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.*

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)
- Pesticde 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

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.1. 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–2003–0404. 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–2003–0404. 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–2003–0404.

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–2003–0404. 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 12, 2004.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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 the EDEN Bioscience Corporation, 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.

EDEN Bioscience Corporation

PP 3F6765

EPA has received a pesticide petition (3F6765) from EDEN Bioscience Corporation, 3830 Monte Villa Parkway, Bothell, WA 98021–6942, 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 establish an amendment of the existing tolerance exemption for the biochemical pesticide harpin protein on all raw agricultural commodities. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, EDEN Bioscience Corporation has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by the EDEN Bioscience Corporation; and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

In the **Federal Register** of September 9, 1999 (64 FR 49010) (FRL–6095–9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition (PP 9F6027) by the EDEN Bioscience Corporation. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. This petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for the biochemical pesticide harpin protein in or on all food crops. The final rule exempted the biochemical harpin from the requirement of a tolerance on food commodities when applied/used in agricultural fields and greenhouses for the management of plant diseases, the significant improvement in growth and yields, and the suppression of certain insects and other pests. EPA published a final rule establishing a tolerance exemption in the **Federal Register** of May 3, 2000 (65 FR 25660) (FRL–6497–4), amending 40 CFR 180.1204. Research on other harpin proteins that are similar to this active ingredient indicates that many of these proteins also exhibit activities of commercial value in crop production. Because 40 CFR 180.1204 does not specify the scope of harpin proteins that are exempt, EDEN proposes to clarify this exemption by specifying the criteria a protein must meet in order to be subject to the exemption.

A. Product Name and Proposed Use Practices

All products containing harpin protein(s) that meet the specifications proposed in this exemption. Products containing harpin protein are used to enhance plant growth, quality, and yield, to improve overall plant health, and to aid in pest management.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Harpin proteins share several identifying characteristics. Harpin proteins are less than 100 kilo Dalton (kD) in size. They are acidic proteins, with Daltons an iso-electric point (pI) of less than 7.0. They are comprised of at least 10% of the amino acid glycine and contain no more than one cystine amino acid residue. Harpin proteins elicit the hypersensitive response (HR). HR is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves. Harpin proteins possess a common secondary structure consisting of alpha and beta units that form an HR domain. They are readily degraded by proteinase, and are heat stable, meaning that they retain HR activity when heated to 65 ^{o}C for 20 minutes.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* No residues of harpin protein are expected to occur at the time of harvest because harpin protein is rapidly degraded by environmental factors such microbial digestion and ultraviolet (UV) irradiation. For example, studies demonstrate that harpin is degraded within minutes by SubtilisinA, a microbial enzyme that

occurs commonly in the environment. In fact, this mode of rapid degradation in the environment is one of the proposed criteria for including a harpin protein in the exemption from the requirement of a tolerance. Specifically, the proposed criterion is ''no protein fragments >3.5 kD after 15 minutes degradation with SubtilisinA.'' Residue studies submitted to support the existing exemption from tolerance demonstrate that harpin protein is not detectable at the time of harvest. In these studies, no harpin protein residues could be detected in samples taken immediately after harpin protein was applied at the maximum application rate. Because there is no detectable residue at harvest, an analytical method is not relevant.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* No analytical method to detect and measure residues of harpin protein is needed because harpin protein poses no hazard to humans. Results of mammalian toxicology studies conducted at the limit dose indicate no observed adverse effects associated with harpin protein. Moreover, no residues of harpin protein are expected to occur at the time of harvest because harpin protein is rapidly degraded by environmental factors such as microbial digestion and UV irradiation.

C. Mammalian Toxicological Profile

Products containing harpin proteins exhibit little or no mammalian toxicity. To qualify for exemption, a harpin protein must exhibit a rat acute oral toxicity lethal dose (LD_{50}) of greater than 5,000 mg product/kg body weight Toxicity Category IV. The source(s) of genetic material that encode the harpin protein(s) is limited to bacterial plant pathogens that are not known to be pathogenic to mammals. Harpin proteins must be readily degraded by a proteinase that is representative of environmental conditions. Specifically, there must be no protein fragments of a size greater than 3.5 kD after 15 minutes degradation with SubtilisinA, a proteinase that is common and widespread in the environment. Further, harpin proteins have a nontoxic mode of action; they activate the treated plant's own growth and defense systems. EDEN Bioscience Corporation has concluded that harpin proteins pose no unique or additional risk to children or infants, and proposes an exemption from the requirement of a tolerance for all harpin proteins that meet the following specifications:

1. Consists of a protein <100 kD in size that is acidic pI <7.0, glycine rich >10% and contains no more than one cystine residue.

2. The source(s) of genetic material encoding the protein are bacterial plant pathogens that are not known to be mammalian pathogens.

3. Elicits the hypersensitive response (HR) which is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves.

4. Possesses a common secondary structure consisting of alpha and beta units that form an HR domain.

5. Is heat stable (retains HR activity when heated to 65 °C for 20 minutes).

6. Is readily degraded by a proteinase representative of environmental conditions (no protein fragments >3.5 kDa after 15 minutes degradation with SubtilisinA).

7. Exhibits a rat acute oral toxicity LD_{50} of >5,000 mg product/kg body weight.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Because harpin proteins are rapidly degraded in the environment by common proteinases, UV irradiation, and oxidizing agents, no active ingredient residues are detectable, using available methods, on treated crops even immediately after application. Dietary exposure to harpin via consumption of treated food or feed is negligible, if any at all.

ii. *Drinking water.* Harpin proteins readily degraded by common proteinases and UV irradiation, and are highly sensitive to very small amounts of chlorine or similar oxidizing agents as contained in many municipal water systems. Therefore, residues of harpin are unlikely to occur in drinking water or food, given its rapid degradation in soil and water.

2. *Non-dietary exposure.* The company believes that the potential for non-dietary exposure to the general population including infants and children is unlikely as the proposed use sites are primarily commercial, agricultural and horticultural settings and that non-dietary exposures would not be expected to pose any quantifiable risks due to lack of residues of toxicological concern. Increased nondietary exposure of harpin via home and garden use, etc., is not considered likely because of the typically low use rates and volumes, and the lack of persistence of the active ingredient in the environment.

E. Cumulative Exposure

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of harpin protein and no information that indicates that toxic effects would be cumulative with any other compounds. Moreover, harpin proteins do not exhibit a toxic mode of action in its target pests or diseases.

F. Safety Determination

1. *U.S. population.* Harpin's lack of toxicity is demonstrated by the results of acute toxicity testing in mammals in which harpin causes no adverse effects when dosed orally at the limit dose for the study. Thus, the aggregate exposure to harpin over a lifetime should pose negligible risks to human health.

2. *Infants and children.* Based on the lack of toxicity and low exposure, there is a reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to harpin residues. Exempting harpin proteins that meet the specified criteria from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Effects on the Immune and Endocrine Systems

EDEN Bioscience Corporation has no information to suggest that harpin proteins will adversely affect the immune or endocrine systems.

H. Existing Tolerances

An existing exemption from tolerance has been established for harpin protein in the United States, 40 CFR 180.1204.

I. International Tolerances

EDEN Bioscience Corporation is not aware of any tolerances, exemptions from tolerance or maximum residue levels issued for harpin protein outside of the United States.

[FR Doc. 04–1242 Filed 1–27–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

January 16, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it