

*F. International Tolerances*

No international tolerances have been established under CODEX. Therefore there is no need to ensure consistency. [FR Doc. 97-30813 Filed 11-25-97; 8:45 am]

BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-776; FRL-5753-3]

**Notice of Filing of Pesticide Petitions**

**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 the docket control number PF-776, must be received on or before December 26, 1997.

**ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** The Regulatory Action Leader listed in the table below:

Regulatory Action Leader	Telephone Number/E-mail Address	Office Location/Address
Driss Benmhend .... Michael Mendelsohn.	703-308-9525, e-mail: benmhend.driss@epamail.epa.gov. 703-308-8715, e-mail: mendelsohn.mike@epamail.epa.gov.	5th floor CS#1, 2800 Crystal Drive, Arlington, VA 22202 Do.

**SUPPLEMENTARY INFORMATION:** EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-776] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:  
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF-776] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

**List of Subjects**

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 18, 1997.

**Janet Andersen,**

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

**Summaries of Petitions**

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing

them in any way. 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.

**1. Engelhard Corporation***PP 7E4908*

EPA has received a pesticide petition (PP 7E4908) from Engelhard Corporation, 101 Wood Avenue, Iselin, NJ 08830, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a, to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of kaolin in or on all food commodities. Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Engelhard Corporation has submitted the following summary of information, data, and arguments in support of their pesticide petition.

*A. Proposed Use Practices*

Kaolin is to be used as an aid in control of damage to plants from insects, mites, fungi, and bacteria. Kaolin is used at the rates of 6.25 to 12.4 lbs/acre for row crop vegetables, 25 to 175 lbs/acre for tree fruit crops, and 12.5 to 37.5 lbs/acre for small fruit crops. Treatment is made prior to leaf or plant emergence and applied to crops at 7 to 10 day

intervals depending on the pest to be controlled. Dosage rates are applied with standard spray equipment.

#### B. Product Identity/Chemistry

Kaolin is a white, nonporous, nonswelling, natural occurring aluminosilicate mineral with the chemical formula  $Al_2Si_2O_5(OH)_4$ . Kaolin is one of the most highly divided and highly refined naturally occurring minerals. Median particle size of commercial products vary between 0.1 – 10 microns. Kaolin is nonreactive. Its hydrophilic surface allows kaolin to be easily dispersed in water at neutral pH values of 6–8. Common physical properties of kaolin are: platy shape, high brightness (80–95), specific gravity 2.58–2.63, refractive index 1.56–1.62, and Mohs hardness 2–3.

#### C. Toxicological Profile

**Acute toxicity.** An acute oral toxicity limit test, acute dermal toxicity test on the active ingredient and an acute oral toxicity test, a primary skin irritation test, and primary eye irritation test on the end use product have been submitted. The acute oral limit dose test on the active ingredient showed that the single dose Acute Oral  $LD_{50}$  is greater than 5,000 mg/kg of bodyweight of rats. The acute dermal toxicity limit test on the active ingredient showed that the single dose Acute Dermal  $LD_{50}$  is greater than 5,000 mg/kg of bodyweight. The primary skin irritation study on the end use product showed that the test substance is classified as slightly irritating to the skin. The primary eye irritation study on the end use product showed that the test substance is classified as minimally irritating and non-irritating to the unrinsed and rinsed eye respectively.

Kaolin is used as an indirect food additive for paper/paper board dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used in pharmaceuticals, tablet diluents, poultices, and surgical dusting powders. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe "As an indirect human food ingredient with no limitation other than current good manufacturing practice."

#### D. Aggregate Exposure

1. **Dietary exposure.** Dietary exposure of kaolin via food or water is difficult

to estimate due to the use of kaolin in thousands of products. Kaolin is an inert mineral naturally occurring in the environment, and has no known toxicological effects.

2. **Non-dietary exposure, non-occupational exposure.** Increased non-dietary exposure of kaolin via lawn care, topical insect repellents, etc., is not applicable to this application.

#### E. Cumulative Exposure

Kaolin has no mode of toxicity and therefore cumulative exposure is not applicable. Kaolin is used in thousands of products as well as being a naturally occurring part of the environment. Cumulative exposure is not possible to calculate nor is it necessary due to the non-toxic nature of kaolin.

#### F. Endocrine Disruptors

Engelhard Corporation has no information to suggest that kaolin will adversely affect the immune or endocrine systems.

#### G. Safety Considerations

The lack of toxicity of kaolin is demonstrated by the above summary. Based on this information, the aggregate exposure to kaolin over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to kaolin residues. Exempting kaolin from the requirement of a tolerance should be considered safe and pose insignificant risk.

#### H. Analytical Method

An analytical method for residues is not needed as this petition requests an exemption from the requirement of a tolerance.

#### I. Existing Tolerances

Kaolin is exempted from the requirement of a tolerance "when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest." (40 CFR 180.1001).

The registrant does not know if international tolerance exemptions exist. (Driss Benmhend).

#### 2. Plant Genetic Systems (America) Inc.

##### PP 7G4921

EPA has received pesticide petition (PP 7G4921) from Plant Genetic Systems (America), Inc., 7200 Hickman Road, Suite 202, Des Moines, IA 50322, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a temporary exemption from the requirement of a tolerance for residues of the plant-

pesticide *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in corn for feed use only. The summary of the petition published in this notice was proposed by the petitioner. This request proposes to amend Experimental Use Permit, 70218-EUP-1, issued to Plant Genetic Systems (America), Inc. on February 5, 1997, issued under crop destruct conditions.

Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Plant Genetic Systems (America) has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Plant Genetic Systems (America) and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

#### A. *Bacillus thuringiensis* subsp. *tolworthi* Cry9C Protein Uses

Corn plants have been protected from lepidopteran insect pests such as European corn borer *Ostrinia nubilalis* (Huber), by expressing a Cry9C protein. The Cry9C protein expressed by the corn plants corresponds to the insecticidal moiety of the Cry9C crystal protein of a *Bacillus thuringiensis* subsp. *tolworthi* strain. Transgenic corn plants, expressing Cry9C protein, represents an excellent addition to growers' options for insect control that reduces or eliminates the need for chemical inputs and fits well within an integrated pest management program.

#### B. Product Identity/Chemistry

The cry9C gene, was isolated from the *Bacillus thuringiensis 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 CBH351. The Cry9C protein was produced and purified from a bacterial host, for the purposes of mammalian toxicity studies. Product analysis that compared the Cry9C protein from the two sources included: SDS-PAGE, Western blots, N-terminal amino acid sequencing, glycosylation tests (for possible post-translational modifications) and insect bioassays.

No analytical method is included since this petition requests a temporary exemption from the requirement of a tolerance.

### C. Mammalian Toxicological Profile

*Bacillus thuringiensis* proteins have been used commercially for more than 30 years without any evidence for adverse health effects. *Bacillus thuringiensis* mode-of-action can be divided into a series of critical steps: ingestion by the insect, specific binding to brush border membrane receptors, membrane insertion, and pore formation thus destroying the midgut lining and causing death of the insect. *Bacillus thuringiensis* proteins do not bind or cause these types of effects to mammalian gut membranes. The extensive mammalian toxicity studies performed to support the safety of *Bacillus thuringiensis* - containing pesticides clearly demonstrate that the tested isolates are not toxic or pathogenic (McClintock, *et al.*, 1995, Pestic. Sci. 45:95-105). Although *Bacillus thuringiensis* strains have been used for decades as sprayable microbial products, no confirmed cases of allergic reactions have been documented, despite dermal, oral and inhalation exposures. A reference to this is made by the EPA in a **Federal Register** notice, dated August 16, 1995 (60 FR 42443) (FRL-4971-3).

The Cry9C protein insecticidal mode-of-action is apparently similar to that of the well known Cry1A proteins. In addition to the safe history of *Bacillus thuringiensis* proteins outlined above, several other studies were performed to evaluate mammalian safety of the Cry9C protein. An acute toxicological study was performed with mice, which demonstrated that the Cry9C protein had an LD<sub>50</sub> >6,500 mg/kg. A test for *in vitro* digestibility under simulated gastric conditions showed that the Cry9C protein found in bacteria and the protein produced in plants was stable for 4 hours when exposed to simulated gastric juice. However, an amino acid sequence homology search performed using three different data banks (against 135,867 sequences) only found homology to other related *Bacillus thuringiensis* proteins. To determine possible short stretch homology, an 8-amino acid homology search was also performed. Except with the *Bacillus thuringiensis* proteins, no identical 8-amino acid peptide sequences could be detected in the searches. Therefore, it is unlikely that Cry9C protein would have significant allergenic potential.

The Cry9C protein or metabolites of the protein are not expected to interact with the immune or endocrine system, since the protein sequence does not match any known allergens or hormones. Since proteins, in general, are not known to be carcinogenic it is

unlikely that the Cry9C protein would have carcinogenic properties.

All living organisms contain DNA and there are no examples of nucleic acids causing any toxicological effects from dietary consumption. The genetic material necessary for the production of the Cry9C protein in plants includes the genetic construct that encodes the Cry9C protein and all other necessary genetic elements for its expression. These elements include: a promoter, polylinker sequences, leader sequences and terminators and none of which are expected to cause any toxicological effects.

Taken together, the data supports the lack of mammalian toxicological effects for the plant-pesticide *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material necessary for the production of this protein in corn for feed use only.

### D. Aggregate Exposure

Since the Cry9C protein is expressed in plant tissues, dermal or inhalation will be negligible to non-existent. Drinking water is unlikely to be contaminated with Cry9C protein due to the rapid degradation of plant materials in the soil. Furthermore, no direct human dietary exposure to Cry9C protein will occur since this request is for animal feed use only.

### E. Cumulative Effects

The unique mode-of-action of Bt proteins in general, coupled with the lack of mammalian toxicity for the Cry9C protein provides no basis for the expectation of cumulative effects with other compounds.

### F. Safety Determination

Bt microbial pesticides containing Cry proteins have been applied for more than 30 years to food and feed crops consumed by the US population. There have been no human safety problems attributed to Cry proteins. The extensive mammalian toxicity studies performed to support the safety of *Bacillus thuringiensis* - containing pesticides clearly demonstrate that the tested isolates are not toxic or pathogenic (McClintock, *et al.*, 1995, Pestic. Sci. 45:95-105). The lack of mammalian toxicity of the Cry9C protein provides support for our request of a temporary exemption from the requirement of a tolerance set forth in this petition. Non-dietary exposure of infants, children or the US population in general, to the Cry9C protein expressed in corn plant materials, are not expected due to the uses of this product for animal feed use only.

### G. Existing Tolerances

No tolerances or tolerance exemptions have been granted for the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in corn for feed use only. (Michael Mendelsohn)

[FR Doc. 97-31131 Filed 11-25-97; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-779; FRL-5755-6]

### Notice of Filing of Pesticide Petition

**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 the docket control number PF-779, must be received on or before December 26, 1997.

**ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m.,