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–2002–0270. 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–2002–0270. 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), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2002–0270.

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–2002–0270. 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. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. 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. Registration Application

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

Product Containing an Active Ingredient Not Included in any Previously Registered Products

File symbol: 74411–R. Applicant: Insect Biotechnology, Inc., 100 Capitola Drive, Suite 307, Durham, NC 27713. Product name: Technical Trypsin Modulating Oostatic Factor (TMOF). Product type: Insecticide. Active ingredient: Trypsin Modulating Oostatic Factor at 100%. Proposed classification/Use: Manufacturing use product for formulation into insecticidal products for mosquito control.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: September 30, 2002.

Janet L. Andersen,

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

[FR Doc. 02–25684 Filed 10–8–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0244; FRL–7198––2]

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–2002–0244, must be received on or before November 8, 2002.

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**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0244 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Leonard Cole, Biopesticide and Pollution Prevention Division, Office of Pesticide Programs, (7511C) Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food

manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit I.A. above. 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 identification (ID) number OPP–2002–0244. 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. 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 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–2002–0244. 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–2002–0244. 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.

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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–2002–0244.

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–2002–0244. 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?

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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. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. 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 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: September 24, 2002.

Janet L. Andersen,

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

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by Mycogen Seeds c/o Dow AgroSciences LLC, and represents the view of the Mycogen Seeds. 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.

Mycogen Seeding c/o Dow AgroSciences LLC

PP 2G6494

EPA has received a pesticide petition 2G6494 from Mycogen Seeds c/o Dow AgroSciences LLC , 9330 Zionsville Road, Indianapolis, IN 46268–1054, 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 temporary tolerance for the plant-incorporated protectant *Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) insect control protein and the genetic material responsible for the production of this protein in or on cotton. (See EPA document OPP–2002–0244, FRL–7196–2 published elsewhere in this issue of the **Federal Register**.)

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Mycogen Seeds c/o Dow AgroSciences LLC has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Mycogen Seeds c/o Dow AgroSciences LLC 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

This notice of filing summarizes information submitted and cited by Mycogen Seeds c/o Dow AgroSciences LLC in support of a request for a temporary exemption from tolerance residues of the plant incorporated-protectant *Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) insect control protein and the genetic material responsible for the production of this protein in cotton.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues. Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) insect control protein is expressed in cotton plants to provide protection from key lepidopteran insect pests such as the tobacco budworm and pink bollworm. Cry1F (synpro) transgenic plants are derived from transformation events that contain the insecticidal gene via a plasmid insert. The Cry1F (synpro) protein poses no foreseeable risks to non-target organisms including mammals, birds, fish, beneficial insects, and earthworms. Cry1F (synpro)-protected cotton provides growers with a highly efficacious tool for controlling important insect pests in cotton in a manner that is fully compatible with integrated pest management practices.

2. *Analytical method.* A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed. No analytical method is included because this petition requests a temporary exemption from the requirement for a tolerance.

C. Mammalian Toxicological Profile

Cry proteins have been deployed as safe and effective pest control agents in microbial *Bacillus thuringiensis* formulations for almost 40 years. There are currently 180 registered microbial *Bacillus thuringiensis* products in the United States for use in agriculture, forestry, and vector control. The numerous toxicology studies conducted with these microbial products show no significant adverse effects, and demonstrate that the products are practically non-toxic to mammals. An exemption from the requirement of a tolerance has been in place for these products since at least 1971 (40 CFR 180.1011).

Toxicology studies conducted to determine the toxicity of Cry1F (synpro) insect control protein demonstrated that the protein has very low toxicity. In an acute oral toxicity study in the mouse (male and female), the estimated acute LD_{50} was determined to be >2,000 mg/kg of the microbially produced test substance.

In an *in vitro* study, Cry1F protein was rapidly and extensively degraded in simulated gastric conditions in the presence of pepsin at pH 1.2. Cry1F (synpro) was completely proteolyzed to amino acids and small peptide fragments in <1 minute. This indicates that the protein is highly susceptible to digestion in the human digestive tract and that the potential for adverse health effects from chronic exposure is virtually nonexistent. Moreover, proteins in general are not known to be carcinogenic. A search of relevant databases indicated that the amino acid sequence of the Cry1F (synpro) protein exhibits no significant homology to the sequences of known allergens or protein toxins. Thus, Cry1F (synpro) is highly unlikely to exhibit an allergic response.

The results of a study to determine the lability of the Cry1F (synpro) protein to heat demonstrated that the protein was deactivated after exposure to 75° or 90°C for 30 minutes, according to bioassay results on tobacco budworm.

The genetic material necessary for the production of the Cry1F (synpro) insect control protein are nucleic acids (DNA) which are common to all forms of plant and animal life. There are no known instances of where nucleic acids have caused toxic effects as a result of dietary exposure.

Collectively, the available data on Cry1F (synpro) protein along with the safe use history of microbial *Bacillus thuringiensis* products establishes the safety of the plant pesticide *Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) insect control protein and the genetic material necessary for its production in all raw agricultural commodities.

D. Aggregate Exposure

Non-dietary exposure. Insecticidal crystal proteins of *Bacillus thuringiensis* are known to have a high degree of insect specificity via binding to specific receptors in the insect gut, and do not harm people, wildlife or many beneficial insects (Ballester et al., 1999; Aronson and Shai, 2001). The level of protein that is expressed in corn plants is very low. The small amount of Cry1F (synpro) in plant tissue is deep in the plant matrix, which greatly reduces availability for dermal or respiratory exposure. Significant dietary exposure to Cry1F (synpro) protein is unlikely to occur. Dietary exposures at very low levels, via ingestion of processed commodities, although they may occur, are unlikely to be problematic because of the low toxicity and the high degree of digestibility of the protein. In addition, the protein is not likely to be present in drinking water because the protein is deployed in minute quantities within the plant, and studies demonstrate that Cry1F (synpro) protein is rapidly degraded in soil. In summary, the potential for significant aggregate exposure to Cry1F (synpro) protein is highly unlikely.

E. Cumulative Exposure

Common modes of toxicity are not relevant to consideration of the cumulative exposure to *Bacillus thuringiensis* Cry1F (synpro) insect control protein. The product has demonstrated low mammalian toxicity and Bt insecticidal crystal proteins are known to bind to specific receptors in the insect gut, such that biological effects do not appear to be cumulative with any other known compounds.

F. Safety Determination

1. *U.S. population.* The deployment of the product in minute quantities within the plant, the very low toxicity of the product, the lack of allergenic potential, and the high degree of digestibility of the protein, are all factors in support of Mycogen's assertion that no significant risk is posed by exposure of the U.S. population to *Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) insect control protein.

2. *Infants and children.* Non-dietary exposure to infants and children is not anticipated, due to the proposed use pattern of the product. Due to the very low toxicity of the product, the lack of allergenic potential, and the high degree of digestibility of the protein, dietary exposure is anticipated to be at very low levels and is not anticipated to pose any harm to infants and children.

G. Effects on the Immune and Endocrine Systems

Given the rapid digestibility of Cry1F (synpro) insecticidal crystal protein, no chronic effects are expected. Cry1F (synpro) insecticidal crystal protein, or metabolites of the insecticidal crystal protein are not known to, or are expected to have any effect on the immune or endocrine systems. Proteins in general are not carcinogenic, therefore, no carcinogenic risk is associated with the Cry1F (synpro) protein.

H. Existing Tolerances

There are no existing tolerances or exemptions from tolerance for *Bacillus thuringiensis* subspecies aizawai Cry1F (synpro) granted to Mycogen Seeds c/o Dow AgroSciences LLC.

[FR Doc. 02–25584 Filed 10–8–02; 8:45 a.m.]

BILLING CODE 6560–50–S