observed? For example, would a lower threshold of regulation (perhaps the 98th percentile) be warranted for fully-reversible effects (such as mild anemia) or would a more stringent threshold (perhaps the 99.9th percentile or higher) be justified for severe, non-reversible effects (e.g., birth defects)? Finally, should the Agency regulate pesticides at different percentiles according to the nature and size of the subpopulation groups (i.e., use the 99.9th percentile for larger groups and another percentile for smaller groups)?

5. How should ''outliers'' be identified for food consumption data sets? For residue data sets? When an ''outlier'' is identified, how should the data point be handled in generating probabilistic exposure estimates?

6. If OPP conducts a Critical Exposure Contribution (CEC) analysis, and excludes one or more data points because they appear to drive the high-end estimates of exposure, should OPP perform an additional CEC analysis on any revised estimate of the exposure distribution?

7. Should OPP's probabilistic assessments attempt to reflect variability in human sensitivity to toxic effects, as suggested by the FIFRA Scientific Advisory Panel? If so, how should this be done?

V. Policies Not Rules

The draft policy document discussed in this notice is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this guidance is not binding on either EPA or any outside parties. Although this guidance provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should be abandoned.

EPA has stated in this notice that it will make available revised guidance after consideration of public comment. Public comment is not being solicited for the purpose of converting any policy document into a binding rule. EPA will not be codifying this policy in the Code of Federal Regulations. EPA is soliciting public comment so that it can make fully informed decisions regarding the content of each guidance document.

The ''revised'' guidance will not be unalterable. Once a ''revised'' guidance document is issued, EPA will continue to treat it as guidance, not a rule. Accordingly, on a case-by-case basis EPA will decide whether it is appropriate to depart from the guidance or to modify the overall approach in the guidance. In the course of inviting comment on each guidance document, EPA would welcome comments that specifically address how a guidance document can be structured so that it provides meaningful guidance without imposing binding requirements.

VI. Contents of Docket

Document that are referenced in this notice will be inserted in the docket under the docket control number ''OPP–00593.'' In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) have also been inserted in the docket under docket control number OPP–00557.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests.

Dated: April 1, 1999.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 99–8636 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–867; FRL–6069–8]

AgrEvo USA Company; Cry9C Plant-Pesticides; Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the amendment of a regulation to exempt from the requirement of a tolerance residues of plant-pesticides *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

DATES: Comments, identified by the docket control number PF–867, must be received on or before May 7, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division, (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 9th floor, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 22202, telephone (703) 308–8715; e-mail:mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: 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 all raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition 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, as well as the public version, has been established for this notice of filing under docket control number PF–867 (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 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (insert docket number) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 21 U.S.C. 346a.

List of Subjects

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

Dated: March 24, 1999.

Janet L. Andersen,

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

Petition Summary

Below a summary of the pesticide petition is printed. The summary of the petition was prepared by 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.

AgrEvo USA Company

9F5050

EPA has received a pesticide petition 9F5050 from AgrEvo USA Company, Little Centre One, 2711 Centerville Rd., Wilmington, DE 19808, proposing the amendment of 40 CFR 180.1192 to exempt from the requirement of a tolerance residues of the plant-pesticides *Bacillus thuringiensis* subspecies *toliworthi* Cry9C protein and the genetic material necessary for the production of this protein in or on all raw plant agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a(d).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, AgrEvo USA Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by AgrEvo USA Company and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

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. The Cry9C protein poses no foreseeable risks to non-target organisms, including mammals, birds and non-target insects. 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 *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. 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 an exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

Bacillus thuringiensis proteins have insecticidal properties and have been used commercially for more than 30 years. This long history of safe use is the primary reason that *Bt* proteins have been chosen as the basis for the first insecticidal plants produced by biotechnology. *Bt* 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. *Bt* proteins do not bind or cause any other effects to mammalian gut membranes thereby displaying human safety properties. The Cry9C protein mode-of-action is apparently similar to that of the well known Cry1A proteins. Although *Bt* 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 FR notice, dated August 16, 1995, (60 FR 42443)(FRL–4971–3).

In addition to the safe history of *Bt* proteins outlined above, several other studies were performed to provide evidence for mammalian safety of the Cry9C protein. An acute toxicological study was performed with mice, which demonstrated that the Cry9C protein had an LD_{50} >3,760 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. An amino acid sequence homology search performed using three different data banks (against 135,867 sequences) only found homology to other related *Bt* proteins. All other proteins in the data bank have no major stretches of sequence homology, indicating that the sequence homology is not significant. Therefore, no homology with any known allergen or protein toxin could be demonstrated.

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

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 it's expression. These elements include: a promotor, 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 or on all raw plant agricultural commodities.

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. Processed plant products may allow for low levels of exposure to the Cry9C protein, but the lack of mammalian toxicity and the lack of sequence homology to known toxins or allergens, has already been demonstrated.

E. Cumulative Exposure

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 exposure 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 U.S. 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 or allergenic properties of the Cry9C protein provides support for our request of an 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 plant materials, are not expected due to the uses of this product within agricultural settings.

G. Existing Tolerances

An exemption from the requirement of a tolerance for residues of the insecticide, *Bacillus thuringiensis* subspecies *tolworthi* 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 was issued on May 22, 1998.

[FR Doc. 99–8260 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50857; FRL–6074–1]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following applicant. The permit is in accordance with, and subject to, the provisions of 40 CFR part l72, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

FOR FURTHER INFORMATION CONTACT: By mail: Maria Rodriguez, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Highway, Rm. 251, CM #2, Arlington, VA, 703–305–6710, e-mail: rodriguez.maria@epa.gov.

SUPPLEMENTARY INFORMATION: EPA has issued the following EUP:

59981–EUP–1. Issuance. Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234. This experimental use permit allows the use of 313 pounds of the plant growth regulator (4-aminophenyl) arsonic acid on 50 acres of grapefruit to evaluate enhancement of ripening. The program is authorized only in the State of Florida. The experimental use permit is effective from February 28, 1999 to February 28, 2001. A tolerance has been established for residues of the active ingredient in or on grapefruit.

Persons wishing to review this EUP are referred to the designated contact person. Inquires concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.

Dated: March 30, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99–8634 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00591; FRL–6071–1]

Pesticides; Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: To assure that EPA's policies related to implementing the Food Quality Protection Act (FQPA) are transparent and open to public participation, EPA is soliciting comments on a draft policy paper entitled ''Data for Refining Anticipated Residue Estimates Used in Dietary Risk Assessments for Organophosphate Pesticides.'' This notice is the sixth in a series concerning science policy documents related to FQPA and developed through the Tolerance Reassessment Advisory Committee (TRAC).

DATES: Submit written comments for this policy paper, identified by docket control number OPP–00591, on or before June 7, 1999.

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'' section of this document.

FOR FURTHER INFORMATION CONTACT: Margaret Rice, Environmental Protection Agency (7508), 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–8039; fax: 703–308–8041; e-mail: rice.margaret@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Notice Apply to Me?

You may be potentially affected by this notice if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to: