



Regulating Bio-Engineered Foods

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Issue. Use of biotechnology can increase the quality and quantity of food. Although biotechnology is being used to develop many food products, there may be delays in providing such products to consumers. Concerns have been raised about effects of biotechnology on food and environmental safety, and the structure of the agricultural industry. Adequacy of laws and regulations covering agricultural biotechnology to protect public interests has been questioned. The General Accounting Office has identified potential conflicts of oversight jurisdiction between government agencies as an impediment to safe development and marketing of biotechnology products. The U.S. Department of Agriculture (USDA) is devising a management strategy to institute a clear regulatory authority and review process.

Context. Biotechnology can be broadly defined as the use of living organisms to solve problems or to make useful products. This definition includes traditional plant and animal breeding methods, and bioprocessing, such as fermentation. The new biotechnology is the application of cellular and molecular biology to meet human needs, a definition that includes use of monoclonal antibodies, cell culture, biosensors, antisense, and genetic engineering (recombinant DNA and cell fusion) technologies. Biotechnology can be used to increase a plant's ability to control pests and disease, tolerate environmental stress, and enhance food quality, such as flavor, texture, shelf-life, and nutritional content. Biotechnology can be used for animals to promote growth and develop vaccines. Other uses include increasing food processing efficiency and developing more effective diagnostic techniques for testing food safety.

Many bio-engineered food products are being developed. Commercial success of these foods will depend on industry and farmer profits, public acceptance of biotechnology products (consumer demand), and the regulatory environment. Lack of confidence in the effectiveness and timeliness of existing safety regulations has caused delays and additional costs. Consumers, biotechnology industry representatives, researchers, environmentalists, agricultural producers, and food processors have expressed concern about current regulatory policies. Confusion exists over which agencies will exercise jurisdiction over the many elements of developing, testing, and marketing bio-engineered foods. Primary agencies involved are the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the USDA.

At Stake. Many technologies have helped increase productivity and cost efficiency in agricultural production, as well as provide consumers with a cheaper, higher quality, and more diverse food supply. Such benefits may not be realized with agricultural biotechnology unless public concerns are addressed and a well-articulated regulatory policy is established. There will be no market for the products of biotechnology without public acceptance of the products.

Delays in resolving intellectual property rights (patent) issues and in establishing clear regulations for field testing and product marketing could be costly. Firms have already invested over \$1 billion in agricultural biotechnology, and Federal investment is expected to be about \$600 million between 1991 and 1993. Lack of international harmonization in patenting and regulating bio-engineered food products could restrict international trade and harm U.S. competitiveness. Companies may reduce investment if the regulatory environment remains uncertain.

Use of biotechnology could variously affect food safety. Biotechnology methods can be used to develop quicker and more efficient techniques for detecting and reducing microbial contamination and concentrations of allergens and toxins in foods. However, use of biotechnology may cause unintended changes in the concentration in foods of allergens, toxins, and nutritional content. Traditional breeding methods pose a similar risk. Ethical concerns have been raised about the transfer of human and animal genes into plants and animals different from the host species (transgenics).

Dependence on pesticides and fertilizers might be reduced if plants were developed to resist pests and disease, and to more efficiently use soil nitrogen. In addition, plants developed with the ability to withstand such environmental stress as drought might prove less demanding on natural resources. One environmental concern is that adoption of herbicide-resistant crops may encourage continued use of chemicals, albeit less harmful chemicals in some cases. Another concern is that genetically engineered crops and animals, in competing with indigenous populations, may strain biodiversity and disrupt the ecological balance.

There are many issues associated with the introduction of foods produced using biotechnology, but most of the concerns would be relevant for any new agricultural technology. A technology resulting in significant changes in costs or production can cause structural changes in agricultural industries and regional shifts in production and income, as well as potentially affect environmental and food safety.

Alternatives. Clear, definitive regulatory policies for patenting, field testing, and ensuring food and environmental safety of agricultural biotechnology could reduce costs of commercializing bio-engineered foods. Biotechnology researchers and regulators generally acknowledge that biotechnology techniques are not inherently risky. Therefore, science- and risk-based regulations focusing on products of biotechnology could ensure adequate oversight.

There are several recent developments in the reformulation of regulatory policy. The FDA and the USDA's Food Safety and Inspection Service (FSIS) are establishing food safety policies for transgenic animals. The FDA has announced that food from new plant varieties developed using biotechnology will be regulated the same as food from plant varieties developed using traditional methods. USDA's Animal and Plant Health Inspection Service (APHIS) has streamlined the permit process for the field testing of certain crops for which some scientific assurance of safety exists. These decisions could reduce delays in commercialization and lower costs of product development, but only if the public, industry, and scientific community have confidence in the regulatory process.

Agenda. Agencies responsible for regulating bio-engineered foods and restructuring regulatory policy need to coordinate efforts to establish unified regulatory policies and to respond to public concerns. Efforts should include the public, industry, agricultural producers, academics, and the international community. International trade agreements need to resolve patent issues. If concerns are addressed in an open and accessible decisionmaking process, confidence in the regulatory system could be enhanced and agricultural biotechnology products would be developed to accommodate global needs.

Information Sources. Office of Technology Assessment (OTA), *A New Technological Era for American Agriculture*, Aug. 1992; Purdue Agricultural Experiment Station, *Agricultural Biotechnology: Issues and Choices*, edited by Bill Baumgardt and Marshall Martin, 1991; U.S. Government Printing Office, *Biotechnology for the 21st Century*, a report by the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) Committee on Life Sciences and Health, Feb. 1992; and General Accounting Office, *U.S. Department of Agriculture: Improving Management of Cross-Cutting Agricultural Issues*, GAO/RCED-91-41, 1991.