AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

March 13, 2001

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

Re: Docket Number OOD-1598; Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

The American Society for Microbiology (ASM) welcomes this opportunity to comment on the Food and Drug Administration (FDA) draft guidelines on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." The ASM has a special interest in issues and policies relating to biotechnology research and development. With a worldwide membership that exceeds 42,000, the ASM includes scientists working in academic, governmental and industrial institutions with expertise in molecular biology and genetics as well as in environmental microbiology, medical microbiology, agricultural microbiology, and industrial microbiology - including the microbiology of food.

On November 30, 1999, in Washington, D.C., at a public hearing conducted by the FDA, the ASM stated that labeling should be based on significant alterations in the composition of the food and not on the process by which the food is produced. The FDA has found "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." Therefore, the FDA has not established a special labeling requirement for bioengineered food - a position the ASM firmly supports.

The Federal Food, Drug and Cosmetic Act requires that labeling be truthful, not misleading, and reveal material facts relevant to the use of the product, where "material facts" refers to composition not to method of manufacture. If a bioengineered food has a significantly different nutritional property than the unmodified food, its labeling currently must describe the difference. Accordingly, the FDA recently required labeling of bioengineered soybean and canola oils with altered fatty acid composition. Likewise, if an allergen has been bioengineered into a new food, the producer presently is required to disclose the presence of the allergen in the labeling. Statements like "GM free," "GMO free," "biotech free," and "no genetically engineered materials," if applied to food and feed, would be misleading because "free" and "no" imply "zero

1752 N Street, NW • Washington, DC 20036-2804
tel: 202-942-9209 • fax: 202-942-9335 • email: publicaffairs@asmusa.org

content." For centuries farmers and gardeners have selectively bred crop and ornamental plants to produce varieties with novel, desirable characteristics. It is exceedingly important for the public to understand that all commercially important plants have been genetically modified by individuals (biotechnologists) whose job or hobby it was to produce improved varieties of plants. Biotechnology as it is practiced today is part of a continuum of ever more refined attempts by man to breed better plants and animals for food or show.

Food labeling is justified if it identifies real risk and provides information for the safety of consumers. To label a product only because it is genetically modified would be punitive. Conventional breeding techniques may also produce food or feed that is toxic or allergenic, but there is no requirement for labeling to alert the public that such a possibility exists. Labeling will require the establishment by the FDA and the food and feed industries of guidelines and standards as well1 as testing, certification and enforcement provisions and procedures. These requirements will impose significant costs to farmers, to food processors and others who would have to detect and separate genetically modified from non-genetically modified products in the field, during processing, and in the marketplace. This increased cost ultimately would be borne by the consumer. Since there is no simple, inexpensive and reliable procedure to differentiate genetically modified from non-genetically modified products and assure that permissible levels of genetically modified products have not been exceeded, a requirement to label would invite deception, and be exceedingly difficult and expensive to regulate.

We agree with the FDA that consumers will benefit from knowing more about bioengineered foods, and it is prepared to help the FDA and the food and feed industries determine the nature of such information as well as how it might best be disseminated using avenues of communication other than labeling. The ASM welcomes any opportunity to assist the FDA in accomplishing its mission of protecting the public health.

Sincerely,

Gail H. Cassell, Ph.D.
Chair, Public and
Scientific Affairs Board

David Pramer, Ph.D.
Chair, Committee on
Biotechnology and
Industry

Anne K. Vidaver, Ph.D.
Chair, Committee on
Agricultural and Food
Microbiology

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