POLICY FORUM: GENETIC ENGINEERING

A Rational Approach to Labeling Biotech-Derived Foods

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Scientists around the world are using recombinant DNA techniques to improve plants. These transgenic plants can have enhanced resistance to pests, disease, drought, salinity, frost, and herbicides, as well as enhanced nutritional value, improved processing characteristics, and better taste. In 1998, they were cultivated on about 69.5 million acres (*1*).

In the United States, the Food and Drug Administration (FDA) is responsible for ensuring the safety and wholesomeness of the nation's food supply (except poultry and most meats). Most biotechnology-derived products are regulated under the agency's official policy on foods derived from new plant varieties (*2*), which applies irrespective of whether the plant arose by molecular or conventional methods. The policy elaborates a scientific and "transparent" (that is, clear and predictable) regulatory approach, mandating when consultations with the FDA are necessary, when labeling is required, and what information should be conveyed in labels. At a time when there are international debates regarding food labeling (see also related News story), it is useful to review the rationale behind the FDA approach.

A Risk-Based Policy

The FDA does not routinely subject foods from new plant varieties to premarket review or to extensive scientific safety tests, although there are exceptions. The agency has judged that the usual safety and quality control practices used by plant breeders, such as chemical and visual analyses and taste testing, are generally adequate for ensuring food safety.

Additional tests are performed, however, when suggested by the product's history of use, composition, or characteristics. If present, certain safety-related characteristics of new foods require greater scrutiny by the agency. These include the presence of a substance that is completely new to the food supply (and that therefore lacks a history of safe use) or of an allergen presented in an unusual or unexpected way (for example, a peanut protein transferred to a potato). New carbohydrates with unusual structural or functional groups, or oils that contain new or unusual fatty acids, may require premarket approval as food additives (*2*). Other characteristics of potential concern are changes in amounts of major dietary nutrients or increased concentrations of toxins normally found in foods. For example, potatoes are generally tested for the glycoalkaloid solanine—which has been linked to the birth defect spina bifida (*3*)—because toxic amounts of this natural toxicant have been detected in some new potato varieties.

This focus by the FDA on safety-related characteristics, rather than on the method by which the plant was genetically modified, reflects the scientific consensus that, as expressed in an analysis by the National Research Council, "the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods," and therefore, "no conceptual distinction exists" (*4*). Following this logic, the use of any particular genetic manipulation should not in itself determine the need for or the degree of governmental review. However, this is not universally followed by other U.S. and foreign regulatory agencies. The U.S. Department of Agriculture and Environmental Protection Agency oversee the field testing and use of biotechnology under regulations that are triggered by the use of recombinant DNA techniques; in other words, regulation is focused on process rather than risk (*5*). This unscientific approach has elicited widespread condemnation from the scientific community (*6*).

Counterproductive labeling? The labeling on consumer products may actually increase public anxiety.

The "Guidance to Industry" section in the FDA's 1992 policy statement instructs food producers who use novel plants to consider the characteristics of the host plant that is modified, the donor organism that contributes genetic information, and the genetic material and other substances introduced or modified. It also enumerates the safety-related characteristics for determining whether a substance intentionally introduced or altered by genetic modification will require premarket review and approval. The lengthy premarket review process requires submission of data to demonstrate safety.

In general, neither premarket review nor consultation with the FDA is required for introduced or modified proteins of known function if they are derived from food sources or are substantially the same as existing food substances, if they are not known to be toxic or to raise food safety concerns, and if they will not be a major constituent of the diet. Nevertheless, the FDA intends to follow the development of foods made with new biotechnology (*7*) via noncompulsory "informal consultation procedures."

To Label or Not to Label

The question of whether foods derived from organisms containing recombinant DNA ("biotech foods") should be specially labeled has received a great deal of attention (*8*). The FDA's approach to the labeling of foods, including those genetically engineered or otherwise novel, is that the label must be accurate and "material." There are only two situations in which the FDA can require that a transgenic origin or ingredient be disclosed on the food label: (i) The FDA may mandate the disclosure of facts on a product label that relate

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to material consequences that can follow the consumption of a food (for example, certain beans that must be soaked and cooked before eating). (ii) The FDA can require that a label reveal facts necessary to correct or balance other representations made by the manufacturer or seller (*9*). Accordingly, labeling is required "if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies, or if a safety or usage issue exists to which consumers must be alerted" (*2*). The policy statement also emphasizes that no premarket review or approval is required unless characteristics of the biotech food explicitly raise safety issues, and that—inasmuch as the genetic method used in the development of a new plant variety does not meet either of the two criteria for "materiality"—the FDA cannot require the labeling to include this information.

The policy has already been tested, in a way that constitutes a kind of positive control. Pioneer Hi-Bred International produced a recombinant soybean for animal feed that contained an allergenic protein transferred from Brazil nuts (*10*). Before release of the product, during consultation with the FDA, Pioneer Hi-Bred identified the allergen. Confronted with potential product liability and the costs of labeling all products derived from the new plant variety, the company abandoned plans to use the new soybeans in consumer products. No consumers were exposed to injury.

The FDA's approach is consistent with the scientific consensus that the risks associated with recombinant organisms, and with products derived from them, are fundamentally the same as for nonrecombinant products. Dozens of new plant varieties modified with traditional genetic techniques (such as hybridization and mutagenesis) enter the marketplace every year without premarket regulatory review or special labeling (*11*). Many are from "wide crosses" in which genes have been moved across natural breeding barriers, that is, from one species or genus to another. None of these plants exist in nature. Nonetheless, they have become an integral, familiar, and safe part of our diet; they include bread and durum wheat, corn, rice, oats, black currants, pumpkins, tomatoes, and potatoes (*12*).

The massive accumulation of sequencing data shows extensive genetic similarity between genomes of organisms that are only remotely related. For example, parts of the nucleic acid sequence of *Escherichia coli* are identical to that of organisms such as oilseed rape, amphibians, birds, grasses, and mammals—including humans (*13*). Such findings put in doubt the value of assigning genes to a particular species.

Economics and Psychology of Labeling

Special-interest groups have called for stringent labeling requirements, but these may not be in the best interest of consumers. Labeling can add significantly to production costs of foods, particularly those that are produced from pooled fresh fruits and vegetables. To maintain the accuracy of such labels, recombinant DNA–modified fruits and vegetables would have to be segregated through all phases of production (planting, harvesting, processing, and distribution), which would add costs and compromise economies of scale. These added production costs constitute, in effect, a special tax levied on producers who use a new technology. They reduce profits to plant breeders, farmers, food processors, grocers, and others in the distribution pathway, while also decreasing competition and increasing prices.

Furthermore, overregulation in the form of compulsory labeling could change the course of future research and development. In the United States and other countries, under current regulatory regimes for field testing that focus exclusively on organisms manipulated with recombinant DNA techniques, R&D has become limited primarily to a small number of commodity crops that are grown on a vast scale, at the expense of opportunities to improve important small-acreage crops (*5*). In 1998, the top four recombinant crops (soybean, corn, cotton, and oilseed rape) accounted for more than 99% of the global acreage (*1*); innovation seldom targets the genetic improvement of environmentally threatened species such as trees, or of subsistence crops such as millet, cassava, and yams.

The language of the FDA's principal enabling statute—the federal Food, Drug, and Cosmetic Act—firmly supports (indeed, to a large extent, dictates) the FDA's policies toward biotech foods. These policies were upheld indirectly by the U.S. Court of Appeals for the Second Circuit, which found in a pivotal 1996 decision regarding another product of biotechnology that food labeling cannot be compelled just because some consumers wish to have the information. In overturning a Vermont law that required labeling of dairy products from cows treated with recombinant bovine somatotropin, the court found that such regulation merely to satisfy the public's "right to know" is a constitutional violation of commercial free speech. "Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods," the court wrote (*14*).

Why is so much attention paid to the issue of labeling? The answer lies in the intentions and actions of ideological opponents of the new biotechnology. Labeling raises costs, which discourages producers and consumers and destroys markets for new products, so for those wishing to block the commercialization of biotech products, forcing an increase in costs is an effective strategy. Regulatory stringency is also an unmistakable signal to the public that there is something fundamentally different and worrisome about biotech foods. Anti-biotechnology activists argue that we need regulation because consumers are apprehensive, and then, when consumers become apprehensive because the products are stringently regulated, these activists say we need more regulation to assuage consumers' concerns. A similar strategy was used by activists in the 1980s to increase consumer anxiety regarding irradiated foods. The psychological aspect of this general strategy was conveyed to the National Biotechnology Board by the head of a national consumer advocacy group: "The consumer views the technologies that are *most* regulated to be the *least* safe ones. Heavy involvement by government, no matter how well intended, inevitably sends the wrong signals" (*15*).

The FDA's policy toward labeling biotech food is in contrast to that in Europe and Asia, where regulators have permitted politics, public misapprehensions, the blandishments of anti-technology activists, and nescience to dictate policy. Perhaps the scientifically defensible and risk-based approach of the FDA in the United States can illustrate that sound public policy can safeguard public health and stimulate new technology.

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