted dose (cPAD) for the U.S. population, and 51% of the cPAD for the most

highly exposed population subgroup (children 1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and run off to surface water under certain environmental conditions. The modeling data for tebufenozide indicate levels less than the Agency's DWLOCs. There are no chronic non-occupational/residential exposures expected for tebufenozide. Therefore, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to tebufenozide residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systematic toxicity.

FFDCA section 408 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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

There is a complete toxicity data base for tebufenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. For the reasons summarized above, Dow AgroSciences concludes

that an additional safety factor is not needed to protect the safety of infants and children.

Using the exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, the Agency has concluded that dietary (food only) exposure to tebufenozide will utilize 21% of the cPAD for the U.S. population, and 51% of the cPAD for the most highly exposed population subgroup (children 1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary non-occupational exposure, Dow AgroSciences does not expect the aggregate exposure to exceed 100% of the RfD.

#### *F. International Tolerances*

Codex MRLs have been established for residues of tebufenozide in/on pome fruit 1.0 ppm, husked rice 0.1 ppm and walnut 0.05 ppm. Tebufenozide is registered in Canada, and a tolerance for residues in/on apples is established at 1.0 ppm. EPA has set the pome fruit tolerance at 1.5 ppm based on U.S. field residue trials.

[FR Doc. 04–1241 Filed 1–27–04; 8:45am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0404; FRL–7339–2]

### Harpin Protein; 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–2003–0404, must be received on or before February 27, 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:** Diana Horne, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8367; e-mail address: [horne.diana@epa.gov](mailto:horne.diana@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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–2003–0404. 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