

VIA ELECTRONIC MAIL

August 9, 2004

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

RE: Docket No. 1998N-0359

Dear Sir/Madam:

My name is Kerry-Ann T. Powell and I am a Food Safety Advocate with U.S. Public Interest Research Group. U.S. PIRG is the national lobbying office for a number of affiliated State PIRGs, a nationwide network of nonprofit, nonpartisan advocacy groups working on consumer rights, democracy and campaign finance reform, and environmental issues.

I am writing regarding the notice published in the Federal Register on June 24, 2004, pp35380-35381, titled "Program Priorities in the Center for Food Safety and Applied Nutrition." In the notice the agency indicates that it will be establishing fiscal year 2005 (FY2005) program priorities for the agency's Center for Food Safety and Applied Nutrition (CFSAN) and requests comments on program areas or activities that CFSAN should prioritize. The State PIRGs having a history of advocating for the safety of the foods are concerned about the risks posed by genetically engineered foods and as a result submits the following comment.

We appreciate the Food and Drug Administration (FDA) proactively including three 'A-list' and four 'B-list' goals in the CFSAN's program priorities for FY 2004 that specifically address the safety of genetically engineered foods. We encourage the FDA to elevate to 'A-list' status its goal to address the presences of allergens in genetically engineered foods and institute a mandatory pre-market assessment of allergens according to commonly accepted protocols, such as the ones laid out by the Food and Agriculture Organization and the World Health Organization.

The FDA should also make mandatory labeling of genetically engineered foods a priority, as the recent National Academies of Sciences report "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects" recommends, "so that consumers can receive more complete information about nutritional components in GM foods introduced to the marketplace." Finally, FDA must continue to view transparency as an 'A-list' priority for the agency and make safety applications available to the public for review and comment before marketing.

Overall U.S. PIRG calls on the FDA and CFSAN to make it a priority in FY 2005 to implement regulations that would directly address consumer concerns about the safety of genetically engineered foods by 1) implementing mandatory pre-market review; 2) requiring labeling; and 3) increasing transparency by allowing for public review and comment of safety applications.

Sincerely,

Kerry-Ann T. Powell
Staff Attorney
U.S. Public Interest Research Group
218 D Street, SE
Washington, DC 20003