

US EPA ARCHIVE DOCUMENT

Questions for the FIFRA Scientific Advisory Panel  
Assessment of Scientific Information Concerning StarLink Corn Cry9C, Bt Plant-Pesticide  
November 28, 2000

Allergenicity

1. Based on your review of the currently available data, how would you assess the likelihood (high, medium, or low) that the Cry9C protein is a food allergen? Please explain the basis for that conclusion.

Sensitization

2. Assuming the Cry9c protein has the potential to act as a human allergen and taking into account the limited duration (four years) and amount of exposure (no StarLink corn produced after 2000) to Cry9C in the food supply, how would you assess the likelihood (high, medium, or low) that the use of StarLink corn in making processed food has resulted in the sensitization of some individuals to the Cry9C protein? Please explain the basis for that conclusion. What difference would it make if the amount in the food supply is one or two orders of magnitude lower or higher?

3. The submission from Aventis CropSciences contends that “[i]t is unlikely that a protein, which is present at low levels in the diet, would become an allergen. . . . Allergic responses are not induced by . . . minor components, but are specific for a few usually highly expressed proteins.” (Submission, p.21) Aventis contends that Cry9C represents less than 0.0129% of the corn protein, and therefore that it is very unlikely to become a food allergen. Please comment on the scientific basis for this approach to evaluating the potential allergenicity of a protein.

4. Please comment on the relevance of the Bernstein, *et al* study on dermal and inhalation sensitization to microbial *Bacillus thuringiensis* pesticide products to sensitization and allergenicity of the Cry9C protein in food.

5. Please comment on the CDC and FDA analysis of reports from individuals who claim to have experienced adverse effects after consuming food that might have been made from StarLink corn?

Exposure Estimates

6. Please comment on EPA’s methodology for estimating dietary exposure to the Cry9C protein, especially on whether the upper bound estimates are meaningful given corn processing pathways, processed food distribution pathways, and individual consumption patterns.

7. The submission from Aventis CropSciences contends that “[i]n the most conservative approach to safety assessment of the Cry9C protein, the reasonable worst case dietary exposure to the Cry9C protein per day is compared to the amount of peanut allergen required to elicit a clinical response in peanut sensitized individuals.” Please comment on whether the comparison

of the levels of potential human exposure to Cry9C protein with the levels of peanut allergen causing allergic symptoms in peanut-sensitive individuals is a reasonably conservative approach to assessing the potential risks of Cry9C protein.

### Overall

8. Based on your review of the currently available data, how would you assess the overall probability (high, medium, or low) that the likely levels in the US diet of Cry9C protein are sufficient to cause significant allergic reactions in the exposed population? Please explain the basis for that conclusion.

9. Please indicate the priority that should be given to obtaining the following types of additional information for the purpose of improving the scientific basis of assessing the potential allergenic risk of the Cry9C protein:

- data on the impacts of different processing methods on the level of Cry9C protein in processed food
- data on the levels of Cry9C protein found in processed food
- data on the extent of mixing of StarLink corn grain with StarLink-free corn grain
- data on the presence of specific antibodies in individuals either who claim to have experienced adverse effects after consuming food that might have been made from StarLink corn or who have significant occupational exposure to StarLink corn or corn products
- monitoring of reports from the medical community for individuals who claim to have experienced adverse effects either after consuming food that might have been made from StarLink corn or from occupational exposure to StarLink corn.