



**United Fresh Fruit &
Vegetable Association**

January 24, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2004D-0369, Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

Dear Sir or Madam:

Founded in 1904, the United Fresh Fruit and Vegetable Association (United) is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry; promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

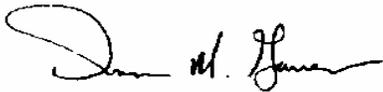
We have a direct and vested interest in food safety, and as such, the Agency's efforts to provide guidance to developers of new plant varieties intended for food use, focusing on bioengineered plants. United supports the Agency for drafting the guidance and believes that all federal regulatory agencies with any biotechnology oversight should continually move to integrate the producers of biotechnology into the existing regulatory framework in a manner which ensures protection of the public while being responsive to the produce industry's needs.

An abundant and affordable supply of fresh fruits and vegetables is critical to the nation's health and wellbeing and biotechnology may represent a significant step forward in the process of fruit and vegetable production. United has long supported the development and application of biotechnology as a tool in the production of fruits and vegetables. The technology can be used to confer desirable traits to enhance pest resistance, improve nutrient uptake, enhance efficiency of water utilization, improve the efficacy of biocontrol agents and otherwise reduce production inputs into the environment to assure the sustainability of fresh produce.

With this being said, we concur with the FDA that early communication with the Agency on the part of the developer is important as both parties may discuss any possible scientific and regulatory issues that might arise at the onset of plant production. We also support the voluntary nature of this guidance and believe that the biotechnology industry will follow the Agency's recommendations helping to ensure that there is no inadvertent introduction of harmful plant varieties into the food supply.

While biotechnology is another tool for plant producers to use, it does remain critically important that all plants or plant foods grown for human consumption are safe. The fresh fruit and vegetable industry will continue to support the development and use of technologies such as bioengineering as long as the industry can ensure the safety of the products being developed and we believe that continued federal oversight through guidance documents such as this will assist in our efforts. Moving forward, we remain confident that the Agency will extend outreach to biotechnology developers providing awareness that documents of this type are available and they serve as good proactive safety advice.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna M. Garren". The signature is fluid and cursive, with the first name being the most prominent.

Donna M. Garren, Ph.D.
Vice President, Scientific and Technical Affairs