

pure VIP3A protein is >3,675 mg/kg body weight. The VIP3A protein in both the microbial and plant derived test substance was determined to be substantially equivalent to VIP3A produced in event COT102 derived cotton plants, as measured by biological activity, protein size, immunoreactivity, mass spectral analysis of amino acid sequence, and apparent lack of post-translational modifications.

The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public databases. The VIP3A protein is not derived from a known source of allergens and does not display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

VIP3A protein appears to be present in multiple commercial formulations of Bt microbial insecticides at concentrations estimated to be *ca.* 0.4, 32 ppm. This conclusion is based on the presence of proteins of the appropriate molecular weight and immunoreactivity (by SDS-PAGE and western blot), and quantitation by ELISA. Therefore, it is conceivable that small quantities of VIP3A protein are present in the food supply because VIP3A (or a very similar protein, based on size and immunoreactivity) appears to be present in currently registered insecticide products used on food crops, including fresh market produce. These commercial Bt products are all exempt from food and feed tolerances.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Food products derived from cotton (refined cottonseed oil and cellulose “linters” fiber) are highly processed and are essentially devoid of any proteins. Moreover, no VIP3A protein was detected in refined cottonseed oil or cotton fiber produced from event COT102-derived VIP3A cotton plants. Therefore, no human dietary exposure to VIP3A protein is expected to occur *via* VIP3A cotton. Even if dietary exposure to VIP3A protein were to occur, data derived from bioinformatic analyses as well as direct *in vitro* and *in vivo* testing collectively indicate that the VIP3A protein is unlikely to have allergenic potential. The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public databases. The VIP3A protein is not derived from a known source of allergens and does not

display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

ii. *Drinking water*. No exposure to VIP3A and the genetic material necessary for its production in cotton *via* drinking water is expected. The proteins are incorporated into the plant and will not be available. However, if exposure were to occur by this route, no risk would be expected because the VIP3A protein is not toxic to mammals.

2. *Non-dietary exposure*. Non-dietary exposure is not anticipated, due to the proposed use pattern of the product. Exposure *via* dermal or inhalation routes is unlikely because the plant-incorporated protectant is contained within plant cells. However, if exposure were to occur by non-dietary routes, no risk would be expected because the VIP3A protein is not toxic to mammals.

E. Cumulative Exposure

Because there is no indication of mammalian toxicity to the VIP3A protein, it is reasonable to conclude that there are no cumulative effects for this plant-incorporated protectant.

F. Safety Determination

1. *U.S. population*. The lack of mammalian toxicity at high levels of exposure to the VIP3A protein demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated *via* consumption of processed food products produced from VIP3A cotton. Moreover, little to no human dietary exposure to VIP3A protein is expected to occur *via* VIP3A cotton. Due to the lack of toxicity of the VIP3A protein and its very low potential for allergenicity, dietary exposure is not anticipated to pose any harm for the U.S. population. No special safety provisions are applicable for consumption patterns or for any population sub-groups.

2. *Infants and children*. The plant-incorporated protectant active ingredient, *Bacillus thuringiensis* VIP3A insect control protein and the genetic material necessary for its production in cotton, demonstrates no mammalian toxicity. Thus, there are no threshold effects of concern and, consequently, there is no need to apply an additional margin of safety.

G. Effects on the Immune and Endocrine Systems

The safety data submitted show no adverse effects in mammals, even at

very high dose levels, and support the prediction that the VIP3A protein would be non-toxic to humans. Therefore no effects on the immune or endocrine systems are predicted. When proteins are toxic, they are known to act *via* acute mechanisms and at very low dose levels. Sjoblad, Roy D., *et al.*

“Toxicological Considerations for Protein Components of Biological Pesticide Products,” *Regulatory Toxicology and Pharmacology* 15, 3–9 (1992). Further, the VIP3A protein is derived from a source that is not known to exert an influence on the endocrine system.

H. Existing Tolerances

There are no existing tolerances for the Bt VIP3A protein and the genetic material necessary for its production. Other Bt-based pesticide products are exempt from tolerances.

I. International Tolerances

There are no existing international tolerances or exemptions from tolerance for the Bt VIP3A protein and the genetic material necessary for its production.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0358; FRL–7334–7]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials took place during the period April 1, 2003 to September 30, 2003 to control unforeseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption or denial for the name of a contact person. The following information applies to all contact persons: Team Leader, Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9366.

SUPPLEMENTARY INFORMATION: EPA has granted or denied emergency exemptions to the following State and