

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0350; FRL-7332-8]

Bacillus Thuringiensis VIP3A Insect Control Protein as Expressed in Event COT102; Notice of Filing a Pesticide Petition to Establish an Exemption from the Requirement of 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 identification (ID) number OPP-2003-0350, must be received on or before December 26, 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:** Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: leonard.cole@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-2003-0350. 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 EPA's 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 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-2003-0350. 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-2003-0350. 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-2003-0350.

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-2003-0350. 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: November 12, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner 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 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.

Syngenta Seeds, Incorporated

PP 3F6756

EPA has received a pesticide petition (3F6756) from Syngenta Seeds, Incorporated, P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709-2257, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the plant-pesticide *Bacillus*

thuringiensis VIP3A Insect Control Protein as Expressed in Event COT102 and the genetic material necessary for its production in or on cotton.

Pursuant to section 408(d)(2)(A)(i) of the FFDCFA, as amended, Syngenta Seeds, Incorporated has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Syngenta Seeds, Incorporated 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.

A. Product Name and Proposed Use Practices

Syngenta has developed a new cotton line that expresses an insect control protein designated VIP3A. It has been genetically incorporated into a cotton plant product identified as *Bacillus thuringiensis* (Bt) VIP3A Insect Control Protein as Expressed in Event COT102. VIP3A is one of a novel class of recently discovered insecticidal proteins that occur naturally in *Bacillus thuringiensis*. The VIPs (vegetative insecticidal proteins) are produced during vegetative bacterial growth.

Other than its demonstrated insecticidal activity, VIP3A is not known to have any other biological or catalytic function. Although VIP3A protein shares no homology with known Cry proteins, extensive testing has established that VIP3A is similarly very specific in its activity, and has demonstrated toxicity only to the larvae of certain lepidopteran species, including key pests of cotton. Further, because VIP3A appears to target a different receptor than Cry proteins in sensitive species, it represents a potentially useful tool in the prevention or management of pest resistance to Cry proteins.

Upon commercial introduction, the use of transgenic VIP3A cotton plants is expected to offer an important new option in lepidopteran pest control and integrated pest management programs. Moreover, VIP3A cotton will be an attractive, biologically based alternative to the use of foliar insecticides. The use of VIP3A cotton plants is expected to offer substantial environmental and worker safety benefits associated with the reduced need for broad-spectrum insecticides. Additionally, benefits to cotton growers will likely include greater profitability, convenience and

predictability in producing a high-yielding cotton crop.

VIP3A expressing cotton plants derived from transformation event COT102 have been field tested under U.S. Department of Agriculture (USDA) Notifications and in compliance with the guidelines for USDA regulated plantings in 2000, 2001, and 2002. The overall results of those trials have indicated that cotton plants derived from event COT102 have significant and specific insecticidal activity against several lepidopteran pests including, but not limited to, *Helicoverpa zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm), and *Pectinophora gossypiella* (pink bollworm).

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Cotton, *Gossypium hirsutum*, has been genetically modified to be resistant to selected lepidopteran insect pests. Insect protection was accomplished by the insertion of the VIP3A(a) gene, which was cloned from *Bacillus thuringiensis* strain AB88. The identity of the active pesticidal ingredient in cotton plants derived from transformation event COT102 includes the protein VIP3A and the genetic material necessary for its production in cotton. Research has demonstrated the specific insecticidal properties of VIP3A to certain lepidopteran insects in cotton as well as its lack of effects on nontarget organisms such as mammals, birds, fish, and beneficial insects.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* A determination of the magnitude of residue at harvest is not required for residues exempt from tolerances. However, the petitioner has provided data on the quantity of VIP3A protein measured in various plant parts including seeds of VIP3A cotton, as measured by enzyme linked immunosorbent assay (ELISA). Additionally, the petitioner has provided data on the quantity or presence of VIP3A protein in processed cottonseed products.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method is not required because this petition requests an exemption from tolerances. However, the petitioner has submitted an analytical method for detection of the VIP3A protein in cottonseed by ELISA analysis.

C. Mammalian Toxicological Profile

The VIP3A(a) gene expressed in Event COT102 cotton is very similar (ca. 99%

homology) to VIP3A or VIP3A--like genes that appear to occur commonly in Bt strains from a variety of sources. In addition, it has been determined that the VIP3A protein demonstrates insect specific toxicity and must be ingested to be active. Once in the insect gut, the VIP3A protein binds to specific receptors (different from those bound by Cry1A proteins), inserts into the membrane and forms ion-specific pores. These events disrupt the digestive processes and cause death of the insect. The lack of mammalian toxicity has been confirmed in numerous safety studies conducted in laboratory animals, which are traditional experimental surrogates for humans. These studies, summarized herein, demonstrate the lack of toxicity of the VIP3A protein following high-dose acute oral exposures to mice, rapid degradation of VIP3A upon exposure to simulated gastric fluid, and the lack of amino acid sequence similarity of the VIP3A protein to proteins known to be mammalian toxins or human allergens. It can be concluded from these studies that the VIP3A protein will be non-toxic to humans.

When proteins are toxic, they are known to act via acute mechanisms and at very low doses (Sjoblad, R.D., J.T. McClintock and R. Engler (1992) "Toxicological Considerations for Protein Components of Biological Pesticide Products." *Regulatory Toxicol. Pharmacol.* 15: 3-9). Therefore, when a protein demonstrates no acute oral toxicity in high-dose testing using a standard laboratory mammalian test species, this supports the determination that the protein will be non-toxic to humans and other mammals, and will not present a hazard under any realistic exposure scenario, including long-term exposures.

Studies conducted to assess the mammalian safety of VIP3A protein have demonstrated no toxicity. Four acute oral toxicity studies in mice have been completed. Three of the VIP3A test substances used were produced via microbial expression systems and one prepared by extracting protein from leaves of VIP3A event Pacha-derived corn plants. The four test substances contained VIP3A protein that differed from the VIP3A protein expressed in event COT102 by zero to two amino acids. At maximum dosage the microbially expressed test substance was administered at a level of 5,000 milligrams/kilogram (mg/kg) with an estimated acute lethal dose (LD)₅₀ by gavage determined to be >3,675 mg VIP3A/kg (mg/kg body weight). Because toxicity was not observed at this dose, it can be concluded that the LD₅₀ for

pure VIP3A protein is >3,675 mg/kg body weight. The VIP3A protein in both the microbial and plant derived test substance was determined to be substantially equivalent to VIP3A produced in event COT102 derived cotton plants, as measured by biological activity, protein size, immunoreactivity, mass spectral analysis of amino acid sequence, and apparent lack of post-translational modifications.

The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public databases. The VIP3A protein is not derived from a known source of allergens and does not display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

VIP3A protein appears to be present in multiple commercial formulations of Bt microbial insecticides at concentrations estimated to be *ca.* 0.4, 32 ppm. This conclusion is based on the presence of proteins of the appropriate molecular weight and immunoreactivity (by SDS-PAGE and western blot), and quantitation by ELISA. Therefore, it is conceivable that small quantities of VIP3A protein are present in the food supply because VIP3A (or a very similar protein, based on size and immunoreactivity) appears to be present in currently registered insecticide products used on food crops, including fresh market produce. These commercial Bt products are all exempt from food and feed tolerances.

D. Aggregate Exposure

1. *Dietary exposure—i. Food.* Food products derived from cotton (refined cottonseed oil and cellulose “linters” fiber) are highly processed and are essentially devoid of any proteins. Moreover, no VIP3A protein was detected in refined cottonseed oil or cotton fiber produced from event COT102-derived VIP3A cotton plants. Therefore, no human dietary exposure to VIP3A protein is expected to occur *via* VIP3A cotton. Even if dietary exposure to VIP3A protein were to occur, data derived from bioinformatic analyses as well as direct *in vitro* and *in vivo* testing collectively indicate that the VIP3A protein is unlikely to have allergenic potential. The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public databases. The VIP3A protein is not derived from a known source of allergens and does not

display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

ii. *Drinking water.* No exposure to VIP3A and the genetic material necessary for its production in cotton *via* drinking water is expected. The proteins are incorporated into the plant and will not be available. However, if exposure were to occur by this route, no risk would be expected because the VIP3A protein is not toxic to mammals

2. *Non-dietary exposure.* Non-dietary exposure is not anticipated, due to the proposed use pattern of the product. Exposure *via* dermal or inhalation routes is unlikely because the plant-incorporated protectant is contained within plant cells. However, if exposure were to occur by non-dietary routes, no risk would be expected because the VIP3A protein is not toxic to mammals.

E. Cumulative Exposure

Because there is no indication of mammalian toxicity to the VIP3A protein, it is reasonable to conclude that there are no cumulative effects for this plant-incorporated protectant.

F. Safety Determination

1. *U.S. population.* The lack of mammalian toxicity at high levels of exposure to the VIP3A protein demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated *via* consumption of processed food products produced from VIP3A cotton. Moreover, little to no human dietary exposure to VIP3A protein is expected to occur *via* VIP3A cotton. Due to the lack of toxicity of the VIP3A protein and its very low potential for allergenicity, dietary exposure is not anticipated to pose any harm for the U.S. population. No special safety provisions are applicable for consumption patterns or for any population sub-groups.

2. *Infants and children.* The plant-incorporated protectant active ingredient, *Bacillus thuringiensis* VIP3A insect control protein and the genetic material necessary for its production in cotton, demonstrates no mammalian toxicity. Thus, there are no threshold effects of concern and, consequently, there is no need to apply an additional margin of safety.

G. Effects on the Immune and Endocrine Systems

The safety data submitted show no adverse effects in mammals, even at

very high dose levels, and support the prediction that the VIP3A protein would be non-toxic to humans. Therefore no effects on the immune or endocrine systems are predicted. When proteins are toxic, they are known to act *via* acute mechanisms and at very low dose levels. Sjoblad, Roy D., *et al.*

“Toxicological Considerations for Protein Components of Biological Pesticide Products,” *Regulatory Toxicology and Pharmacology* 15, 3–9 (1992). Further, the VIP3A protein is derived from a source that is not known to exert an influence on the endocrine system.

H. Existing Tolerances

There are no existing tolerances for the Bt VIP3A protein and the genetic material necessary for its production. Other Bt-based pesticide products are exempt from tolerances.

I. International Tolerances

There are no existing international tolerances or exemptions from tolerance for the Bt VIP3A protein and the genetic material necessary for its production.

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0358; FRL–7334–7]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials took place during the period April 1, 2003 to September 30, 2003 to control unforeseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption or denial for the name of a contact person. The following information applies to all contact persons: Team Leader, Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9366.

SUPPLEMENTARY INFORMATION: EPA has granted or denied emergency exemptions to the following State and