FDA and Biotech: Food for Thought

Few issues of food law and policy have generated more controversy in recent years than the regulation of food products derived from biotechnology. Biotechnology presents the type of technological advancements that has often required the U.S. Food and Drug Administration (FDA) to develop policies for situations not explicitly anticipated by the Food Drug and Cosmetic Act (FD&C Act). In 1986, FDA published a policy statement on products of biotechnology in which the Agency concluded that the regulatory status of bioengineered products would be determined on a case-by-case basis, using the existing statutory and regulatory framework. FDA stated that it was unnecessary to develop new procedures to address generic concerns about biotechnology because the existing statutory structure, particularly sections 402(a)(1) and 409 of the FD&C Act, provided the Agency with ample authority to ensure the safety of foods derived from genetically modified plant varieties.

In a policy statement published in May of 1992, FDA reaffirmed the 1986 policy that foods produced by new methods would be regulated within the existing statutory and regulatory framework. Under this framework, FDA explained, the regulatory status of a food is dependent upon the objective characteristics of the food and its intended use. Although the methods by which a food is developed or produced, including the use of biotechnology, are relevant in a safety evaluation, it is primarily the characteristics of the finished food that determine its safety. Accordingly, FDA's practice has been to subject substances present in food as a result of genetic engineering to the premarket approval process for food additives only if the substances differ substantially from their counterparts found in conventional foods.

While FDA did not institute a mandatory preapproval process for foods derived from modern biotechnology following the publication of its 1992 policy statement, the Agency did encourage developers of such foods to consult with FDA prior to marketing. Informal consultation procedures intended to facilitate the resolution of potential safety, nutritional, and regulatory issues have been developed for this purpose. As part of these procedures, FDA evaluates a summary of a safety and nutritional assessment prepared for the food, and determines whether a comprehensive scientific review is required. FDA also provides advice regarding labeling of biotech products. FDA has said special labeling is not needed unless the biotech food is substantially different from its conventional counterpart.

Since the publication of the 1992 policy statement, FDA has cleared the way for the marketing of a number of biotech products. In May 1994, FDA concluded its review of the FLAVR SAVR™ tomato and announced with great fanfare its conclusion that the biotech tomato was as safe as other commercial varieties of tomato. As of May 2005, FDA had completed voluntary consultations with developers of nearly 100 products derived from modern biotechnology. The products reviewed include fruits, vegetables, and grains engineered to exhibit insect resistance, pesticide tolerant, or modified ripening traits. Recent Revisiting of the Policy

Prompted by widespread criticism from consumers, U.S. trading partners, and anti-biotech activists, FDA, in late 1999, began to revisit in earnest its longstanding policy regarding foods developed from modern biotechnology. In May 2000, following a series of public meetings on the issue in the fall and winter of 1999, FDA announced plans to
refine its regulatory approach.

On January 18, 2001, FDA proposed a major change to the regulatory framework governing foods derived from biotechnology. The change came in the form of a proposed rule issued by the Agency that would require food producers to notify FDA prior to marketing a food derived from biotechnology. As a practical matter, the proposal would convert the current voluntary premarket notification system for bioengineered foods into a mandatory program requiring the submission of safety data and related information in the form of a premarket biotechnology notification (PBN) 120 days prior to marketing. Under the proposal, biotech foods could not be marketed until a favorable response is received from FDA. To date, the Agency has not taken any further action to issue a final rule.

On the same day it proposed creation of a PBN system, FDA also released a draft guidance for industry on voluntary labeling for biotech and non-biotech foods. The guidance, entitled "Voluntary Labeling Indicating Whether Foods Have or Have not Been Developed Using Bioengineering," is intended to assist food producers who would like to voluntarily label their foods as being made with or without the use of bioengineering or the use of bioengineered ingredients. The purpose of the draft guidance is to ensure that biotech-related labeling is truthful and not misleading.

The guidance does not require special labeling for biotech foods. As expected, FDA is maintaining its position that the mere fact that a food product has been developed using bioengineering is not a material fact requiring disclosure on the product label. The guidance therefore does not alter FDA’s current biotech labeling policy, under which special labeling for biotech foods is required only when the product contains potential allergens or otherwise differs significantly from traditional food.

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2 Section 402(a)(1) of the Act renders a food adulterated if it contains an added poisonous or deleterious substance that may be injurious to health. Section 409 provides a framework for the premarket approval of food additives.

