

January 6, 2005

Docket No. 2004D-0369

Comment submitted by The Food Allergy & Anaphylaxis Network (FAAN) via <http://www.fda.gov/dockets/ecomments>

The Food Allergy & Anaphylaxis Network (FAAN) submits the following comments regarding FDA's draft guidance for industry entitled "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."

FAAN is pleased that FDA is continuing its efforts in the area of food allergy, an emerging food safety and public health issue. The disease affects approximately 11 million Americans (4% of the U.S. population), and it is widely believed that its prevalence has yet to peak. Food-allergic reactions continue to be the leading cause of anaphylaxis (a severe, potentially life-threatening allergic reaction) outside the hospital setting, accounting for an estimated 30,000 emergency room visits, 2,000 hospitalizations, and 150-200 deaths each year in the U.S. alone. There is no cure in sight for food allergy; strict avoidance of the allergenic protein is the only way to avoid a reaction.

Bioengineering is an expanding area of science, one that holds tremendous promise but also enormous risk. As a result, food-allergic individuals and their families count on federal entities such as FDA to help ensure that potential allergens from new plant varieties do not inadvertently enter the food supply.

FDA first addressed the issue of new proteins in bioengineered plants with a policy released in 1992. Since that time, to the best of our knowledge, no allergens have entered the food supply, and the FDA appears to have done a thorough job with its voluntary premarket biotechnology consultation process (BNF, or biotechnology notification file), through which FDA consults with developers of new plant varieties to identify any potential problems.

However, FDA now appears to be stepping up its efforts by recommending the voluntary submission of an early food safety evaluation of new proteins by new bioengineered plant varieties being developed for food use but which have not been evaluated via a BNF.

FAAN, then, recommends that FDA moves forward with its guidance for the submission of early food safety evaluations. These evaluations will occur during the very early stages of potential product development, prior to the product field trials, and should prove vital in identifying any potential unintended introduction, or adventitious presence, of a protein into a food crop and, in turn, into the nation's food supply.

*FAAN is a nonprofit organization whose mission is to raise public awareness, provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis.*