guidelines in the **Federal Register** specifying minimum standards for certification and recertification of operators of community and nontransient noncommunity public water systems. The final guidelines are required to be published by February 6, 1999. States then have two years to adopt and implement an operator certification program that meets the requirements of these guidelines. After that date, if a State has not adopted and implemented an approved program, the EPA must withhold 20 percent of the funds a State is otherwise entitled to receive in its Drinking Water State Revolving Fund (DWSRF) capitalization grants under section 1452 of SDWA.

Elizabeth Fellows,

Acting Director, Office of Ground Water and Drinking Water, Environmental Protection Agency.

[FR Doc. 98–9242 Filed 4–7–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5992–8]

National Drinking Water Advisory Council, Open Meetings

Under section 10(a)(2) of Pub. L. 92–423, ''The Federal Advisory Committee Act,'' notice is hereby given that a meeting of the National Drinking Water Advisory Council (NDWAC) established under the Safe Drinking Water Act, as amended (42 U.S.C. S300f *et seq.*), will be held on April 29, 1998 until 6 p.m. and April 30, 1998, from 8:30 a.m. until 5 p.m., in the Auditorium at the Environmental Protection Agency's (EPA) Environmental Research Center (ERC), located on the corner of Alexander Drive and Route 54, Research Triangle Park, North Carolina. The purpose of this meeting is to provide the opportunity for the Council to discuss and make recommendations on the EPA's plans to meet future needs to support the sound science requirements for upcoming programmatic deadlines. In addition, the Council will be briefed on and discuss the NDWAC working groups and the Drinking Water Strategic Needs Assessment Project. Presentations will also be held on the draft First Annual Compliance Report and the Water Conservation Plan Guidelines.

This meeting is open to the public. The Council encourages the hearing of outside statements and will allocate one hour on April 30, 1998, for this purpose. Oral statements will be limited to ten minutes and it is preferred that only one person present the statement. Any outside parties interested in presenting an oral statement should petition the Council by telephone at (202) 260–2285 or by E-Mail at shaw.charlene@epamail.epa.gov by April 23. 1998.

Any person who wishes to file a written statement can do so before or after a Council meeting. Written statements received prior to the meeting will be distributed to all members of the Council before any final discussion or vote is completed. Any statements received after the meeting will become part of the permanent meeting file and will be forwarded to the Council members for their information.

Members of the public that would like to attend the meeting, present an oral statement, or submit a written statement, should contact Ms. Charlene Shaw, Designated Federal Officer, National Drinking Water Advisory Council, U.S. EPA, Office of Ground Water and Drinking Water (4601), 401 M Street SW, Washington, DC 20460. The telephone number is Area Code (202) 260–2285 or E-Mail shaw.charlene@epamail.epa.gov.

Dated: April 3, 1998.

Charlene Shaw,

Acting Director, Office of Ground Water and Drinking Water.

[FR Doc. 98–9248 Filed 4–7–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–800;FRL–5781–1]

Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of petition (PP 7F4822), submitted by Monsanto Company, proposing the establishment of a regulation for an exemption from the requirement of a tolerance for residues of the plant pesticide, active ingredient, *Bacillus thuringiensis variety kurstaki* (*B.t.k.*) insect control protein (CryIIA), when used in or on all food and feed crops.

DATES: Comments, identified by the docket control number PF-800, must be received on or before May 8, 1998.

ADDRESSEES: 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. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, 22202.

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 of the 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: Willie H. Nelson, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticides Programs, Environmental Protection Agency, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8682; e-mail:nelson.willie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals/microbials in or on various food commodities under section 408 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 petitions.

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-800] (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 included any information claimed as CBI, is available for inspection from 8:30 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. Comments and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–800] 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: March 20, 1998

Janet L. Andersen,

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

Summary of Petition

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

Monsanto Company

PP 7F4822

1. *Plant-pesticide uses*. Cotton, *Gossypium hirsutum*, has been genetically engineered to be resistant to selected insect pests of the taxonomic order Lepidoptera. Insect protection was accomplished by the insertion of the *cryIIA* gene from *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) which encodes for the production of a protein specifically insecticidal to Lepidopteran larvae in cotton but safe to nontarget organisms such as mammals, birds, fish and beneficial insects. Larvae of Lepidopteran pests are the most important insect pests impacting successful cotton production and numerous chemical insecticide treatments are typically applied for their control. The production of cotton varieties containing the *CryIIA* gene from *B.t.k.* is expected to significantly reduce chemical insecticide use in cotton and; therefore, provide a major benefit to cotton growers and the environment.

2. *Safety*. The CryIIA protein produced in Bollgard™ Cotton is >99.9% identical to the protein produced by the *B.t.k.* HD-1 bacterial strain found in nature and in commercial *B.t.k.* formulations registered with the EPA. These microbial *B.t.k.* formulations have been commercially available for the last 30 years. This strain controls insect pests by the production of crystalline insecticidal proteins known as delta-endotoxins. To be active against the target insect, the protein must be ingested. In the insect gut, the protein binds to specific receptors on the insect mid-gut, inserts into the membrane and forms ion-specific pores. These events disrupt the digestive processes and cause the death of the insect.

There are no receptors for the protein delta-endotoxins of *B. thuringiensis* subspecies on the surface of mammalian intestinal cells; therefore, humans are not susceptible to these proteins. This has been confirmed in numerous safety studies carried out in laboratory animals which are traditionally experimental surrogates for humans. The results of some of these studies have been published in scientific reviews (Ignoffo,1973; Shadduck *et al.*, 1983; Siegel and Shadduck, 1990). Results of unpublished safety studies generated by registrants of *B. thuringiensis* commercial preparations have also been summarized in a recently issued EPA Registration Standard for *Bt* Formulations (EPA, 1988). In published reviews and the EPA document, studies are referenced in which large doses (5,000 mg/kg) of *B. thuringiensis* formulations were administered as single or multiple oral doses (up to 2 years) to different laboratory animals, with no adverse effects.

Avian and aquatic organisms have also been fed *B. thuringiensis* formulations, with no adverse effects. A typical formulation is composed of *Bt* spores and *Bt* protein endotoxin, the latter compromising up to one-third of the weight of the spores. While target insects are susceptible to oral doses of *B.t.k.* proteins, there was no evidence of any toxic effects observed in non-target laboratory mammals, fish or birds given the equivalent of up to 10^6 g of protein per gram of body weight. No deleterious effects were observed on non-target insects at doses over 100 fold higher than needed to control target insects (EPA 1988).

In addition to the lack of receptors for the *B.t.k.* proteins, the absence of adverse effects in non-target animals is further supported by the poor solubility and stability of the *B.t.k.* proteins in the acid milieu of the stomach. The acid conditions in the stomach and the presence of bile acids denature the *B.t.k.* proteins facilitating their rapid degradation by pepsin. *In vitro* enzymatically activated delta-endotoxins are also non-toxic when administered orally to laboratory animals (Nishitsutsuji-Uwo *et al.* 1980). Even if activated *B.t.k.* protein toxins could enter the mammalian gastrointestinal tract, there are no receptors on the surface of gastrointestinal tissues to permit binding of the protein toxin to the cell surface. These scientific considerations are experientially support by the history of completely safe use of *B. thuringiensis* preparations. Based on the available scientific data, EPA and other regulatory scientists worldwide have determined that use of registered *B. thuringiensis* products pose no risks to human health or non-target organisms.

Monsanto Company has also submitted several toxicology studies in support of the CryIIA protein as a plant pesticide. According to Monsanto Company, there is no acute toxicity of the CryIIA protein. In addition, the CryIIA protein is also produced at low levels by Bollgard cotton plants and is contained within the cells of the cotton plant. Consequently, there would be negligible exposure to the protein from handling cottonseed, leaf tissue or lint at planting, during growth, or at harvest. In addition, there would be no potential hazard during storage, transportation, or disposal of Bollgard cottonseed as the protein cannot drift or volatilize from the plant and its bioactivity is rapidly lost upon decomposition of the plant tissue.

The following mammalian toxicity studies have been conducted to support this exemption from the requirement of a tolerance:

i. A mouse acute oral gavage study in which the No-Observed-Effect-Level (NOEL) for toxicity of the CryIIA protein administered as a single dose was considered to be 4,000 mg/kg (the highest tested dose).

ii. *In vitro* digestive fate of the CryIIA protein in simulated gastric and intestinal fluids. The results of this study established that the CryIIA protein and its associated functional activity will be efficiently degraded upon exposure to gastric and intestinal fluids in the mammalian digestive tract. A lack of stability to digestion is a characteristic of proteins which are non-allergens.

iii. Amino acid sequence homology assessment of the CryIIA protein to known allergens and toxins. The results of this analysis establish that the CryIIA protein expressed in Bollgard cotton shares no significant sequence similarity with known toxins, allergens or gliadin proteins. In addition, the CryIIA protein

appears to contain no sequences relevant to allergy or coeliac disease.

3. *Threshold effects*— i. *Acute toxicity*. Based on the available acute toxicity data for the CryIIA protein and on the safe use of microbial *Bacillus thuringiensis* foliar formulations containing the same protein and registered with the EPA and used commercially for 30 years, no acute dietary risks are posed.

ii. *Chronic effects*. The CryIIA protein is degraded upon exposure to gastric and intestinal fluids in the mammalian digestive tract. Consequently, no chronic effects are expected. In addition, in published reviews and the EPA Registration Standard for *Bt* Formulations (EPA, 1988) studies are referenced where large doses (5,000 mg/kg) of *B. thuringiensis* formulations were administered as single or multiple oral doses (up to 2 years) to different laboratory animals, with no adverse effects.

4. *Non-threshold effects*. Carcinogenicity: Proteins are not considered to be carcinogenic (Pareza and Foster, 1983) and consequently, there is no carcinogenic risk associated with the CryIIA protein.

5. *Aggregate exposure*. Cottonseed meal is not currently used for human consumption in the United States (Morgan, 1990; Cottonseed Oil, 1990). The presence of gossypol and cyclopropenoid fatty acids in cottonseed also limits its use as a protein supplement in animal feed except for cattle, which are unaffected by these components. Inactivation or removal of these components during processing, which entails heating and chemical treatment, enables the use of some cottonseed meal for catfish, poultry and swine. However, as the CryIIA protein is heat labile, the biological activity of the protein is expected to be lost upon processing as demonstrated by Sims and Berberich with other *B.t.* proteins (1996).

Refined cottonseed oil and cottonseed linters (the fiber remaining after ginning seed cotton) are also highly processed and are the only cotton products consumed as food by humans. Cottonseed oil is typically removed from the meal by direct solvent extraction with hexane and is further processed and refined by exposure to extreme heat and alkaline pH. Processed cottonseed oil contains no detectable protein (Fuchs, 1994; Fuchs *et. al.*, 1993). Cotton linters are essentially comprised only of cellulose (>99.9%) and Sims *et. al.* (1996) have demonstrated that processed linters, which also undergo exposure to temperatures exceeding 100°C and alkaline treatment do not contain detectable levels of transgenic proteins such as CryIIA.

Based on these results, aggregate exposure to the CryIIA protein through ingestion of cottonseed oil and linters derived from bollgard cotton would be negligible.

6. *Determination of safety for U.S. population*. The toxicity data support an exemption from the requirement of a tolerance for the CryIIA protein expressed in Bollgard cotton indicate that there would be no risk from exposure to the CryIIA protein by the overall U.S. population. In addition, the CryIIA protein expressed in Bollgard is more than 99.9% identical to the natural protein, which is component of microbial *Bacillus thuringiensis* subsp. *kurstaki* formulations that have been registered with the EPA and available commercially for the last 30 years. The EPA and other regulatory scientists worldwide have determined that use of registered *B. thuringiensis* products pose no significant risks to human health or non-target organisms (EPA, 1988).

7. *Determination of safety for infants and children*. Monsanto considers the acute toxicity data, the rapid degradation of the CryIIA protein in the mammalian digestive system, the lack of homology to known proteinaceous allergens or toxins and a 30 year history of safe use of microbial *B. thuringiensis* containing the near identical CryIIA protein as ample evidence to support the safety of this protein to neonatal infants, infants and children.

8. *Estrogenic effects* Not applicable. Proteins are not capable of direct estrogenic activity as they are incapable of binding to an estrogen receptor.

9. *Chemical residue*. Not applicable. In the United States, only refined cottonseed oil and cottonseed linters (the fiber remaining after ginning seed cotton), which are highly processed, are the only cotton products consumed as food by humans. Cottonseed oil is typically removed from the meal by direct solvent extraction with hexane and is further processed and refined by exposure to extreme heat and alkaline pH. Processed cottonseed oil contains no detectable protein (Fuchs, 1994; Fuchs *et. al.*, 1993). Cotton linters are essentially comprised only of cellulose (>99.9%) and Sims *et. al.* (1996) have demonstrated that processed linters, which also undergo exposure to temperatures exceeding 100°C and alkaline treatment do not contain detectable levels of transgenic proteins such as CryIIA.

10. *Environmental fate*. The CryIIA protein expressed in Bollgard cotton plant tissue was evaluated over 120 d in both a laboratory microcosm and under field conditions. DT_{50} values were 15.5 d and 31.7 d for the laboratory and field respectively. These results demonstrate that CryIIA protein, as a component of post-harvest Bollgard cotton plants, will dissipate when cultivated into soil.

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[FR Doc. 98–8659 FIled 4–7–98; 8:45 a.m.]

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