

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: May 29, 2003.

**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 Syngenta Seeds, Inc. 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, Inc.**

*PP 3G6547*

EPA has received a pesticide petition (PP 3G6547) from Syngenta Seeds, Inc., P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709-2257, 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 exemption from the requirement of a tolerance for the 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 FFDCA, as amended, Syngenta Seeds, Inc. has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Syngenta Seeds, Inc., 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