

application (see 18 CFR 4.36).

Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01-15527 Filed 6-19-01; 8:45 am]

BILLING CODE 6717-01-M

## ENVIRONMENTAL PROTECTION AGENCY

[PF-1029; FRL-6787-9]

### 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 control number PF-1029, must be received on or before July 20, 2001.

**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-1029 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Registration Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 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" "Regulation

and Proposed Rules,” 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-1029. 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-1029 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, 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](mailto: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-1029. 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 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: June 7, 2001.

**Kathleen D. Knox,**

*Director, Biopesticides and Pollution Prevention Division.*

### 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. 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.

#### Aventis CropSciences

##### PP 1F6308

EPA has received a pesticide petition [1F6308] from Aventis CropSciences, 2 TW Alexander Drive, Research Triangle Park, NC 27709, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the plant-pesticide Cry9C and the genetic material necessary for its production in or on the raw commodity corn at 20 parts per billion (ppb).

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

EPA has not fully evaluated the merits of the pesticide petition. The following summary is directly from the Aventis submission, and does not necessarily reflect the findings of the EPA.

#### A. Product Name and Proposed Use Practices

StarLink corn contained the insect control protein named Cry9C, which is derived from the common soil bacterium, *Bacillus thuringiensis* subsp. *tolworthi*. Aventis voluntarily canceled the registration for StarLink corn. However, StarLink corn grain grown in previous growing seasons and other corn containing Cry9C protein may continue to be used for animal feed or non-food industrial uses in accordance with the existing exemption from the requirement for a tolerance for these uses.

#### B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The Cry9C gene was isolated from the *B.t. tolworthi* strain, truncated, and modified before it was stably inserted into corn plants. The tryptic core of the microbially produced Cry9C delta-endotoxin is similar to the Cry9C protein found in event CBH-351. The Cry9C protein was produced and purified from a bacterial host, for the purposes of mammalian toxicity studies.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* The proposed enforcement method for use on raw corn destined for dry milling is the EnviroLogix or Strategic Diagnostics Inc. Lateral Flow Strip Test, both of which have been validated by USDA GIPSA and Aventis. The limit of detection for these two test is 20 ppb Cry9C protein. The method must be used in accordance with the recommended sampling methods (FDA Recommendations for Sampling and Testing Yellow Corn and Dry-milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues, FDA-CFSAN, January 19, 2001).

#### C. Mammalian Toxicological Profile

Aventis has conducted an extensive array of toxicological testing including oral and intravenous administration, as well as acute and short-term exposure. EPA has reviewed these data and concluded that there is no toxicological endpoint of concern, with the possible exception of allergenicity.

The gene for the Cry9C protein comes from a non-allergenic common soil bacterium, *Bacillus thuringiensis*. The corn plant, into which the gene for the Cry9C protein was inserted, is rarely allergenic to humans. Expression of the

gene for the Cry9C protein did not enhance the potential of corn to be allergenic, as demonstrated by the absence of any difference in reactivity to StarLink corn than to wild type non-transgenic corn in radioallergosorbent tests (RAST) performed with human sera from corn allergic patients (MRID Number 443844-05).

The Cry9C protein was not toxic upon single oral or repeated dietary administration to rats and has no linear amino acid sequence homology to any known human allergen or toxin (Oral LD<sub>50</sub> > 3,760 mg/kg/day, MRID Number 442581-07; Acute intravenous LD<sub>50</sub> > 0.3 mg/kg/day (MRID Numbers 447343-02); 30-day repeated dose toxicity test in rats: up to 328 mg/kg/day produced no adverse effects, no binding to villi or enterocytes lining gastrointestinal tract (GI) crypts of both large and small intestines, MRID Numbers 447343-03, 443844-04, and 442581-09). RAST tests performed with sera from individuals allergic to the well-known human food allergens, wheat; rice; buckwheat; soy; peanut; milk; eggs; and shrimp confirmed that even individuals with pre-existing food allergies demonstrated no cross-reactivity to Cry9C (MRID Number 452464-01). The level of the Cry9C protein in whole corn grain, 0.0129%, is a very low level of total protein expression in the plant compared to most allergens which are present at 1-40% of the total plant protein (MRID Number 450257-01).

The Cry9C protein is somewhat more stable than the other *Bt* Cry proteins already approved for food use. Cry9C does digest in simulated stomach fluids at pH of 1.2-1.5 within 30-60 minutes (within normal stomach emptying time) and does denature at temperatures likely to be encountered during cooking and processing (MRID Numbers 447343-05, 442581-08, 451144-01, 4451144-02). Although Aventis interprets these data to mean that Cry9C protein is not an allergen, regulatory officials have not been able to confirm this assessment.

#### D. Aggregate Exposure

Aventis developed an analytical method to determine Cry9C protein levels in intermediate and finished food products. Studies were conducted to assess the level of Cry9C protein typically found in 12 representative food products made from 100% StarLink corn. These studies demonstrate that there is significant reduction (80-99.9%) of Cry9C protein levels, relative to levels found in raw corn, during the manufacture of food products. Three processing factors are responsible for destruction of Cry9C

protein: heat, shear or pressure, and alkali treatment.

1. *Dietary exposure.* Aventis has performed a new dietary risk assessment. Worst case estimates of potential dietary intake of Cry9C protein were calculated using Novigen Sciences, Inc., Food and Residue Evaluation Program (FARE) software, food consumption data in the 1994-1996 USDA's Continuing Survey of Food Intakes by Individuals (CSFII), and the new Aventis study on reduction in Cry9C protein levels resulting from food processing. In essence, dietary intake of Cry9C protein was calculated as the product of consumption of corn protein-containing foods and the expected concentration of Cry9C protein in such foods. Intakes were estimated on a "per consumer" basis for the overall U.S. population, children 1-6 years of age, children 7-12 years of age, the Hispanic population in the U.S., Hispanic children 1-6 years of age, and Hispanic children 7-12 years of age.

2. *Non-dietary exposure.* Since the Cry9C protein is expressed in plant tissues at very low levels, and since the StarLink product will no longer be used, exposure will be negligible to non-existent via all non-food routes.

#### E. Cumulative Exposure

Common modes of toxicity are not relevant to the consideration of the cumulative exposure to Cry9C protein.

#### F. Safety Determination

1. *U.S. population.* Dietary exposure will be the major route of exposure to the U.S. population. Estimated potential daily exposures for all subpopulations at the 99<sup>th</sup> percentile are below 0.37 microgram per day, the exposure for the general population. The U.S. population in general had the highest estimated daily intake of all subpopulations examined. This newly refined dietary intake estimate of the Cry9C protein is 67 times lower than the EPA's November 2000 upper bound estimate for the U.S. population (25 micrograms per day, 99<sup>th</sup> percentile), and 10 times below the highest estimate from the Aventis November 2000 estimate (3.9 micrograms per day for the Hispanic population, 99<sup>th</sup> percentile). Such exceedingly low levels of exposure, coupled with insufficient information to conclude whether or not Cry9C protein is actually a human food allergen, further support the SAP finding that the levels of Cry9C protein present in the human diet are insufficient to either sensitize or cause an allergic reaction. Therefore, the data support a finding of reasonable certainty of no harm and justify a tolerance at 20 ppb.

2. *Infants and children.* As with the rest of the population, the primary route of exposure is dietary. The dietary exposure assessment indicates that children have less exposure than the general U.S. population. Accordingly, there is no need to apply an additional safety factor for infants and children.

#### G. Effects on the Immune and Endocrine Systems

EPA's review of the submitted data concluded that there is no toxicological endpoint of concern, with the possible exception of allergenicity.

#### H. Existing Tolerances

On May 22, 1998, EPA established an exemption from the requirement of a tolerance for residues of Cry9C protein and the genetic material necessary for its production in corn for feed use only; as well as in meat, poultry, milk or eggs resulting from animals fed such feed. This exemption remains in effect.

#### I. International Tolerances

To date, no Codex, Canadian or Mexican tolerances exist for *Bt* subsp. *tolworthi* Cry9C protein in corn.

#### J. Conclusions

Aventis CropScience believes that this petition provides adequate grounds for the establishment of a tolerance of 20 ppb for residues of the insecticide, *Bt* subsp. *tolworthi* Cry9C protein in or on the raw agricultural commodity, corn. [FR Doc. 01-15294 Filed 6-19-01; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-1026; FRL-6785-9]

### Notice of Filing Pesticide Petitions 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 pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-1026, must be received on or before July 20, 2001.

**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-1026 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Treva C. Alston, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373; e-mail address: alston.treva@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**.

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2. *In person.* The Agency has established an official record for this action under docket control number PF-1026. 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-1026 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, 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](mailto: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