monetized benefits of reductions in exposure to HAPs. The first will be a workshop focusing on developing best estimates of dose-response functions that relate changes in HAP exposure to changes in health outcomes. The second activity will focus on (1) integrating these dose-response functions with appropriate models of HAP concentrations and human exposure and (2) translating these into economic benefits that would estimate changes in health risks resulting from regulations that reduce HAP emissions.

The overall goal of these two activities is to identify methods for the Agency to consider using in estimating changes in health risks resulting from HAP regulations that can be combined with valuation functions to estimate monetized benefits of HAP reductions.

Risk assessments for HAPs have been developed to help decision makers set health-based standards that are consistent with EPA's mission to protect human health. The quantitative toxicity values from these assessments (that is, the cancer slope factors and the noncancer reference concentrations and reference doses) are typically based on animal and epidemiologic studies that involve higher exposures than those encountered in the environment. The gap between environmental doses and study doses has led to toxicity values that can put a bound on the actual risk without being able to provide a reliable central estimate or distribution of risks. It is these latter terms (central estimates and distributions) that economists have traditionally used to estimate the economic value of potential changes in risks.

In contrast, risk assessments for criteria pollutants have been based on epidemiologic and clinical studies of exposures similar to those encountered in the environment. This has allowed development of standard statistical confidence intervals and distributions. With this information, economists have been able to develop economic benefit estimates for many health endpoints related to criteria pollutants. Criteria pollutant benefit estimates have been feasible because of the availability of: (a) Well-defined health endpoints such as hospital admissions or premature mortality; (b) dose-response functions from epidemiological and clinical studies which support estimates of risk reductions in terms amenable to economic valuation; (c) reliable estimates of ambient concentration and population exposure change; and (d) dose-response functions available from epidemiological and clinical studies in which the exposures were similar to those being experienced in the ambient environment. Uncertainties related to the health benefits of criteria pollutants have generally been represented by standard confidence intervals based on measures of within and between study variation in the estimated health effects.

While mortality from HAP-related cancer is a well-defined endpoint, there are very few validated exposure-response relationships. For the many other potential health effects from exposure to HAPs, such as changes in reproductive functions or mutagenic effects, there are major information gaps in all aspects of risk assessment, as well as in exposure-response and valuation. The focus of this workshop will be the development of best-estimates and uncertainty characterizations for hazard and dose response functions for use in benefits analyses of HAP regulations, with a focus on providing potentially useful data and tools to support HAP-related benefit assessments, including national-scale program evaluations.

For Further Information—Any member of the public wishing further information concerning this workshop should consult the website for this workshop at *http://www.epa.gov/ttn/ecas/meetings/coverhap.html* or contact Ms. Heather Hodgeman in EPA's Office of Air and Radiation via email at *hodgeman.heather@epa.gov* or by telephone at (919) 541–5668.

Dated: June 7, 2000.

John R. Fowle III,

Acting Staff Director, Science Advisory Board.

[FR Doc. 00–15158 Filed 6–14–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–944; FRL–6558–6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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 control number PF–944, must be received on or before July 17, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–944 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–944. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–944 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3.*Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–944. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic 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 supports 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 24, 2000.

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 section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. This summary was prepared by Mycogen Seeds c/o Dow AgroSciences LLC. 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. 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. Mycogen Seeds c/o Dow AgroSciences LLC

0G6112

EPA has received a pesticide petition 0G6112 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 tolerance for the plant-pesticide *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in plants in or on all food commodities.

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.

A. Product Name and Proposed Use Practices

Mycogen Brand B.t. Cry1F Corn Insect Resistant Corn used as part of the EPA experimental use permit no. 68467–EUP–2

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The Cry1F gene was isolated from *Bacillus thuringiensis* subspecies *aizawai* and modified before it was inserted into corn plants. The Cry1F Insecticidal protein has been adequately characterized. Several safety studies were conducted using a microbially produced test substance that contained 11.4% Cry1F protein. Studies conducted to establish the equivalence of the Cry1F protein 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.

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 insect control protein demonstrated that the protein has very low toxicity. In an acute oral toxicity study in the mouse, the estimated acute LD_{50} by gavage was determined to be >5,050 milligrams/kilograms (mg/kg) of the microbially produced test substance. This dose is 12,190 x greater than the estimated 95th percentile for human dietary exposure to Cry1F protein resulting from consumption of foods derived from Cry1F protected corn. This estimate assumes that 100% of the corn crop produces Cry1F protein and that the protein is not degraded or otherwise eliminated in food processing. This extremely conservative estimate of the margin of exposure further supports the safety of Cry1F proteins to humans.

In an *in vitro* study, Cry1F protein was rapidly and extensively degraded in simulated gastric conditions in the presence of pepsin. Cry1F was completely proteolyzed to amino acids and small peptide fragments within 5 minutes at molar ratios approximating 1:100 (Cry1F:pepsin). 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 protein exhibits no significant homology to the sequences of known allergens or protein toxins. Thus, Cry1F is highly unlikely to exhibit an allergic response.

The genetic material necessary for the production of the Cry1F 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 protein along with the safe use history of microbial *Bacillus thuringiensis* products establishes the safety of the plant pesticide *Bacillus thuringiensis* subspecies *aizawai* Cry1F insect control protein and the genetic material necessary for its production in all raw agricultural commodities.

D. Aggregate Exposure

Because *Bacillus thuringiensis* subspecies *aizawai* Cry1F insect control protein 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 Cry1F 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 protein is rapidly degraded in soil. In summary, the potential for significant aggregate exposure to Cry1F protein is highly unlikely.

E. Cumulative Exposure

Common modes of toxicity are not relevant to consideration of the cumulative exposure to *Bacillus thuringiensis* Cry1F insect control protein. 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 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 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 delta endotoxin, no chronic effects are expected. Cry1F delta endotoxin, or metabolites of the endotoxin 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 protein.

H. Existing Tolerances

There are no existing tolerances or exemptions from tolerance for *Bacillus thuringiensis* subspecies *aizawai* Cry1F.

I. International Tolerances

There are no existing international tolerances or exemptions from tolerance for *Bacillus thuringiensis* subspecies *aizawai* Cry1F.

[FR Doc. 00–15167 Filed 6–14–00; 8:45 am]

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