

March 13, 2001

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

Re: F.R. 66:4839-4842,2000
Docket no. 00D-1598

The American Phytopathological Society (APS), founded in 1909, is the premier educational, professional and scientific society dedicated to the promotion of the plant health and plant disease control for the common good. The Society represents more than 5,000 microbiologists, including scientists and science administrators in academic, industrial and government institutions working in a variety of areas, including applied and environmental plant pathology, food, horticultural and forestry science, and biotechnology, including basic and applied research on producing transgenic plants resistant to pathogens and abiotic stresses.

The APS welcomes the opportunity to comment on the draft guidelines. The APS has particular interest in issues and policies relating to biotechnology research and development, with members of the society considered leaders in the field.

We remind FDA that at its November 30,1999 public meeting in Washington, D.C., the APS stated that labeling should be based on sound science, i.e. if there are significant alterations in the composition of the food, and not on the process by which the food is produced. We agree with FDA's finding that there is 'no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding techniques.' Thus, the FDA has not required special labeling for such foods, a position which the APS supports.

The Federal Food, Drug and Cosmetic Act further requires that any labeling be truthful, not misleading, and reveal material facts relevant to the use of the product, where 'material facts' refer to composition, not to the method of production. We assert that statements like 'GM free', 'GMO free', 'biotech free' and 'no genetically engineered materials', if applied to food and feed, could be misleading and pejorative. The words 'free' and 'no' indicate 'zero content'. Further, even the European Union allows a current level of 1% of GM food into the food supply without specific labeling. Hence, levels, which trigger labeling requirements, should be evaluated in conjunction with industry and international perspectives. The wording of the labels and information content should also be determined in conjunction with industry.

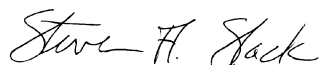
Food labeling on the basis of process, if required, would be punitive and deceiving, implying that conventional foods are absolutely safe and those modified by newer methods are not. Also, it is not clear how fresh food and farmer-market food labels would be dealt with.

In addition, before labeling occurs, either the FDA or industry must arrange for standards, testing, certification of some type and enforcement provision, else there will be additional confusion in the marketplace. The costs of labeling should be considered and evaluated for effectiveness. The increased costs would be borne ultimately by consumers and users. As FDA is aware, there are as yet no standardized, simple, rapid or inexpensive procedures to differentiate genetically modified from non-genetically modified products. Further, false positive and false negative assays reportedly are yet all too common. Thus, a requirement for labeling could lead to difficult to administer procedures and costly outcomes.

The public is unaware that conventional methods of genetics and breeding can produce foods and feeds that contain toxins and allergens, including foods on the GRAS list. Thus, educational materials should be considered illustrating, e.g. the GRAS foods that contain known allergens and are not currently so labeled in the marketplace.

The APS is in concurrence with FDA that consumers will benefit from knowing more about bioengineered foods, and would be pleased to assist the agency in providing such information and assisting in its dissemination. We also would ask FDA to work with sociologists and others, who have determined that food-fear is a growing phenomenon and that firm government action taken in the name of precaution can have the paradoxical effect of increasing rather than allaying concerns.

Sincerely,

A handwritten signature in cursive script that reads "Steve A. Slack".

Steven A. Slack
President, APS