

OTA Report Brief

August 1992

A New Technological Era for American Agriculture

American agriculture is entering a new technological era that holds great promise. Biotechnology and advanced computer systems have the potential to increase productivity, enhance the environment, improve food safety and quality, and bolster U.S. competitiveness.

Many of these new technologies will be available in the 1990s. New tissue culturing and genetic engineering tools are allowing scientists to alter plants:

- to have greater disease, insect, and weed resistance;
- to withstand environmental stresses such as cold, drought, and frost;
- to develop value-added products from agricultural commodities; and
- to improve understanding of plant resistance and of interactions of plants, pests, and biological control agents in the agro-ecosystem.

In animal agriculture, genetically modified vaccines and diagnostics are on the market or will be soon. Growth promotants are going through the regulatory process. Reproductive technologies are advancing at a rapid pace and cloned embryos are currently being marketed. Transgenics are still in the future but considerable strides are being made in the use of livestock to produce high-value pharmaceuticals. Advanced computer systems, such as expert systems, computer-based sensors, and full-text retrieval systems will enhance farm operators' abilities to determine systematically the best decisions in managing their operations.

The advance of these technologies will play an important role in maintaining a growth rate in agricultural productivity that will rival the historical rate of the last two decades. At the same time, they will accelerate structural change in agriculture. These technologies, however, are not magic—agricultural biotechnology will require a higher degree of management skill on the part of the farmer. If they are used in the same manner as current technologies such as chemicals, many of the same problems will occur. It will be important to develop management systems to use these technologies effectively.

The introduction of these new technologies—especially biotechnology—will be under circumstances unlike any met by past technologies. Uncertainties over these new technologies raise questions of potential impacts on food safety and the environment, and possible economic and social costs. Nevertheless, there will be a push for these technologies to be used commercially, adopted by industry, and accepted by the public. Public acceptance will play a major role in determining the fate of these new technologies. Negative experiences with nuclear and chemical industries have made the American public wary of new technologies, and confidence in institutions has eroded. For these reasons, and because the consequences of the introduction of genetically modified organisms cannot be predicted with certainty, biotechnology has been subjected to extensive, apprehensive scrutiny and regulatory oversight. Many institutions will choose to "go the extra mile" to ensure public confidence as policy issues are resolved.

In making policy decisions, it remains important, nevertheless, to distinguish clearly between the technical basis for assessment and regulation of technology-related risks, and what might or might not be done as an extra step to maintain public confidence. Balancing safety and institutional credibility against economic competitiveness will be a skill in much demand throughout the decade.

Biotechnology-derived food products will need to address many scientific questions regarding food and environmental safety. For food safety, these questions include the toxicity of products formed from genetically modified organisms, unexpected secondary effects that may result from gene insertion, and adequacy of the database for traditional counterparts to make comparisons of significant changes. For the environment, scientific questions include adequacy of the knowledge base for risk/benefit assessment, adequacy of the knowledge base for science-based, risk-based regulations, and implementation of science-based regulations in concert with scientific and agronomic methods to manage risk on a large scale.

Lack of confidence in regulatory and research institutions could be a major impediment for these technologies. The Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) are the major regulatory agencies for agricultural biotechnology products. FDA recently put forward its policy for food derived from biotechnology. It is, however, general and short on specifics. Congress may be required to intervene in the development of food safety policy for these products. EPA has yet to establish guidelines on data requirements to establish residue tolerances for pesticidal plants, is inconsistent in its ability to establish science-based regulations for transgenic plants, and needs to be more responsive to public concerns. Biotechnology-derived products, plants in particular, are approaching commercialization at a rapid rate. Clear, concise, science-based policy is needed to guide these products through the regulatory process.

The Office of Technology Assessment (OTA) is an analytical arm of the U.S. Congress. OTA's basic function is to help legislators anticipate and plan for the positive and negative impacts of technological changes.

Similarly, confidence in research institutions is questionable. The land-grant university system is under great strain to meet new public demands, to cope with reduced funds, and to take advantage of new technological opportunities. These universities must be clear about their mission, goals, and priorities. A major source of new funds in the future is the sale of products from biotechnology resulting in the privatization of public sector research. This development could be a disaster or a benefit for universities depending on how they handle it. Congress may need to establish policy in this area.

In the '90s emerging agricultural technologies will encounter public concern for the environment, food safety, industry structure, and institutions. The challenge will be whether government, industry, and the public can strike the proper balance of direction, oversight, and use to allow these technologies to flourish. A range of options is available to Congress. Major environmental and food safety options are summarized below.

Copies of the report for congressional use are available by calling 4-9241.

Copies of the report for non-congressional use can be ordered from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325 (202) 783-3238. The GPO stock number for the OTA report, "A New Technological Era for American Agriculture," is 052-003-01290-1. The price is \$23.00. Summaries of reports are available at no charge from the Office of Technology Assessment.

For further information contact OTA's Publications Office. Address: OTA, U.S. Congress, Washington, DC 20510-8025 (202) 224-8996.

Summary of Major	Environmental and	I Food Safety	Policy Is	sues for (Congressional	Action	
Related to Agricultural Biotechnology							

Issue	Finding	Options		
Environmental safety	Need to establish science- and risk-based regulation in all agencies	Direct all regulatory agencies to make decisions based on the end product not the process		
	•	Maintain current ad hoc approach		
	Need clear, concise decisions for pest-resistant crops	Direct EPA to strengthen its Office of Pesticides Program		
		Direct EPA to adopt USDA model		
		Direct USDA to regulate pest-resistant crops		
	Need sound, expeditious decisions for large-scale planned introductions	Direct EPA to clarify its complex regulatory guidelines		
		Conduct oversight of EPA and USDA		
	Make regulatory agencies responsive to public con- cerns	Direct EPA and USDA to emphasize public input and follow-up problematic cases to assure public confi- dence		
		Require agencies to develop explicit plans for building public confidence		
		Establish new laws to satisfy public demand for accoun- tablilty		
Food safety	Need to establish a policy for requirements of food additive petition	Direct FDA to establish categorical exclusions		
		Direct FDA to establish categorical exclusions but include a formal notification procedure		
		Direct FDA to require a food additive petition for all transgenic food products		
		Direct FDA to make decisions on a case-by-case basis		
	Need to enhance public confidence in regulatory process	Direct agencies to establish mechanisms for public participation		
		Direct agencies to increase use of advisory committees		
		Appoint a task force to study the role of independent safety testing for FDA		
	Need to achieve balance in disclosure of confi- dential business information	Encourage FDA to publish scientific review articles		
		Conduct oversight of agencies to encourage disclosure		
		Liberalize the disclosure policy		
	Need to establish a new paradigm for food safety evaluation	Direct NIH to fund development of new testing proce- dures		
		Direct NIH to develop databases for normal ranges of nutritional and toxic food compounds		
	•	Direct FDA and EPA to request assay procedures from firms that are adaptable for use in field		
	Need to provide information to consumers	Mandate all biotechnology-derived to consumers food products to be so labeled		
		Encourage niche markets for foods <i>not</i> derived through biotechnology		

SOURCE: Office of Technology Assessment, 1992.