mg/kg/day for female dogs in the control through high-dose groups, respectively, with a NOAEL of 24.9 mg/kg/day for males and 29.6 mg/kg/day for females based on hematology effects and microscopic liver changes.

An 18–month feeding/carcinogenicity study in mice was conducted with dietary intake of 0, 46.6, 93.9, 160.5, or 337.6 mg/kg/day for males and 0, 58.0, 116.9, 198.0, or 407.1 mg/kg/day for females. A NOAEL of 93.9 mg/kg/day in males and 116.9 mg/kg/day in females was based on decreases in Hgb and HCT. There were no treatment-related increases in tumors of any kind observed at any dose level.

In a 24–month chronic feeding/carcinogenicity study in rats at dietary doses of 0, 24.3, 40.0, 82.8, or 123.5 mg/kg/day for males and 20.0, 36.4, 67.0, or 124.7 mg/kg/day for females, an overall NOAEL of 40.0 mg/kg/day in males and 36.4 mg/kg/day in females was based on hematology effects and reduced body weights. There was no evidence of a carcinogenic response.

6. *Animal metabolism*. A metabolism study in rats indicated that approximately 84 to 104% of the orally administered dose of sulfentrazone was excreted in the urine, and that the pooled urinary radioactivity consisted almost entirely of 3-hydroxymethyl sulfentrazone. Pooled fecal radioactivity showed that the major metabolite consisted of 3-hydroxymethyl-sulfentrazone (1.26 to 2.55% of the administered dose). The proposed metabolic pathway appeared to be conversion of the parent compound mainly to 3-hydroxymethyl-sulfentrazone (excreted in urine and feces).

7. *Endocrine disruption*. An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that sulfentrazone causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. A Tier 3 short-term exposure analysis has been performed to estimate the exposure for all adults, adult females, and toddlers (3 to 4 years of age) in the U.S. population for these raw commodities and processed commodities. This analysis utilized Novigen's (Novigen Sciences, Inc.) Dietary Exposure Evaluation Model (DEEM) software; field trial data for registered and pending crop uses; percent crop treated information; and consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1994–1996.

ii. *Drinking water*. A Tier 1 short-term drinking water exposure assessment was conducted to determine exposure risk of sulfentrazone residues from consumption of water. This analysis was performed utilizing EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure Risk Assessments (DUS EPA, 1997b), the absorbed (systemic) aggregate exposure estimates, and water data from FMC Corporation ground water study conducted in North Carolina.

2. *Non-dietary exposure*. The primary source for human non-dietary exposure to sulfentrazone will be from post-application exposure to treated residential turf grass. The routes of sulfentrazone exposure were dermal post-application exposure for adults and toddlers, and post-application incidental ingestion of sulfentrazone due to the hand-to-mouth behavior of toddlers. A worst case short-term non-dietary exposure analysis was conducted using algorithms and default factors published in EPA's SOPs for Residential Exposure Assessments.

D. Cumulative Effects

Cumulative exposure to substances with common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide residue and ''other substances that have a common mechanism of toxicity.''

In the case of sulfentrazone, EPA has determined that it does not have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment. This tolerance determination therefore does not take into account common mechanism issues. The Agency will reexamine the tolerances for sulfentrazone, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

E. Safety Determination

1. *U.S. population*. The absorbed (systemic) aggregate exposure estimates for all adults, and adult females were found to be 0.0015 mg/kg/day and 0.0017 mg/kg/day, respectively. The acute dietary (99.9%), non-dietary, and aggregate margin of exposure (MOE) for all adults were found to be 12,353, 7,571, and 6,726 respectively. The acute dietary (99.9%), non-dietary and aggregate MOE for adult females were 22,857, 6,327, and 5,717 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to the U.S. population from exposure to sulfentrazone.

2. *Infants and children*. The absorbed (systemic) aggregate exposure estimates for toddlers were found to be 0.0054 mg/kg/day. The acute dietary (99.9%), non-dietary, and aggregate MOE for toddlers were found to be 6,721, 2,048, and 1,869 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to infants and children from exposure to sulfentrazone.

The calculated drinking water levels of concern for all adults, and adult females were estimated to be 298 parts per billion (ppb), 250 ppb, respectively. These values exceed the maximum water-monitoring residue of 42 ppb (from the North Carolina study). Therefore, the data indicate a low risk potential due to the aggregate (food, water and residential) exposures to sulfentrazone residues.

F. International Tolerances

There are no Codex Alimentarius Commission (Codex) maximum residue levels for sulfentrazone.

[FR Doc. 03–5319 Filed 3–6–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0350; FRL–7285–8]

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–2002–0350, must be received on or before April 7, 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: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@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 categories and 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–2002–0350. 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 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. 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–2002–0350. 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–2002–0350. 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–2002–0350.

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–2002–0350. 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: February 28, 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 Mycogen/Dow AgroSciences 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.

Mycogen/Dow AgroSciences PP 0G6112

This notice of filing summarizes information submitted and cited by Mycogen/Dow AgroSciences in support of a request for a temporary exemption from tolerance residues of the plant-incorporated protectant *Bacillus thuringiensis* (*B.t.* Cry34/35Ab1 Insecticidal Crystal Protein (ICP), and the genetic material necessary for its production in corn (formerly known as *Bacillus thuringiensis* (*B.t.*)) 149B1 protein and the genetic material necessary for its production in corn). The Mycogen/Dow AgroSciences and Pioneer Hi-Bred experimental use permits associated with the petition are 68467–EUP–3, 68467–EUP–5, 68467–EUP–T, 68467–EUP–I, 29964–EUP–1, 29964–EUP–3, 29964–EUP–U, and 29964–EUP–L.

A. Petition Summary for B.t. Cry34/35Ab1 ICP Uses

B.t. Cry34/35Ab1 ICP is expressed in corn plants to provide protection from key coleopteran insect pests such as the western corn rootworm. *B.t.* Cry34/35Ab1 transgenic plants are derived from transformation events that contain the insecticidal genes via a plasmid insert. The *B.t.* Cry34/35Ab1 ICP poses no foreseeable risks to non-target organisms including mammals, birds, fish, beneficial insects, and earthworms. *B.t.* Cry34/35Ab1-protected field corn provides growers with a highly efficacious tool for controlling important insect pests in corn in a manner that is fully compatible with integrated pest management practices.

B. Product Identity and Chemistry

The Cry34Ab1 and Cry35Ab1 genes were isolated from *Bacillus thuringiensis* strain PS149B1 and modified before insertion into corn plants. The Cry34/35Ab1 ICP has been adequately characterized. Several safety studies were conducted using microbially produced test substances that contained 54% of the Cry34Ab1 (14 kDa) protein and 37% of the Cry35Ab1 (44 kDa) protein. Studies conducted to establish the equivalence of the Cry34/35Ab1 ICP obtained from corn or from a microbial source demonstrate that the materials are similar with respect to molecular weight, immunoreactivity, lack of post-translational modification (glycosylation) N-terminal amino acid sequence, and spectrum of bioactivity.

A qualitative analytical method (lateral flow immunoassay) for the detection of the Cry34Ab1 (14 kDa) protein has been submitted (MRID #45383401).

C. Mammalian Toxicity 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 Cry34/35Ab1 ICP demonstrated that the proteins have very low toxicity. The acute oral LD_{50} of Cry34Ab1 (14 kDa) is greater than 5,000 milligrams/kilogram (mg/kg), and at 54% purity, the acute LD_{50} for pure protein is greater than 2,700 mg/kg. The acute oral LD_{50} of Cry35Ab1 (44 kDa) is greater than 5,000 mg/kg, and at 37% purity, the acute LD_{50} for pure protein is greater than 1,850 mg/kg in male mice when the proteins were tested individually. When tested as a mixture (1:3 molar ratio of Cry34Ab1:Cry35Ab1 proteins), the acute oral LD_{50} of PS149B1 Cry34/35Ab1 proteins in male and female mice is greater than 5,000 mg/kg, and greater than 2,000 mg/kg of an equimolar (1:3) mixture of pure proteins.

In *in vitro* studies, Cry34/35Ab1 ICP exhibited a high rate of digestibility under simulated gastric conditions (referred to as SGF) in the presence of pepsin. The Cry34Ab1(14 kDa protein) was greater than 90% digested in SGF 6.2 minutes. The Cry35Ab1 (44 kDa protein) was greater than 97% digested in less than 5 minutes. Also, thermolability testing results showed that the ICP was deactivated following exposure to 60 °C, 75 °C, and 90 °C for 30 minutes. A search of relevant data bases indicated that the amino acid sequences of the Cry34/35Ab1 ICP exhibit no significant homology to the sequences of known protein allergens. Thus, Cry34/35Ab1 ICP is highly unlikely to exhibit an allergic response.

The genetic material necessary for the production of the Cry34/35Ab1 ICP is nucleic acid (DNA) which is common to all forms of plant and animal life. There are no known instances where nucleic acids have caused toxic effects as a result of dietary exposure.

Collectively, the available data on Cry34/35Ab1 ICP along with the safe use history of microbial *Bacillus thuringiensis* products establishes the safety of the plant-incorporated protectant *B.t.* Cry34/35Ab1 ICP and the genetic material necessary for its production in all raw agricultural commodities.

D. Aggregate Exposure

Because *B.t.* Cry34/35Ab1 ICP is expressed in minute quantities and is retained within the plant, there is virtually no potential for dermal or inhalation exposure to the protein. Significant dietary exposure to Cry34/35Ab1 ICP 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 Cry34/35Ab1 ICP is rapidly degraded in soil. In summary, the potential for significant aggregate exposure to Cry34/35Ab1 is highly unlikely.

E. Cumulative Exposure

Common modes of toxicity are not relevant to consideration of the cumulative exposure to *B.t.* Cry34/35Ab1 ICP. The product has demonstrated low toxicity, and these 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 proteins, are all factors in support of Mycogen/Dow AgroSciences' assertion that no significant risk is posed by exposure of the U.S. population to *B.t.* Cry34/35Ab1 ICP.

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 proteins, 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 System

Given the high degree of digestibility of the Cry34/35Ab1 ICP, no chronic effects are expected. Cry34/35Ab1 ICP, or metabolites of the ICP 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 Cry34/35Ab1 ICP.

H. Existing Tolerances or Exemptions from Tolerance

There are no existing tolerances or exemptions from tolerance for *B.t.* Cry34/35Ab1 ICP.

[FR Doc. 03–5620 Filed 3–7–03; 2:17 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0016; FRL–7289–3]

Experimental Use Permit; Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application 68467–EUP–4 from Mycogen Seeds/Dow Agrosciences LLC requesting an experimental use permit (EUP) amendment/extension for *Bacillus thuringiensis* moCry1F protein and the genetic material necessary for its production (plasmid insert PHP 12537) in corn. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments, identified by docket ID number OPP–2003–0016, must be received on or before April 7, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or