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**Economic Issues in Agricultural Biotechnology.** Edited by Robbin Shoemaker, with contributions from Joy Harwood, Kelly Day-Rubenstein, Terri Dunahay, Paul Heisey, Linwood Hoffman, Cassandra Klotz-Ingram, William Lin, Lorraine Mitchell, William McBride, and Jorge Fernandez-Cornejo. Resource Economics Division, Economic Research Service, U.S. Department of Agriculture. Agriculture Information Bulletin No. 762.

#### **Abstract**

Agricultural biotechnology has been advancing very rapidly, and while it presents many promises, it also poses as many questions. Many dimensions to agricultural biotechnology need to be considered to adequately inform public policy. Policy is made more difficult by the fact that agricultural biotechnology encompasses many policy issues addressed in very different ways. We have identified several key areas—agricultural research policy, industry structure, production and marketing, consumer issues, and future world food demand—where agricultural biotechnology is dramatically affecting the public policy agenda. This report focuses on the economic aspects of these issues and addresses some current and timely issues as well as longer term issues.

*Keywords:* Biotechnology, economics, adoption, patents, research policy, markets, market segregation, and identity preservation.

*Note:* The use of commercial or trade names does not imply approval by USDA or ERS.

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## **Summary**

The issues associated with agricultural biotechnology are complex and varied. Biotechnology poses many outstanding possibilities for agriculture and other important areas like medicine, the environment, and biodiversity. While biotechnology could greatly expand our frontiers of knowledge and production potential, many issues must be addressed as we move forward. The array of issues includes the legal, the ethical, and the economic. This report addresses some of the economic issues confronting agriculture.

The complexity of issues stems from the creation and management of the science, the ownership in intellectual property, the economic nature of the industry undertaking the research, the interaction between public and private research, and the marketing of products. Adding to the complexity are concerns about the implications of biotechnology for new agricultural products, markets, and contractual arrangements between producers, processors, and marketers. The acceptance of the technology depends critically on the perceptions and attitudes of consumers, both domestic and foreign, and on the expected impacts on food safety, health, and the environment. The degree of foreign acceptance can significantly affect international trade and may create the need to segregate and identify genetically engineered (GE) products.

The science and its manifestation in new products and markets has been evolving very rapidly, so it is difficult to provide a current and timely exposition of the issues. Nonetheless, this document is an attempt to present and explore the relevant issues to date.

Much of the current interest in biotechnology stems from two recent phenomena: the extremely rapid diffusion in North America and other exporting countries, like Argentina, of GE crops, such as cotton, soybeans, corn, and canola; and the different consumer response in Europe, as compared with the United States, to products derived from genetically modified crops. U.S. producers and policymakers are concerned about policies being developed by trading partners, potential loss of markets, and the additional marketing costs that might result from segregated or identity-preserved marketing. These phenomena, in turn, might reduce incentives for the development of new agricultural biotechnology products.

## **Research Policy Issues**

In one form or another, however, agricultural biotechnology is here to stay, despite the changes that will be determined by demand-side factors. Supply-side factors will also affect the direction and pace of biotechnology innovation in the long run. Intellectual property rights (IPR) and market concentration in the agricultural input industries are intertwined areas that are shaped by public policy. The ways in which IPR and market concentration influence innovation are not well understood. In general, public policy affecting agricultural biotechnology is less well developed than it is for information technology. Open but informed debate on these issues is necessary to assess barriers to entry at key points in the flow of new technology and to devise appropriate public policy responses.

The response of public-sector agricultural research to increased private-sector research investment is somewhat better understood, although also subject to debate. Public-sector agricultural research increasingly targets basic science and applied science with a public good component. Good examples include natural resource research and research on food safety. Even in areas increasingly dominated by the private sector, such as plant breeding, there are appropriate topics for public-sector research to pursue—for example, fundamental issues concerning gene interaction, regulation, and expression.

A critical role for public research is in the conservation, management, and characterization/evaluation of genetic material. An estimated 50 percent of yield gains in major cereal crops since the 1930's have come from genetic improvements through conventional breeding techniques. Also, it has been estimated that biological improvements contributed to 50 percent of the yield growth in corn, 85 percent for soybeans, 75 percent for wheat, and 25 percent for cotton.

Future crop yield growth will also depend on biological improvements that will largely come from genetic material that is either in the wild or in gene banks. The U.S. National Germplasm System is one of the world's largest collectors and distributors of germplasm; yet, according to the General Accounting Office, it does not have sufficient funding for evaluation and documentation or to perform necessary regeneration of seed

accessions. Advances in biotechnology offer new possibilities to more rapidly evaluate and characterize germplasm as well as to transfer and regulate it in seeds. Biotechnology may increase the demand for public genetic resource management by increasing the potential uses of genetic material and enhancing the ability to learn more about the characteristics of the genetic resource.

## **Production and Marketing Issues**

Vertical integration of chemical companies into the seed and biotechnology industries has led to increasing concentration within the U.S. seed industry. Acquisition and joint ventures and massive investments made by leading chemical companies in biotechnology research allow these firms to maintain a competitive position and to capture profits from biotechnology innovations. The large biotechnology firms have also merged with or acquired seed companies to obtain sources of germplasm for further development of genetically modified seed varieties and to have an outlet for delivery of the new technology, usually as seed.

The increasing dominance of a few major players and biotechnology and chemical patent restrictions on what competitors can do raise questions about the potential for too much market power in parts of the seed and chemical industries. Several antitrust cases in seed and chemical markets raise concern about the potential adverse impact on market competition resulting from the removal of competitors from already concentrated seed markets. The use of licensing agreements and strategic alliances by leading biotechnology firms might also bar entry of potential competitors to the herbicide market. In addition, grower agreements signed by producers and seed companies impose planting restrictions on producers, raising fear that farmers might become "hired hands" for biotechnology companies.

Increased value from output-enhanced crops will lead to further coordination within the market. The technology provider creates the original value of this crop and will want to control this value and share it according to each market participant's bargaining position, assumed risk, or additional costs relative to the traditional commodity system. The type of coordination mechanism used will depend on the product's value, volume, and competitive market characteristics and on the firm's desired control, capital resources, costs, and asset specificity. An array of coordinating mechanisms will likely be used, depending on the specific situation. Open markets, licensing agreements, contracts, strate-

gic alliances, cooperatives, and full vertical integration are all likely candidates in conjunction with a segregated or identity-preserved (IP) handling system. There are concerns about the transparency of the price discovery process and potential negative impact on market efficiency.

Variety approval processes, labeling requirements, and expressed market demand for non-GE crops could fundamentally alter the structure of the current marketing system. Demand for nonbiotech crops could lead to segregated marketing. Segregation is also needed to preserve end-use characteristics for value-enhanced crops (including non-GE's). At the core of the concerns about segregation are questions such as: How much will segregation add to total costs of marketing? Who will bear the cost? How much premium will the market prescribe for non-GE crops? While segregation or IP marketing is nothing new, the viability of segregated or IP marketing would critically depend on the speed, accuracy, and costs of testing for the presence of GE's.

The costs of segregation vary significantly among grain elevators and by the method of segregation. Also, a considerable degree of uncertainty is associated with any cost estimates at present. Major factors that affect the distribution of segregation costs include (1) demand price elasticity, (2) competitive structure of the food industry, (3) the proportion of ingredient in the value of the final product, and (4) alternative sourcing of supply by foreign buyers.

If consumer resistance to GE's persists in a segment of U.S. export markets (such as the European Union) while producers continue to rapidly adopt input-trait GE's and a string of value-enhanced new products emerges, can the current grain grades and standards continue to function effectively without change? If not, what changes would be needed to facilitate marketing and trade? In the near- to mid-term, increasing sophistication and detail will be added to contract specifications as well as to the grading system. Labeling regulations and/or market segmentation might require contracts to be amended to ensure that the level of GE's does not exceed what those demanding nonbiotech products will tolerate, which is occurring now. It is conceivable that a specialty grade of high-oil corn, similar to the case of waxy corn, eventually could be included in the grading system if the demand for the specific output trait becomes more common. Thus, U.S. grain grades and standards, by and large, are likely to remain intact in the near- to mid-term as long as output-trait GE's remain as niche markets.

In the longer run, if specialty grades become so widespread (including many stacked output and input traits) and if these specialty crops become widespread, then the grain grades and standards could begin to cease their basic functions and may require complete revamping. At that point, grain grades and standards dominated by physical characteristics and dominance of specialty grades in foreign buyers' imports might become irreconcilable. At a certain point, if the rate of change and multitude of specialty products accelerate—particularly with stacked traits—IP marketing could become the only way to market these value-enhanced products.

#### **Consumer Issues**

The response from U.S. consumers to the increasing prevalence of foods containing biotech products has been generally small, and the U.S. public appears to have confidence in the regulatory system to ensure an abundant and safe food supply. When the first biotech food product was released in the United States, a tomato engineered for longer shelf life, it was accompanied by information in the media and at the markets that increased familiarity and reduced fear of this new technology. However, commodity crops, such as corn and soybeans with altered agronomic traits, have subsequently been released without much public notice. While it is generally agreed that consumers have little cause to be concerned about the safety of biotech products in food and feed, some consumers object to consuming food produced with any new technology that lacks a long established history of use. In addition, food labeling has become an issue of consumers' "right to know."

## Biotechnology and Future Agricultural Demands

Agricultural biotechnology has also been hailed as a key strategy to raising world food supplies. World food demand, driven by growth in both population and incomes, is projected to rise 35-45 percent in volume over the next 20 years. The increase will mostly come from developing countries. Increased production must come from a land base that will not expand very much, and it is desirable that these production gains not come at increasing environmental costs. Biotechnology clearly holds promise as a solution to some developing-country production problems, and to solving them in an environmentally friendly manner. Several factors, however, both technical and institutional, must be resolved if biotechnology is to fulfill that promise.

On the technical side, crop improvement, of which biotechnology is a part, must be complemented by innovative crop management research if supplies are to keep pace with demand. As for crop improvement itself, the application of biotechnology at present is most likely to reduce yield variability but not to increase maximum yields. More fundamental scientific breakthroughs are necessary if yields are to increase.

On the institutional side, policies on intellectual property rights, market concentration, and agricultural research are likely to take on even greater importance worldwide than they have now in industrialized countries. In most developing countries, the legal and public policy systems are less prepared to deal with the challenges of the biotechnology revolution than they are in industrialized nations. Furthermore, public-sector agricultural research in many developing countries is severely underfunded, and human capital development may not be adequate for the successful deployment of useful agricultural biotechnology. The appropriate international framework for bringing advanced research from developed countries, whether it is from private multinational corporations or from public research institutes, to bear on total world food supply has only begun to be addressed. Furthermore, this research stands a much greater chance of success if it is not performed in top-down fashion but in collaboration with talented scientists from developing countries and with real understanding of the constraints.

# Economic Issues in Agricultural Biotechnology

## Introduction

U.S. agriculture has always been one of the most highly productive sectors in the economy. Productivity growth rates since 1947 have averaged nearly 2 percent per year, resulting in continual supplies of food, feed, and fiber produced at affordable prices. Continuous advances in productivity are the result of the development of improved production inputs (feed, fertilizers, pesticides, etc.) and technologies combined with effective onfarm management of these new technologies. These advances come from research and development (R&D) investments within both the public and private agricultural research sectors.

Historically, private research focused on mechanical and food processing technologies, while the public sector emphasized the development of new plant varieties and improvement of animal breeds using traditional breeding techniques. While these methods produced many important advances, such as hybrid and other high-yielding crops, the research required to introduce desirable traits was slow and labor intensive. Since the discovery of the double-helix structure of DNA and the subsequent innovations in gene manipulation, scientists have struggled to find ways to exploit this knowledge. These efforts have significantly advanced biological science and the development of biotechnologies, which will be major contributing factors to future agricultural productivity growth.

Modern plant biotechnology methods, such as cell culture and genetic engineering, have led to the development of novel plant varieties that would not have been possible using traditional breeding methods. Advances in genetic mapping and gene transfer and in the manipulation of gene regulation are allowing scientists to redraw the genetic blueprints of plants and animals. The genetic modification of organisms by recombinant DNA techniques can range from either enhancing or suppressing the performance of existing genes to transferring genetic information from one organism into a

host organism. Genetic engineering simplifies the identification of the genes responsible for particular desirable traits and allows scientists to precisely transfer single traits between species. Thus, seed developers can decrease the number of unintended characteristics that are possible with traditional breeding methods and speed up the development of new strains by reducing the need for repeated backcrossing when breeding in new traits.

The ability to insert or affect desirable traits in plants has produced a *first generation* of biotechnology products that enhance the production practices of farmers. For example, the insertion of the insecticidal Bt gene from the bacterium *Bacillus thuringiensis* into cotton reduces the need for some chemical insecticides and has the potential of reducing production costs for farmers. A *second generation* of biotechnology products expands the opportunities for farmers even more through various quality enhancements, such as corn or soybeans with higher protein or oil content—modifications that facilitate processing (high-solids potatoes)—or crops designed to produce high-value pharmaceuticals or industrial chemicals.

As with most technological advances, the benefits come at some costs. Changes in technological possibilities often result in some displacement or changes in institutional arrangements. The advent of the internal combustion engine and ultimately the automobile. while clearly a benefit, displaced horse-shoeing and buggy whip manufacturing and produced environmental consequences unforeseen and undesirable. At the same time, new technologies create new jobs and opportunities. Some have called the last half century "The Age of Physics" due to the important scientific advances associated with subatomic particles and to learning more about the origins of the universe. The explosion of discoveries and advances in the science of biology suggests that the next century may well be "The Age of Biology." The age of biology will present significant opportunities for agriculture but will also involve numerous issues and concerns that need to be

addressed along the way. This document presents a discussion from the perspective of economics of many of those issues and their potential impact on the structure of the U.S. agricultural economy.

The issues associated with agricultural biotechnology are varied and rapidly evolving. New issues develop even as we write this document, making it difficult to keep current.

We have divided the issues into three sections. First, we provide some background and identify important advances in biological science, where these advances occurred between the public and private research sectors, and the changes in patent law that allowed private firms to capitalize on these discoveries.

Second, we consider important trends, especially in current adoption rates of biotechnologies by farmers and in farm-level effects of adoption. New marketing and contractual arrangements between farmers and grain and food processors are beginning to develop and will likely become critical issues as more genetically engineered (GE) crops enter the marketplace. These issues are explored, along with the implications for grades and standards for GE products.

Third, we address issues associated with production and distribution of GE products, as the ability for the agbiotech market to expand depends on the demand for these new products. We look at the demand side—that is, we consider consumer preferences, particularly the difference in perspective between U.S. and European consumers and the implications for trade. We examine public policies that affect the distribution of biotechnology research between the public and private sectors. We also look at biotechnology in a global context, including the potential role biotechnology can play in feeding a growing world population and how agricultural research can help address these issues.

## **Background**

## Important Changes in the Agricultural Input Industry

## **Issues**

What are the major changes in the agricultural input industry? How has the application of biotechnology to agriculture been integrated within the input industry?

## Context

Over the past several decades, the agricultural input industry has undergone many notable changes. These changes accelerated in the 1990's. Greater private-sector investments in agricultural research and development (R&D) have been accompanied by changes in investment composition and by recent consolidation of chemical, seed, and biotechnology companies into "life sciences" enterprises that work in areas not only related to food production but also to medicine and health.

## **Specific Changes**

## Increasing Private-Sector Investment in Agricultural and Food R&D

Private investments in agricultural and food R&D have nearly tripled in real terms (1992 dollars) from about \$1.2 billion in 1960 to \$3.4 billion in 1995 (Fuglie et al.). Furthermore, private-sector investments to agricultural research have outpaced public-sector agricultural research spending since the early 1980's. Public-sector expenditures in 1995 were \$2.8 billion, about 17 percent less than private-sector expenditures (fig.1).

## Changes in the Composition of Private-Sector Agricultural R&D

The composition of private-sector research has also changed considerably. The share of agricultural R&D expenditures for biological and chemical inputs (plant breeding, agricultural chemicals, and veterinary pharmaceuticals) rose from 19 percent of total research

spending by private firms in 1960 to 58 percent in 1995 (fig. 2). Although absolute private-sector R&D spending also increased for agricultural machinery and processing, the relative expenditures in these areas have substantially decreased.

## Consolidation in the Agricultural Input Industry

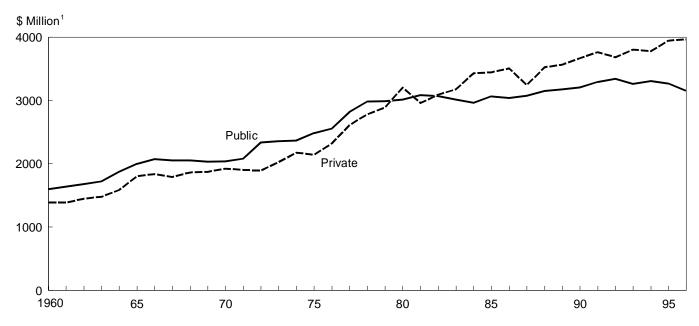
Mergers, acquisitions, and strategic alliances in the agricultural input industry have risen substantially in recent years. There were 167 mergers, acquisitions, and other strategic alliances in the agricultural biotechnology industry between 1981 and 1985. This number climbed to 801 during 1991-96. About 90 percent of these alliances were between larger, more established firms and technology startup companies (Kalaitzandonakes and Bjornson).

## **Major Players Today**

Mergers and acquisitions by Monsanto in the 1990's highlight the trend toward consolidation. Between 1996 and 1998, Monsanto acquired Calgene, a biotechnology company, and numerous seed companies, including Asgrow, Corn States Hybrid, DeKalb Genetics, Holden's Foundation Seed, the Plant Breeding Institute Cambridge, Sementes Agroceres, and Cargill's foreign seed business. In 1998, Monsanto also announced plans to buy Delta & Pineland, the company with the largest share of the U.S. market for cottonseed—a deal that subsequently fell through. These acquisitions have increased Monsanto's market share for many major crop varieties. This acquisition activity is only the latest stage in Monsanto's transformation from a company largely concentrated in plastics and other petrochemicals in the 1970's to a major life sciences player today.

Monsanto is not the only agrochemical or pharmaceutical firm to stake out a claim in the rapidly changing world of agricultural biotechnology. Some of the fol-

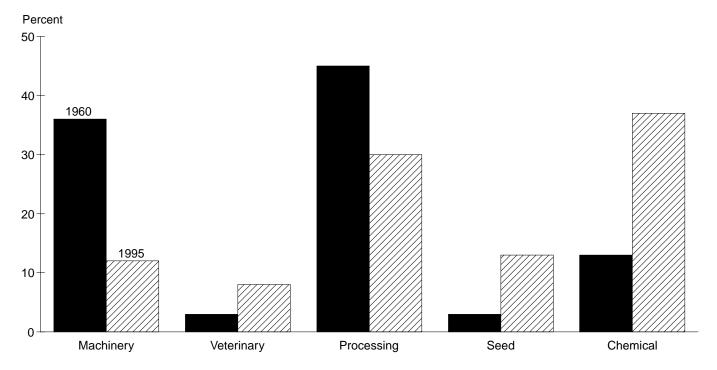
Figure 1
Public and private agricultural research expenditures in the United States, 1960-96



<sup>1</sup>In 1992 dollars.

Source: Economic Research Service, USDA.

Figure 2 Allocation of private research and development spending, 1960 and 1995



lowing companies have sales volumes across all product lines that are considerably higher than Monsanto's.

- DuPont, which has bought Pioneer Hi-Bred International, the leading supplier of corn seed in the United States.
- Novartis, formed in 1996 from the merger of the Swiss pharmaceutical and agrochemical companies Ciba and Sandoz.
- Aventis, created in 1999 in a merger of Hoechst and Rhône-Poulenc.
- AstraZeneca, formed from a merger of Swedish pharmaceutical company Astra with British bioscience company Zeneca, also in 1999.

Empresas la Moderna, a Mexican company with smaller sales volume than some of the other giant firms, is nonetheless the world's leading supplier of vegetable and fruit seeds and a company with a growing investment in biotechnology.

In the second half of 1999, however, several developments suggested at least a temporary downturn in investment volume for the life sciences organizations. In early December, Novartis and AstraZeneca announced that they would merge and, at the same time, merge their agricultural units and spin them off from the parent pharmaceutical company into an independent firm dedicated to agribusiness. Later in December, after more than a year of merger rumors concerning Monsanto, Monsanto and pharmaceutical

manufacturer Pharmacia & Upjohn announced a merger. Early reports of the merger suggested the new company might try to sell or spin off its agribusiness unit. At the same time, Monsanto announced that it was abandoning its plan to purchase Delta & Pineland because of lengthy delays in the approval process.

## **Analytical Issues**

A key question concerns the amount of resources that should be devoted to modeling industry structure in the agricultural inputs industry. In an extremely dynamic and fluid situation, how can this structure be characterized in a way that identifies major empirical regularities? How should changes in that structure be measured? How can a better understanding of industry structure assist in identifying important policy issues, such as those listed in subsequent sections of this report?

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## **Background**

## Forces Driving Changes in the Agricultural Input Industries

## **Plant Breeding and Biotechnology**

### Issue

Understanding the forces that have been driving changes in the agricultural input industries is key to understanding how public policies might affect structure and performance in the industries.

## Context

Many different forces are driving the changes in agricultural input industries. The most significant changes have been in agricultural research, particularly plant breeding. At least four major factors are believed to increase private-sector investment in agricultural research and plant breeding—scientific advances, changes in intellectual property rights (IPR) regimes, new institutional structures for public- and private-sector research and development (R&D) collaboration and technology transfer, and increasing globalization of agricultural input markets.

## **Specific Factors**

## **Advances in Science**

Advances in science have created technological opportunities, which in some areas, have translated into the ability for agricultural input companies to create additional value, part of which they capture. Biotechnology methods, such as tissue cell culture, genetic engineering, and molecular mapping, have made it possible for researchers to reduce the time to develop new plant varieties and to increase their precision in modifying plant traits. As a result, developing new crop varieties with productionor quality-enhancing traits appears to be increasingly profitable for the agricultural input industry. Many of the developments in crop varieties have capitalized on linkages between seed and chemical inputs. New her-

bicide-resistant crops complement established herbicide product lines and boost sales by expanding the number of crops resistant to herbicides. The development of insect-resistant crops enables seed and chemical companies to offer new crop protection technologies.

## **Changes in IPR Regimes**

Intellectual property protection is expected to stimulate private R&D because it allows companies to recoup major investments in developing new technology and to appropriate a greater proportion of the returns to these investments. Expanded IPR's for biological inventions have led to greater private-sector plant breeding efforts over the past 30 years.

In 1970, the U.S. Congress instituted the Plant Variety Protection Act (PVPA), which awarded plant breeders' rights for new crop varieties produced from seed, particularly field crops. Since then, the PVPA has been revised to expand coverage to vegetables and tubers, to restrict farmers' rights to resell protected seed, and to disallow protection for new varieties that simply involve superficial changes in appearance.

The Patent and Trademark Office first granted utility patents for biological inventions in 1980, when the Supreme Court authorized the use of standard utility patents for microorganisms. Utility patents were authorized for plants and animals in 1985 and 1987.

Evidence suggests that these decisions, particularly the utility patent extensions, have promoted private-sector plant breeding activities. Private-sector R&D efforts in plant breeding, measured in scientist years, have intensified and are now slightly more than twice the plant breeding effort in the public sector (Frey). Moreover, the private sector owns the majority of plant variety protection certificates (PVPC's) and

utility patents awarded for multicellular living organisms (Fuglie et al.).

## Expanded Public- and Private-Sector Research Collaboration

Collaboration between the public and private sectors has been enhanced by legislation that promotes greater collaboration and exchange between Federal laboratories and the private sector. In most cases, this legislation has reversed earlier policy.

The Government Patent Policy of 1980 (Bayh-Dole Act) granted all institutions "certainty of title" for inventions from federally funded research. The Bayh-Dole Act also allowed Federal laboratories to issue exclusive licenses for patents of their inventions, which are more attractive than the nonexclusive or open licenses previously granted to firms.

The 1980 Stevenson-Wydler Technology Innovation Act mandated that each Federal research agency develop specific mechanisms for disseminating government innovations.

The 1986 Technology Transfer Act gave government agencies additional means to foster technology transfer by authorizing Cooperative Research and Development Agreements (CRADA's). CRADA's allow direct research collaboration, which was not authorized before the passage of the Act, between Federal researchers and the private sector. USDA's collaborations with the private sector have significantly increased over the last decade (Day-Rubenstein and Fuglie).

## Globalization of Agricultural Input Markets

Globalization of agricultural input markets resulting from increased global demand for agricultural products and falling barriers to trade has provided opportunities for private industry to expand sales and increase research efforts in other countries. An indicator of this expansion is the 2.2-percent increase in real annual U.S. exports of agricultural inputs since 1983 (Pray and Fuglie). Foreign market and investment opportunities have also been broadened by trade agreements, such as the General Agreements on Tariffs and Trade, the World Trade Organization, and the North American Free Trade Agreement. The number of foreign-owned patents for agricultural technologies and research investments by multinational firms has been expanding in many countries (Pray and Fuglie).

## Research Issue

Quantitative measures of various causes and an appropriate economic model relating them to private-sector investment would be useful in explaining the importance of the issues just discussed (and possibly others) in driving the increase in private-sector investment in agricultural biotechnology and plant breeding. Current analyses, however, are based largely on theoretical arguments, plausibility, or anecdotal evidence. As Jaffe argues concerning patent policy in general, "despite the significance of the policy changes and the wide availability of detailed data relating to patenting, robust conclusions regarding the empirical consequences for technological innovation of changes in patent policy are few." Similarly, though the empirical importance of changes in science, technology transfer, and globalization is likely to be great, precise empirical studies of these phenomena are relatively sparse.

## **Policy Issues**

Strengthening intellectual property protection for biological inventions has encouraged private firms to pursue basic research previously addressed by the public sector. While the use of patents facilitates knowledge spillovers by broadening the dissemination of research findings, certain key questions arise for science policy.

- Should the goals of public research policy be reevaluated so that strategies that generate the greatest social return on R&D investments can be identified?
- Key to policy planning is determining when and how the public sector should interact with the private sector. When is an area of inquiry purely in the public domain, appropriate for public-private partnership, or most suitable for the public sector to pursue to prevent control by the private sector?

Some areas of research lack incentives for the private sector and remain distinctly in the public domain—for example, mitigating food safety risks, improving nutritional health, and enhancing environmental quality. Others areas of research in the public sector may depend on discoveries made and patented in the private sector. The potential for public-sector research to benefit from private-sector discoveries suggests a need to expand opportunities for partnerships. Despite many complementary research interests, public-private partnerships are not easy to forge, and disagreements over patent arrangements and licensing rights can be major barriers.

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## Milestones in Molecular Biology and U.S. Agricultural Biotechnology

## Scientific/Regulatory

**1866**—Mendel postulates rules to explain inheritance of biological characteristics

1908—First hybrid corn produced

**1918**—Economically feasible hybrid corn developed at the Connecticut Agricultural Experiment Station

**1930's**—Rapid diffusion of hybrid corn in Corn Belt

1952—First hybrid sorghum produced

**1953**—Watson and Crick discover double-helix structure of DNA

1960—Genetic code deciphered

**1960's**—Entire U.S. corn area planted to hybrid corn

**1960's**—Hybrid wheat developed, but not economically feasible

1973—First gene cloned (for insulin)

**1974**—Article in *Science* magazine on potential risks of genetic engineering research

**1976**—Founding of Genentech, Inc., first biotech company

**1981**—First transgenic animal (mouse) developed

1982—First transgenic plant produced

**1986**—Coordinated framework for regulation of biotechnology-derived products

**1986**—First transgenic livestock animals (pigs) developed at USDA's Agricultural Research Service (ARS)

**1987**—First U.S. field trials of transgenic plants (insect-resistant tomatoes) and microorganisms

**1989**—First recombinant DNA vaccine developed

**1990**—Food and Drug Administration (FDA) approves chymosin produced in genetically engineered (GE) bacteria for production of hard cheeses

**1990**—Human Genome Project initiated to map all genes in the human body

**1991**—USDA's Animal and Plant Health Inspection Service (APHIS) publishes guidelines for field trials of GE crops

**1992**—FDA announces policy on food derived from new plant varieties, including GE crops

**1993**—USDA/APHIS introduces simplified notification procedure for field trials of some GE plants

**1993**—FDA approves rBST for commercial use

**1994**—First deregulation of a GE plant (FlavrSavr tomato)

1994—Environmental Protection Agency proposes rules regulating plant pesticides. The rule was signed in 2000, although additional issues remain. The rule changes the name of these pesticides to plant-incorporated protectants (PIPS)

**1996**—First wide-scale planting of GE crops, including Bt corn, Bt cotton, and Roundup Ready soybeans

**1997**—First release of crop with stacked traits (Bt/Roundup Ready cotton)

**1997**—First animal cloned from adult cell (Dolly the sheep)

1997—USDA/APHIS expands simplified notification procedures for release of genetically modified organisms (GMO's) meeting certain criteria

**1998**—European Union requires labeling of GMO's

**1998**—USDA/APHIS introduces pilot program for comprehensive permitting for field tests of GMO crops

**1999**—FDA approves first nutraceuticals Take Charge and Benecol margarines

## **Intellectual Property**

1790—U.S. Patent Act

**1930**—Plant Patent Act allows patenting of asexually reproduced plants

**1970**—Plant Variety Protection Act (PVPA) permits patenting of plant genetic traits and transformation method for plants

**1980**—Patent granted on basic recombinant DNA technology to Cohen and Boyer, Stanford University

**1980**—U.S. Supreme Court rules that GE microorganisms can be patented under existing law

**1985**—U.S. Patent and Trademark Office rules that plants, including GMO's, can be patented under U.S. utility patent law

1980—Patent and Trademark Amendments passed that allow federally funded researchers to obtain patents (Bayh-Dole Act; Stevenson-Wydler Act)

1986—Federal Technology Transfer Act established Cooperative Research and Development Agreements (CRADA's) to facilitate technology transfer of publicly funded technologies

**1988**—First patent granted for a transgenic mammal (Harvard "onco-mouse," engineered for increased susceptibility to cancer)

**1990**—Patent granted for microprojectile accelerator ("gene gun") for delivery of DNA into plant cells

**1993**—Agracetus granted patent covering all transgenic cotton; canceled by U.S. Patent and Trademark Office on December 7, 1994; currently in appeal

1994—PVPA amended to protect breeders from cosmetic infringements, restricts farmers rights to sell seed, extends patent protection from 17 to 20 years

1998—USDA/ARS and Delta and Pine Land patent "Technology Protection System" for production of plants with nonviable seeds

## **Trends and Contributing Factors**

## Farm-Level Effects of Adopting Genetically Engineered Crops

## Preliminary Evidence from the U.S. Experience

### Issue

Driven by farmers' expectations of lower production costs, higher yields, and reduced pesticide use, the rate at which U.S. farmers adopted genetically engineered (GE) crop varieties jumped dramatically between 1996 and 1998. Actual benefits in terms of these factors are mixed.

## Context

Between 1996 and 1998, the number of U.S. acres planted with GE cotton more than doubled. Bt and herbicide-tolerant corn acreage rose from 4.4 percent to nearly 40 percent of total corn acreage. Herbicide-tolerant soybean acreage grew from 7 percent to 44 percent of total soybean acreage. Adoption rates of these varieties suggest they are becoming significant in the total mix of major field crop varieties. About 98 million acres of GE crops were cultivated worldwide in 1999, a 43-percent increase over acreage in 1998 (James, 1999). U.S. acreage accounts for approximately 72 percent of the world total. These rapid rates of adoption lead us to ask: Why are farmers adopting these crops so rapidly and what are the benefits of adoption for farmers?

## **Background**

Most of the commercially available GE crops have been developed to carry herbicide-tolerant or insect-resistant genes. Crops carrying herbicide-tolerant genes were developed to survive certain herbicides that previously would have destroyed the crop along with the targeted weeds. Development of these crops has allowed farmers to use a broader variety of herbicides to control weeds.

The most common herbicide-tolerant crops are Roundup Ready (RR) crops that are resistant to glyphosate. Glyphosate tolerance has been incorporated into cotton, corn, soybeans, and canola. Other genetically modified herbicide-tolerant crops include Liberty Link (LL) corn, resistant to glufosinate-ammonium, and BXN cotton, resistant to bromoxynil. There are also traditionally bred herbicide-tolerant crops, such as corn resistant to imidazolinone (IMI) and sethoxydim (SR) and soybeans resistant to sulfonylurea (STS). Some of these, such as IMI corn, have been marketed since the early 1990's.

Bt crops containing the gene from a soil bacterium, *Bacillus thuringiensis*, are the only insect-resistant crops commercially available. The bacteria produce a toxin that can rupture an insect's gut. Crops containing the Bt gene are able to produce their own toxin, thereby providing protection throughout the entire plant. Bt has been incorporated into many crops, such as corn and cotton, and is effective in controlling particular insect pests, depending on the crop. For example, Bt cotton is primarily effective in controlling tobacco budworms and somewhat effective in controlling bollworms. However, Bt corn protects against the European corn borer (ECB) and, to a lesser extent, the corn earworm, the southwestern corn borer, and the lesser cornstalk borer.

Lower pesticide application rates or more effective herbicides may increase savings in pest management costs. For Bt crops, farmers can discontinue use of Bt foliar sprays and possibly decrease applications of other insecticides, such as pyrethroids in cotton. Farmers planting Bt crops may depend less on variable weather conditions. They would not have to worry about the timing of pesticide applications because the Bt toxin remains active throughout the plant. Planting flexibility may also rise. For example, herbicide-tolerant crops may alleviate problems from the carryover of herbicides. Farmers may be able to practice strip-crop-

ping (a practice where corn and soybeans are grown in alternating rows) or grow corn and soybeans in rotation. Also, farmers that use such production practices as no-till may benefit if adopting herbicide-tolerant crops allows them to use a more effective herbicide treatment system.

Herbicide-tolerant and insect-resistant crops may lower chemical pesticide use in agriculture. One estimate suggests that converting 30 percent of cotton acreage to cotton varieties tolerant to bromoxynil, which is effective at much lower rates than traditional herbicides, could reduce herbicide use by 10 million pounds.

Although lower pest management costs and higher revenues may be attributed to herbicide-tolerant and insect-resistant crops, seed costs for these varieties are greater than traditional seed. Not only is there a seed price premium, but farmers were also required to pay a technology fee. Despite paying more for these seeds, U.S. cotton farmers share in the overall economic benefits of Bt cotton seed with the companies that developed the seed (Falck-Zepeda and Traxler, 1998). They each receive about 49 percent of the total economic benefits. Consumers, however, do not benefit that much. Only about 2 percent of the surplus goes to consumers in the United States and the rest of the world combined. Regional benefits will vary because of differences in pest infestation, seed prices, and technology fees.

## Measuring the Effects of GE Crops

The following is a summary of principal findings of these farm economic studies, including estimates from USDA survey data on yields and pesticide use associated with adoption.

#### Field Tests

Many field tests have been aimed at analyzing the agronomic effects of adopting GE crops (for example, Culpepper and York). Relatively fewer studies have investigated the actual yield, pesticide management, and profit effects from farm-level adoption (Marra, Carlson, and Hubbell; Fernandez-Cornejo and Klotz-Ingram; Fernandez-Cornejo, Klotz-Ingram, and Jans).

Herbicide-Tolerant Crops. Weed control is critical in the production of many crops, especially cotton. Crops usually require several types and applications of herbicides to control weeds. However, glyphosate is one herbicide that is effective on many species of grasses, broadleaf weeds, and sedges. Some of the studies on

herbicide-tolerant crops (Culpepper and York; Marra, Carlson, and Hubbell; Fernandez-Cornejo and Klotz-Ingram) found that adopting these varieties did not necessarily translate into yield gains. However, Fernandez-Cornejo, Klotz-Ingram, and Jans estimated a model using USDA survey data that indicates significant yield increases for farmers who adopted herbicide-tolerant cotton or soybeans. In addition, Roberts, Pendergrass, and Hayes concluded that herbicide treatments that included glyphosate on RR soybeans had the highest yields and net returns among weed management regimes.

Estimates on the effect of adoption on herbicide use were mixed. While herbicide-tolerant crops would be expected to increase glyphosate use, less total herbicide may be required to combat weeds since glyphosate is considered a more effective post-emergent herbicide. Herbicide treatments that included glyphosate were as effective, if not more effective, than traditional herbicide treatment systems on RR cotton and soybean varieties (Culpepper and York; Roberts, Pendergrass, and Hayes). Herbicide treatment systems with glyphosate on RR cotton required fewer herbicide treatments and less total herbicide to produce equivalent yields and net returns (Culpepper and York).

Two studies analyzed the effects of adopting herbicidetolerant corn, soybeans, and cotton on yields, herbicide use, and profits (Fernandez-Cornejo and Klotz-Ingram; Fernandez-Cornejo, Klotz-Ingram, and Jans). The analyses in these studies used USDA field-level survey data on the use of herbicide-tolerant (mainly IMI) corn in 1996 and (mainly RR) soybeans and cotton in 1997.

According to the studies, adopting herbicide-tolerant corn did not increase yields. Herbicide-tolerant soybeans and cotton, however, did increase yields.

The findings on herbicide use varied greatly. The use of herbicide-tolerant corn was negatively and significantly related to acetamide herbicide applications. Although the use of glyphosate increased significantly with the adoption of herbicide-tolerant soybeans, the use of other herbicides (such as 2,4-D, acifluorfen, bentazon, clomazone, pendimethalin, and trifluralin) decreased. These studies found no change in herbicide use with the adoption of herbicide-tolerant cotton.

Adopting herbicide-tolerant cotton increased profits; adopting herbicide-tolerant corn and soybeans did not change farmer profits. A study by Marra, Carlson, and Hubbell, however, determined that farmers had greater net returns from RR crop varieties. They estimated that the net gain from using RR soybeans was about \$6 per acre. The lower herbicide costs alone were enough to outweigh the higher seed costs.

Bt Crops. Insect pests can considerably damage crops. Bollworms and budworms combined are the number one pest for cotton. In 1995, these pests reduced cotton yields by about 4 percent (Williams, 1997). However, partly as a result of introducing Bt cotton in 1996, yield losses from these pests fell. Yield losses were about 2.4 percent in 1996 and 2.0 and 2.7 percent in 1997 and 1998 (Williams, 1997, 1998, 1999). In 1998, about 9 million cotton acres were infested with bollworms and budworms, accounting for about \$186 million in cotton losses and treatment expenses. The European corn borer (ECB) is one of the major pests in corn production. Damages from ECB amount to about \$1 billion per year. About 50 percent of 80 million U.S. corn acres are infested with ECB (James, 1999).

Many studies have found that Bt varieties have higher yields and lower insecticide costs than their conventional counterparts, which may translate into a significant increase in farmer profits, depending on adoption rates and the nature of demand for the commodity.

Marra, Carlson, and Hubbell conducted a Bt cotton survey to determine the effects of adoption on yields, net revenues, and pesticide use. Surveys were returned by 300 farmers in North and South Carolina, Georgia, and Alabama. Among them, yields were significantly greater for farmers planting Bt cotton in the lower southern States and for the entire sample. This was not true for the upper southern States. Marra, Carlson, and Hubbell found that farmers growing Bt cotton had fewer insecticide applications, especially for pyrethroids. The rate of return was less in the upper South than in the lower South. The additional crop revenues and insecticide savings outweighed the higher seed and technology costs in the lower South only. Marra, Carlson, and Hubbell determined that better control of ECB boosted yields 4-8 percent, depending on location and year. The study by Fernandez-Cornejo, Klotz-Ingram, and Jans supported the Bt cotton findings of Marra, Carlson, and Hubbell. They found that adopting Bt cotton decreased insecticide use (only for such insecticides as aldicarbs, chloropyrifos, oxamyls, and endosulfans).

Bt corn use resulted in only modest savings from reduced insecticide applications. Returns from increased corn yields, however, were greater than the seed premiums and technology fees, translating into net gains of about \$3-\$16 per acre (Marra, Carlson, and Hubbell).

For farmers to receive economic benefits from adopting herbicide-tolerant and insect-resistant crops, it takes a certain infestation level to break even. The expected benefits from adopting these varieties greatly depend on infestation levels and the associated yield advantages and pesticide application rates. Therefore, farmers in regions that have an increased probability of pest infestations would benefit from reduced pesticide applications and higher expected yields. Their willingness to pay for Bt seed should be higher, all else constant.

#### USDA Survey Data—ARMS<sup>1</sup>

The effects of GE crops just discussed were obtained from limited regional studies or field trials. USDA's Economic Research Service (ERS) and the National Agricultural Statistical Service (NASS) annually conduct the Agricultural Resources Management Study (ARMS) survey to estimate agricultural inputs use and costs of production for major commodities and to support farm income and other financial indicators. The ARMS survey was used to estimate the extent of adoption of genetically modified crops and to compare yield and pesticide use with traditional crop varieties. The survey was not designed to statistically test the difference in the yield performance and input use between varieties, but it can provide insight into the effects of using GE crops.

A summary of the results from the ARMS survey on the adoption of GE cotton, corn, and soybeans follows. The tables include the extent of adoption in terms of the percentage of acres planted and production by type of technology, crop, and region for 1996, 1997, and 1998. These data were compared with estimates from industry sources and were found generally to agree, with a few exceptions.

#### ARMS Survey Results—Adoption Rates

The survey suggests that adoption of GE soybeans, cotton, and corn has increased dramatically since introduction in the mid-1990's, encompassing 20-44 percent of acreage planted in 1998 (table 1). Acreage planted with GE crops increased from about 8 million acres in surveyed States in 1996 to more than 50 mil-

<sup>&</sup>lt;sup>1</sup>Information is drawn from and additional detail can be found at the ERS website: <a href="http://www.ers.usda.gov/data/arms/">http://www.ers.usda.gov/data/arms/</a>

lion acres in 1998. Bt cotton became available to farmers in 1995, and its use expanded rapidly, reaching 15 percent of cotton acreage in 1996 and about 17 percent in 1998. The Environmental Protection Agency (EPA) approved Bt corn in August 1995, and its use has grown from about 1 percent of planted corn acreage in 1996 to 19 percent in 1998.

Adoption rates for herbicide-tolerant crops have been particularly rapid. Herbicide-tolerant sovbeans initially became available to farmers in limited quantities in 1996, but its usage expanded to about 17 percent of

Table 1—Adoption of genetically engineered U.S. field crops, 1996-98

	Year of	Estimated planted acreage		
Field crop	introduction	1996	1997	1998 <sup>1</sup>
	Percent of planted acreage			
Cotton:				
Bt	1995	14.6	15.0	16.8
Herbicide-resistant	1996	i.d.	10.5	26.2
Corn:				
Bt	1996	1.4	7.6	19.1
Herbicide-resistant <sup>2</sup>	1996	3.0	4.3	18.4
Soybeans:				
Herbicide-resistant	1996	7.4	17.0	44.2

i.d. = Insufficient data for a reliable estimate.

Source: Calculated from USDA's ARMS data for 1996, 1997, and 1998

the soybean acreage in the major States surveyed in 1997 and to more than 40 percent of the soybean acreage in 1998. Herbicide-tolerant cotton expanded from 10 percent of surveyed acreage in 1997 to 26 percent in 1998.

**Reasons for Adoption.** According to the 1997 ARMS survey, most farmers surveyed (54-76 percent of adopters) indicated that the main reason they adopted GE crops with pest management traits was to "increase yields through improved pest control" (table 2). The second reason (19-42 percent of adopters) was "to decrease pesticide costs." All other reasons combined ranged between 3 and 15 percent of adopters. These results confirm traditional theories of adoption, which show that expected profitability positively influences the adoption of agricultural innovations. Hence, factors expected to increase profitability by increasing revenues per acre or reducing costs are generally expected to positively influence adoption.

## ARMS Survey Results—Effects of GE Crop Use on Yields, Pesticide Use, and Net Returns

An essential factor in determining adoption of a new technology is that it must be more profitable relative to existing alternatives. As just discussed, farmers believe that the use of these crops will offer many benefits, such as increased yields, decreased pest management costs, and greater cropping practice flexibility. Benefits and performance of these crops are expected to vary greatly by region, pest infestation levels, seed and technology costs, irrigation, and other factors. Performance may improve after popular regional varieties containing these genes are developed. For many farmers, expected benefits appear to have outweighed expected costs, as evidenced by the rapid adoption rates.

Table 2—Top five reasons U.S. farmers gave for adopting herbicide-tolerant soybeans/cotton and Bt cotton, 1997

	Share of acreage among adopters			
	Herbicide-tolerant:			
Reason	Soybeans	Cotton	Bt Cotton	
		Percent		
Increase yields through improved pest control	65.2	76.3	54.4	
2. Decrease pesticide input costs	19.6	18.9	42.2	
3. Increased planting flexibility (for example, easier to rotate				
crops, reduce carryover, use reduced tillage or no-till systems, etc.)	6.4	1.8	2.2	
4. Adopt more environmentally friendly practices	2.0	.9	0	
5. Some other reason(s)	6.8	2.3	1.2	

<sup>&</sup>lt;sup>1</sup>Includes stacked varieties (with Bt and herbicide-tolerant genes).

<sup>&</sup>lt;sup>2</sup>Includes seeds obtained by traditional breeding but developed using biotechnology techniques that helped to identify the herbicide-tolerant genes.

The results of an econometric analysis from ongoing ERS research shows that the effects of GE crops on pesticide use, crop yields, and net returns vary with the crop and technology examined (table 3).<sup>2</sup> Controlling for other factors, such as climate, pest management strategies, crop rotation, and tillage, results indicate that increases in adoption of herbicide-tolerant cotton is associated with statistically significant increases in yields and net returns but not with changes in herbicide use. On the other hand, increases in adoption of herbicide-tolerant soybeans are associated with small, but statistically significant, increases in yields and significant decreases in herbicide use. Increases in adoption of Bt cotton in the Southeast were associated with significant increases in yields and net returns and decreases in insecticide use.

We generally can use our evaluations of new technologies to get some sense of the future expansion of the technology. Based on observed adoption rates of GE crops, one might expect a rapid diffusion of their use. However, based on the results just discussed, the advantages of current GE crops are clearly regionally dependent—that is, they are not uniformly beneficial,

so we should not expect 100 percent adoption of these varieties. Furthermore, uncertainties with respect to foreign demand for these commodities and reductions in pest infestations make adoption patterns somewhat volatile.

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Table 3—Effects of herbicide-tolerant and insect-resistant field crops on economic returns, crop yields, and pesticide use, 1997

	Effect with respect to change in the adoption of:1			
	Herbicide-t	Bt cotton		
Item	Soybeans	Cotton	(Southeast)	
Change in yields	Small increase <sup>2</sup>	Increase <sup>3</sup>	Increase <sup>3</sup>	
Change in net returns	$0^4$	Increase <sup>3</sup>	Increase <sup>3</sup>	
Change in pesticide use:4				
Herbicides—				
Acetamide herbicides	0 <sup>5</sup>			
Triazine herbicides	0 <sup>5</sup>			
Other synthetic herbicides	Decrease <sup>3</sup>	0 <sup>5</sup>		
Glyphosate	Increase <sup>3</sup>	$0^{5}$		
Insecticides—				
Organophosphate insecticides			$0^{5}$	
Pyrethroid insecticides			0 <sup>5</sup>	
Other insecticides			Decrease <sup>3</sup>	

<sup>&</sup>lt;sup>1</sup>Based on Fernandez-Cornejo, Klotz-Ingram, and Jans.

<sup>&</sup>lt;sup>2</sup>For a more thorough discussion of this analysis and results, see Fernandez-Cornejo and McBride.

<sup>&</sup>lt;sup>2</sup>Small increases or decreases are less than 1 percent for a 10-percent change in adoption.

<sup>&</sup>lt;sup>3</sup>Increases or decreases are more than 1 percent but less than 5 percent change for a 10-percent change in adoption.

<sup>&</sup>lt;sup>4</sup>Percentage change in acre-treatments.

<sup>&</sup>lt;sup>5</sup>Underlying coefficients are not statistically different from zero.

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## **Trends and Contributing Factors**

## Enhanced Output Traits and Market Coordination

#### Issue

The first generation of biotechnology involves crop traits that affect crop production—for example, herbicide or pest resistance. Biotechnology's second generation involves crops with enhanced output characteristics, such as high oil content or other specialized features. As crop differentiation advances, marketing channels will likely emerge to facilitate the coordination of end-user desires and grower crop management and production. What mechanisms will likely coordinate the production, processing, and end-user phases of output-enhanced commodities? How will the value from enhanced-output traits be shared? How will market coordination change as enhanced-output traits are introduced?

## **Background**

Contracting and some vertical coordination have been the predominant mechanisms of coordination in the broiler industry since the 1960's, and more recently, the hog industry appears to be following a similar coordination strategy. Contracting and some vertical integration are frequently found in vegetable production but less so in grain, oilseeds, and cotton production (Barkema and Drabenstott). The availability of government support programs for producers of these crops may have lessened the need for other forms of coordination.

Traditionally, open-market prices have been able to provide signals for grain production and distribution that resulted in efficient commodity production. The open-market system requires minimal control and information from the buyer. A system of grades and standards provides a set of criteria that can distinguish grain by its physical characteristics. Tests are available to measure a commodity's grade level or to measure upon request non-grade-determining factors, such as moisture, oil, protein, and starch. Production (yield and quality) and price risk are the sole responsibility of the producer. Lastly, prices are discovered through the futures market, and these

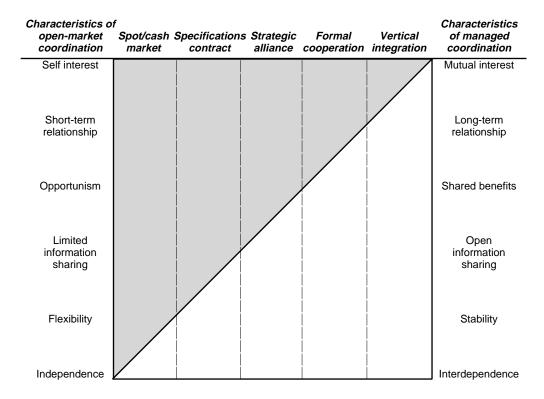
prices are transmitted to country cash markets incorporating spatial, time, and form characteristics. However, prices do not always transmit specifications desired by end-users. All commodities are assumed homogeneous, and extra value, unless segregated, is lost in the commingled system. Thus, the existing open-market system does not work well for some commodities with value-enhanced traits and needs to be changed, supplemented, or replaced by other coordinating arrangements.

It has been predicted that the next wave of biotechnology products on the market will be crops modified to target the needs of the end-user or consumer, such as foods with altered nutritional qualities, crops with improved processing characteristics, or plants that produce specialty chemicals or pharmaceuticals. Producing and marketing commodities with these enhanced-output traits—possessing greater value than regular commodities—may require greater control and more formal information exchange than the existing open-market system. Information beyond price and grade must be transmitted between the producer and buyer. Genetics, production practices, harvesting, handling, storage, and processing may need to be more closely coordinated in order to preserve the desired traits for the end-user. Product certification or testing may be required to validate product content. Producers of value-enhanced commodities may need to know their price before they produce because of increased complexity and costs. As coordination increases, both risk and additional value will be shared among the market participants, but the distribution of this risk and value is yet to be determined.

## **Alternatives**

The array of coordinating mechanisms presently ranges from an open market to complete vertical integration, with contracts, strategic alliances, and formal cooperation falling between the two extremes (fig. 3). The open market allows market participants to follow

Figure 3
Strategic options for vertical coordination



Note: The diagonal line represents the mix of open-market and managed coordination characteristics found in each of the five alternative strategies for vertical coordination. The area above the diagonal indicates the relative level of invisible-hand characteristics, and the area below the diagonal indicates the relative level of managed characteristics.

Source: Peterson and Wysocki.

their self-interests and engage in exchange relationships that are short term, opportunistic, limited as to information sharing, and flexible, and that preserve the participants' independence. At the other extreme, managed coordination is built upon mutual interests of the exchange participants who pursue relationships that are long term, that encourage benefit sharing, and that are open as to information flow, stable, and supportive of interdependence. Control increases as we move from left to right in figure 3. The factors that are controlled are price, quantity, quality, and terms of exchange.

Can increased information flow and testing permit the open-market system to handle output-enhanced commodities? Or will the developers of the value-enhanced crop try to capture most of the value in tightly controlled market channels? Advances in testing may enable grain to be graded on numerous criteria, ranging from milling characteristics to the content of various oils and amino acids (Barkema and Drabenstott). Such a system could handle some of the output-enhanced commodities, but their developer would have to allow them to enter the

open market. For example, the estimated value of these traits will guide the direction of coordination. As value increases, coordination increases, the genetic technology developer would want to control the commodity from seed to final consumer, and the open market would be completely bypassed. However, if the value is low and fluctuates more with the market of competing commodities, then the developer may release the rights to this seed and simply charge a technology fee, requiring a licensing agreement between the technology developer and seed company.

Contracts are another means to coordinate a market of enhanced output traits. Partial or full vertical coordination can be obtained with contracts. Contracts are used for limited duration, and the number of actions and decisions involved are fewer than under full vertical integration. If a market is coordinated by contracts, there is usually a desire to minimize capital outlays. Firms under contract also maintain their separate identities. One disadvantage to producers is the loss of independence.

## **Genetically Engineered Products**

## Transgenic Agricultural Products Approved for Unregulated Release as of May 1999

Product	Number	Agronomic traits	Value-enhanced traits
Crop:			
Beet	2	Herbicide tolerance	
Carnation	3		Altered flower color
Chicory	1	Herbicide tolerance	
Corn	13	Herbicide tolerance, insect resistance (Bt)	
Cotton	5	Herbicide tolerance, insect resistance (Bt)	
Flax	1	Herbicide tolerance	
Papaya	1	Virus resistance	
Potato	4	Insect resistance (Bt)	
Rapeseed	4	Herbicide tolerance	High-lauric-acid oil
Rice	1	Herbicide tolerance	_
Soybean	5	Herbicide tolerance	High-oleic-acid oil
Squash	2	Virus resistance	_
Tomato	11	Delayed ripening	
Noncrop:			
Chymosin		Enzyme used in cheese production; produced in bacteria	
RBST		Bovine growth hormone; produced in bacteria	

Contracts allow for a higher level of control and information exchange beyond what the open-market system offers. Requirements can be specified and will be upheld in courts of law. The buyer must specify desired price and grade information, product attributes, shipment procedures, production methods, varieties, testing requirements, quality requirements, and quality control measures. If special tests are to be performed, the buyer must specify them—for example, tests for a specific trait for the presence or absence of genetic modification of the crop. Contracts can reduce the level of risk by clearly stating the responsibility of the producer and the contractor.

There are many different types of contracts, however, and as some production or price risk may be reduced, other types of risk may be increased. Some contracts specify a price before planting, while others identify only a premium before harvest. For example, producers need to be aware of quantity and quality obligations, time of ownership transfer, and contract termination risk.

There are several different categories of contracts (Grinder):

- Marketing Contracts. Producer provides a quantity
  of commodities with specified physical or chemical
  traits or that has been produced using a specified
  set of practices. Pricing may be set before production, or it may be established from a commodity
  market (futures or local cash) with a premium.
- Production Contracts. Title to the growing and harvested crop remains with the contractor. The producer in this case is a temporary holder of the genetically modified seed. The producer usually agrees to repurchase the grain or oilseeds produced from the contractor's seed. However, the producer does not own the crop and, therefore, may not qualify for crop insurance or government program benefits.
- Fee for Service Contract. Contractor usually provides most of the nonland production inputs and sometimes more of the management decisionmaking. These fee contracts provide compensation to the producer for use of land, labor, and tillage machinery. Because the contractor has title and control of the crop produced, the producer may be viewed as a bailee.

## **Genetically Engineered Products**

## **Examples of Transgenic Products "in the Pipeline"**

## Input traits:

- Introduction of herbicide tolerance into sugar beet, wheat, alfalfa, sugarcane, potatoes, forestry products, specialty fruits and vegetables.
- Introduction of insect resistance into tomato, sugarcane, soybeans, rapeseed, peanuts, eggplants, poplar; includes using other Bt toxins with different specificities and developing other toxins that could alleviate the problems associated with development of resistance to Bt.
- Introduction of disease resistance (to viruses, fungi, and bacteria) in corn, potatoes, and a variety of fruits and vegetables.
- Introduction of genes for other agronomic traits, including drought tolerance, frost tolerance, enhanced photosynthesis, more efficient use of nitrogen, increased yield.
- Increasing use of "stacked" traits (herbicide tolerance and Bt resistance in one plant, for example).

## **Output traits**

Feed quality, food quality, value-added traits, specialty chemical production

- Traits affecting quality of animal feed:
  - Low-phytate corn.
  - Soybeans and corn with altered protein or oil levels (nutritionally dense).
- \* Traits affecting food quality for human nutrition (nutraceuticals):
  - Canola and soybeans producing oils high in stearate or low in saturated fats.
  - Canola with high beta-carotene (antioxidant) content.
  - Tomatoes with elevated lycopene levels (anti-cancer agent).
  - Grains with optimized amino acid content.
  - Rice with elevated iron levels.
  - Increased vitamin content.
  - Production of "low-calorie sugar" (indigestible fructans) in sugar beets.
  - Increased sugar levels in corn, strawberries, for enhanced flavor.
- Traits that affect processing:
  - Colored cotton.
  - Cotton with improved fiber properties.
  - High-solids tomatoes and potatoes.
  - Delayed-ripening fruits and vegetables, such as melon, strawberries, raspberries.
  - Altered gluten levels in wheat to alter baking quality.
  - Naturally decaffeinated coffee.
- Production of specialty chemicals (plants as bioreactors):
  - Production of pharmaceuticals, antibodies, vaccines, industrial chemicals in transgenic plants; examples
    include diarrhea vaccines in bananas, blood proteins in potatoes, rabies vaccine in corn, monoclonal
    antibodies in corn.
- \* Transgenic livestock:
  - Pharmaceuticals produced in milk in cows, pigs, or sheep; examples include antithrombin III (a blood anticoagulant, currently in phase III clinical trials), alpha-1-antitrypsin (used to treat cystic fibrosis), alpha lactalbumin (a human milk protein to use as a nutritional supplement).
  - Livestock with more rapid growth, less fat, disease resistance; more long term.

Sources: Information Systems for Biotechnology website at Virginia Polytechnic Institute and State University (www.isb.vt.edu); APHIS Agricultural Biotechnology website (http://www.aphis.usda.gov/biotech/); Biotechnology Industry Organization website (www.bio.org); Monsanto website (www.monsanto.com); OECD BioTrack Online website (www.oecd.org//ehs/Service.htm).

• Pool Contract With a Closed Cooperative. A member of a cooperative delivers a commodity to a closed cooperative facility jointly owned and operated by a group of producers whose goal is to add value to the raw product they produce. Usually the cooperative requires the producer to purchase an equity instrument in direct proportion to the producer's rights and commitment to deliver under the contract. These contracts are generally sales contracts. However, because the member producers are contracting with an organization they own and control, these contracts may be treated differently than a sales contract under warehouse regulations, grain dealers' laws, farm programs, and other governmental institutions.

## Strategic Alliances

A strategic alliance is a business venture involving two or more entities striving to achieve a mutually identified objective. Strategic alliances allow two or more entities to join each of their strengths. A contract may be involved as part of the alliance. The alliance is simultaneously a single organizational arrangement and a product of sovereign organizations. For example, an alliance could be an acquisition, license agreement, or research and development partnership. Alliances provide firms with a unique opportunity to leverage their strengths with the help of another organization.

Asset specificity encourages additional coordination (strategic alliances) and explains recent arrangements between Optimal Quality Grain and Continental Grain. Continental's grain storage, handling, and transportation assets are used to market Optimum Quality Grain's high-oil corn to export destinations. Also, Monsanto and Cargill have entered into a similar alliance.

A strategic alliance is an exchange relationship in which firms share risks and benefits from mutually identified objectives. For an exchange relationship to be a strategic alliance, it must exhibit the following three characteristics: mutuality in objective identification, mutuality in controlling decisionmaking processes, and mutuality in sharing risks and benefits. Thus, coordination in a strategic alliance arises from mutual control. Coordination control arises from mutual interests, but both parties retain their separate external identity. The control level is higher than for contracts or the open market. The focus of control becomes the relationship between the parties, with the immediate transaction being only one element of the relationship.

## **Formal Cooperation**

Organizational forms included are joint ventures, partial ownership relationships, clans, agricultural cooperatives, and other organizational forms that involve some equity commitment. The distinguishing feature between this portion of the continuum and strategic alliances is the presence of a formal organization that has an identity distinct from the exchange actors and that is designed to be their joint agent in the conduct of a coordination transaction. This organizational structure represents the center of control.

An agricultural cooperative could be used to source specific types of enhanced-output crops. They could contract with member producers for supply and merchandise or process the crop. Several U.S. cooperatives are planning to participate in such activities.

## **Vertical Integration**

Vertical integration is the creation of one organization that has control over the coordination transaction. This can result from a merger of two parties, the acquisition of one party by the other, or one party internally committing resources to replace the market function of the other party. In any event, coordination control is exercised within the policies and procedures of a single organization.

Vertical integration occurs when successive stages of marketing or of production and marketing are not linked through prices through direct ownership or contracting. One reason for vertical integration is to assure a flow of product with certain specifications and delivery terms. Such integration may reduce marketing costs, and these savings may or may not be passed on to consumers, depending on the firm's market power. Horizontal expansion must often be used as well if the vertical expansion is to accomplish its purpose.

Vertically integrated systems usually produce high-value but low-volume segregated crops. Such systems allow technology developers to capture innovator profits and maintain rigid quality controls (Kalaitzandonakes and Maltsbarger).

What coordinating mechanisms are likely to be used in the future? The type will depend on the product's value, volume, and competitive market characteristics, and on the firm's desired control, capital resources, costs, and asset specificity. An array of coordinating mechanisms appears likely to be used depending on the situation.

## Genetically Engineered Fruits, Vegetables, and Livestock

## Fruits and Vegetables

The development of transgenic fruits and vegetables has lagged behind the work on commodity crops, such as corn and soybeans, due to the high cost of development and regulatory approval of foods from genetically engineered (GE) crops and because of smaller markets for fruits and vegetables. Much of the work, thus far, to develop transgenic produce has been done with public funds at such institutions as Cornell and the University of California at Davis. However, a number of biotech and seed companies are now entering the field, and a significant number of genetically modified fruit and vegetable products will likely enter the market within the next few years.

The first GE food on the market was the FlavrSavr tomato, which was engineered to remain on the vine longer and ripen to full flavor before harvest. (This product was eventually pulled from the market primarily due to problems with harvesting and marketing.) As with GE commodity crops, the bulk of the first new GE fruits and vegetables will be modified for improved agronomic properties, such as resistance to fungal or viral infection, tolerance to herbicides, or delayed ripening. Thus far, virus-resistant papaya and squash have been approved for release, in addition to a number of types of delayed-ripening tomatoes.

The second wave of GE fruits and vegetables will target characteristics that appeal to the consumer directly—for example, apples that do not brown when cut, strawberries with enhanced sugar levels for improved taste, or "greener" green beans. Many companies are also using genetic engineering to develop "functional foods," products with additives that enhance the nutritional value or health benefits, such as lycopene-rich tomatoes or foods producing extra vitamins or anti-oxidants.

The cost of development and obtaining regulatory approval for biotech food products is quite high, and it can take 8 years or more to bring a product to market. To recapture their investments, seed developers can be expected to charge higher prices for the seed; the producers will in turn charge a premium for the new product (for output traits) or recoup these costs in savings on pesticides or labor (for input traits). Officials in the fruit and vegetable seed industry do not foresee a need for restructuring the supply chain for their commodities, as the many varieties of fresh fruits and vegetables are not bulked and stored but often transported in small lots to markets. Thus, it should be relatively simple to incorporate GE varieties with value-added traits into the current marketing system.

#### Livestock

The first transgenic livestock—sheep and goats-were produced in 1985, using techniques similar to those used to produce transgenic mice in 1981. Genetic transformation of animals has become fairly routine, although it remains a time-consuming and expensive process. To introduce foreign DNA, newly fertilized eggs are flushed from an animal's reproductive tract and the cells are individually injected with DNA. The eggs are implanted into a surrogate mother, and the offspring are tested for the presence of the new gene. Fewer than 1 in 10 babies are transgenic, and the overall efficiency of the process is actually lower, as most of the fertilized embryos do not develop following implantation.

Because the development of transgenic animals is slow, inefficient, and expensive, much of the research to date has been performed at USDA's Agricultural Research Service or at private companies that have identified potential products with high payoffs. The three major types of research involve (1) genetic modifications that promote

animal growth or health, including introduction of growth hormone genes or disease-resistance genes; (2) modifications that allow the use of animals as human disease models or as human organ donors (for example, expression of human proteins in a pig heart to lessen the risk of rejection in cross-species organ donations); and (3) use of animals as bioreactors to produce pharmaceuticals in milk.

Research and development in the last category is progressing rapidly, with several products currently in clinical trials. The first product to be approved will likely be antithrombin III, an anticoagulant used during heart bypass operations. Other promising products are alpha-glucosidase, used to treat patients with the muscle disorder Pompe's disease, and alpha-1-antitrypsin, a protease inhibitor used to treat cystic fibrosis. The potential for use of transgenic animals will probably increase as the technology improves for cloning animals. In contrast to production of a transgenic, cloning allows the exact genetic reproduction of an adult animal. This technique would allow the inexpensive reproduction of a transgenic animal to produce identical herds with certain desirable characteristics.

**Policy Issues.** The use of animals as bioreactors and as sources for human organs could raise ethical issues as well as concern about animal welfare. There should be little effect on the markets for beef and pork for consumption, as GE meat, if leaner and tastier, would likely be sold as a specialty product. The production of pharmaceuticals in milk would not likely have any effect on the dairy industry, as the numbers of animals used in a production facility would be small and the animals would be well isolated. However, this technology could significantly reduce the cost of production for many pharmaceuticals, which could have a major impact on the current drug industry.

Open markets, licensing agreements, contracts, strategic alliances, cooperatives, and full vertical integration are all likely candidates in conjunction with a segregated or identity-preserved handling system.

Increased value will tend to lead to further coordination within the market. The technology provider creates the original value of this crop and will likely want to control this value and share it according to each market participant's bargaining position, assumed risk, or additional costs relative to the traditional commodity system.

According to some industry sources, as the biotechnology industry commercializes more value-enhanced traits, market channels may become more coordinated and involve fewer participants. Specifically, the vertical value chain will be shorter and more coordinated (Renkoski). It has been suggested that value-added commodities will need contract production in conjunction with segregated or identity-preserved handling systems (Hayenga). Others suggest that future merchandising systems for value-enhanced crops may parallel a diminished traditional commodity system but possess added value (expand market, create new markets. increase product differentiation, and improve management of both logistics and supply) (Kalaitzandonakes and Maltsbarger). A modified open market could continue to provide a way to coordinate output-enhanced commodities with minor additional value, especially considering the introduction of new testing procedures for selected end-use traits.

## **Policy Issues**

Marketing arrangements, like contracting and various forms of vertical integration, have emerged as important coordination mechanisms for moving products from producers to processors to consumers. Some important questions for policymakers to consider are: When are contractual arrangements detrimental to farmers? When

are they beneficial? And what role, if any, should government play in regulating contracts? Cooperatives represent opportunities for farmers to gain more leverage in the marketplace. While cooperatives have existed for a long time, their importance has grown as a form of countervailing power to gain bargaining clout in both input and output markets. Cooperative arrangements also need to be explored, particularly the potential for their further development and government's role in promoting and strengthening them.

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## **Trends and Contributing Factors**

# Implications of Testing and Segregating Nonbiotech Crops for Grain Grades and Standards

#### Issues

Testing for the presence of genetic content in grains and oilseeds becomes crucial in order to segregate nonbiotech commodities from the rest of the bulk-commodity supply chain in responding to emerging regulations and shifting consumer preferences in some segments of export markets. Also, testing is required to preserve specific end-use characteristics throughout the supply chain for value-enhanced products. To fit in with the current supply chain for bulk commodities, these tests must be rapid, economical, and accurate.

What tests are currently available for detecting biotech content in grains and processed foods? What tests would satisfy those concerned about food safety? Is there a role for the Federal Government in standardizing the sampling and detection methods used in the commercial market, in implementing genetic modification testing methods, and in providing quality assurance through certification? If producers continue to rapidly adopt biotech crops with input traits and if a string of new, value-enhanced products emerges, can the current grain grades and standards continue to function effectively without change? If not, what changes would be needed to facilitate marketing and trade?

#### Context

Segregation, as used in this article, refers to a process by which crops are kept separate to avoid commingling during harvesting, loading and unloading, storing, and transporting. This supply chain system thus requires that equipment, such as combines and augers, and transportation and storage facilities be cleaned. Such a handling process has been used for some time for specialty grains, such as high-oil corn. Although this handling process may not involve containerization, testing for the presence of biotech content throughout the marketing system is critical. This process is frequently used to meet a threshold level of biotech content around 5 percent of grain volume.

Identity preservation (IP), in contrast, is the more stringent (and expensive) process of differentiating commodities, requiring that strict separation, which typically involves containerized shipping, be maintained at all times. IP is often used for marketing commodities like food-grade corn and soybeans. Commodities typically are tested for biotech/nonbiotech status just before they are put in containers. IP lessens the need for additional testing as control of the commodity changes hands, and it lowers liability and risk of biotech/nonbiotech commingling for growers and handlers. This handling process might be required to meet a stringent threshold level of biotech content, such as the 1 percent required in European Union (EU) labeling regulations. However, no segregation system can guarantee 100-percent purity.

The current U.S. grain marketing system is characterized by high-volume, high-speed operations. Other than a few niche markets, the system reflects a traditional bulk commodity supply chain with trade taking place at spot markets. However, the rapid adoption of biotech crops with input traits and the emergence of a number of value-enhanced products (including nonbiotech varieties) promise to fundamentally alter the structure of the current marketing system. If foreign buyers in export markets, such as the EU, require that products containing biotech ingredients be segregated. marketing of nonbiotech commodities in the supply chain might be necessary. Also, grain segregation is needed to preserve enhanced value and identity—for example, virtually all high-oil corn varieties are marketed under the OPTIMUM brand developed by DuPont—and unique end-use characteristics. However, such segregated marketing requires rapid, accurate, and economical tests.

Several methods are available for detecting the presence of biotech content in grains and oilseeds and their processed products. A pre-emergence treatment and germination test for determining the presence of the Roundup Ready gene in soybean seeds was recently developed by the Iowa State University Seed Testing Laboratory and approved by Monsanto. The procedure evaluates the presence of the Roundup Ready gene in soybean seed by comparing seedlings from various seed lots. All seed lots are imbibed in a 2-percent solution of the ROUNDUP formulation (41-percent active ingredient). Two replications of 100 seeds of each lot are placed overnight in paper towels treated with the solution. Imbibed seeds are then germinated and evaluated after 7 days. Seedlings of Roundup Ready soybeans developed normally. This test is simple and inexpensive to perform but requires about 7 days to complete.

A more sophisticated technique, called the polymerase chain reaction (PCR), can be used to detect specific foreign genetic material inserted into the plant's DNA. In PCR, specific DNA fragments are separated on a gel, and the size and intensity of the DNA band produced indicates the presence and relative level of foreign DNA within the sample. PCR is not easily adaptable for rapid onsite testing and is currently offered commercially by some private companies.<sup>3</sup> The test takes 2-10 days and costs \$200-\$450 per test. According to a trade source, a reliable sample size, for example, would be at least 80 pounds for a shipment volume of 1,500 metric tons on the barge. A key issue in deciding the adequate sample size is the sampling procedures, which ideally should reflect that a particular sample accurately represents the biotech content of the entire lot of grains or product lines from which the sample is drawn.

The PCR test is a very sensitive technique that can reliably detect about 0.1 percent biotech content in a sample. It has the advantage of being easily adapted to screen DNA from several biotech gene lines—such as Bt corn, Roundup Ready corn, or high-lysine corn—in one set of tests (Schuff). However, PCR tests are also susceptible to errors due to contaminants or DNA breakdown, so testing must be performed under rigorous laboratory conditions with appropriate controls. Also, detection of DNA in processed foods derived from biotech crops can be problematic due to breakdown or degradation of DNA during processing.

A British firm, RHM Technology, reportedly has overcome these technical hurdles by modifying the PCR test to detect DNA in processed foods. Several companies, including Cepheid and Qualicon (a subsidiary of DuPont) were developing methods in 2000 for PCR-based diagnostic tests for rapid, simple onsite testing. Genetic ID, also in 2000, developed a program to combine its testing with a certification program for producers who want to sell segregated, nonbiotech crops. The certification program, called "CertID," is a joint venture with LawLabs in the United Kingdom (Schuff).

A third method for detecting biotech content is the protein-based enzyme-linked immunosorbent assay (ELISA). The ELISA test analyzes for a specific antibody reaction that marks the presence of the new protein produced in biotech crops. Strategic Diagnostics, Inc. (SDI), of Newark, Delaware, was working in 2000 with Monsanto and other biotech or seed companies to develop ELISA-based test kits to detect such traits as glyphosate tolerance in soybeans or Bt production in corn.

The ELISA microwell test can be used at grain elevators or processing plants to quantitatively detect biotech content in grain samples within 2 hours at a cost of about \$10 per test. This test has been validated by the EU for testing. In addition, SDI has developed a rapid dipstick test that can detect as little as 0.1 percent biotech protein in Roundup Ready soybeans in 5-10 minutes at a cost of about \$3.50 per test. That test gives farmers and elevators a "yes-no" (that is, qualitative) answer based on the presence of the Roundup Ready trait. As of September 2000, the test kit had not yet been approved in Europe for compliance with EU food labeling requirements. On September 20, 1999, SDI announced that the Japanese Government had obtained a license to use the test kits (Schuff). A nonexclusive license agreement was signed with Japan Oilstuff Inspector's Corp. (JOSIC) for detecting biotech content in grain and food ingredients.

Current ELISA testing methods require that a separate test be performed to detect the presence of each biotech gene line, so several tests may be required to determine if a truckload of corn is free of any biotech content. ELISA test kits are currently limited to testing Bt corn varieties. SDI is also developing a strip test kit that will detect, in a single test, all the biotech corn gene lines that are approved for use in the United States. The ELISA method could also be adapted for analyzing crops with high-value output traits, such as those containing vaccines or pharmaceuticals.

<sup>&</sup>lt;sup>3</sup>The Japanese Ministry of Agriculture, Forestry & Fisheries used PCR testing to determine whether biotech content in certain processed products could be detected after processing. Processed products for which PCR testing could not detect biotech contents, such as soybean oil, are exempt from labeling requirements. (Japan is scheduled to begin its labeling requirements in April 2001.)

Another test that shows considerable promise for rapidly assessing output traits in value-enhanced crops, such as high-oil corn, is called near-infrared spectroscopy (NIRS). The pattern of absorption or reflection of NIRS light is unique for every compound, so the identity and quantity of materials like oils, proteins, and starches can be easily determined for both whole seeds or processed grains. Following the initial purchase of the NIRS spectrophotometer (about \$20,000), the tests are inexpensive and rapid and can be performed on site at elevators. NIRS potentially could be used to detect the presence of input-trait biotech material. Iowa State University filed a patent application in 2000 to do just that. If permission is granted, NIRS can detect the presence of input-trait biotech material within a few minutes.

Although a rapid test is required to segregate nonbiotech crops from the rest of bulk commodities in order to maintain the efficiency of the U.S. grain marketing system, IP, with carefully supervised contract production, lessens the need for additional testing as control of the commodity changes hands. In addition, it lowers liability and risk of biotech/nonbiotech commingling for growers and handlers. IP preserves the unique enduse characteristics and identity of a nonbiotech crop throughout the production-marketing system through contract production and stringent separation of commodities, including containerized shipments. This process gains some additional value when the lack of consistent test results—a major difficulty facing the current testing methods—is taken into consideration.

## At Stake

If consumer demand for nonbiotech food strengthens and/or expands to new markets, segregation or IP marketing might be necessary to accommodate labeling requirements (whether voluntary or mandatory) in these markets. While segregated or IP marketing is nothing new, the viability of segregated marketing would depend on the speed, accuracy, and costs of biotech content testing. Rapid, accurate, and economical testing methods are essential to maintain the efficiency of the existing grain marketing system. Tests to rapidly detect modified DNA or protein in biotech crops are entering the marketplace; however, as of 2000, the most accurate quantitative tests still take several hours to a few days to complete and may add significantly to total marketing costs. Less than 2 minutes are typically required to test grain for physical characteristics such as test weight (U.S. Grains Council); thus, the efficiency of the U.S. grain marketing system could be compromised unless

more rapid, accurate, and economical biotech testing methods are developed. This capability is essential in establishing a segregated nonbiotech marketing channel that is able to coexist with the existing high-volume, high-speed bulk commodity marketing.

The high costs of segregated marketing for nonbiotech grains and oilseeds to a segment of export markets and the current weak demand for nonbiotech crops contributed to limited segregation by producers and elevators during fall 1999. A survey conducted in mid-September 1999 by Sparks Companies, Inc., found that only 8 percent of Midwest grain elevators were segregating nonbiotech soybeans from commingled soybeans and only 11 percent were segregating nonbiotech corn (Muirhead). However, the extent of segregation could well increase in the 21st century. Elevators are likely anticipating food-labeling regulations in other countries. In mid-October 1999, most premiums for nonbiotech soybeans averaged around 10-15 cents per bushel, while the premiums offered for corn were in the range of 5-10 cents per bushel (Muirhead).

According to a 1999 ERS study, the average preliminary cost to the U.S. grain handling system of segregating nonbiotech corn (excluding a purchasing premium for nonbiotech crops) was an estimated \$0.22/ bushel (12 percent of the farm price for corn forecast for 1999/00). Similarly, the 1999 cost of segregating nonbiotech soybeans was an estimated \$0.54/bushel (12 percent of the forecast farm price for soybeans) if the segregation is patterned after that for Synchrony Treated Soybeans—a herbicide-tolerant, but nonbiotech variety of soybeans (Lin, Chambers, and Harwood). However, the costs of segregating nonbiotech soybeans become smaller, at \$0.18/bushel (4 percent of the farm price for soybeans forecast for 1999/00), if segregation follows that for high-oil corn. The costs of segregation would become considerably higher if segregation is performed in the same manner as that for food corn and food soybeans through IP.

Sampling problems will be a key issue in addressing low or zero tolerance for biotech ingredients in foods or the demand for meeting labeling requirements. Small sample size and a lack of standardized sampling procedures contribute to the lack of consistent test results. At a 99-per-

<sup>&</sup>lt;sup>4</sup>The cost of segregation varies among grain elevators and is subject to change as testing methods for detecting the presence of biotech content in grains and oilseeds evolve and as economies of scale are achieved in segregating larger volumes of nonbiotech crops from the rest of the grain supply chain. The cost estimates presented here are intended to show only an approximation of the general magnitude relative to farm prices of corn and soybeans.

cent purity level, a typical ELISA test at country elevators currently uses a sample of 50-60 kernels out of close to 1,000 bushels in a truckload. A smaller sample size (40-50 kernels) would be used for testing at a 95-percent purity level. Detecting biotech content in grain has other uncertainties, depending on where the truck is in the system and how often a truck is probed.

In the near- to mid-term, increasing sophistication and specificity will be added to contract specification as well as to the grading system. In some export markets, labeling regulations may well require an amendment to contract specification indicating that the presence of biotech content cannot exceed a specified tolerance level. In the case of high-oil corn, a nonbiotech variety, a minimum oil content of 6 percent is now included in contract specification. It is conceivable that a specialty grade of highoil corn, similar to the case of waxy corn, which is particularly suited for certain food processing and industrial uses, eventually could be included in the grading system if the demand for the specific output trait becomes more common. Thus, U.S. grain grades and standards, by and large, are likely to remain intact in their current basic structure in the near- to mid-term so long as output-trait biotech crops remain as niche markets.

However, in the longer run, the current grain grades and standards could begin to cease their basic functions if specialty grades become widespread and if these specialty grains and oilseeds account for a majority of imports from the United States by foreign buyers. These specialty grains and oilseeds (including those biotech varieties presently in the commercial market and in the pipeline) could include high-oleic-acid soybeans, modified-starch corn, low-phytate corn, and stacked high-oil and high-lysine corn. At that point, it might be difficult to reconcile between the physical characteristics-dominated grain grades and standards and the dominance of specialty grades in foreign buyers' imports. The value of output-trait biotech crops may then be discovered primarily through the price that buyers are willing to pay for intrinsic characteristics of the commodity, not the price discovered for the base grade in grain trade (for example, U.S. No. 2 yellow corn). Physical characteristics in the current grain grades and standards, in essence, would likely play a minimal role in pricing the commodity.

## **Alternatives**

Alternatives for addressing issues related to testing and segregating nonbiotech crops are included here for discussion and consideration. (1) The Federal Government plays an active role in implementing a voluntary quality-assurance program for nonbiotech products to facilitate a voluntary labeling program. The existing testing methods for detecting the presence of biotech content in grains and oilseeds are either too slow or too costly, far from meeting a rapid testing of less than 2 minutes for measuring physical characteristics in the current grain handling system (U.S. Grains Council).

Also, some of the test kits developed by private firms, such as the ELISA test kit developed by Monsanto and marketed by SDI, were available in 2000 only to allied seed companies, research laboratories, and limited groups of producers. Although the company reportedly sold 6 million units of the soybean tester in 1999, it was *not* available to all producers or handlers as of late 2000.

However, at this writing, USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) is assessing the need for a quality-assurance program for the production, handling, and processing of nonbiotech crops to facilitate a voluntary food-labeling program, as announced by the Clinton Administration in May 2000. A quality-assurance program could provide the food industry with an independent, third-party verification and certification process for differentiating and segregating biotech and nonbiotech crops, and strengthen high consumer confidence in labeling programs implemented by the food industry.

In addition, GIPSA is establishing a reference laboratory in Kansas City, Missouri, to (1) evaluate and verify analytical procedures applied to the detection and quantification of biotech content in grains and oilseeds, (2) evaluate the performance of detection methods, (3) evaluate and accredit, upon request, non-USDA testing laboratories for their certification programs (that is, to certify tests), and (4) establish recommended sampling procedures for use in testing biotech content in grains and oilseeds. However, the certification will not be a prerequisite for grain exports. Also, GIPSA will not be involved in providing a testing regimen.

(2) The buyer can augment contract specification by setting the maximum tolerance level of biotech content in grains and oilseeds. A zero tolerance for the presence of biotech material in grains and oilseeds through segregation is a scientifically

- untenable expectation. Instead, the buyer can request delivery of material that meets or exceeds a specified tolerance limit. EU food labeling regulations, which took effect in April 2000, require that foods be labeled if they contain individual ingredients that exceed a 1-percent threshold of biotech content. Furthermore, exporters and retailers must show that any biotech content present in grain shipments is accidental and therefore will require some sort of paper trail to prove that only nonbiotech ingredients were used. In contrast, Japan's 2000 labeling regulations have a 5-percent tolerance level for biotech ingredients in foods.
- (3) The buyer can augment contract specification in the case of soybeans by setting the maximum tolerance level of biotech corn in foreign material. Increasing sophistication and detail might be added to contract specification in the case of soybeans in order to meet consumer demand in a segment of exports market, such as the EU. In U.S. soybean grades and standards, corn is a part of soybean foreign material, a grade-determining factor, which has a 2 percent maximum limit for the base grade (U.S. No. 2). If European buyers are not willing to accept soybeans that contain more than 1 percent of any biotech material (including biotech corn), for example, a contract specification without this additional specificity could cause a stalemate in which sellers can meet the U.S. soybean grades and standards, but EU buyers would not accept its importation.
- (4) The buyer can augment contract specification by setting the minimum level of a certain intrinsic, end-use characteristic in the case of biotech crops with a single output trait, or specific end-use characteristics in the case of stacked output traits. More specificity will likely be added to contract specification to reflect a string of emerging value-enhanced biotech or nonbiotech crops. In the case of high-oil corn, for example, a 6 percent minimum oil content could be added to current contract specifications. With the increase in the multitude of specialty grains and oilseeds in future years, more specificities (such as high-protein corn with desired amino acid, high-lysine soybeans, etc.) could be added to contract specification.

(5) The Government could augment the U.S. grain grades and standards to include specialty grades that are determined outside the numerical U.S. grading system. Increasing sophistication and specificity could be added to the current grain grades and standards to explicitly reflect buyers' quality preference in intrinsic, end-use characteristics, which are typically excluded in the grades and standards. In the case of high-oil corn, for example, a specialty grade could be created, similar to the case of waxy corn, to reflect the higher value buyers place on high-oil corn. The price that buyers agree to pay for high-oil corn, in this case, would exclusively reflect its higher oil content, not any of its physical characteristics.

## **Policy Issues**

Contract specifications are augmented voluntarily by grain sellers and buyers. As a string of new specialty grains and oilseeds emerges, the rate and the number of possible commodities that require specific testing could increase as well. At a certain point, if the rate of change and multitude of products accelerate, IP marketing could become the only way to market these specialty crops.

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## **Public Policy Considerations**

## **Consumer Acceptance**

#### Issue

Consumer responses to genetically engineered (GE) foods have varied widely worldwide. How commonly held are specific consumer preferences with respect to GE products? What impact do they have on domestic policies and consumption of biotech crops? What implications do policies and differences in policies have for trade in agricultural products?

#### Context

U.S. consumers have voiced little objection to genetically modified foods, while EU consumers have been vocal in their disapproval. Attitudes of consumers in Japan and Australia in the mid-1990's were generally favorable toward biotech crops, although Australian consumers generally regard biotech crops as risky. These attitude differences have resulted in differences in regulatory policies and in the potential for trade disputes.

In response to increases in calls to consumer helplines, vocal consumer concern, and the initial actions of one or two retail chains, a number of the major European grocery chains and food processors are attempting to eliminate GE ingredients from their foods. Reaction in other countries has not been quite as severe. Some food processors in Japan are worried enough about consumer perceptions that they have begun trying to use non-GE ingredients in their food products. In the United States, only a few protests have been heard and few major food manufacturers have reacted. Australian opinion polls indicate a desire for benefits and positive characteristics but a fear of the risks.

Results of attempts to measure these differences with opinion polls within and across countries have varied. Leopold and Hoban (1996) both note differences across EU countries. Some of the EU survey results are similar to those for the United States.

One can draw a few conclusions from the results of the surveys. Surveys that asked the same questions of both EU and U.S. consumers generally elicited less favorable responses toward genetic engineering in food from EU consumers than from U.S. consumers (see the Environics and *Economist* polls). Greater approval is associated with survey questions in which the surveyors suggested that the food would have desirable characteristics (Hoban, 1993, 1998) (compare table 4 with tables 5 and 6). Zechendorf and Frewer, Howard, and Shepherd note that specific applications really make a difference in determining public acceptance of biotechnology—for example, consumers support medical applications more than food applications.

With respect to the existence of GE foods in the marketplace, Hoban and Katic found that 37 percent of U.S. respondents did not think that GE foods were currently sold and that 23 percent did not know whether or not they were sold. The 1999 International Food Information Council (IFIC) poll found similar results. IFIC's May 2000 poll, however, indicates that only 23 percent do not think that GE foods are sold, while 34 percent do not know. Hoban's work also indicates that genetic engineering of animals is less accepted in the United States than engineering of plants (table 7) (Frewer, Howard, and Shepherd).

Finally, Australian and European consumers seem more likely to attach risk to genetically modified foods (table 8). A 1995 Food Marketing Institute survey indicated that most U.S. and European consumers are much less concerned about risks from biotechnology than about risks from pesticides and other food safety hazards (Hoban, 1998). The percentages were closer in Australia: 71 percent considered GE plants a big concern, and 79 percent considered pesticides that way (Kelley).

There are many possible reasons for increased concern in Europe compared with the United States. The Bovine Spongiform Encephalopathy (BSE), or Mad Cow Disease, crisis in England and other food safety scares, like the Belgian dioxin scare, have raised concern about food safety and have increased distrust of government assurances of safety.<sup>5</sup> In these cases, the national governments either originally underestimated the extent of a foodborne health problem or delayed giving the public information about it.

The September 1999 Gallup poll indicated that 61 percent of Americans place "a fair amount" and 15 percent place a "great deal" of confidence in the Federal Government to ensure the safety of the food supply. European results are more mixed. When asked what gave them certainty about a food's safety, 66 percent of European consumers reported national controls to be a factor (*Eurobarometer* 49). More chose national controls than any other

Table 4—Survey results on consumer attitudes toward biotechnology in agriculture

Country	Year	Question/issue	Response
United States	1988/89	Plant GE (asked to assume not harmful to humans or environment) (Hoban, Woodrum, and Czaja)	<ul><li>54 percent said desirable,</li><li>23percent neutral,</li><li>23 percent undesirable</li></ul>
Australia	1993	Would you eat genetically modified foods? (Kelley)	56-66 percent said yes, depending on the food
United States	1999	Biotechnology used in agriculture and food production (Gallup)	51 percent strongly supported or moderately supported
United States	1999	Would they be more or less likely to buy a food because it was genetically modified? ( <i>The Economist</i> )	57 percent said less likely
United Kingdom	1998	GM products (Greenberg)	51 percent said unacceptable
Germany	1999	Would they be more or less likely to buy a food because it was genetically modified? ( <i>The Economist</i> )	95 percent said less likely

Table 5—Survey results on consumer attitudes toward biotechnology to improve foods

Country	Year	Question/issue	Response
Japan	1995	Biotechnology used to develop improved crop varieties (Hoban, 1996)	10 percent strongly supported, 72 percent supported
United States	1992, 1994, 1997,	Biotechnology used in agriculture and food production to improve foods (Hoban, 1998)	2/3 support
United States	1995	Biotechnology used to make foods taste better, stay fresh longer, prevent disease (Hoban, 1996)	75 percent support
United States	1997, 2/99, 10/99, 5/00,	How likely to buy produce modified by biotechnology to taste better or fresher? (IFIC, 10/99, 5/00)	55 percent likely/somewhat likely, 62 percent, 51 percent, 54 percent
Europe	1996	Genetic modification to change food characteristics ( <i>Eurobarometer</i> 46.1)	53 percent said useful, 47 percent said risky, 40 percent said morally acceptable
Australia	1993	Genetic modification to change food characteristics (Kelley)	64-82 percent said "good idea," depending on the food

<sup>&</sup>lt;sup>5</sup>In spring 1999, dioxin was introduced into the Belgian food supply, including exports, via contaminated animal fat used in animal feeds supplied to Belgian, French, and Dutch farms. Hens, pigs, and cattle ate the contaminated feed, and high levels of dioxin were found in meat products and eggs.

determinant. However, when asked whether various institutions tell the whole truth, part of the truth, or none of the truth about food safety, 52 percent of European consumers chose the whole truth for consumer associations, while only 26 percent chose that option for government authorities (*Eurobarometer* 49).

Another reason for increased European concern is that Europe's dense population places population and farming centers very close to wildlife centers, which creates concerns about encroachment. Many European countries have very vocal Green parties, and environmental concerns about crops produced with biotechnology are thus at the forefront of policy discussions.

Table 6—Survey results on consumer attitudes toward biotechnology to make plants resistant to pests or herbicides

Country	Year	Question/issue	Response
United States	1992	GE used to make cotton plants resistant to herbicide (Hoban, 1993)	70 percent said acceptable
United States	1999	Do you favor the use of biotechnology to grow pest-resistant crops that require fewer farm chemicals? (Environics, <i>The Washington Post</i> )	78 percent favor/somewhat favor
United States	1997, 2/99, 10/99, 5/00	How likely to buy produce modified by biotechnology to be protected from insect damage and require fewer pesticides (IFIC, 10/99, 5/00)	77 percent very/somewhat likely, 77 percent, 67 percent, 69 percent
Europe	1996	Genetic modification to make crops disease resistant ( <i>Eurobarometer</i> 46.1)	68 percent said useful, 53 percent said risky, 63 percent said morally acceptable
France	1999	Do you favor the use of biotechnology to grow pest-resistant crops that require fewer farm chemicals? (Environics, <i>The Washington Post</i> )	52 percent favor/somewhat favor

Table 7—Survey results on consumer attitudes toward biotechnology in animal production

Country	Year	Question/issue	Response
United States	1992	GE used to make larger sport fish (Hoban, 1993)	35 percent said acceptable
United States	1988/89	Animal GE (asked to assume not harmful to humans or environment) (Hoban, Woodrum, and Czaja)	26 percent said desirable, 21 percent neutral, 53 percent undesirable

Table 8—Survey results on consumer attitudes toward biotechnology in agriculture as a health hazard

Country	Year	Question/issue	Response
Australia	1993	GE food plants might be a danger to human health over time (Kelley)	71 percent said a big worry
Europe	1995	Genetically modified crops as health hazards	33-50 percent in each country said health hazard
United States	1999	Does food produced using biotechnology pose a health hazard to consumers? (Gallup)	27 percent said yes, 53 percent said no

Consumer advocacy groups have been more vocal in their complaints about crops produced with biotechnology in the EU than in the United States. Some have suggested that Nazi emphasis on eugenics during World War II caused Europeans to regard genetic manipulation with suspicion (Davison, Barns, and Schibeci). In several studies in the U.K., Frewer, Howard, and Shepherd found that British consumers view minor food changes as frivolous or unnecessary.

### **Policies**

# **Approval Policies**

Most industrialized countries require crops produced with biotechnology to be assessed for both their environmental impacts and their safety as foods. Regulation of GE commodities in the EU has been conservative, involving considerable scrutiny and featuring separate regulations for different types of GE crops. Overall, fewer varieties of GE crops are allowed in Europe than in the United States (table 9).

The United States has incorporated regulation of biotech crops into its current regulations for foods, plants, and pesticides. The fact that the plant has been genetically altered is less important than the specific effects of the alteration. The United States requires just a few additional regulatory steps for GE varieties where the food, its donor organism, and its host organism are generally regarded as safe for consumption and the environment. As with other types of foods, the regulatory agencies would pay much more attention to genetically modified varieties that are significantly different from currently available foods.

The Food and Drug Administration (FDA), regulating food applications of crops produced with biotechnology, relies on current laws, which hold manufacturers of foods responsible for providing safe foods. FDA considers a GE crop safe if it is substantially the same as its non-GE version and the genetic modification does not cause the crop to produce a substance that is new or used in a new way or that is present in much larger amounts than in currently safe food. If the genetic modification produces a new substance that is not an approved food additive, the safety of the new substance as a food must be proven. If natural levels of toxins are increased or if allergens are transferred to a new variety, FDA recommends that the firm consult with it on safety procedures (Federal Register, May 29, 1992).

FDA has a consultative process that it recommends to all manufacturers of food produced with biotechnology, and thus far, all manufacturers have used the process. Firms submit data on the genes, the host plant, and any quantities of various proteins that are different than in foods already on the market. FDA then examines the data (FDA Consumer). As of May 2000, with the Clinton Administration initiative, this consultation process became mandatory White House Press Release).

USDA's Animal and Plant Health Inspection Service (APHIS) regulates the planting and cultivating of the crop. Companies notify APHIS that they are planning a field trial of a GE plant. In addition, APHIS can require more careful isolation if the plant might become a pest (*Federal Register*, May 2, 1997). To grow a GE crop commercially, a company can petition for unregulated status for the crop. The application

Table 9—Regulation of agricultural biotechnology by agency

Item	United States	EU	
Release into environment for commercial production, field tests	Regulated by USDA's Animal and Plant Health Inspection Service	Regulated by member state governments, with input, if members disagree, from Scientific Committee, European Commission, and possibly the Council, under Regulation 90/220	
Food safety Regulated by FDA		Regulated by member state governments, with input, if members disagree, from Scientific Committee, European Commission, and possibly the Council, under Regulation 258/97, the Novel Foods Act	
Pesticidal or herbicidal varieties	Regulated by EPA	Subsumed under one of the processes above	

must include descriptions of plant pest risk, weediness, and transfer of genetic material, as well as field trials (*Federal Register*, May 2, 1997).

Finally, if the plant has been engineered to produce a substance that "prevents, destroys, repels or mitigates a pest"—or example, an insect herbivore—EPA regulates the substance as a pesticide and determines how much of the substance may be present in food. The level that may be present in food is called a "tolerance." EPA also has the authority to exempt a pesticide from the requirement of a tolerance. When an exemption is granted, no limit is set on the amount of the pesticide that may be present in food. EPA may exempt a pesticide from the requirement of tolerance only if the pesticide is safe for consumption. EPA also regulates pesticidal substances to ensure that they do not present unreasonable risk to the environment. EPA has the authority to require that data be developed and submitted to ensure that there is no harm to human health and no unreasonable risk to the environment.

In 1994, EPA published a statement describing its policy for substances in living plants that prevent, destroy, repel, or mitigate a pest (*Federal Register*, November 23, 1994). Because herbicides are pesticides, EPA establishes tolerances for herbicides used on herbicideresistant biotech crops. EPA also regulates the use of the herbicide in the environment. Through this regula-

tion, EPA can evaluate aspects of the trait endowing the plant with the ability to resist the herbicide.

The United States has subsumed regulation of biotech crops under its established food and environmental regulations, while the EU has designed regulatory processes specifically for biotech crops, and each GE crop is evaluated, regardless of similarity to existing varieties. In the EU, Regulation 90/220 currently regulates release of biotech crops into the environment (European Union, 1997). Regulation 258/97, established January 27, 1997, and known as the Novel Foods Act, requires that all biotech crops sold as food go through an approval process (European Union, 1990). Both regulations require an environmental impact assessment and follow a similar pattern. The approval process came to a halt in 1999 as the EU began redesigning its regulations.

Japan, like the United States, regulates biotech crops by dividing the responsibility among established agencies. Companies submit field tests to the Ministry of Agriculture, Forestry and Fisheries (MAFF) for an environmental impacts assessment. The Japanese MAFF also assesses the safety of the product as a feed, while the Ministry of Health and Welfare assesses the safety of biotech crops as food (Japanese Ministry of Agriculture, Forestry and Fisheries).

# Biotechnology and the Environment

Some consumers and interest groups have expressed concern about the potential effects of large-scale release of biotech crops into the environment.

The following are frequently mentioned areas of concern:

- Potential spread of transgenes into other plants, resulting in unintended harmful consequences—that is, development of resistant weeds and contamination of non-GE or organic crops.
- Development of Bt resistance by the target insects.
- Unanticipated harmful effects on nontarget organisms in the ecosystem.

There is little evidence, thus far, of any environmental damage from the release of biotech crops; however, planting of GE crops has been widespread for only 4 years. While field tests show no evidence similar to that of the highly publicized Monarch butterfly laboratory studies, the associated concerns suggest the need for continued monitoring and testing of the environmental impact of GE crops in actual field situations. These concerns have led USDA to propose the establishment of regional centers to monitor long-term effects of biotech crops on environments.

Concern about the environmental safety of GE crops suggests the need

for comprehensive risk assessments of GE products. Risk analysis of biotechnology is very complex, as the situation is unique for every crop, each genetic modification, and each environment. Comparing any risks associated with biotechnology with risks of competing technologies is important that is, chemical pesticides versus Bt crops, increased use of glyphosate versus other herbicides, or planting a GE crop with increased productivity versus bringing new land into production for a standard variety with lower productivity. Risk assessment that enhances consumer confidence and trust is likely to contribute to the smooth running of markets.

## **Labeling Policies**

A number of governments require or are considering requiring that foods with genetically modified ingredients be labeled as such. The United States requires labeling only if GE versions of foods are substantially different from their traditionally bred counterparts—for example, if allergens are added or nutritional content is changed. The EU requires that all foods containing biotech commodities be labeled. Japan, Australia, and New Zealand have draft legislation for labeling, and other countries are considering requiring labeling (New Zealand Ministry of Health and Australia New Zealand Food Authority).

Deciding what to label has proven difficult for retailers and regulators. Some consumers would like to buy GE-free products, and firms would like to provide them. However, if the same trucks, containers, ships, or processing plants have been used for both non-GE and GE varieties, cross-contamination can occur. Thus, regulations specifying what must be labeled as containing GE material or what can be labeled "not genetically engineered" will have to specify some minimum tolerance level for GE material. Otherwise, "not genetically engineered," while technically possible, will be a prohibitively expensive standard to attain (Lin, Chambers, and Harwood). The EU, for instance, has enacted a 1 percent tolerance level (European Union, 2000).

# At Stake

Consumer preferences and the design of policies to reflect those preferences could affect trade in three areas: approval regulations, labeling, and consumer demand for products. In addition to regulating whether or not products of biotechnology may be sold in a country, a government might enact labeling regulations or voluntary policies. The effect on trade would be dictated by the costs of labeling and by how consumers use the information.

# **Effects of Approval Regulations on Trade**

EU regulations have kept most U.S. corn from entering Europe. Because some GE varieties had not been approved for sale in the EU, U.S. corn exports to the EU fell from \$190 million in 1997 to a mere \$35 million in 1998 and to \$6 million in 1999. This phenomenon has affected all U.S. corn exports to the EU, even exports destined for animal feed. (U.S. corn exports to the EU were only about 4 percent of total U.S. corn

exports before 1998.) The most widely used variety of GE soybeans has been approved in the EU, however. In 1998, \$1.5 billion in U.S. soybeans entered the EU, and in 1999, \$1.2 billion, each making up 33 percent and 27 percent of U.S. soybean exports (U.S. Department of Agriculture, 1998).

# Effects of Foreign Labeling Regulations on Trade

The effects of labeling on trade depend on the products that must be labeled and the costs of labeling. As previously discussed, a number of countries have drafted legislation to require that certain products made from biotech commodities be labeled accordingly. When commodity dealers in these countries import U.S. biotech crops, they must consider these labeling requirements.

Specific product requirements for labeling are important in determining the effect of labeling requirements on trade. Of the biotech crops currently produced in the United States, the two most commonly exported are corn and soybeans. Some of the exports are used in food, but most exported corn and soybeans are used for animal feed. Whether or not U.S. exports of these crops are affected by labeling requirements depends on whether the country requires labeling for feed or just for food. In addition, the types of food products that must be labeled can affect trade. Some countries exempt certain products from labeling but require labeling for others. In these cases, the effect of labeling on trade will depend on whether or not U.S. exports to that country are composed of foods for which labeling is required (U.S. Department of Agriculture, 2000).

The cost of labeling could also affect U.S. exports. The cost of simply putting a label on a shipment is not very high. However, labeling could have a number of other costs. For instance, an exporter selling U.S. crop varieties not produced with biotechnology would not have to label the product. However, the usual method of exporting grains is to mix them together to take advantage of grain shipping, storing, and inspecting systems, which keeps costs low by processing grains in bulk. In order to avoid mixing the product with GE varieties and, thus, having to label it, the U.S. exporter who is selling nonbiotech varieties would have to carefully separate the grain from the normal shipping channels and handle it separately. This would result in higher costs (Lin, Chambers, and Harwood).

#### **Effects of Consumer Preferences on Trade**

The purpose of labeling, whether mandatory or voluntary, is to provide information to consumers. Consumers then use the information to decide whether or not to alter their purchasing behavior. The size of the impact that consumer demand for GE crops has on U.S. exports depends on how much consumers change their purchasing behavior in response to labeling.

According to consumer surveys, some consumers in some countries may prefer not to eat genetically modified products (table 4). In some countries, some supermarket chains and food processors have pledged to exclude GE crops from their own brands of processed foods. They are doing this by either eliminating corn and soybeans from processed products or buying non-biotech grain. Finding alternatives to U.S. soybeans as an animal feed has proven to be much more difficult.

In essence, these consumers, by demanding nonbiotech food products, are shifting their demand away from bulk shipments of soybeans and corn, which could contain GE crops. The lower demand for GE grains, if sufficiently large, could reduce the price of bulk shipments. The size of the reduction, however, would depend on the number of customers who wanted non-GE crops, and this currently appears to be a niche market. The price of non-GE crops would be high because of the expensive handling requirements. The market for non-GE grains will exist as long as some consumers' willingness to pay for this type of food is as high as the costs of manufacturing such food (U.S. Department of Agriculture, 2000).

Foreign approval regulations, foreign labeling regulations, and consumer preferences, therefore, can affect trade in biotech crops. The size of the effects will vary, depending on the types of goods and crops considered.

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# **Public Policy Considerations**

# **Public and Private Agricultural Research**

#### Issues

Many policies related to agricultural biotechnology are directed toward the output, intended or unintended, that results from using biotechnology products. Such policies include those that affect market segregation for quality-enhanced products, consumer information, and environmental issues. But other public policies are aimed directly at influencing the amount, pace, and direction of agricultural research performed by both the public and the private sectors. What policies are available to influence this research toward greater public benefits?

#### Context

Many studies on the returns to agricultural research focus on the amount spent on research. The public policy tools used in this instance are the funding of public-sector research and the allocation of those funds to different activities and institutions. Other public policies, however, are very important in influencing the overall scope and direction of agricultural research, particularly the research performed by the private sector. Among the most important of these policies are those that focus on intellectual property rights (IPR), such as plant varietal protection and patent policies, and those that address market concentration, such as antitrust policies. In fact, these two sets of policies, although usually administered by different government agencies, are quite interrelated.

# **Specfic Policies**

# Intellectual Property Rights and Scientific Advance

As biotechnology becomes increasingly important in agricultural research and product development, public policy on intellectual property rights becomes increasingly important in shaping the pace and direction of agricultural research. At the first level, IPR's trade off some monopoly power for greater incentives for private

research and innovation, which leads to differing distributions of benefits from new technology and "deadweight" losses. At the second level, greater market power from industry concentration and stronger IPR's can enhance incentives for private innovation. But IPR's can also inhibit technological progress by creating barriers to new firms entering the research arena and associated markets and limiting their access to new innovation, including innovation from academic research.

An optimal patent policy would try to balance these conflicting trends to maximize social benefits, but the elements of such a policy are difficult to discern in a rapidly evolving industry based on accelerated scientific advance (Evenson). Even the ideal patent policy is what economists call a "second-best" solution for encouraging innovation (Deardorff).

Consolidated firms with large market share and strong patent portfolios may motivate private research efforts because these firms are often in a better position to capture the economic gains from research investments. Greater ability to appropriate new technology through such vehicles as the establishment of plant breeders' rights and the development of hybrid seed technology can also motivate private innovation. Hybrid seed technology, in which investment is protected through trade secrets, provides a good illustration of this. The private sector is able to appropriate more of the gains from hybrid research efforts because the yield vigor of hybrid crops decreases in subsequent growing seasons, requiring farmers to repurchase seed every year. As a result, private-sector research investments in hybrid crops, such as corn and sorghum, as a share of seed sales have been much greater than research spending on nonhybrid crops, such as wheat, soybeans, and cotton (Fuglie et al.).

Too much market power, however, may inhibit technological advancement. Concentrated firms with strong patent portfolios may have greater access to capital and markets than smaller, startup technology firms (Barton). There is already evidence that entries of startup agricul-

tural biotechnology companies have declined dramatically (Kalaitzandonakes and Bjornson). These startup companies are important because they often conduct midlevel research, or more specifically, they develop technologies that bridge the gap between knowledge produced by basic research and new product development (U.S. House of Representatives). Greater market power from ownership of intellectual property may limit access to new technology that could affect both privateand public-sector innovation if it inhibits the right to use certain technology. Conflicting claims and "reachthrough" patents (in which firms claim ownership to both the upstream and downstream stages of research) may lead to a "tragedy of the anti-commons" in which innovation is delayed or deterred altogether (Heller and Eisenberg). As a result, improved technologies or technologies with public benefits may not be developed.

As we have noted, the empirical record concerning the economic effects of intellectual property protection in general and in agriculture is inconclusive. At the retail level for corn and soybean seed, foundation seed companies generally have access to herbicide-tolerant and Bt technologies through licensing, and thus, even the smallest seed companies can use these technologies if they wish (Duvick, 2000). At the more fundamental research level, however, whether the current intellectual property regime is stimulating or hampering research is unclear.

# Concentration in the Agricultural Input Industry

Antitrust policies generally address excessive market concentration, but several important changes in the agricultural input industry merit attention. Advances in science represented by biotechnology and changes in IPR regimes contribute to varying degrees of concentration in the seed industry, but they are not the only factors. Historical data (tables 10-13) reflect the effects of both IPR and other factors, but these cannot yet be interpreted as indicators of the effects of biotechnology. Soybeans, cotton, and wheat are all self-pollinating crops for which research spending has been a smaller proportion of seed sales than spending for hybrid crops. Each of the three crops, however, has a different history of private-sector involvement in the seed industry's concentration of seed sales. Despite greater market concentration in corn seed, by some accounts, U.S. farmers and consumers have been well served by the

Table 10—U.S. corn seed market shares

Year	Share of seed sales by leading four companies		
	Percent		
1950's	≅ 50		
1973	60		
1980	60		
1991	≅ <b>65</b>		
1997	69		

Sources: Duvick (1998); Hayenga; Butler and Marion.

Table 11—U.S. soybean area market shares

		Share of a	rea planted	
		Public-	Private-	Leading
		sector	sector	four private
Year	Unknown	varieties	varieties	companies
	Percent			
1980 1997	22	70	8	7
estimated <sup>1</sup>	n.a.	10-30	70-90	37-47

n.a. = Not available.

<sup>1</sup>Smaller figure for public sector (and larger figure for private sector) assumes planted areas are roughly proportional to seed sales. Larger figure for public sector (and smaller figure for private sector) assumes most farmer-saved seed is from public-sector varieties. About 25 percent of soybean seed in 1997 was estimated to be farmer-saved.

Sources: Hayenga; Butler and Marion.

Table 12-U.S. cotton seed market shares

	Share of seed sales				
Year	Public- sector varieties	Small private companies	Leading private company		
	Percent				
1970-74	29	42	29		
1975-79	37	25	38		
1980-84	28	25	47		
1985-89	985-89 18		62		
1990-94	90-94 12		82 <sup>1</sup>		
1997	≅ 7	≅ 21	72 <sup>1</sup>		
1998 ≅ 7		≅ <b>22</b>	71 <sup>1</sup>		

<sup>1</sup>Many earlier estimates for 1997 and 1998 assumed Monsanto was the owner of Delta & Pineland, Stoneville, and several smaller cotton seed companies. Monsanto did own Stoneville, but never completed the purchase of Delta & Pineland, which was called off at the end of 1999. Furthermore, Monsanto has divested itself of Stoneville. The 1997 and 1998 figures now give the market share of Delta & Pineland alone. It is also likely that the 1990-94 figure should be reduced somewhat, but the raw data allowing disaggregation are less readily accessible.

Sources: USDA, Agricultural Marketing Service, as reported by Traxler (personal communication); Hayenga.

<sup>&</sup>lt;sup>6</sup>In Hardin's (1968) original "tragedy of the commons," too few property rights led to overuse of a common pool resource. In a "tragedy of the anti-commons," too many property rights may lead to underuse of research resources.

Table 13-U.S. wheat area market shares

	Share of area planted			
		Public-	Private-	Leading
Variety/		sector	sector	four private
year	Unknown	varieties	varieties	companies
	Percent			
Hard Red				
Winter Wh	eat:			
1981	36	58	6	n.a.
1997	n.a	85	15	n.a.
Hard Red				
Spring Wh	neat:			
1981	37	57	7	n.a.
1997	n.a.	85	15	n.a.
Soft Red				
Winter Wh	neat:			
1981	37	63	0	n.a.
1997	n.a.	35	65	n.a.

n.a. = Not available.

Sources: Sears; Butler and Marion.

seed industry, especially when viewed in a world context (Morris). However, some features of current industry organization are new and merit further analysis.

First, the vertical coordination that will become necessary with the introduction of many value-enhanced biotech products is not new within agriculture, but it will involve the seed industry to an unprecedented extent. (Related issues are discussed elsewhere in this publication.)

Second, the seed industry itself may be concentrated at different levels, at different degrees of vertical integration, and in different parts of the market. For example, the corn seed industry could be broken down into trait suppliers, foundation seed suppliers, retail seed suppliers, and distributors. The estimates in table 10 report concentration only at the level of retail seed supply and do not say anything about concentration at other levels or about vertical integration (Goodhue et al.).

Third, antitrust policy in a rapidly evolving industry driven by technical change is still a contentious subject, as recent experience in the software and computer industries indicates.

Fourth, many consumer advocates are uneasy about the domination of agriculture by a few large, international life sciences companies. Finally, the very longrun commitment to agriculture by these life sciences giants may change. Pharmaceuticals and other health-related products are characterized by a high income elasticity of demand, whereas basic agricultural products have relatively limited income elasticities<sup>7</sup> (we are grateful to R. Herdt of the Rockefeller Foundation for this observation). This is one of the reasons for the strong likelihood of success for many value-enhanced products. However, markets for many of these products are likely to be niche markets, which could lead to further industry reorganization. Furthermore, some means will have to be found to continue to direct scientific advancements toward worldwide benefits and to apply new technologies to the production of basic staples (see "Meeting World Food Demand—The Role of Biotechnology" on p. 47).

# **Agricultural Research Policy**

Even though policies are in place to monitor antitrust behavior, public research policy may still need to address implications from the increasing role of the private sector in agricultural research. In response to increased private-sector activity, public research institutions have been directing more resources to research that offers the greatest overall benefit to society and to areas where private incentives are weak. For example, USDA is targeting more resources toward basic science and applied science with a public goods component (National Science Foundation). Public goods include environmental protection, natural resource conservation, and food safety and nutrition. The private sector has little market incentive to conduct this research.

Differences between the public and private sector can be seen specifically in agricultural input research, such as plant breeding. A recent comprehensive survey of plant breeding research in both the public and private sectors showed that USDA's Agricultural Research Service (ARS) concentrates most of its research on long-term pre-breeding activities, while the private sector devotes most of its resources to short-term varietal development (Frey). ARS has terminated most of its research on variety development, preferring to concentrate on areas of research not pursued as intensely by the private sector.

USDA's research agenda has increasingly accounted for private-sector research as ARS sets its research priorities. At the same time, USDA has also sought to

<sup>&</sup>lt;sup>7</sup>Corporate ambiguity about the synergies to be derived from a broad life sciences portfolio is illustrated by the recently announced Novartis/Astra Zeneca and Monsanto/Pharmacia & Upjohn mergers. In both cases, the merged companies intend to spin off or sell some or all of their agribusiness operations.

strengthen research collaborations with the private sector. Joint research with the private sector—for example, patent licensing, research consortia, contracted research, and Cooperative Research and Development Agreements (CRADA's)—can promote the use of public-sector research results, while providing additional resources for public research. USDA uses research collaborations to bring a particular invention or line of research inquiry to the private sector, thus fostering certain types of research. Day-Rubenstein and Fuglie compared public, private, and joint public-private

research, using CRADA's as the measure of joint research. The pattern of research suggests that closer research and development cooperation between USDA and the private sector may have enabled the public sector to focus resources on areas where private incentives for research are relatively weak.

Public research can also foster market competition more directly. One way that public researchers promote market competition is by "inventing around" technologies held by companies. If a critical agricul-

# **Seed Technology**

Genetically modified organisms (GMO's) are mostly characterized by inserting a single new trait into a given crop. Continuing applications will feature "stacked" traits-for example, varieties featuring both the Bt gene and herbicide tolerance. Other genetic technologies, however, are also of scientific interest and have the potential to be applied commercially. For example, scientists would like to understand more about gene interaction and about complex traits that are governed by more than one gene. Two areas of particular interest are control of plant reproduction and inducible traits—that is, traits that can be turned "on" or "off" by human intervention. Apomixis and the Technology Protection System (TPS, popularly known as "terminator" technology) illustrate these lines of research [see boxes, "Seed Technology: Apomixis" and "Seed Technology: The Technology Protection System ('Terminator')"]. Scientists at USDA's Agricultural Research Service (ARS) have contributed to the development of both technologies.

Both apomixis and the TPS technology are being developed with the help of public-sector funding. Both apomixis and TPS allow greater human control over plant reproduction. This control, however, could be put to quite different ends with either of the two technologies. A dramatic difference between the two is that apomixis could

be used to reduce farmers' dependence on seed companies while the TPS could be used to increase their dependence on seed companies.

Apomixis is potentially a much more drastic change than the TPS, as it would imply major changes in both breeding and seed production. The TPS would be unlikely to change the actual processes of breeding and would change seed production very little. Both might imply some changes in farmers' practices, particularly in less industrialized agriculture. At the seed industry level, a feasible apomixis aimed at poor farmers would make those farmers depend more on the providers of apomictic seed. Because in this case financial rewards to the institutions that develop and provide apomictic seed would be relatively low, these providers would likely be in the public sector. Thus, such a strategy would rely on strong support for public-sector plant breeding efforts, which appears to contrast with current trends in plant breeding. One argument in favor of the TPS is the incentives it might create for privatesector investment.

The juxtaposition of the two technologies illustrates one policy issue: Should public funds be used to develop a technology that appears to shift the benefits to the private sector as with the TPS, if, as some argue, apomixis can shift benefits to farmers? At the same time, should a technology such as apomixis be seen as a solution for poor farmers if it is not linked with firm long-term commitments to strong public-sector plant breeding programs directed at their needs?

But there are also other broad similarities between the technologies. Given they both become technically feasible, the probability of their widespread use and the desirability of certain forms of that use are likely to differ between industrialized agriculture and semi-subsistence farming. With either technology, the size of economic benefits and the distribution of those benefits between biotechnology suppliers, seed companies, farmers, and consumers are likely to be determined by both the institutional configuration of the parties generating the technology and the distribution of intellectual property rights.

In a very broad sense, the social benefits of apomixis, the TPS, and other genetic use restriction technologies are likely to be maximized if the technological components are widely accessible at the same time that private companies receive a reasonable return on their research investments (Bicknell and Bicknell). The policies that will lead to these results are currently quite unclear, however, and will doubtless be subject to considerable debate over the years ahead.

tural technology is protected by a patent, for instance, public researchers may work to develop new technologies that perform similar functions. This can limit the effects of a concentrated input market. For example, USDA conducts research on apomixis traits (see boxes, "Seed Technology" and "Seed Technology: Apomixis") (Adams). Apomixis provides a way of circumventing the hybrid barrier and could be a boon for farmers in developing countries who cannot always afford to repurchase seed.

Apomixis, however, could also be useful in seed production, and a number of large companies have shown interest in the technology. For the moment, USDA has decided to develop the technology in-house so that it is more widely available. At the same time, USDA is co-holder of the patent for the technology protection system, known commonly by the derogatory label "terminator," which could be used by seed companies to restrict access to their materials [see boxes, "Seed Technology" and "Seed Technology: The Technology Protection System ('Terminator')"]. These two technologies provide a good illustration of the complexities surrounding public-sector research in an era of rapidly evolving technology.

# **Seed Technology**

#### **Apomixis**

Apomixis is a naturally occurring trait in some plant species. Most plant species reproduce sexually through the fertilization of an egg cell by a pollen cell to form the embryo within a seed. Other plants can reproduce artificially through some method of asexual reproduction, or cloning. Apomictic plants combine the characteristics of reproduction through seed and clonal means. In apomixis, as in cloning, the daughter plant is genetically identical to the mother plant, but reproduction is effected through seed. There are different forms of apomixis, and apomixis and sexual reproduction are not always mutually exclusive within the same species. Except for a few tropical fruit trees or some forage species, very few economically valuable plants are natural apomicts.

If apomixis could be introduced into other crops, it could have many benefits. In crops traditionally propagated through seed, apomixis could lead to faster development of new hybrid varieties; large reductions in costs of hybrid seed production, possibly allowing the profitable production of hybrid seed in crops that currently do not support hybrid technology; and hybrid seed that could be maintained indefinitely by a farmer without losing hybrid vigor (see illustration on next page). In crops

propagated vegetatively, apomixis could reduce the transmission of disease from one generation to the next and make handling of propagation material much easier (Bicknell and Bicknell).

Apomixis could have a few drawbacks. First, it is not universally agreed that apomixis would reduce the cost of breeding, as recombination of genotypes could be considerably more difficult with apomicts. Second, widespread and continuous planting of crop varieties that are genetically uniform could make breakdowns in resistance to diseases and pests more likely. Third, particularly in open-pollinated crops like corn, gene flow from apomictic crops to landraces or wild relatives could result in reductions in genetic diversity and, conceivably, to the development of "super weeds." Fourth, in vegetatively propagated crops, the advantages of apomixis (such as much reduced bulk in propagation materials) might be countered by the disadvantage of longer time in the reproductive cycle if seed were involved.

So far, public-sector research organizations in a number of countries have taken the lead in transferring apomixis to certain crops, although private companies have also researched some of the processes involved in apomixis (see

Bicknell and Bicknell for a partial listing of patents related to apomixis). Scientists at USDA's Agricultural Research Service (ARS) have been particularly active in apomixis research for corn and pearl millet (Becker).

Commercial applicability in any crop may be at least 15 years away. But apomixis poses some interesting issues for both public- and private-sector agricultural research. On the one hand, because rights to many biotechnology techniques, some of which may be necessary for developing apomictic crops, are now held by the private sector, commercial development will proceed faster with private-sector participation. On the other hand, the private sector would clearly wish to develop inducible apomixis—for example, apomixis turned "on" to reduce seed costs but turned "off" after delivery to farmers so that farmers would purchase seed in subsequent years. Even in such a case, some of the benefits of reduced seed costs and other desirable traits fixed in the apomictic crop would probably be shared with farmers and consumers. Clearly, however, the private sector's proportion of the economic gains would be higher than they would be if superior apomictic crops themselves were distributed to farmers.

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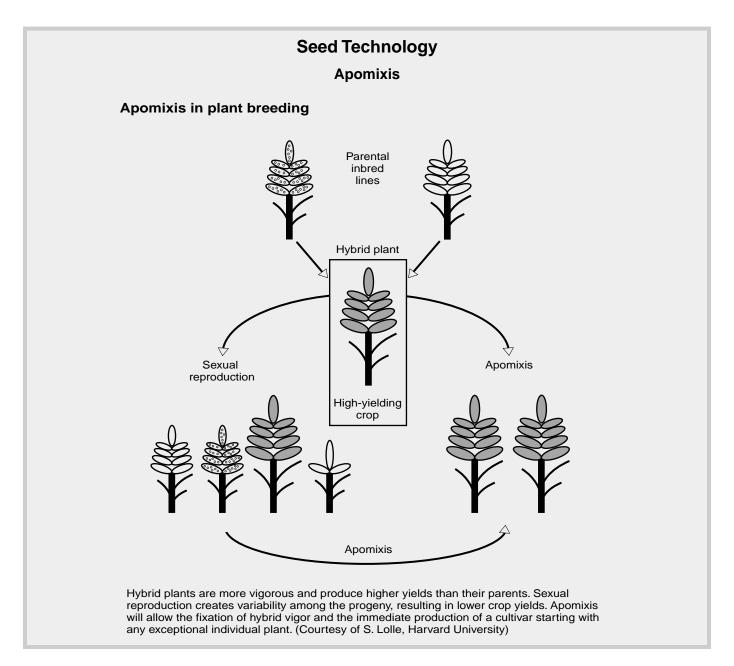
<sup>&</sup>lt;sup>8</sup>In some cases, other private firms would also have incentives to "invent around" a critical patented technology.

Public research can also foster competition by providing competing technologies. In the past, public research has enhanced competition in the agricultural input industry (Ruttan). One example is the hybrid corn industry. Before the 1980's, State agricultural experiment stations and USDA released parent lines of hybrid corn varieties, which benefited small companies that relied heavily on these public-sector lines (Huffman and Evenson; Duvick, 1998). If growing concentration in the input industry were to have negative effects, USDA and other public research entities, such as State agricultural experiment stations, could direct public-sector research in such a way as to encourage competition. Public-sec-

tor institutions must guard, however, against transforming themselves into profit-seeking entities at the expense of conducting more fundamental research that does not have immediate market applicability.

# **Policy Issues**

The debate over IPR, concentration and antitrust, and public agricultural research policy will continue for years to come. Does the current system of patents and plant varietal protection stimulate or hamper the public benefit from private agricultural research? Could welfare-increasing changes be made to this system? How



# Seed Technology

# The Technology Protection System ("Terminator")

Many of the earliest genetically engineered (GE) organisms have been in nonhybrid, self-pollinating crops, such as soybeans and cotton. With these crops, farmers can replant seed from the first-generation crop without losing expected yield, and they still can enjoy the benefits conferred by the transgene. When farmers replant saved seed, however, the total rents obtained by the seed producer are reduced. So far, seed producers have relied on contracts, signed by the farmer and enforced through contract law, to restrict replanting and sale of seed to other farmers. Although, to date, enforcement costs have not appeared to be too high, there have been some widely publicized cases concerning farmers who are suspected of breaking the contract, and enforcement that is considered too harsh may cost seed producers good will in the future. Private biotechnology-related companies, therefore, have begun to develop alternative, technical means of protecting their investments in research.

The best known technology directed at protecting research investment is the Technology Protection System (TPS), which received a U.S. patent in early 1998. The patent is jointly held by USDA's Agricultural Research Service (ARS) and Delta & Pineland, the Nation's dominant cottonseed company. The TPS is a multiple-gene technology. Plants that contain TPS genes can be grown and reproduced normally. However, pretreatment of seeds from a TPS plant with a specific chemical inducer before planting causes that crop to produce seeds that cannot germinate (see illustration on next page). This technology has been highly publicized and has been christened "Terminator" technology by some of its opponents.

The TPS allows production of viable seed, as long as the repressor

gene is active. After the seed is produced, it is treated with the regulator, which inactivates the repressor, and sold to the farmer. The farmer plants the seed, which germinates normally, and the plant is productive. However, seed saved from the farmer's crop will not germinate when planted.

Successful commercial deployment of a TPS-like system may be possible in about 5 years. For one thing, current transgenic technology does not provide very reliable control of introduced gene expression, which means meeting quality control standards of a seed industry is difficult. For example, incompletely expressed genes could result in the producer's seed crop not germinating; on the other hand, poor expression of the recombinase gene could lead to fertility of many seeds sold to farmers, thus, perhaps, defeating the purpose of the TPS (Jefferson et al.). In the latter case, however, even a partially effective TPS could keep farmers from saving seed, particularly in more industrialized agriculture.

These technical difficulties may be greatly reduced. Furthermore, the TPS is only one example of possible technologies for achieving desired fertility or sterility in seed. There are other possible inducible technologies that act on plant traits, and not on the entire plant. In one example, application of a regulator would be necessary for the valueadded trait to be expressed. For example, a corn variety might contain an insect-resistance gene, but this gene would be activated (for example, by spraying the standing crop with an environmentally benign substance such as ethyl alcohol) only in years when insect populations happened to be unusually high. Otherwise, the trait would not be expressed, but the seed would germinate normally. Jefferson et al. describe all these technologies as "genetic use restriction technologies"

(GURT's). They define technologies that act at the level of the entire variety as "V-GURT's," or Variety-Level Genetic Use Restriction Technologies. Technologies that act at the level of an individual trait or traits are "T-GURT's," for Trait-Specific.

These technologies, in particular the TPS technology, have provoked considerable opposition on the part of some nongovernment organizations with interests in agriculture. The technology has been criticized on the grounds that it makes farmers dependent on seed companies, that gene flow from fields planted to TPS seeds could make plants growing in other nearby fields sterile, and that regulator chemicals or antibiotics could have adverse environmental consequences.

The TPS has often been compared with hybridization, another means companies have used for many years to protect their research or seed development investment in certain crops. Hybrids, however, provide a yield advantage to the farmer through the phenomenon of hybrid vigor, and although replanting F1 hybrid seeds results in yield losses, this practice is sometimes used by farmers in developing countries.

The TPS technology in and of itself does not convey an advantage until it is coupled with other desirable traits. This distinction may not be very important in commercialized agriculture, since hybrid vigor in a given crop does not appear to increase over the years, but it is crucial in understanding the relative incentives for the first-time adoption of hybrids or TPS crops. In industrialized agriculture, reducing the cost of producing hybrid seeds might be a more feasible way than the TPS to achieve technical protection of intellectual property for such crops as wheat, where hybrids are very infrequently grown at present.

Continued on next page

# Seed Technology

# The Technology Protection System ("Terminator")

On the other hand, supporters of the TPS argue that it will induce more private-sector investment in crop improvement research, particularly in self-pollinated crops, such as soybeans, cotton, and wheat, or in specialty crops for which planted area is small. Furthermore, the TPS might provide a means to prevent other transgenes from spreading to other plants in wild populations (Radin). In nearly all farming situations, germination is never 100 percent, and it is probably lower when

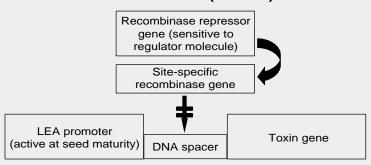
farmers save their own seed. Gene flow from TPS fields is unlikely to reduce germination percentages very much for biological reasons.

In light of the concerns raised about TPS and similar GURT technologies, however, the developers have expressed some desire for further studies of the social and economic implications of their introduction. Monsanto, for example, which had planned to buy Delta & Pineland, stated in early October 1999 that it would not commercialize the

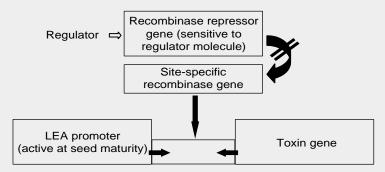
TPS. At the same time, Delta & Pineland announced it would continue to finance TPS research as long as it remained independent. The implications of the recent announcement that Monsanto would not acquire Delta & Pineland are still unclear. In the medium term, the major determinants of the use of GURT technology will probably be the rapidity with which the technologies can be made robust and the value of the traits that are coupled with these technologies in new crop varieties.

## **Technology Protection System**

#### **Elements of TPS (dormant)**



#### **Elements of TPS (activated)**



One basic element of the TPS is a gene that codes for a toxin (several different plant-produced toxins are possible), which works in combination with a LEA (Late Embryo Active) promoter. The promoter is separated from the toxin gene by a DNA spacer; as long as the spacer is present, the toxin gene will not produce the toxin protein. A second element is a site-specific recombinase gene, which, when activated, will code for a recombinase enzyme that will cut the DNA spacer and allow the LEA promoter to cause the toxin gene to work. A third element is a recombinase repressor gene, which is sensitive to a regulator molecule. When the recombinase repressor gene is active, it will not allow the recombinase gene to activate. When the regulator (in the TPS patent, this is an antibiotic) is introduced, the recombinase repressor gene will become inactive; the site-specific recombinase gene will code for the recombinase enzyme, which will, in turn, cut the DNA spacer; and the LEA promoter will be activated. Since the promoter is a "late" promoter, it will be active only at seed maturity, at which time it will produce the toxin that will kill the embryo in the seed, which as a result will not be able to germinate (Jefferson et al.; Crouch).

can IPR and antitrust policies affecting agricultural research best be coordinated? Given the current dynamism and complexity of the agricultural input industries, policies aimed at fostering competition might be directed less at concentration ratios and more at accurately describing relevant markets, identifying key "choke points" in technology flow, and assessing barriers to entry at those choke points.

Public research policy begins with allocating public funds to agricultural research, directing the funds to selected research themes, and choosing institutions to carry out the themes. Many questions can be raised here.

- Is total funding for public-sector research adequate? Is the research portfolio balance of basic and applied research optimal?
- Are current methods of funding agricultural research appropriate? Or would changes, such as more competitive grant funding, be beneficial? On the one hand, more competitive grant funding could lead to better agricultural science through open competition that might attract more than the traditional agricultural science community and through peer review (National Academy of Sciences; Rockefeller Foundation; Alston and Pardey). On the other hand, competitive grant funding in agriculture may direct resources toward flashy, shortrun projects at the expense of research requiring steady effort over many years. In addition, competitive grant funding has resulted in an inordinate amount of scientists' time being spent in writing proposals (Buttel; Just and Huffman; Huffman and Just, 1994, 1999).
- Is the current public-sector institutional configuration—research conducted by State agricultural experiment stations and USDA—suitable? Or would different arrangements, such as regional research coordinated by State agricultural experiment stations or agriculturally oriented research performed by basic science departments in nonland-grant universities, bring benefits?
- Is the prospect of addressing issues of competition through research policy—for example,
   "inventing around" patents—feasible? Or would correctly allocating research resources and addressing concentration issues primarily through antitrust policy better serve the public? In this, as in other areas of research policy, there are argu-

ments on both sides of the issue. On the one hand, to be able to "invent around" crucial technology bottlenecks, the public sector might need to be more nimble and familiar with cutting-edge technology than it has been accustomed to. On the other hand, antitrust policy is, in essence, reactive and does little to stimulate new research.

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# **Public Policy Considerations**

# Meeting World Food Demand The Role of Biotechnology

### Issue

Discussions on how science can be used to increase the world's food supply often focus on biotechnology as the key to rapid expansion (Mann, 1999a; National Academy of Sciences). Critics argue that biotechnology could export environmental problems to developing countries or put small farmers in developing countries at the mercy of large corporations. What is the potential for biotechnology to increase the world's food supply? How will biotechnology affect farmers and consumers in developing countries?

#### Context

World food demand grew at historically unprecedented rates over four decades from about 1950 to about 1990. Although this growth in consumption is slowing, population and income growth will continue to drive food demand higher. By far, the largest part of increased food demand will come from developing countries. Increases in income will also result in a shift in food composition—for example, toward greater consumption of livestock products.

By 2020, in one simple comparison, world demand for cereals is projected to be some 40 percent higher than it is today (Rosegrant, Agcaoili-Sombilla, and Perez; Pinstrup-Andersen, Pandya-Lorch, and Rosegrant). This increased demand will have to be met from a nearly constant land base, and at the same time, it is highly desirable that agricultural production not lead to environmental degradation (see box, "World Food Demand: Medium-Term Prospects"). In all countries, developing or developed, trade could become an even more important option in satisfying local food demand than it is today.

# Challenges in Applying Biotechnology to Global Food Problems

# Technical Options for Increasing Yields and the Role of Biotechnology

Increased yields through improved plant cultivars can be attained in two ways: increased yield at the fundamental physiological level, and improved response to stress, which reduces the gap between realized yields and the yield frontier. In essence, the higher physiological yield shifts the yield frontier, and maximum yield, upward. Improved stress response increases mean yields by raising the lower part of the yield distribution.

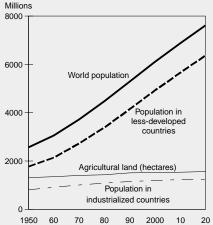
Most near-term biotechnology options to address problems of food production in developing countries involve better stress resistance or stress tolerance. Many presentations from the biotechnology industry provide fairly generic overviews of the three projected phases of biotechnology deployment—agronomic traits, value-enhanced products, and nutraceuticalswith some emphasis on agronomic traits and nutrientenriched crops (see Kishore and Shewmaker, for example). Agronomic traits, such as resistance to pests and diseases, drought tolerance, tolerance to aluminum toxicity, and tolerance to salinity, could be addressed through genetic engineering and other biotechnology techniques, such as using molecular markers and tissue culture to facilitate the transfer of desirable alleles from wild relatives to cultivated plants. This research could have obvious benefits in developing countries.

Some scientists, however, such as Thomas Sinclair of USDA's Agricultural Research Service (ARS), point out that yield potential, or maximum possible crop yield, "is limited by the physics of intercepting photons and capturing carbon dioxide, the biochemistry of photosynthesis and the physiology of nutrient uptake

# World Food Demand **Medium-Term Prospects**

Although the world population continues to grow, world agricultural land has expanded at a much slower rate (fig. A). Furthermore, food demand is projected to grow at a faster rate than population growth, as income growth contributes to growth in demand as well. Rising incomes can also lead to a

Figure A World population growth, population projections, and agricultural land



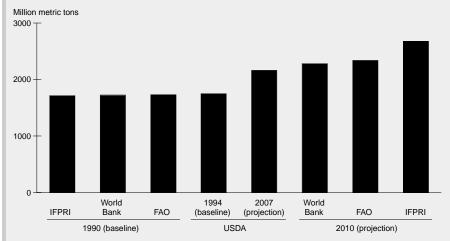
Sources: U.S. Bureau of the Census; IFPRI (Rosegrant, Agcaoili-Sombilla, and Perez); FAO (Alexandratos).

change in dietary composition, with, for example, greater demand for livestock products. Over the next 20 years, population is projected to grow at about 1.1 percent annually, and demand for cereals is estimated to grow between 1.4 percent and 1.6 percent annually (fig. B).

Both per capita food and feed demand are forecast to increase in most developed countries in the near term, while feed demand is expected to shrink in the transitional economies of Eastern Europe and the former Soviet Union (fig. C). Total per capita food demand will remain fairly steady in developing countries, but per capita feed demand will increase. Although the absolute amount of this increase is relatively small, in percentage terms, it is much larger than the growth in food or feed per capita demand in developed countries. All in all, around 80 percent of the near-term increase in cereals demand is expected to come from developing countries: Over 50 percent due to population growth, 20 percent due to increased per capita feed demand, and a small amount due to the interaction of these two factors.

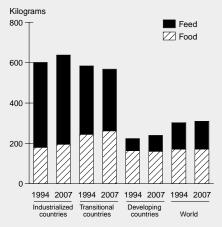
Agricultural land, on the other hand, has been growing only at less than 0.3 percent annually; there are relatively few areas in the world where relatively high-quality land lies unexploited. As a result, it is clear that increasing crop yields must be the primary means by which food supply is increased to meet demand at the same time that real food prices remain stable or continue their historical downward trend. Although these yield increases will be less than those of the last few decades, they pose a considerable challenge to agricultural researchers and the agricultural input industry. First, over the last decades, higher rates of fertilizer application and expanded irrigated area contributed a great deal to increased crop yields. Over the coming years, expansion of fertilizer consumption and irrigated area is expected to be much slower. Second, renewed appreciation for the environmental services consumed by agricultural production means that it is highly desirable that expanded agricultural production not come at the cost of damage to the natural resource base.

Figure B Baseline and projected world cereals demand



Sources: IFPRI (Rosegrant, Agcaoili-Sombilla, and Perez); World Bank (Mitchell, Ingco, and Duncan); FAO (Alexandratos): USDA, ERS.

Figure C World per capita cereal consumption, 1994 and 2007



Source: Calculated from ERS data, Market and Trade Economy Division, Economic Research Service, USDA, 1998.

and utilization" (Fedoroff and Cohen). In the longer term, biotechnology may contribute to increasing world food supplies by manipulation of multiple genes to alter such basic processes as photosynthesis (Mann, 1999b). At present, this appears to be a very long-term goal.

# Alternatives to Crop Improvement for Increasing Yields

Other observers suggest that, as long as crop yields in some parts of the world remain well below potential yields, crop improvement, where biotechnology could make an immediate contribution, may not be the major means of increasing the world's food supply. Alternatives include precision crop management (Cassman), including integrated pest management (Thomas), and reducing losses in post-harvest storage and distribution (Fedoroff and Cohen). A key question is how to raise yields in parts of the world—for example, in some regions in sub-Saharan Africa, that have been relatively unaffected by pre-biotechnology yield-increasing techniques that are in wider use elsewhere.

# Intellectual Property Rights, the Private Sector, and Biotechnology Applications in Developing Countries

Commercial application of biotechnology has taken place primarily in the United States, to date, and primarily through the private sector. How can biotechnology be brought to bear on the agronomic and nutritional problems of developing countries? Dating at least to Griliches, it has been recognized that key determinants of the private sector's decision to invest in agricultural research are the perceived size of the market and the ability to reduce transaction costs when farms are larger. Both developing-country markets and farms, in many instances, are small.<sup>9</sup>

Lack of intellectual property protection could make private companies less willing to invest in developing countries. Indeed, in developing countries with more advanced scientific capabilities, piracy rather than market transfer might be an alternative means of biotechnology acquisition (Tarvydas et al.). The Technology Protection System (see box on p. 42), or lower cost hybridization methods, could increase incentives for private companies to invest in research for self-pollinating crops like wheat, where the ability

of farmers to replant saved seed without yield loss has meant that private firms capture a relatively low proportion of the benefits from research.

Unless research and seed delivery institutions are redesigned, however, it is unclear that strengthened property rights in plant breeding products is likely to lead to substantially greater private-sector investment in research for crop production in developing countries, particularly for staple foods. Consider the prebiotechnology record of adopting improved varieties in developing countries. In maize, as corn is known worldwide, hybridization allows "trade secret" protection, and thus greater incentives for private research. Yet only 45 percent of area in developing countries is planted to hybrids, and 40 percent is planted to unimproved materials. Excluding China, Brazil, Argentina, and South Africa, only 20 percent of the maize area is planted to hybrids and 60 percent is planted to unimproved materials. 10 In contrast, improvements in wheat and rice in developing countries have relied primarily on public-sector breeding and farmer-to-farmer seed diffusion. In these crops, at least 75-80 percent of the total area is planted to semidwarf or hybrid varieties (fig. 4).

Furthermore, historical experience with adoption of "green revolution" wheat and rice in developing countries and, for that matter, hybrid maize in the United States suggests certain rules of thumb for widespread adoption of new yield-increasing technology. In relatively low-yielding environments, rapid diffusion is usually stimulated by yield increases of at least 15-20 percent over farmers' varieties, coupled with seed prices that are no more than 5-10 times the price the farmer receives for grain. Whether or not private companies can package enough traits to create this kind of yield advantage at these seed-grain price ratios is unclear. It appears more likely that initial applications of biotechnology in developing countries will be confined to countries with more commercialized agriculture (for example, Argentina and Brazil), higher current yields, or certain specialty crops. Consumer acceptance of genetically modified crops, in trading partners or domestically, is likely to be a major determinant of the use of biotechnology in these countries in the short run, just as it is in large, industrialized agricultural producers like the United States.

<sup>&</sup>lt;sup>9</sup>Some examples from developing countries demonstrate that the obstacle of small farm size is not insurmountable, if other conditions favor small-farm use of such purchased inputs as seed.

<sup>&</sup>lt;sup>10</sup>In these countries, maize is primarily planted by large-scale farms, planted in temperate growing areas, or both. Temperate maize growing areas can benefit much more readily from research spill-ins from the United States.

#### Other Issues Facing Developing Countries

Developing countries may find gaining access to biotechnology difficult because of insufficient numbers of trained resources. In countries with severe resource constraints, the allocation of training across a large number of apparently high-priority areas, and the assurance that sufficient resources are working productively within these countries, are difficult issues to resolve.

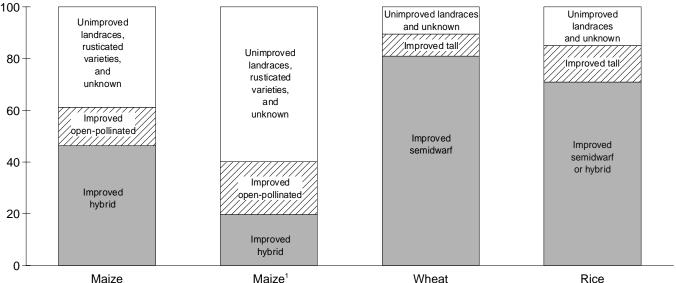
As in industrialized countries, biotechnology might not be universally accepted. Environmental and food safety concerns might play a role in developing countries, although these concerns are likely to have different dimensions than in industrialized nations (see "Consumer Acceptance" on page 28). For example, regulatory systems in developing countries are generally far less mature than in developed countries. Relatively rich developing countries that are major agricultural exporters, like Argentina and Brazil, might face the same questions of access to European markets as does the United States. Another concern, particularly relevant in poorer countries, is that small farms could become increasingly dependent on large corporations and lose many of their genetic resources.

Advances in agricultural biotechnology, particularly in developed countries, may have additional impacts on trade with developing nations. First, biotechnology-derived substitutes for commodities traditionally exported from developing countries may lower incomes in these developing countries. Second, as in the case of any technology that shifts supply out in one region but not another, producers in nonadopting regions or countries may be hurt as prices fall. To the extent that biotechnology and other agricultural technologies improve productivity in developing countries, this tendency could be counteracted.

# **Policy Issues**

In short, biotechnology is likely to be a major option for meeting increased world food demand over the next several decades, but it is not the only one (Weeks and others; Persley and Lantin). What is the appropriate role of biotechnology in the research portfolios of international and national public-sector research programs directed at developing countries? How can scientific capacity in these countries be increased? On the one hand, given the resources and experience of large private-sector life sciences firms, it is unlikely that many biotechnology options will be developed fully without the





<sup>1</sup>Excluding China, Brazil, Argentina, and South Africa. Source: CIMMYT; Morris and Heisey; Heisey, Lantican, and Dubin; Pingali and Smale. participation of these companies. On the other hand, present incentives for private investment are unlikely to direct large-scale resources toward solving many problems in developing countries. How can institutions be redesigned to allow access to knowledge and technologies in the private sector to benefit the international public? What intellectual property arrangements and regulatory mechanisms will be most successful in harnessing private-sector research for the purpose of real increases in the world's food supply? How can possible adverse trade-mediated biotechnology impacts on developing countries be mitigated?

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## Conclusion

We have identified several key areas—agricultural research policy, production and marketing, consumer issues, environmental safety, and future world food demand—where agricultural biotechnology is dramatically changing the public policy agenda. The current situation is extremely fluid, with the day's headlines, rather than the underlying issues, often dominating discussion. Public policy is made more difficult by the fact that, in essence, "agricultural biotechnology" encompasses multiple policy objectives targeted by multiple policy instruments.

For example, public research funding, the intellectual property regime, and antitrust policy particularly influence the speed and direction of agricultural research. Intellectual property policy and antitrust policy, as well as regulation, including the system of grades and stan-

dards for agricultural commodities, affect agricultural production and marketing. Regulation, along with public collection and dissemination of information on risk, plays a role in food safety and environmental issues.

Public policy becomes even more complicated when international jurisdictions are involved, whether the subject is U.S. exports of biotech crops to traditional markets, such as the EU, or the potential benefits and risks of biotechnology in developing countries. The development of appropriate policies requires the participation of all interested parties, including consumers, producers, agricultural input firms, firms at various points in the marketing channels, and government. Markets will indeed determine the future of agricultural biotechnology, but it is important to remember that these markets will always function in the context of the policy issues and policy alternatives discussed in this document.