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BY MESSENGER

September 28, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 98N-0359

Dear Sir/Madam:

These comments are submitted on behalf of the Biotechnology Industry Organization (BIO) in response to the July 18, 2001 Federal Register notice requesting public comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition for fiscal year 2002. (66 Fed. Reg. 37480). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Consumers look to FDA to provide strong oversight for the safety of all food, including food improved through biotechnology. Technology providers and seed companies developing crops in the U.S. improved through biotechnology are committed to strict compliance with domestic and foreign laws governing the testing and commercialization of those crops. The industry uses state of the art technologies and agricultural practices to provide the highest possible degree of safety and integrity for these products. Even so, one of the emerging areas in biotechnology both in the U.S. and internationally is the need to address adventitious presence of plant material from crops improved through biotechnology that have not completed the regulatory review process in the U.S. or other country in which the material is found. Adventitious presence is defined as the unintended presence of plant material occurring in seed, grain, or food products, at trace levels, through naturally occurring pollen flow or unintended commingling during the production process.

Therefore, BIO recommends that FDA address, as a program priority in the Center for Food Safety and Applied Nutrition during the coming year, the adventitious presence of plant material derived from crops improved through biotechnology that have not completed the regulatory

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review process in the country in which the material is found. We would be pleased to provide additional information on this important issue at your request.

Sincerely,



Stanley H. Abramson

cc: Dr. Michael Phillips  
Biotechnology Industry Organization