DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 4, 2002

Governor John A. Kitzhaber, MD
State Capitol Building
900 Court Street NE
Salem, Oregon 97301-4047

Dear Governor Kitzhaber:

This letter explains why FDA objects to the pending ballot initiative to require the mandatory labeling of foods and food additives produced using genetic engineering sold in Oregon, or produced in Oregon and shipped to other states. In brief, FDA's scientific judgement is that there is no significant difference between foods produced using bioengineering, as a class, and their conventional counterparts. (By "genetic engineering," we refer to foods produced using recombinant deoxyribonucleic acid (rDNA) technology and not traditional breeding techniques; this technology is also referred to as "bioengineering" or "biotechnology.") Further, FDA's scientific evaluation of bioengineered foods continues to show that these foods, as currently marketed in the United States, are as safe as their conventional counterparts. Moreover, mandatory labeling to disclose that a product was produced through genetic engineering does not promote the public health in that it fails to provide material facts concerning the safety or nutritional aspects of food and may be misleading to consumers.

Under the Federal Food, Drug and Cosmetic Act ("the FD&C Act"), FDA is responsible for ensuring the safety of the nation's food supply, ensuring that food labeling is truthful and not misleading, and for regulating food additives. 21 U.S.C. § 321, *et. seq*. Foods and food ingredients produced using bioengineering must adhere to the same safety and labeling standards under the FD&C Act as their conventionally bred counterparts. FDA is not aware of any information or data that would suggest that any genetically engineered foods that have been allowed for human use are not as safe as conventional foods.

After numerous meetings and public comments on this issue,[1] FDA concluded that a safety assessment of any new food should focus on the traits and characteristics of that food, no matter which techniques (traditional breeding or genetic engineering) were used to develop the food. Food produced via bioengineering should be treated just like its conventional counterparts because, from a scientific standpoint, there is no evidence that these foods differ as a class from traditionally bred foods in any meaningful or uniform way. Nor is there evidence that, as a class, foods developed by rDNA breeding techniques present any different or greater safety concerns

[1] FDA has carefully considered the issues surrounding foods produced using bioengineering. As part of this consideration, FDA has reviewed public comments on its bioengineered food policies and has held public hearings on FDA's approach and experiences with foods produced via bioengineering. In May 1992, FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy), which is available for your information at 57 Federal Register 22984 (May 29, 1992) or the FDA's web site at www.fda.gov.

than foods developed via traditional breeding. FDA's scientific evaluation to date has shown that the substances added to food via bioengineering have been well-characterized proteins that are functionally very similar to other proteins that are commonly and safely consumed in the diet every day.

FDA has previously concluded that requiring mandatory labeling for bioengineered foods is not scientifically or legally warranted. Rather, the labeling for foods produced using bioengineering must comply with the law applying to the labeling for all foods. Among other things, food labeling must reveal all facts that are material in light of representation made in the labeling or in light of consequences that may result from the use of foods. 21 U.S.C. § 321(n).

For example, FDA would consider mandatory labeling where:

- the food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food – FDA has required labeling for two foods (a soy oil and a canola oil) where the fatty acid composition was changed to mimic that of food oils not associated with the modified plant;
- an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use;
- the food has significantly different nutritional properties; or
- a new food includes an allergen that consumers would not expect to be present in the food based on the food's name.

Accordingly, the proposed legislation for mandatory labeling of foods produced using bioengineering would be contrary to FDA's position that the use of bioengineering, standing alone, is not a material fact that requires disclosure in food labeling. Moreover, as is summarized above, and described in more detail in FDA's public notices cited above, mandatory labeling of bioengineered foods is contrary to the science that currently shows no significant difference between foods produced using bioengineering and their conventional counterparts.

Moreover, the proposed legislation would impermissibly interfere with manufacturers' ability to market their products on a nationwide basis. If passed, manufacturers producing products in Oregon or manufacturers selling products in Oregon produced in another state would be required to create special labeling to comply with Oregon law – labeling not required by FDA or other states. Thus, as a practical matter, the Oregon law would require different labels for different states impeding the free flow of commerce between the states.

We hope you find these views useful.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner