3823 '01 MAR 16 A10:01

March 13, 2001

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

Re: Docket No. OOD-1598
Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering
Fed. Reg., Vol. 66, No. 12, pp. 4839-4842, (January 18, 2001)

These comments are made on behalf of the International Dairy Foods Association (IDFA). IDFA is America's leading trade association representing the dairy industry. IDFA's approximately 600 member companies manufacture the entire range of dairy products and include processors, manufacturers, marketers, distributors, and suppliers. IDFA consists of three constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. Member companies in these groups account for 85 percent of the dairy products consumed in the United States.

The dairy industry has benefited significantly from agricultural biotechnology. The first genetically engineered food ingredient on the American market was recombinant chymosin, the enzyme used to make cheese. Fermentation-produced chymosin was created by inserting a gene from a cow into the food grade bacterium *Escherichia coli*. In the decade since this product was introduced, billions of pounds of cheese have been made using recombinant chymosin and safely consumed by the public.

OOD_1598

C2653

Conventional chymosin is derived from the tissue of young calves. Biologically-enhanced chymosin is produced from a controlled fermentation process, which results in higher purity and more predictable performance. The new process also provides a more consistent supply of the enzyme at higher prices.

The dairy industry also uses other ingredients derived from biotechnology. For example, recombinant bovine somatotropin is used to increase milk production in cows, corn syrup made from bioengineered corn is used in a variety of dairy products, particularly ice cream, and genetically enhanced bacterial cheese cultures show better performance in cheese production.

IDFA supports FDA's recommendations published as Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. Existing FDA policy states that a food made using biotechnology does not require special labeling if the food is not significantly different from its conventionally produced counterpart. Current policy does require label information if a bioengineered food contains an allergen not normally present in the food, or if the food has significant compositional differences from its conventional counterpart. Special labeling is also required if the bioengineered food performs differently than a consumer might reasonably expect. FDA has concluded that if a bioengineered food is not significantly different from its conventional counterpart, there is no scientific or public health justification for special labeling.

Existing FDA policies on biotech labeling are based on science and common sense. IDFA is gratified to see that science and common sense prevailed in the new guidance as well. In most cases, bioengineered food is very similar to its conventional counterpart, and special labeling is not required. However, some food marketers may wish to indicate to the consumer that the product was produced using biotechnology. IDFA believes that food companies should be able to provide that information voluntarily if they choose. Likewise, food marketers who wish to voluntarily make a claim that their product is not produced using biotechnology should be free to do so if testing or documentation can substantiate their claim.

IDFA encourages the FDA to continue its practice of using sound science to develop policies regarding agricultural biotechnology. The only criterion that cannot be subverted politically is hard data derived from well-designed studies. IDFA believes the safety record of bioengineered foods developed by American companies is unblemished. There have been no food safety issues despite the fact that today, over 60 percent of foods in stores across America contain bioengineered ingredients. The science-based approach has served the public interest well and should continue.

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

March 13, 2001

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

Dear Sir or Madam:

Enclosed are comments from IDFA on the FDA's draft guidance on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" and on the " Premarket Notice Concerning Bioengineered Foods."

If you have any questions or comments regarding IDFA's position, please contact Gordon Brown, Senior Vice President of Regulatory Affairs at (202) 220-3524.

Thank You.

Sincerely,

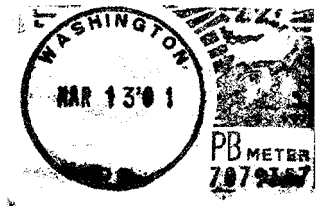
C. Gordon Brown
Senior Vice President of Regulatory Affairs

1250 H St., NW, Suite 900, Washington, DC 20005
phone: 202-737-4332 fax: 202-331-7820 fax-on-demand: 888-607-7718 www.idfa.org

Dairy Foods Association
Foundation
se Institute
ce Cream Association

uite 900
20005

CEREQUESTED



First Class Mail

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

MIC-5M00