

DC 20460-0001, Attention: Docket ID Number OPP-2003-0317.

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-2003-0317. 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: October 9, 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.

I. Monsanto Company

PP 7F4888

EPA has received a pesticide petition request from Monsanto Company, 800 North Lindberg Blvd., St. Louis, Missouri 63167, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by removing the time limitation for the exemption from the requirement of a tolerance for the plant-incorporated protectant *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn in or on field corn, sweet corn, and

popcorn. The tolerance exemption was originally requested under pesticide petition number PF 7F4888.

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

Corn has been genetically transformed to produce variants of the *Bacillus thuringiensis* protein Cry3Bb1. The production of Cry3Bb1 protein in root tissue protects corn from damage caused by corn rootworm larval feeding. Plants producing this protein are derived from transformation events that contain the insecticidal gene and the genetic material necessary for its expression in corn. Data developed with multiple Cry3Bb1 variants and corn transformation events indicate that the protein poses no foreseeable risks to nontarget organisms, including mammals, birds, fish, beneficial insects and earthworms. Cry3Bb1 corn is less toxic than all other currently registered rootworm control products. Cry3Bb1 corn provides growers with a highly efficacious product for controlling damage caused by corn rootworms that is compatible with integrated pest management practices.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The gene encoding Cry3Bb1 protein was isolated from *Bacillus thuringiensis* subspecies *kumamotoensis* and modified before insertion into corn. Data characterizing the Cry3Bb1 variant produced in corn have been submitted to and reviewed by EPA. Safety studies were conducted with purified extracts of Cry3Bb1 produced in a heterologous bacterial fermentation system. Data submitted by Monsanto demonstrate that the plant- and bacterial-produced proteins are equivalent with respect to immunoreactivity, molecular weight, amino acid sequence, level of glycosylation, and insecticidal activity. Production of microbial Cry3Bb1 was