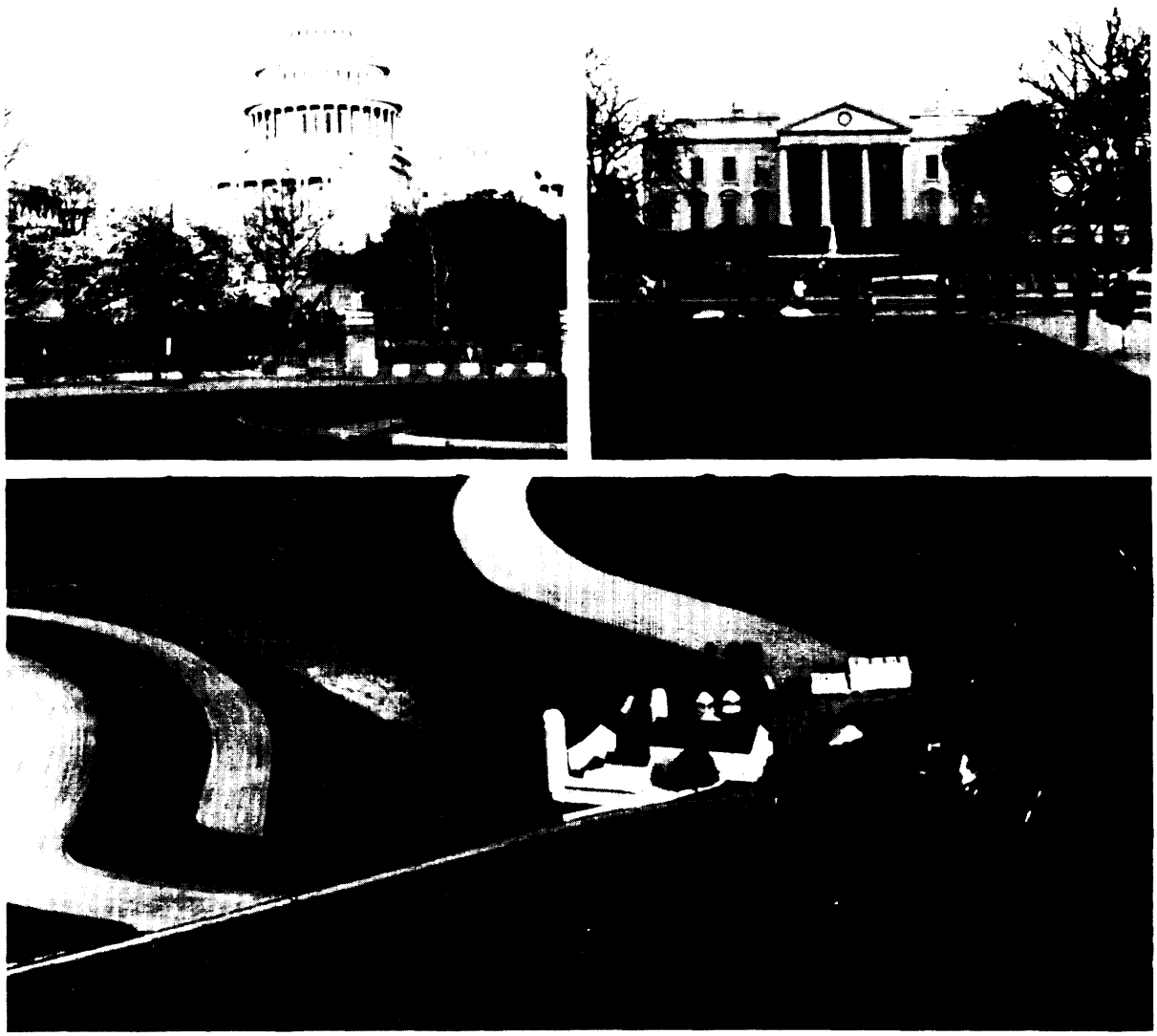
Chapter 1

Overview and Summary



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Overview and Summary

Technological innovation has played a significant role in transforming American agriculture in the past and again promises major impacts on the U.S. food production and processing industries. The transition from horsepower to mechanical power (1920– 1950) boosted the productive capacity of agriculture even as farm labor requirements decreased dramatically. From 1950 to 1980 agricultural productivity rose further as chemical fertilizers, feed additives, and pesticides increased yields and helped farmers control pests and disease. Biotechnology and advanced computer systems now are ushering American agriculture into a new technological era. These technologies have the potential to increase U.S. agricultural productivity and competitiveness, enhance the environment, and improve food safety and quality.

Many of the new technologies will be commercially viable in the 1990s. However, they will not automatically be put to use. Today's public increasingly questions whether technological change is always good or needed and is voicing new concerns about the safety of the food supply, the environment, and the changing structure of agriculture. These issues as well as declining public confidence in institutions create an atmosphere in which agricultural biotechnology may not readily be approved for commercial use or adopted by industry. Lack of public acceptance could prevent some technologies from being used even if they are approved by regulatory agencies. To avoid this fate, agricultural biotechnology must meet rigorous scientific standards of safety and efficacy. And, institutions regulating these products must satisfy unprecedented demands for accountability.

This report focuses on the new technologies for agriculture and the related issues that policy makers most likely will face during this decade. Part I identifies advances being made in agricultural biotechnology for crops, animals, and food processing, and in computer technologies to improve agricultural management. Part 11 analyzes ways in which these technologies might improve agricultural productivity and discusses certain adjustments that industry will need to make to capitalize on this potential. Part 111 considers scientific and institutional issues relevant to environmental benefit and risk assessment of biotechnology. Part IV focuses on food safety and quality issues, presenting institutional, scientific, and public perspectives on these issues. Finally, Part V analyzes some of the implications of the technologies for intellectual property rights and science policy.

ADVANCING TECHNOLOGIES FOR AGRICULTURE

Biotechnology

Biotechnology, broadly defined, includes any technique that uses living organisms or processes to make or modify products, to improve plants or animals. or to develop microorganisms for specific uses. It rests on two powerful molecular genetic tools: recombinant deoxyribonucleic acid (rDNA); and cell fusion technologies. Using these techniques, scientists can isolate. clone, and study the structure of an individual gene and explore the gene's function. Such knowledge and skills allow scientists to exercise new control over biological systems, leading to significant improvements in agricultural plants and animals.

Plant Technologies

Each year in the United States, weeds, insects, and disease (as well as weather and soil conditions) significantly decrease potential crop yields and cost farmers billions of dollars in lost revenues. New approaches to control pests include the use of biological agents to manage pests and the application of biotechnology to produce plants with new genetic characteristics.

Biological control of pests is the use of living natural enemies to reduce pest populations to levels lower than would otherwise occur. The classical (searching native lands for control agents to pests of foreign origin) and augmentation (periodic release of control agents to increase populations) approaches are the most commonly used biological control tactics. To date, biological control has been most successfully used in orchards and vegetables; efficacy in field crops has been 'limited. Insect and weed control using biological control agents has been most successful; use of biological agents to control disease is lagging. Traditional selection and breeding approaches, as well as new biotechnology approaches are being used to improve the control and range of biological control agents. Several biocontrol agents currently are available or could be in the next 10 years, but the field is not sufficiently advanced to replace most pesticides in that time.

New tissue culturing and genetic engineering tools combined with traditional agricultural research methods are allowing scientists to alter plants to have greater dis-

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

Genetic Engineering of Plants for Insect Control— Traditional breeding programs have and will continue to produce insect-resistant or insect-tolerant varieties of crops. However, the tools of biotechnology can be used to selectively engineer plants for this trait. Candidate genes must code for proteins that are stable in the plant cell and insect midgut; have high activity against target insects; and are safe for non-target invertebrates and animals. Genes coding for trypsin inhibitors and for bacterial Bacillus thuringiensis (Bt) toxin are two possible candidates. The gene coding for the Bt toxin has been cloned and inserted into plants; transgenic plants producing Bt toxins are expected to be commercially available by the mid to late 1990s.

Genetic Engineering of Plants for Weed Control— Improved understanding of the mechanisms of action of herbicides is leading to the improved ability to design herbicides effective against some plants (target weeds) but inactive against others (nontarget weeds or crops). The lack of naturally occurring resistance genes in crops limits the ability to use traditional breeding methods to develop herbicide tolerant crops; however genetic engineering techniques can overcome these constraints. The first herbicide tolerant crops are expected to be available commercially by the mid 1990s.

Photo credit: Richard Nelson, Samual Roberts Noble Foundation

Transgenic tomato plant expressing the coat protein gene of tobacco mosaic virus (left) and control plant (right).

Genetic Engineering of Plants for Disease Control— Biotechnology is being used to elucidate the mechanisms by which pathogenic organisms cause disease and to engineer plants with enhanced disease resistance. Genes coding for virus coat proteins (i. e., the proteins that make up the shell that surrounds viruses) can be genetically engineered into plants to elicit resistance to infection by the source virus, and in some cases to related viruses having similar coat proteins. Several plant viral coat proteins have been transferred to plants to confer resistance.

Genetically engineered dicotyledonous plants resistant to certain viruses are expected to be available commercially by the mid 1990s. But virus resistant monocotyledonous plants will probably not be available until the late 1990s or early 21st century. Plants resistant to bacteria and fungi are not expected to be developed until the end of the decade and not available commercially until after the year 2000.

Animal Technologies

Biotechnology has the potential to improve feed efficiency, reduce losses from disease, and increase reproductive success in all sectors of the livestock industry. Advances in growth promotants, reproductive technologies, and animal health will play a major role in enhancing the efficiency of animal agriculture and the quality of its products.

Growth Promotants-Currently used growth promotants such as anabolic steroids and antimicrobial compounds will continue to be used in the livestock sector. However, rDNA techniques are being used to produce new products such as a new class of protein hormones called somatotropins.

Porcine Somatotropin—Pigs administered porcine somatotropin (pST) for a period of 30 to 77 days show increased average daily weight gains of approximately 10 to 20 percent, improved feed efficiency of 15 to 35 percent, decreased adipose (fat) tissue mass and lipid formation rates of as much as 50 to 80 percent, and concurrently increased protein deposition of as much as 50 percent without adversely affecting the quality of the meat. Prolonged release formulations and daily injection produced similar growth rates and feed efficiencies. PST is currently being reviewed by Food and Drug Administration (FDA) for commercial use.

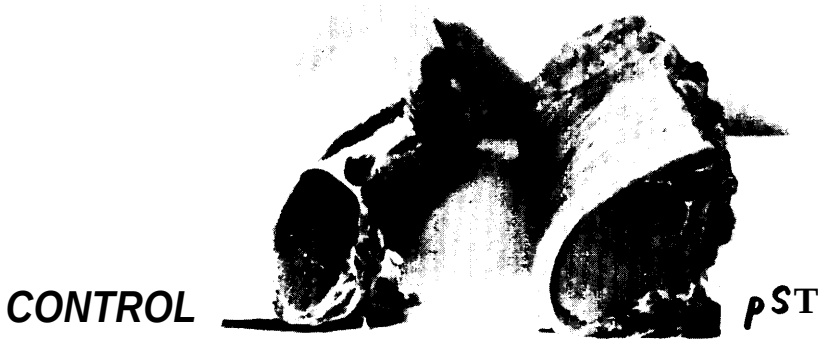


Photo credit: Terry Etherton, Pennsylvania State *University*

Comparison of pork loins that show the effect of pigs treated with porcine somatotropin (pST). The loin-eye area of the loin treated with pST is *8* square inches; the control is *4.5* square inches.

Bovine Somarotropin—Bovine somatotropin (bST) is currently undergoing FDA review for use in lactating dairy cows to increase milk production. While individual gains rely on the management ability of the producer, on average, gains of about 12 percent are reasonable. Bovine somatotropin does not alter the composition of milk. The fat, glucose, protein, mineral, and vitamin composition of milk fall within the range of values normally observed in milk from cows not supplemented with bST. Bovine somatotropin decreases pregnancy rates (proportion of cows becoming pregnant), increases days open (days from parturition to conception), but does not alter conception rates (services per conception). These observed effects are similar to those occurring in high-producing cows that do not receive bST. Implications of using bST in dairy production are discussed more thoroughly in the OTA publication U.S. *Dairy Industry at a Crossroad: Biotechnology and Policy Choices.*

Reproduction Technologies—The field of animal reproduction is undergoing a scientific revolution. For example, in the cattle industry it has become possible to induce genetically y superior females to shed large numbers of eggs (superovulation); and to fertilize these eggs in vitro with the sperm of genetically superior males. Each resulting embryo can then be sexed and split to produce multiple copies of the original embryo. Each of these new embryos can then be frozen for later use, or transferred to a recipient cow whose reproductive cycle has been synchronized to accept the developing embryo. The recipient cow carries the embryo to term and gives birth to a live calf. It may be possible in the near future to sex the sperm rather than the embryo, and to create more copies of each embryo than currently is possible. New techniques being developed will make it easier to insert new genes into the embryos to produce transgenic animals. Embryos produced by new reproductive methods are being marketed, although as yet no transgenic animals are available.

Transgenic Animals—The combination of new reproductive technologies with recombinant DNA technologies (the identification. isolation, and transfer of selected genes), provides opportunities to produce transgenic animals efficiently and cost effectively, and to improve livestock quality more rapidly than could be done with traditional breeding. Some transgenic livestock may contain genes that improve growth characteristics or resistance to disease. These new developments also have human medical implications. It may be feasible to produce important human pharmaceuticals in livestock. Transgenic animals can also serve as a powerful research tool to understand genetic and physiological functions, and to provide a model system to study human disease. For example, pigs display striking physiological similarities to humans and because of this, transgenic pigs are currently being developed to serve as a model system to understand and treat gastrointestinal cancers. Commercial availability of transgenic animals is not expected before the year 2000.

Animal Health Technologies—improvements in animal health will lead to considerable cost savings to the animal industry. Biotechnology rapidly is acquiring a prominent place in veterinary medical research. New vaccines include those created by deleting or inactivating

the genes in a pathogen that cause disease. The first gene-deletion viral vaccine to be approved and released for commercial use was the pseudorabies virus vaccine for swine.

Many currently used diagnostics tests are costly, time consuming, and labor intensive, and some still require the use of animal assay systems. Monoclinal antibodies and nucleic acid hybridization probes can be used to produce simpler, easily automated, and highly sensitive and specific diagnostic procedures. At least 15 different rapid diagnostic tests based on monoclinal antibodies are on the market or soon will be.

Food Processing Technologies

Historically, the food processing industry has had to accept and adapt to heterogeneous raw materials. Biotechnology can be used to tailor food crops to meet food processing and consumer needs. For example, new plant tissue culture techniques can be used to produce food flavor and coloring ingredients. These methods potentially could replace production and extraction of these ingredients from plants.

Genetic engineering can also be used to alter food characteristics. Genes coding for enzymes involved in starch and lipid biosynthesis are being isolated and cloned, enhancing the prospects of engineering plants with specific compositions of starch and oil. And, genetic engineering is being used to eliminate toxins, allergic compounds, or off-flavor components in plants, and to delay ripening of tomatoes.

New biotechnology products are being developed for food manufacturing and monitoring of animal products for food safety. For example, a genetically engineered version of the enzyme rennet, which is normally extracted from the forestomach of calves, has recently been approved by FDA for use in cheese manufacturing systems. Bacteria and yeast strains engineered to convert waste products such as blood, bone, and milk whey into useful products could decrease the costs associated with their disposal. For example, engineered yeast strains are capable of fermenting the lactose in whey to value-added products, such as vitamin C, biofuels, or pharmaceuticals. Food safety monitoring will be enhanced by the development of nucleic acid probes and monoclinal antibodies; raw materials, ingredients, and finished products can be analyzed for the presence of pathogenic organisms and chemical and biological contaminants. Detection kits are also commercially available for monitoring several pesticides, antibiotics, and bacterial contaminants.

Advanced Computer Technologies

Since the industrial revolution, agricultural systems have intensified, and agricultural productivity has increased significantly along with farm size. Labor-saving devices on farms have increased output per worker several fold, and advances in understanding and application of biological principles have boosted agricultural yields significantly. With increased production, however, farm management becomes correspondingly more challenging and complex. In general, methods for making management decisions have failed to meet this challenge. As a

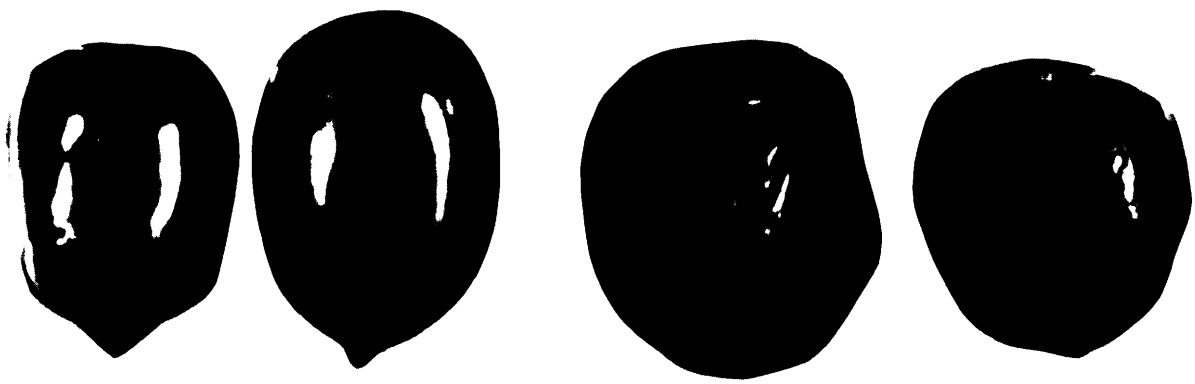


Photo credit: Calgene, Inc

Tomatoes with genes that delay ripening (left) and control (right) 3 weeks after harvest.

result, many decisions are ''uninformed' and many agricultural systems poorly managed.

The application of advanced computer technologies to agricultural management can help remedy this situation. Improved access to information will allow farmers to monitor progress more effectively and to determine suboptimal performance. For example, close monitoring of animal performance will allow early detection of diseases and can help reduce stress in animals.

Overall, advanced computer technologies can provide managers with the ability to systematically determine the best decision rather than arrive at decisions in an ad hoc fashion. Optimal decision making requires a holistic view of a farm enterprise, factors that affect it, and probable consequences of management decisions. Thus, a farmer deciding whether to plant a specific crop on a specific field should weigh the profitability of the crop as well as overall farm needs (e. g., nutrition requirements if it is an animal enterprise). The decision will impact land sustainability and the need to use certain pest-control strategies.

By-and-large, computers have had little impact on production agriculture to date. Predictions that every farmer would own a computer by 1990 have not come true. Few farmers have computers and those that do use them primarily for book keeping and general calculations (e. g., ration balancing).

The largest impact of computers in American agriculture has been in support industries. Using computer networks and tracking systems, equipment dealers can provide faster service, and feed dealers are better able to manage feed inventories. Most of these advances have come from directly adopting general business software with little or no input from the agricultural academic community.

The primary agricultural application of advanced computer technology by the mid - 1990s will be ad hoc expert systems (i.e., computer programs that use knowledge to solve well-defined problems). Problem diagnosis expert systems currently are under development, and farmers will have a cadre of these systems at their disposal to diagnose diseases and to evaluate production performance. These systems generally will not be integrated with one another and each will consider only one aspect of a problem. Integrated systems that solve production problems while considering economic consequences will not become available until the later part of the decade.

The primary use of expert systems within the next 5 years may be by agribusiness which will be able to leverage the cost of adopting these technologies across a number of farms. Using expert systems to increase service to farmers may change the role of some professionals. For example, expert systems can help veterinarians take an epidemiological approach to solving problems. It will also allow some diversification in services provided. For example, animal nutritionists may be more likely to become involved in consulting for the crop program when aided by an expert system.

Photo credit: U.S. Department of Agriculture, Agricultural Research Service

Farmer and consultant examine data from COMAX (COtton Management eXpert) computer program.

Computer-based sensors will be used on a limited basis to collect real-time data for expert systems. The primary use of sensors will be for monitoring weather and field conditions for crop management. Expert systems will help farmers interpret these data and suggest appropriate management strategies such as irrigation, fertilization, or pesticide treatment.

Another technology likely to see application by the mid- 1990s is full-text retrieval systems. It will be possible for farmers and Extension personnel to have a CD-ROM with all of the latest publications at their fingertips. Using a full-text retrieval system, they will be able to retrieve pertinent information that will help them improve their decisions. For example, when a farm experiences a corn mycotoxin problem, the owner-operator can access an information base to find relevant literature.

Robots for highly specialized, labor-intensive tasks will begin to be applied to agriculture in the late 1990s. This would include robot transplanting of seedlings, pork carcass sectioning, and harvesting of fruits and vegeta-

Photo credit: Gerald Isaacs, University of Florida

An experimental fruit picking robot uses a machine sensor and a computer to locate individual fruit for detachment. Approximately 3 seconds per fruit 'are required.

bles. Robots for milking cows, however, may reach commercial application by the mid-1990s.

IMPACTS OF THE NEW TECHNOLOGIES

The new era of biotechnology and advanced computer technologies will be faster paced than previous technological eras. A more rapid pace of technological change will be fostered by major changes in public policy regarding technology. One of the most important changes was the granting of property rights for new plant varieties, new life forms, and computer software. Patent rights were extended to new plant varieties by the enactment of the Plant Variety Protection Act of 1970. This was followed in 1980 by the U.S. Supreme Court ruling in *Diamond vs. Chakrabarty'* that investors in new microorganisms, whose inventions otherwise met the legal requirements for obtaining a patent, could not be denied a patent solely because the innovation was alive. This decision opened the door to patent a broad range of potential new products of the biotechnology era. Capping this series of policy changes was the amendment to the Copyright Act in 1980 that made explicit provisions for computer programs as (literary) works of authorship.

In previous technological eras most technologies were capital intensive and substituted for labor and land. Many emerging biotechnologies will substitute for conventional purchased inputs. For example, biopesticides will replace some chemical pesticides in plant insect control, biotechnology-improved animal disease vaccines likewise will replace some existing vaccines. On the other hand, some biotechnologies will compliment existing technologies. An example is the genetic transformation of plants to incorporate desired traits. In this case, conventional plant breeding will still be required for incorporation of biotechnology-induced traits into commercial lines, for continued plant improvement selection, and for seed multiplication. In addition, for the foreseeable future, chemical fertilizers will remain important in crop production.

As with past technological eras, successful adoption of specific biotechnology innovations will result in additional profits for some, at least the early adopters. As in the past, increased profits will result mainly from reductions in real production costs per unit of output. This, in turn, can increase productivity and the competitive position of U.S. agriculture.

As with past technological innovation, biotechnology is expected to be supply-increasing in the aggregate. The implications, however, can be quite different for different farms. Late adopters of the new technology, for example, will be faced with lower product prices. This is because early adopters have already reduced their production costs, enjoyed increased profits in their period of initial adoption, and are ready to respond to the next wave of technological innovation. Increased supplies are generally associated with lower prices. Consequently, nonadopters often have higher costs while facing lower prices for their products.

Successful use of technologies of this new era most likely will require changes in the production process and may require a higher quality of management. This may mean increased human as well as monetary capital. Less educated farmers with limited capital resources may find it difficult to implement the new technology successfully. Thus, the new technologies may widen the gap between capital-limited and capital-rich farm operators.

Many advancing technologies are approaching commercialization. In crop agriculture, biotechnology research has advanced at a much faster rate than anticipated just a few years ago, and transgenic crops are currently undergoing field trials. in animal agriculture, vaccines and diagnostics are on the market or will be soon. Growth promotants are going through the regulatory process. Reproduction technologies are advancing at a rapid pace and cloned embryos are currently being marketed. Transgenics are still in the future but considerable strides are being made in the use of livestock to produce high value pharmaceuticals. These technologies and others will impact agriculture in a number of ways.

Table l-l—Estimates of Crop Yield and Animal Production Efficiency by 2000

	Actual 1990	Less new technology 2000	Most likely technology 2000	More new technology 2000
Crops				
Corn—bu/acre	116.2	113.8	128.5	141.6
Cotton-lb/acre	600.0	NA	708.0	NA
Soybeans—bu/acre	32.4	32.6	33.7	36.4
Wheat—bu/acre	34.8	37.7	42.6	53.8
Beef				
Lbs meat/lb feed	0.143	0.146	0.154	0.169
Calves/100 cows	90.0	93.750	96,221	102.455
Dairy				
Lbs milk/lb feed	1.010	1.030	1.050	1.057
Lbs milk/cow/year	14,200.0	17,247.200	19,191.600	20,498.800
Poultry				
Lbs meat/lb feed	0.370	0.373	0.389	*0.428*
Eggs/layer/year	250,0	250.500	258.0	*273.125*
Swine				
Lbs meat/lb feed	0.154	0.174	0.181	0.196
Pigs/sow/year	13.900	14.420	15.750	17.791

NOTE: OTA expresses its appreciatio nto Yao-chi Lu and Phil Coiling, Agriculture Research Service, U.S. Department of Agriculture, for their assistance in deriving the estimates for this table,

NA = Not available.

SOURCE: Office of Technology Assessment, 1992,

Table I-2—Projected Annual Rates of Growth (1990-2000)

	Less new technology	Most likely technology	More new technology
Corn	– 0.210/0	1.000%	1.97%
Cotton	NA	1.66	NA
Soybeans	0.06	0.39	1.16
Wheat	0.80	2.02	4.36
Beef			
Lbs meat/feed	0.21	0.74	1.67
Calves/cow.	0.41	0.67	1.30
Dairy			
Lbs milk/feed	0.20	0.39	0.46
Milk/cow/year.	1.94	3.01	3.67
Poultry			
Lbs meat/feed	0.08	0.51	1.46
Eggs/lay/year.	0.02	0.32	0.89
Swine			
Lbs meat/feed	1.22	1.62	2.41
Pigs/sow/year.	0.37	1.25	2.47

NOTE: OTA expresses its appreciation to Yao-chi Lu and Phil Coiling, Agriculture Research Service, U.S. Department of Agriculture, for their assistance in deriving the estimates for this table.

NA = Not available.

SOURCE: Office of Technology Assessment, 1992.

Production Measures

The advance of agricultural biotechnology will play an important role in increasing agricultural productivity at about the historical rate of the last two decades. (See tables 1- I and 1-2.) The most dramatic increase in animal agriculture is in milk production. Since 1960, the annual rate of growth has been about 2.0 to 2.5 percent. OTA's 1985 projection (24,200 pounds of milk per cow by year 2000) was higher than its current one (19,200 pounds of milk per cow by year 2000). A major reason for this change is the slowness to market of bovine somatotropin. In 1985, bST was predicted to be commercially available in 1987. BST had yet to be approved by the Food and Drug Administration as of early 1992.

Efficiencies in crop production will about match historical trends or climb slightly, and for the most part will exceed OTA's 1985 projections. This, in part, reflects the movement of many of the new technologies from the laboratory to the field at a much quicker pace than thought possible in the mid- 1980s. Even though rates of growth may accelerate during the 1990s, the absolute quantity of yields will, for the most part, be lower than projected in the mid- 1980s. This is due, in part, to the fact that many of the early biotechnology inputs will be substitutes for chemical inputs and, hence, the absolute gain in efficiency will in many cases be negligible. Yields are expected to improve in the latter part of the decade as more is learned about the genetic make up of plants.

Agribusiness, Farm Labor, and Rural Communities

Historically, the commodity-oriented agribusiness sector has been driven by economic forces to produce at

maximum efficiency and to maintain low costs. This has resulted in a system that is effective at converting undifferentiated commodities into low-cost food. Today this sector is undergoing change inspired, in part, by the evolution of more demanding and differentiated food consumers. in response, retailer strategies have emerged that focus on improving service to the consumer. information technology has facilitated the shift of marketing efforts toward the discovery of consumer preferences.

To respond to a more consumer-oriented environment, input suppliers may need to explore how information technology can facilitate the coordination of activities needed to assure particular attributes. Information technologies in the future may facilitate new business strategies by providing improved information flows and by facilitating coordination of production and marketing activities.

To date, input suppliers have experienced more consequences of the new technologies than any other part of the agricultural industry. In anticipation of biotechnology-enhanced seed, chemical and seed input industries have transformed structurally. Multinational chemical and pharmaceutical companies have acquired almost all the major seed companies. Concentration of input industries increases the potential for monopoly power, hence the potential for exploiting farmers in their purchase of improved inputs.

The trend toward vertical integration in agriculture and toward proprietary production processes could result in a captive market for some biotechnology products. For example, a genetically engineered seed might be produced by a large, vertically integrated chemical-seed company with specified inputs such as fertilizer, pesticides, and herbicides produced only by that company. Where product quality is influenced strongly by biotechnologies (i. e., pork by pST); and where highly specialized new markets are formed (i. e., for pharmaceuticals), increased incentives for production-marketing links via contracting and other forms of vertical integration can be expected.

The advancing biotechnology and information technologies generally will shift labor from farming as has been true of past technologies. Newly emerging technologies will displace less farm labor than mechanization, but the farm labor force will have to be substantially more skilled than in the past. For example, a key requirement of the new information technology will be computer literacy. Programs to support skill upgrading of the farm labor force will be needed to capture fully the potential benefits of the new technologies.

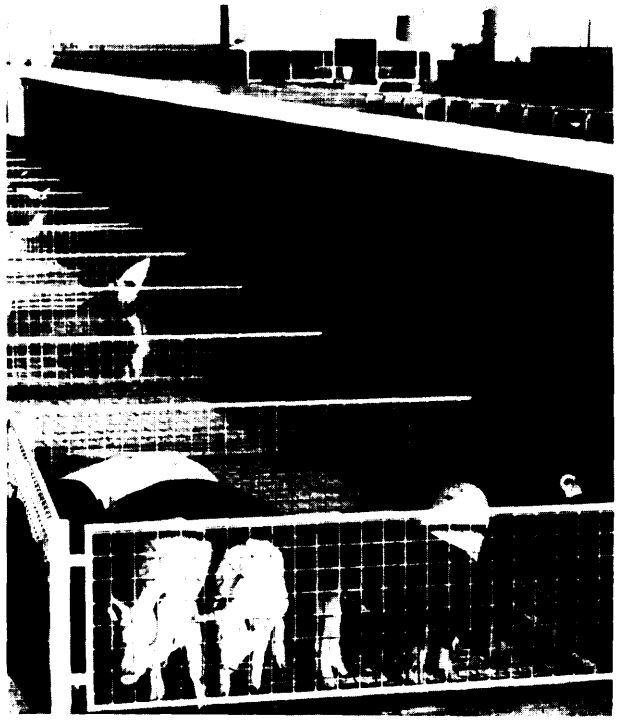


Photo credit: Grant Heilman, Inc.

Production of lean meat with porcine somatotropin (pST) will give meat packers a strong incentive to vertically integrate or contract with farmers. Economic pressures will be strong for most swine producers to adopt pST or exit the industry.

The emergence of biotechnology and computer technologies will most likely spur on the decline of many small farms and agriculturally dependent rural communities. Moreover, increased demand by many farmers for one-stop shopping centers for farm supplies—including those involving biotechnologies and information technologies—may reduce the viability of business enterprises in smaller communities. These enterprises will need to diversify into nonfarm-related economic activities if they are to remain economically viable.

Management

The new technologies will demand greater attention to management issues than have technologies in the past. For crop agriculture, in particular, a systems approach to the use of genetically engineered plants and biocontrol technologies will be needed. Concern about pest resistance to technologies that control pests is reaching a high level. Many chemical technologies are ineffective today because of pest adaptation caused by poor management strategies. As products from biotechnology are used to control pests, management strategies for delaying or pos-

sibly avoiding pest adaptation need to be identified. Evidence exists already that insects are quite capable of adapting to Bt, one of today's most popular genetically engineered protein toxins. At present, there is some information to establish general guidelines about the judicious use of engineered crops with insect and pathogen resistance and herbicide tolerance. However, to establish more detailed guidelines will entail generating a body of empirical knowledge relevant to these products. And, an effective educational program designed to bring these results to the agricultural industry and the public is needed.

For animal agriculture research results clearly show the extent of response achieved from technology depends heavily on the management capability of the producer. Use of somatotropins, for example, may require altering the animals' diets. Administration of somatotropin to lactating cows may require extending the reproductive cycle.

As important as these management issues are, a more pressing issue is that of animal welfare—with or without biotechnology as a complicating factor. Much of the success in increased productivity in agriculture has been the result of lowered costs through the use of confinement systems—which some have coined factory farming. The question from an animal welfare perspective is whether we have gone too far.

The impact of biotechnology on animal well-being is perhaps the most challenging issue genetic engineering raises. The technology is most likely impact neutral in that one could use biotechnology to enhance animal well-being as well as compromise it. Clearly, biotechnology's impact depends on what is done and its effect. If it is used judiciously to benefit humans and animals, with foreseeable risks controlled, and the welfare of animals kept in mind, it is morally defensible and can provide great benefit.

Food Quality

Information about food quality can be provided through labeling, brand names, price, and grades. Food grades are used to classify products according to certain quality characteristics and are established by the U.S. Department of Agriculture (USDA). In particular, they sort a group of foods with heterogeneous characteristics into lots of more uniform characteristics. Biotechnology will challenge the relevance of grades since this new technology is capable of producing products of uniform high quality. For example, as discussed above, pST reduces backfat thickness and increases protein deposition in hogs, resulting in a final product that is more desirable to a health conscious society. Current USDA grading criteria based, in large part, on backfat thickness and degree of marbling will not be relevant since there will be little. if any, difference from animal to animal in these characteristics in products produced with the new technology, For a grading system to be useful, new grading criteria will be needed. What these new criteria should be and how they will be measured are open to question. An argument can be made for providing quality information via labels to consumers and dispensing with USDA grades for most, if not all, agricultural products.

Intellectual Property Rights

Intellectual property protection is one of the most important incentives for the commercial development of biotechnology- and computer-related processes and products. Patents and other forms of intellectual property (plant breeders' rights, trademarks) provide this protection. Patents may be issued in the United States for microorganisms, plants, and nonhuman animals. U.S. patent law is the most inventor-friendly statute in the world: if Congress takes no action regarding patentable subject matter, broad protection for inventions created by biotechnology will continue. The Patent and Trademark Office (PTO) issued its first patent on an animal in 1988. No further patents have been issued since, and the backlog of applications at PTO now numbers at least 160. Since the status of patent applications is, by law, confidential, no way exists to determine when or if the patent office will issue subsequent animal patents; or whether such patents will have agricultural applications. Congress, through its oversight responsibilities, may require PTO to explain the present status of any such patent applications.

Rapid technological advances in computer software is challenging the intellectual property laws in the United States and internationally. Copyright law offers straightforward remedies for the literal copying of program code, although enforcement remains a problem. Functional aspects of computer programs pose difficult questions for application of copyright. The protection of software-related inventions by patent is a fairly recent development and is controversial. PTO faces considerable challenges in examining applications for computer-related inventions. An incomplete data base of "prior art" for computer-related inventions makes it difficult for examiners to judge whether an application describes a "novel" invention. Improving the database of ''prior art' is one important means of improving the quality of the examination but will be difficult because so much of what

constitutes ''prior art' has been in the form of products, not literature or issued patents.

MAJOR FINDINGS AND OPTIONS

For any new technology, it is important to weigh the potential benefits against the risks and possible costs of its widespread adoption. Biotechnology-related risk assessment focuses on the planned introduction of genetically modified organisms into the environment (environmental safety) and on the consumption of products derived from biotechnology (food safety).

In many ways this is a difficult time for a new technology to emerge. Negative experiences with nuclear and chemical industries have made the American public wary of new technologies, and confidence in institutions has eroded. For these reasons, and because the consequences of environmental introductions of genetically modified organisms cannot be predicted with certainty, biotechnology has been subjected to extensive, apprehensive scrutiny and regulatory oversight. Many institutions will choose to "go the extra mile" to ensure public confidence as some policy issues are resolved. In making policy decisions it remains important, nonetheless, to distinguish clearly between the technical basis for assessment and regulation of technology-related risks, and what might or might not be done as an extra step to maintain public confidence. Balancing safety and institutional credibility against economic competitiveness will be a skill much in demand throughout the decade.

Environmental Safety

Findings

Adequacy of a Knowledge Base for Risk Assessment Analysis-After several years of experience with planned introductions, a consensus is growing among scientists that the risks of planned introductions of genetically modified organisms into the environment can, for the most part, be assessed with available analytical capabilities. Although risk assessment is itself a relatively young field, the capacity to identify and weigh risks and benefits in a structured and analytical way has matured rapidly in recent years. Based on experience with other technologically oriented issues such as pollution and its control and food safety, risk assessment as a field has generated principles and methodologies that can be adapted for planned introductions of recombinant-DNA modified organisms in the environment.

The fields of community ecology, population biology, population genetics, evolutionary theory, and agricultural sciences as well as others have contributed to our current understanding of the ecology of planned introductions. Decades of research in life history dynamics, competition, characteristics of colonizing species or disturbed habitats, disease resistance, and gene flow have provided a basis for risk assessment of planned introductions. Thus, while it is impossible to assess the exact consequences of any specific planned introduction, the fact remains that ecological understanding combined with risk assessment methodologies make it possible to analyze the potential risk of each introduction before it is allowed to take place.

Adequacy of a Knowledge Base for Science-Based, Risk-Based Regulations-Reports of the National Research Council, the Ecological Society of America, and the Scope document of the Office of Science and Technology Policy (OSTP) and the Council on Competitiveness all advocate science-based and risk-based regulations of biotechnology applications. The implementation of such regulations draws on the ability of regulators to conduct adequate risk assessments, which in turn rests on the knowledge base and technical capabilities discussed above.

Regulatory oversight rests with Federal agencies, with varying degrees of involvement by state regulatory personnel. USDA's Animal and Plant Health Inspection Service (APHIS) has taken the lead in designing a process for the evaluation of possible risks and benefits when a specific planned introduction of a genetically engineered plant is proposed. Technical information to be provided by an applicant is clearly defined, so that a thorough, science-based risk assessment can be performed. Technical personnel in fields such as genetics and ecology have joined the staff of APHIS's Biotechnology, Biologics, and Environment Program (BBEP), to ensure vigorous assessments. State regulatory personnel are drawn into the process so that they can provide additional technical information specific to local habitats and add an additional perspective.

The Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) has extended its review processes under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) to planned introductions of microbial pesticides; it also cooperates with USDA-APHIS in reviewing proposals for introduction of pest-resistant plants. EPA's Office of Toxic Substances (OTS) has recently published draft regulations to cover planned introductions of genetically modified microorganisms; significant controversy exists as to whether these regulations are indeed science- and risk-based, or whether they sim-

ply single out biotechnology for attention because it is biotechnology. The final status of these regulations, as well as their implementation processes, is not yet known. State agencies have yet to be pulled into EPA regulatory processes to the extent accomplished by USDA.

Extent That Regulations Are Product-Based—Re- ports of the National Research Council and the Ecological Society of America stated that the techniques of biotechnology are not themselves inherently risky or unmanageable. In line with these findings, the early Coordinated Framework, the document that established responsibilities of Federal agencies that regulate biotechnology derived products, and the principles put forth by OSTP and the Council on Competitiveness recommend that biotechnology not be regulated as a process. Rather, a central tenet for biotechnology regulation is that the various products of biotechnology should be regulated, just as are products of other technologies.

The product/process distinction has generated a great deal of controversy in the past. However, as the experience base with biotechnology has grown, the premise of judging each product on its own basis rather than automatically implementing special regulations, has gained wide acceptance. The extent to which this premise has been implemented, however, varies among agencies.

Though its focus is on plant pests, USDA-APHIS has been able to include along with other organisms under its purview any vector, vector agent, donor organism, recipient organism, or any other organism or product produced through genetic engineering if it can be defined as a pest. This product-selective approach makes it possible for regulated articles to become exempted from special review as evidence indicates their safety.

Under FIFRA, EPA-OPP also has applied an existing mandate to products of biotechnology, specifically plants engineered to produce compounds aiding them in resisting pests. By pulling these ‘‘pesticidal plants’ under the rubric of its oversight for pesticides, EPA-OPP seems in one sense to be focusing on the product rather than the process by which it was generated. However, a question exists as to whether or not *‘pesticides’ is the appropriate category into which to place these particular products, especially since naturally occurring plants produce some anti-insect compounds (see next section). To assume authority over plants genetically modified to be resistant to pests, EPA-OPP seems to have chosen to look only at plants that have gone through a biotechnology process, leaving naturally-occurring pest-resistant plants alone.

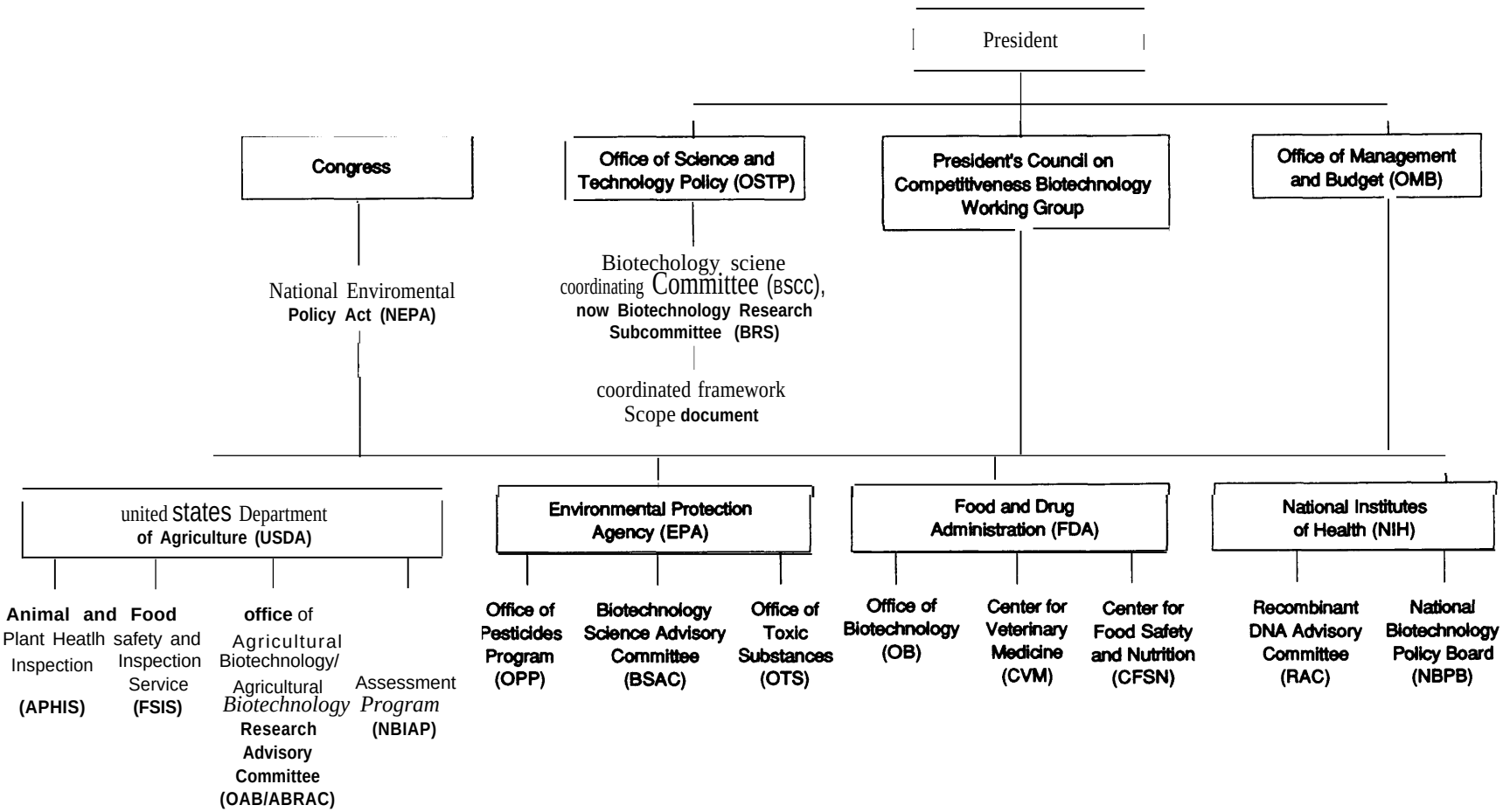
Under the Toxic Substances Control Act (TSCA), EPA-OTS has promulgated draft regulations for oversight of microorganisms that do not fall under other authority. However, under these draft regulations, essentially all microorganisms other than those modified through biotechnology techniques are automatically exempted from review, whereas those modified through biotechnology techniques are labeled “new” and therefore subject to regulation. When the only products subjected to special review are biotechnology products, a question arises as to whether or not the regulations are contradicting the scope principles by focusing on process. The draft regulations under TSCA have been charged by some with automatically and unfairly assigning a special riskiness to organisms modified through biotechnology, while exempting organisms that are known to be potentially dangerous but not produced through a biotechnology process. This discrepancy, and perhaps its final resolution, underscores a central tenet of regulation—that regulation should be based on scientifically determined risk.

Appropriate Review Authority for Plants Genetically Modified for Pest Resistance—Under the Coordinated Framework (figure l-l), which established the responsibilities of Federal agencies with regard to biotechnology, EPA-OPP took on authority for plants into which genes coding for compounds toxic to insects had been introduced. The premise was that these were special “pesticidal plants” that presented risks to the environment, food, and human health similar to traditional chemical pesticides applied externally in large volumes to plants.

This premise is questioned for several reasons. Compounds toxic to insects that are part of plant tissue do not cause pesticide run-off and other such environmental problems (so long as they are alive); they are distinctly localized. Furthermore, most of the compounds are not complex, like many synthetic compounds, and may well be more readily biodegradable.

Another key argument with the premise of singling out plants genetically modified for enhanced resistance to pests is that all plants have natural pest resistance characteristics. Selection pressures over evolutionary time have favored the spread of genes in natural populations that code for characteristics unattractive or harmful to insects. Making a distinction between genetically modified plants and natural plants that are pest resistant, calling the former ‘‘pesticidal plants’ and the latter simply ‘‘plants’ is in fact arbitrary, not science-based. If the “pesticidal plant” premise is disallowed, an argument then exists that EPA-OPP is not automatically the best home for regulatory review of such plants.

Figure I-1—Jurisdiction and Coordination of Environmental Policy for Biotechnology-Derived Agricultural Products.[a]



USDA statutes
- **Plant Pest Act**
- **Plant Quarantine Act**
- **Noxious Weed Act**
- **Virus-Serum-Toxin Act**
- **Federal Meat Inspection Ad**
- **Poultry Products Inspection Act**

EPA statues
- **Federal Insecticide,** Fungicide, **and Rodenticide Act (FIFRA)**
- **Toxic Substances Control Act (TSCA)**

FDA statues
- **Food, Drug, and Cosmetic Act (FDCA)**

[a]OSTP, the Council on Competitiveness, and OMB do not have direct oversight over the Federal agencies; the connections shown here are those of influence through law, key policy documents, or review.

SOURCE: Office of Technology Assessment,1992.

Finally, EPA-OPP has in the past dealt with chemicals and, to a small but growing extent, microorganisms. These are the areas of staff expertise, for the most part, not plant ecology. The latter is the strength of USDA-APHIS. In fact, USDA-APHIS currently takes the lead in assessing applications for field trials of plants genetically modified for enhanced pest resistance. In consultation with EPA-OPP personnel, USDA plant scientists employ their plant expertise and their established review system toward this end. Although companies and universities have moved ahead and conducted tests, the unclarified status of OPP's approach to large-scale commercialization worries these parties as well as State governments. Treating all crop plants as pesticides would take an immense toll in State government time and personnel; yet States cannot plan because they have not as yet received guidance from EPA as to what is coming.

Appropriateness of TSCA for Biological Commercialization- Can or should a law written for chemicals, specifically TSCA, be used to cover living organisms'? Essentially, this is happening as the traditional role of "gap filler" played by TSCA is applied to planned introductions of microorganisms used for purposes other than as pesticides. Approval for the introduction of microorganisms rests on determination that they will not harm human health or the environment. Microorganisms themselves are not toxic; neither are they likely to be applied in the volumes typical of chemical applications. Instead of persisting as do many synthetic chemical compounds, living organisms are eminently biodegradable. However, because they can potentially reproduce themselves and spread in the environment, their use brings up concerns different from those aroused by chemicals.

TSCA could be stretched to cover microorganisms. However, biologically trained staff will have to be given the authority to develop the procedures and requirements of the office. Managers will have to acknowledge the differences between microorganisms and chemicals, and back up their biologically trained staff accordingly, when different treatments are devised. Paradigmatic shifts in management policy need to occur if EPA is appropriately to adapt to living organisms those laws, premises, and procedures originally designed for chemicals. EPA's ability to evidence such flexibility is questioned.

Managing Risks of Large-Scale Introductions—As agricultural biotechnology moves toward commercialization and large-scale planned introductions, the combination of several approaches can maximize benefits and minimize risk. Technically sound implementation of science-based regulations are critical to risk management, as are technically competent regulatory personnel. In addition, specific scientific and agronomic methods are needed to manage risks of particular planned introductions. Examples are methods to reduce the chances for horizontal gene transfer or to diminish the survival potential of any non target recipient of an introduced gene. Scientists are exploring ways in which the gene of interest, or supplementary genes transferred along with it, can be designed to constrain the potential for transfer (a kind of internal, genetic "containment" system).

Agronomic methods can also be used to manage identified risks. For example, physical or spatial barriers could be put in place between a field of genetically modified crop plants and the adjacent field or surrounding natural vegetation. While this sort of barrier would probably not be necessary in most cases, in particular cases where gene flow was of concern (perhaps for canola), this could be useful. Other mechanisms could be used as well, such as surrounding a field of genetically modified plants with barriers of a "trapping" species that attracts any pollinators that might otherwise carry genes from one of the modified crop plants to other plants. The actual need for such ''separations'—whether spatial, or temporal—can be determined by assessing the risk of gene flow or of establishment of genetically modified organisms.

Photo credit: Grant Heilman, Inc.

A traditional approach to isolation **of** plants is to spatially separate desired plants from other plants. Similar guidelines for spatial separation have been applied to transgenic plants as well.

Risks of Genetically Modified Plants or Microorganisms Becoming Pests—Any novel organism potentially represents some level of risk to the environment, whether that organism is naturally occurring or genetically modified. However, the likelihood of a genetically modified plant or microorganism actually becoming a pest is relatively low. The long history of agriculture shows that current crops are not likely to become established as weeds. Long established mechanisms for containment in agricultural systems have been highly successful in the United States. Furthermore, recombinant-DNA modified organisms, unlike wild, naturally occurring organisms, are designed to exist only in a specific environmental regime—the nurturing surroundings of a cultivated field.

Microorganisms modified for agricultural purposes are constrained somewhat like plants, although they are not so dependent on cultivation for continued survival. However, the extensive agricultural experience with microorganisms has not resulted in a pest problem. To become a pest, an agricultural plant or microorganism has to exist independently of cultivation—outside the planted field. Several steps are necessary to its success; each one, from dispersal to the production of viable, competitive offspring, is not likely to occur.

Potential for Gene Transfer or Cross-Hybridization Between Genetically Modified Plants and Wild Plants-Cross-hybridization, the crossing of two plants of different species to produce fertile offspring, is a rare phenomenon. While gene transfer between individuals of the same species is straightforward, gene transfer between different species is not; their genetic compositions are usually sufficiently different that they do not line up and match well for the key molecular and cellular events of reproduction. Even if a transferred gene were involved in such a cross, it would be cast onto an ‘‘alien’ genetic background—its expression could be problematic.

Most crop species in the United States do not have indigenous weedy relatives with which they could cross-hybridize. Canola is the only major crop for which related weedy species exist in the United States. The possibility of cross-hybridization is greater in other countries, where crop species and related weedy species do coexist. Developing countries, in particular are the centers of origin for many crop species. As it exports agricultural biotechnology capabilities, the United States has at least a moral responsibility to provide advice to developing countries as to the management of risk from cross-hybridization.

Options

1. The tools of biotechnology offer great potential to American agriculture; regulatory treatment of agricultural products derived with such tools will play a dominant role in any related gains or losses in economic competitiveness. Science-and risk-based regulation of products can help ensure safety while not impeding the economy.

. *Congress could directFederal regulatory agencies to make science-based, risk-based regulation of biotechnology products (not process) a unifying policy across agencies.*

This would be a clear message to the executive branch that Congress expects a unified approach across Federal agencies based on the product not on the process of biotechnology. Communication through interagency groups would help to ensure a common approach based on scientifically determined product risk. This approach can help protect health and environment and, at the same time, should generate a comprehensive, workable regulatory apparatus for incorporating the tools of biotechnology into American agriculture. However, EPA will need to address their shortage of technical staff needed to conduct technical risk-based reviews.

No scientific evidence exists to justify Congress directing agencies to review and regulate biotechnology as a process, rather than the products produced by it. Nevertheless, EPA-OTS has been accused of regulating the process of biotechnology, not the products, in its proposed rules. If agencies were to ignore the use of risk assessment of products and automatically penalize any efforts made using biotechnology, several impacts would likely occur. Industries and universities probably would ‘‘agency -shop,’ orienting their efforts toward the agency with the clearest analytical assessment of science-based risks—that agency will be the least arbitrary and the most predictable, an approach certainly favored by industry. The agency regulating biotechnology as a process sends out an obvious negative message to industry and perhaps an equally important, if more subtle, message to the public. Regulations based on the assumption that biotechnology is inherently unpredictable and highly risky can lead to reverse public reactions and political pressures that may be detrimental to the economic competitiveness of American agriculture.

2. **Enhanced pest resistance in crops is one of the most promising applications of new biotechnology tools. Obstacles to its development could send a negative message to agribusiness, slowing its incorporation of**

biotechnology as a mechanism fostering increased economic competitiveness.

. *Congress could keep the oversight authority for plants genetically modified, for enhanced pest resistance under EPA Office of Pesticide Programs (OPP), but direct EPA to strengthen OPP.*

If oversight of "pesticidal plants" introduced at a large-scale is to be handled effectively by OPP. several changes would need to occur. Technical staff with plant expertise would need to augment current staff; definitions would have to be clarified, given that some naturally occurring plants contain more "pesticidal compounds'" than will the products of biotechnology: communication with State-level implementors would need to be improved immediately; and a clear approach would have to be articulated so that the public, industry and academia would know where the agency stands and how it will implement its policy.

. *Congress could direct USDA-APHIS to regulate large-scale introducation of plants genetically modified for enhanced pest resistance.*

Since USDA-APHIS-BBEP has taken the lead for field tests of plants genetically modified for enhanced pest resistance, APHIS could handle large-scale introductions. This has the advantages of centralizing plant oversight and making effective use of an already well functioning technical staff and organizational unit. The chief disadvantage would be a disruption in the original Coordinated Framework, which ascribed authority to EPA-OPP.

. *Congress could direct EPA to work with USDA to develop a similar model of operation and to report on progress to Congress within a specified period of time (e.g. ,* 6 *months).*

Despite disadvantages of 'forcing' two very different offices to work closely together, this has the advantage of allowing USDA to handle any risk concerns related to planned introductions, while allowing EPA to continue to handle food-safety concerns related to ''pesticidal' toxins in the food supply. USDA has established a strong track record for taking the lead in field tests of pest-resistant plants.

3. **TSCA is a statute explicitly designed to regulate activity "for commercial purposes. " Academic research, therefore, has been exempt from TSCA oversight. The proposed draft rules for microorganisms, however, greatly expand the regulatory "net." One rationale for including academic research is that sometimes universities engage in technology transfer or patent filing, or receive research funds from companies. Obviously, the effects of microorganisms being placed in the environment by a university scientist are no different from the effects of those same microorganisms being placed in the environment by an industry scientist. Concern exists, however, that the draft rules could have a negative impact on academic research.**

● *Congress could allow the proposed ru1e to stand, placing the same requirements on academic research as on industrial research.*

Subjecting universities to the requirements placed upon companies seems contrary to the Congressional intent behind TSCA. It could have significant negative impacts on university research. Faced with the added bureaucracy and high costs entailed by this rule, the majority of university researchers might deliberately avoid planned introductions of genetically modified organisms. This would leave industry in charge of an area of research that could continue to benefit from broad, objective, openly published study. Such a situation would inhibit the production of new knowledge for use in future risk assessments. However, it is an arbitrary decision to exclude universities automatically from oversight—the release of organisms that pose a risk should be regulated regardless of who conducts the release.

. *Congress could direct EPA to develope an oversight mechanism for planned introductions as an alternative to the proposed TSCA rule.*

Universities could make use of their already existing system of oversight committees and institutional biosafety officers to regulate biotechnology field trials ''in house'. Just as the Institutional Biosafety Committees *(IBCS) review* laboratory research involving recombinant DNA, they could review proposals for planned introductions. It would entail education of laboratory-oriented personnel as to the ecological considerations of field release, as well as possible expansion of committee membership to include appropriate disciplines. Serving on an IBC is a time-consuming effort for university personnel. Many feel that there are already too many university committees on which they must serve. Use of IBCS to provide oversight is a possible trade-off for the university between being able to conduct this research or not.

. Congress could *direct EPA-OTS to develop special procedures to minimize or eliminate any unwarranted regulatory burden on universities, to ensure that public research continues in this area, and to report to Congress on the method selected and its results.*

This option would still hold public scientists accountable but would be aimed at lessening the regulatory burden if the appropriate procedure is used. Several possible procedures exist. One possibility would be that the agency funding the research would have the responsibility for monitoring and reviewing the work. As part of the funding contract, the principal investigator would agree to follow EPA guidelines on management and to contact EPA if the need arose. This makes it possible for the funding agency to monitor the project and enforce regulations through the distribution of funds.

Another approach is to streamline the application for public researchers. For example, an abstract of a grant proposal could be required to contain specific information that would be sufficient to trigger important questions that arise about the project from EPA. Another possibility would be for EPA to set aside a budget for reimbursement of costs incurred in filing an application. However, even if a cost-savings mechanism is developed, a bureaucracy-minimizing mechanism will also be necessary if Congress desires to encourage public researchers and their home institutions to conduct the objective research that will contribute further to our knowledge base.

, Congress *could amend TSCA to exclude universities or to provide alternative means to regulate academic research.*

An argument can be made for including academic researchers. Obviously, genetically modified organisms released into the environment by a public researcher have the same effect as the same organism placed into the environment by an industry scientist. On the other hand, concern exists about the legal precedent that could be set by extending TSCA's scope to noncommercial research and that it could have a negative impact on research. An application fee for a single field trial costs between $180,000 and $600,000. Even the lower cost is more than most universities or research grants are able to cover. Even though companies have personnel and a budget to cope with regulatory processes, universities for the most part do not have regulatory policy offices or the budget for filing applications. However, if universities and industry worked together, industry would benefit by not having universities file applications. Congress could make its intent for universities clear by stating it in legislative language through TSCA.

4. **As large-scale planned introductions become imminent, companies are looking to the regulatory agencies for guidance as to how to proceed. Clear guidance is critical to commercial development of agricultural biotechnology.**

. *Congress could direct EPA-OPP and OTS to clarify their regulatory approaches to large-scale introductions and report back to Congress on their approaches within u specified period of time.*

Interagency work groups, as well as the leadership of EPA, can orient efforts toward assisting EPA staff in clarifying the regulatory guidelines. A flexible approach seems appropriate. Clarifying regulatory guidelines would be particularly helpful to agribusiness working with "pesticidal plants" or microorganisms other than microbial pesticides. USDA-APHIS-BBEP could provide model mechanisms for clear communication of requirements, use of input from outside the agency, addition of technologically-trained personnel, and creation of an effective structure as well as clarification of direction.

. Congress could *direct EPA to continue on its present course.*

This is basically a status quo option. It would mean a continuation of the lack of clarity of regulatory policy for potential applicants at the large-scale stage. This lack of predictability could have a negative impact on industry. The absence of applications to EPA-OTS for environmental releases under TSCA over the last year illustrates industries' response to lack of predictability in the regulatory arena. It also undermines public confidence in the ability of regulatory agencies to regulate biotechnology.

. Congress could *conduct over-sight hearings of EPA and USDA regarding regulatory policy for large-scale release.*

Oversight hearings could assist the agencies to develop policy to meet congressional intent for regulating these products even though the regulatory agencies have stated that current laws are sufficient for regulation of products derived from biotechnology. This could help clarify differences in laws written primarily for chemicals instead of genetically modified organisms.

5. **Institutions handling new technology must win public confidence and be responsive to public concerns. A balance between maintaining the public interest and ensuring industry competitiveness must be achieved.**

. Congress could *direct EPA and USDA to emphasize: 1) increased input of public participation into their* Systems; 2) *an open process;* 3) *scientifically sound procedures communicated clearly to other scientists; and 4) follow-up on appropriate cases.*

Most systems can be made sounder when external input is factored into decisions. External advisory committees, hearings, and informal workshops are examples of mechanisms by which Federal agencies can obtain such input. EPA-OPP for example, cosponsored workshops on transgenic plants to gain scientific advice as they deliberated their approach to "pesticidal plants" and has used its scientific advisory board in deliberations over TSCA draft rules. USDA-APHIS has held a variety of conferences and workshops on planned introductions, stressing public input and State officials' input. In fact, USDA-APHIS has made State input an integral part of its review process; EPA could wisely adopt this approach in OPP and OTS.

By developing scientifically sound procedures for determining data needs and communicating them clearly, an agency can build an accessible database and contribute to and benefit from the input of the scientific community. USDA's Agricultural Research Service is complementing the work of APHIS by building a database on field tests.

Parties concerned about a new technology want to know that potentially problematic cases are being subjected to close follow up. While USDA and EPA can and do impose monitoring requirements on field tests, both agencies could benefit from implementing more extensive follow upon specific cases that might prove troublesome (perhaps by monitoring indicators identified for a Possible worst-case scenario). This is, of course, time consuming. However, if implemented, it should be used in a rigorous manner, so that undue burdens are not placed on straightforward cases, yet so the public feels secure in the knowledge that problematic cases will be tracked after introduction.

. Congress could require regulatory agencies to develop explicit plans for building public confidence and report those plans to Congress.

This option would give agencies maximum flexibility. It would allow for the evolution of regulation based on the experience of the agency. Moreover, this approach would allow for a solution to be developed within the agency as opposed to it being imposed on the agency from outside. Reporting the plan to Congress would allow the public to express its opinion and to exert pressure on the agency to change those parts of the plan found to be unacceptable. On the other hand, this process is time consuming for the agencies and Congress. With the large demands on Congress, some members probably would be concerned that it was not the best use of their time.

. If regulatory agencies fail to maintain public confidence, new Law(s) or congressional oversight could be established to satisfy the public demand for account ability.

This option is relatively drastic and could have several disadvantages. Managing a system from the outside invites logistical and other difficulties. Moreover, the tendency with this approach would be to "freeze" procedures at a particular moment. This could hamstring the natural and positive evolution of regulation, such as the gradual extraction of generic principles from case-by-case reviews. More generally, this approach would be more in the nature of imposed management rather than a solution developed within the agencies, and as such, its own credibility may be weakened. However, it is an option that could ensure accountability to the public if regulatory agencies are incapable of doing so themselves.

Food Safety

Biotechnology is not so different from previous agricultural technologies as to raise novel scientific issues concerning the safety of foods. What is substantially different, however, is the climate in which this new class of technologies is being introduced. Society in general is more skeptical of the need for new technologies. Scientific illiteracy combined with a lack of knowledge about agriculture and biology leads some people to misunderstand how and why these technologies will be used. Society is also skeptical of how new technologies are developed and regulated. Scandals involving institutions that develop and regulate these technologies have shaken the public's confidence in the ability of these institutions to carry out their activities responsibly. Public confidence will sink further if the public feels that food safety standards are too lax, are fraught with scientific uncertainty, or are not adequately enforced.

In addition, uncertainty exists within industries as to how new food technologies will be regulated (table 1-3). FDA policy has been a long time in the making for biotechnology-derived products. EPA has yet to establish guidelines on data requirements to establish residue tolerances for pesticidal plants, and USDA's Food Safety and Inspection Service (FSIS) has not established guidelines concerning transgenic animals. Genetically engineered products, plants in particular, are approaching commercialization at a faster rate than was anticipated even 5 years ago. These agencies no longer have the luxury of long time frames in which to articulate policy.

An end to the uncertainty over how these products will be regulated is needed. Additionally, general need exists

Table 1-3—Federal Agencies Primarily Responsible for Food Safety

Agency	Principal statutory authority	Responsibilities
Food and Drug Administration	Federal Food, Drug, and Cosmetic Act	Safety/quality/effectiveness of animal feeds and drugs, and all foods except meat and poultry
USDA-Food Safety and Inspection Service	Federal Meat Inspection Act and the Federal Poultry Products Inspection Act	Safety/wholesomeness/accurate labeling of meat and poultry products
USDA-Agricultural Marketing Service	Egg Products Inspection Act	Safety/quality of egg products and shell eggs
Environmental Protection Agency	Federal Insecticide, Fungicide, Rodenticide Act	Safety of pesticide products
	Federal Food, Drug, and Cosmetic Act	Pesticide residue tolerance in food/feeds
National Marine Fisheries Service and Food and Drug Administration	Agricultural Marketing Act	Voluntary seafood inspection

SOURCE: Office of Technology Assessment, 1992.

to regain public confidence in the regulatory agencies responsible for determining the safety of new biotechnology products.

Findings

Establishment of Federal Regulations and Guidelines Concerning Biotechnology FoodProducts—in the first half of the 1980s, it was anticipated that animal biotechnologies would be developed more quickly than plant biotechnologies because more was known about animal physiology than plant physiology. However, several scientific breakthroughs have speeded progress toward transgenic plants and some are now in various stages of field testing. As transgenic plants approach commercialization, scientific guidelines for assessing their safety will be needed. Further delay in establishing Federal regulations and guidelines could cause a competitive disadvantage to industry, as well as continue to undermine public confidence in the ability of regulatory agencies to establish a clear policy concerning biotechnology.

FDA is now wrestling with the question of whether to classify all, none, or some transgenic plants as food additives and to require a food additive petition for these foods. In May 1992, FDA published a preliminary proposal regarding the regulation of new varieties of genetically modified crops. This policy states that FDA is concerned with the characteristics of the food product and not with the method used to produce the product. Thus, new genetically modified crop varieties will not automatically be required to obtain a food additive regulation. New varieties that do not contain new toxicants, elevated levels of inherent toxicants, altered nutrient composition or bioavailability, or enhanced allergenic potential may be regarded as not significantly different from conventionally produced new varieties that are generally regarded as safe. These varieties could be marketed without premarket oversight by FDA. The adulteration clauses of the Federal Food, Drug, and Cosmetic Act could be used to remove these varieties from the market if FDA disagrees with a firm's safety evaluation. Varieties that contain substances (either gene expression products or unintended products) that differ significantly in structure, function, and composition from substances currently contained in foods may be required to obtain a food additive regulation.

The lack of a priori oversight of some new varieties, however, may still leave considerable uncertainties in the minds of the public, at least for the first generation of products developed. Public confidence in the process may still require at least a minimum review of the product prior to commercial release. Such review may consist of notifying FDA of the development of a transgenic crop and provision of a minimum level of data so that FDA can make a determination as to whether a food additive petition will be needed. Such a notification process could be open to the public so that any significant concerns can be identified. Additionally, public interest groups have expressed opposition to the policy and have threatened legal action to prevent its implementation. The policy is currently open to public comment, and could be subject to revision. Congress may yet be required to intervene in the development of food biotechnology regulations if differences cannot be resolved in a timely fashion. If such action is needed, several options are available to Congress.

Public Confidence in the Decision making Process— One method of enhancing public confidence in the regulatory process is to make that process open and accessible and to increase public participation in the process. Opponents of increased public input in regulatory decisionmaking processes argue that citizens lack the training needed to understand complicated scientific and technical

issues, and as such their participation only delays the agency's decisionmaking without offering any offsetting benefits. Critics also fear that public representatives may act in emotional and irrational ways and make unreasonable demands. Those who support increased public input argue that such input is invaluable in establishing the legitimacy of regulatory decisions. Indications also exist that public participation can increase the comprehensiveness of agency decisions by encouraging the agencies to focus on a wider range of issues and values than they normally would. Lastly, it is hard to justify no public participation in regulatory processes in a democratic society.

The public will not make the regulatory decisions—that is the responsibility of the State and Federal agencies whose statutory authority requires them to ensure a safe and wholesome food supply. However, public confidence that these agencies are fulfilling their responsibilities will be enhanced if there are mechanisms available for public questions and concerns to be heard and addressed prior to decisionmaking by the regulatory agency. At present, public input into the regulatory process consists of notification and comment procedures and participation on advisory committees.

Recent revelations that companies have withheld negative research results from regulating agencies have also undermined public confidence and raised serious questions about the process used in making safety assessments. Currently, manufacturers of technology submitted to the regulating agency for approval also perform the safety assessment following guidelines established by the agency. This situation creates potential conflicts of interest. Most companies are honest, but given the current climate of public skepticism, the appearance of impropriety may be sufficient to prevent consumer acceptance of a new technology. Given the lack of public understanding about biotechnology, doubts about the validity of the safety data used to make regulatory decisions for this new class of products could be substantial. There may be merit in considering a safety assessment process that includes independent testing of products.

Tradeoffs Between Industry Competitiveness and Society's Right to be Informed About Health and Safety issues—Public interest groups argue that industry claims too much scientific data as confidential business information (CBI) when submitting a new technology for agency approval, thereby limiting the amount of health and safety data available to the public. On the other hand, industry feels that there is too little protection of proprietary data by Federal regulatory agencies. Achieving the proper balance between protecting proprietary rights and disclosing health and safety data to the public is a delicate undertaking.

Disclosure practices are regulated by the Trade Secrets Act and the Freedom of Information Act. The Trade Secrets Act of 1982 subjects government employees to criminal penalties for the disclosure of proprietary data unless authorized by law. The Freedom of Information Act (FOIA) of 1982 permits agencies to protect trade secrets and commercial and financial information that is confidential. Both laws seek to protect information that would be of commercial value to a firm's competitor. However, a congressional order mandates that EPA and FDA release some types of scientific data in certain circumstances.

The FDA has restrictive CBI policies. Although Congress has mandated that health and safety testing data for new drugs can be released after another manufacturer becomes eligible to sell the drug unless extraordinary circumstances are shown, little data are actually released. This is in part because FDA defines extraordinary circumstances to include any claim that the data are CBI, such as a claim that it could be used by competitors in foreign countries.

While FDA usually does not release safety data, it did in the case of bovine somatotropin (bST). For the first time in FDA history, FDA published an article in a peer reviewed scientific journal detailing how FDA reached its conclusion that bST was safe for human consumption. Specific safety data were presented. Additionally, the National Institutes of Health (NIH) and FDA hosted a scientific meeting with public participation to discuss food safety concerns of bST. FDA has also published an article explaining why FDA granted GRAS status to the genetically engineered enzyme chymosin. Thus, FDA has shown that it is possible to release such information when it is in the public interest.

FIFRA protects CBI, but allows release of health and safety testing data for registered pesticides. Also, data concerning production, distribution, sale, or inventories of a pesticide maybe released in connection with a public proceeding if disclosure is in the public interest. Thus, FIFRA permits the release of health and safety data after the decision is made but not during the process.

After notification of a food additive or pesticide registration petition has been published, under FOIA, requests for safety data can be made. However, sometimes it is not possible for agencies to determine whether or not information is CBI in the time allotted to them to make a regulatory decision. Attempts to mitigate these

problems include requesting that companies restrict their CBI claims and that they justify their claims of confidentiality at the time they submit a petition.

Decisions to disclose CBI focus on whether or not such disclosure will be harmful to the company. No attempt is made to weigh this harm against the public's right to be informed about health and safety issues that might affect them. Other countries, most notably Canada, have taken the approach that disclosure of health data is authorized if it is in the public interest as it relates to public health, public safety, or protection of the environment and if it clearly outweighs in importance the financial loss to the competitive position of a company or person.

Enforcement of Regulations-Research indicates that a significant factor in public lack of confidence in regulatory agencies is concern that regulations are not adequately enforced. For example, although Federal law bars sale of produce with pesticide residues above Federal tolerances, recent studies show that consumers are willing to pay for labels assuring them that these tolerances are in fact not exceeded. If the public is to regain trust in regulatory agencies, enforcement of regulations will need to be improved.

This will be difficult as biotechnology becomes a new focus of public concern and a new arena of regulatory responsibility. The regulatory agencies do not have the resources to increase enforcement activities significantly. A recent General Accounting Office study found that the regulatory agencies involved in food safety had fewer staff, less funding and a larger workload in 1989 than in 1980. Available resources already are being stretched, and must be spread even thinner to develop new multiresidue assay procedures and sampling methodologies for tracking genetically modified organisms. A new approach to food safety assessment must be developed as well. Traditional approaches to safety assessments of food additives are inappropriate for the assessment of whole foods because large enough quantities of the food cannot be fed to test animals without invalidating the results of the test. New assay and testing methods applicable to genetically modified foods will thus be needed, and this will require additional agency resources.

Labeling—Many consumers have expressed a desire that food products developed with biotechnology be so labeled. However, while consumers express a desire to have accurate and verifiable labels, many of them are not willing to pay much for those labels. For example, approximately one-third of consumers do not seem willing to pay anything for labels; another 5 to 10 percent of consumers seem willing to pay as much as 50 percent higher food prices for labels. Most consumers seem willing to pay 5 to 10 percent more for labels. Clearly a labeling proposal that is expensive will not be popular with most consumers.

Photo Credit: U.S. Department of Agriculture, *Agricultural Research Service*

Chemist evaluates a screening assay for residues. New analytical methodology will need to be developed for biotechnology-derived foods.

FDA has stated in its preliminary policy that generic labeling of biotechnology food products will not be required but selected products may require labeling. Such products include those for which nutritional composition has been altered or potential allergens introduced.

International Coordination—The United States annually imports billions of dollars worth of food products, many from countries that also use biotechnology in their food industries. If U.S. food safety regulations concerning biotechnology substantially differ from other countries' regulations, difficulties could arise. U.S. producers will likely beat a competitive disadvantage if U.S. policy

is substantially stricter than that of other countries. Enforcement will be difficult—no generic methods exist to detect genetic modification. Reliance on the word of other countries that their products contain no biotechnology-derived constituents may or may not be acceptable. If U.S. regulations are substantially less stringent than those of other countries, then the U.S. agricultural export market could suffer. Agricultural commodities are a major export of the United States. Thus, international coordination will be paramount. Preliminary FDA policy is consistent with international organizations' working papers and reports on food safety assessment procedures for genetically modified organisms.

Options

1. FDA and EPA no longer can delay the development of final regulations and guidelines because transgenic plants are approaching commercialization. FDA **has the choice of requiring a food additive petition for all, some, or no transgenic plants.**

. *Congress could monitor the development of regulations and conduct oversight hearings of FDA and EPA to determine why final regulations and guidelines do not exist and to have them report back to Congress with recommendations in these areas within a specfied period of time.*

This would be a strong signal to the executive branch that Congress is concerned about the delay in providing guidance to the private sector for these new technologies. An oversight hearing would provide the agencies with an opportunity to explain their rationale and concerns in establishing regulations for these new products and allow Congress the opportunity to provide guidance and direction to the agencies.

Congress and the Executive Branch through EPA, FDA, and USDA have a number of options for regulating transgenic organisms. The following part of Section 1 illustrates options available.

. *Congress or FDA could establish categorical exclusions to the requirement of a food additive regulation for certain transgenic organisms and require a case-by-case approach for the remaining products.*

Essentially, this is the policy chosen by FDA. Transgenic organisms that involve gene products that are widely present in the current food supply, and do not introduce new toxicants, elevate levels of existing toxicants, alter the composition or bioavailability of nutrients, or transfer allergenic components, and that use safe marker and promoter sequences can be excluded from the need for a food additive regulation. These products do not introduce new food compounds into the food supply and they have no unintended effects. Therefore, FDA states that they can be classified as GRAS because they are equivalent to traditional new varieties that historically have been given GRAS status. Only products that contain components that are significantly different in structure, function, and composition may be required to obtain a food additive regulation on a case-by-case basis. This option is a risk based option that requires extensive safety testing for products that are not normally found in the food supply, and less testing for products that contain substances already widely consumed. It places responsibility for the initial food safety assessment with industry. Lack of FDA oversight, especially for the first generation of biotechnology-derived food products, may raise public concerns. A number of public interest groups have indicated their opposition to this policy.

. *Option: Congress or FDA could establish a policy similar to the preliminary policy articulated by FDA, and include a formal notification procedure.*

Such a policy would require the establishment of a system for notifying FDA when a new transgenic crop is marketed. As currently outlined, FDA policy allows firms to determine if a new variety contains components that are already widely consumed. Thus, firms can make a determination about the GRAS status of new biotechnology products without consulting FDA. In the beginning, it is quite likely that most firms will consult FDA prior to marketing a new biotechnology-derived variety, but they are not required to do so. This situation is likely to create considerable apprehension among the public. Thus, a formal system of notification may be desirable.

The notification process could include safety data the company used to determine that the product was GRAS. Such data includes the identity of the host and donor organisms, information on the genetic construct, and information on the physiology of the gene product. Additional information required could include compositional data. A comparison of nutrient and toxic component levels in transgenic and counterpart traditional crops could be included, as well as data on allergens. This type of information will be available in the development of transgenic organisms and is required for a company to make its determination of the regulatory status of the product. Thus, requiring this information to be on record with FDA should not present undue burdens on industry. However, requiring FDA to review and act on this information for all transgenic crops will place a strain on the agency's re-

sources. Most likely FDA will need additional resources to implement this policy.

The notification process could be open to the public so that they can raise concerns and issues regarding transgenic organisms. It may also be useful for FDA to use an advisory committee to comment on the data presented. If an advisory committee is used, representatives from the public could be included along with technical representatives.

Such a policy might be effective for the safety assessment of the first biotechnology food products developed. It would allow FDA to provide at least minimal oversight over all biotechnology food products, assure the public that scientific information is available, and thus, might alleviate some public concern. In the short run, such a policy may appear to result in unnecessary regulation of these products. However, it may be the price industry must pay to have their products accepted by the public, at least in the initial stages of commercializing biotechnology food products.

. *Congress or FDA could require a food additive petition for all transgenic crops.*

This policy would force all transgenic food products to undergo a premarket safety approval process. It would only be based on a risk assumed to be inherent in the process of genetic engineering, an assumption not supported by scientific data. This policy would likely delay commercialization of transgenic crops already being developed and possibly could inhibit the development of additional transgenic crops. On the other hand, this policy would not be inconsistent with a broad interpretation of the food additive definition. And it probably would soothe some consumer fears and uncertainties about these products.

. *Congress or FDA could establish some categorical exclusions* ***of*** *transgenic food products from the requirement of a food additive petition, and could require all other biotechnology products to meet the requirements of a food additive petition.*

Once again categorical exclusions might include transgenic crops that do not contain components that are significantly different from those currently present in the food supply and for which unsafe, unintended components have not been introduced. This policy would be more risk based than requiring all transgenic organisms to meet the rigors of a food-additive petition, because transgenic organisms that are essentially the same as products that have historically been viewed as safe would not be required to undergo premarket approval. This policy would ease some of the burden on industry. There may still be public apprehension with respect to those products that have been excluded.

Ž Congress *or FDA could establish a policy in which the gene expression product is classified as a food additive if the same traditionally processed product would have been classified as such. It could exclude from the food additive definition gene products that would not have been classified as a food additive if produced by traditional means.*

Gene products that might be excluded as food additives are those that would code for agronomic functions such as drought resistance. This policy is based more on the intended use of the gene product rather than any safety risk that the gene product may pose, but would be consistent with how FDA has historically interpreted the food additive amendment. It would, however, be difficult to justify on scientific grounds.

. Congress *or FDA could establish a policy that the requirement for a food additive petition for transgenic organisms be determined on u case-by-case basis for each transgenic organism.*

Such a policy would allow FDA to provide oversight of all biotechnology products. This would provide the public with an assurance that all transgenic organisms would be reviewed by FDA. However, continuation of this type of policy indefinitely could overwhelm FDA, since the number of products that could be developed is large. At some point, FDA will likely need to categorize some products as GRAS, just as it does with chemical additives.

. ***Congress or*** *EPA could establish guidelines for the safety evaluation required to establish pesticide tolerances for whole plants.*

Currently, EPA does have guidelines for transgenic pesticidal microorganisms, but has yet to establish such guidelines for whole plants. Transgenic plants producing pesticidal compounds, such as Bt producing plants, are completing small-scale field trials. Guidance from EPA for dealing with such plants no longer can be delayed. Establishment of safety guidelines will require a new assessment paradigm (discussed later). Additionally. because States, FDA, and USDA enforce pesticide tolerances, EPA needs to work closely with appropriate agencies in establishing tolerances. EPA's work with States needs improvement in this area. Only recently has EPA even begun to compile a list of contact persons in State agencies. This ignoring of States could easily lead to State laws that are incompatible with Federal regulations, or

to gaps in State authority or expertise to carry out Federal regulations. Congressional hearings and oversight may be necessary if EPA does not improve this situation.

. *Congress or USDA -FSIS could establish guidelines concerning transgenic animals.*

USDA-FSIS plans to release guidelines in the near future concerning the slaughter of experimental animals in which gene transfer attempts failed. Guidelines concerning the slaughter of transgenic livestock are still in early draft form. Of particular interest will be guidelines concerning the slaughter and potential food use of transgenic animals that produce pharmaceuticals. FSIS and FDA have established a joint committee to deal with issues that jointly affect the two agencies. Careful monitoring of how successful this committee is may be required.

2. **Public confidence in the regulatory process needs to be enhanced. Making the regulatory process open and accessible to the public and above reproach is a key factor in providing trust and confidence in the decisionmaking process.**

. *Congress could direct agencies (FDA, USDA) to establish mechanisms to allow for increased public participation and to report their results to Congress within 1 year.*

This option sends a clear message to the agencies that Congress is concerned about the public's view of regulatory agencies and that the public should be more involved in the decisionmaking process. It gives maximum flexibility to the agencies to determine the method of incorporating the public's input.

A number of mechanisms are available. For example, Federal agencies could establish criteria by which local agencies can be notified any time significant risk or unique questions arise that are pertinent to them. Agencies may wish to adopt a procedure similar to that used by FIFRA, i.e., notification of petitions received, and if public interest warrants, an informal hearing. Increasing public participation will require increased resources and risk politicizing decisions, but could also enhance public confidence in the regulatory process. It might cost less in the long run.

. *Congress could direct the agencies to crease the use of advisory committees for decisions involving biotechnology and to change the composition of their membership to increase the number of nontechnical public representatives.*

For FDA, advisory committees could help establish GRAS and the minimum information needed for food additive applications of genetically engineered whole foods. These committees could be used as a first screening mechanism to see if a food additive petition is actually needed. Public meetings help assure the scientific validity of the process. EPA might also use advisory committees to establish tolerances for genetically engineered plants with pesticidal properties. This might be helpful since in-house expertise to handle this responsibility seems to be lacking. Advisory committees might also prove useful to USDA in establishing a policy on transgenic animals. The credibility of any advisory committee will be enhanced if it includes public representatives.

FDA may need to consider granting current nonvoting members of its advisory committees the right of full voting membership. And they may need to expand the list of technical fields beyond MDs from which experts are drawn.

Use of advisory committees presents some logistical problems and requires additional resources, but provides expertise that currently may be missing. Additionally, the possibility that non-technical representatives will pursue political agendas and unnecessarily delay committee decisions exists. However, used properly, such representatives can focus the attention of the committee on issues that might otherwise be overlooked and provide legitimacy to committee decisions.

● Congress *could direct the agencies (EPA, FDA, USDA) to change the notification procedures for advisory committee meetings.*

The standard method of notification for advisory committee meetings involves publication in the Federal Register. Few members of the public know what the Federal Register is, much less read it regularly. Also, notices published are written by and for those individuals knowledgeable in the field and, thus, the general public might not be clear as to what the issue is. Additionally, most meetings are held in Washington, DC. Agencies could have committees convene in different cities and publish announcements, other then the Federal Register, that are more likely to be noticed by a wider public. Such activities are likely to be more expensive than current ones, however, but make the decision-making process more accessible to the public.

. *Congress may wish to appoint a task force to study the role of independent safety testing of biotechnology products.*

Independent testing is unlikely to be popular with industry, however, a growing perception exists that companies are withholding negative data and that the safety

review **conducted by regulatory agencies is made without accurate and** complete data. Enhanced authority to subpoena data by regulatory agencies, most notably FDA, could be useful. Additionally, it may be worthwhile to consider establishing independent testing of products. FDA, for example, rather than companies could choose outside investigators to perform selected safety assessments, and these contractors could report results directly to FDA rather than the companies. A study to consider the broad range of implications of such a change would be warranted before implementation.

3. **Public interest groups argue that industry claims too much scientific data as confidential business information** (CBI), **and that this restricts the amount of health and safety data available to the public. Industry argues that there is too little protection of proprietary data and that this situation adversely affects their competitive position. Achieving the proper balance between protecting proprietary rights and disclosing health and safety data to the public is a delicate endeavor.**

● *congress could encourage FDA to publish more scientific review articles and hold public meetings in cases that generate public interest.*

Clearly it is possible for FDA to release considerable health and safety information to the public as it has done for bST. The public controversy surrounding this product apparently outweighed any competitive disadvantage presented to the firms producing bST. Such a policy might prove useful in responding to public concerns about other biotechnology products and potentially could enhance the accountability and credibility of FDA decisions.

. *Congress could conduct oversight to provide increased guidance to regulatory agencies attempting to encourage firms to reduce CM voluntarily.*

Congress could monitor whether health and safety data are being made available as products approach commercialization or if firms withdraw their voluntary cooperation and claim more data as CBI. If firms increase CBI claims, Congress could direct Federal agencies to require firms to justify CBI claims when a petition is submitted rather than waiting until a FOIA request is made. Currently, firms realize that it takes regulators longer to determine the validity of CBI claims than the time allotted to make regulatory decisions. This could encourage some firms to make CBI claims of data that in fact are not confidential.

Congress could also direct agencies to facilitate reconsideration of a decision if CBI data are released after a regulatory decision is made and causes public concern. Currently, firms can avoid public disclosure of data during the regulatory process simply by claiming confidentiality and know that the regulatory decision will not be reconsidered. If the decision is allowed to be reconsidered, firms may reduce their CBI claims.

Industry will oppose increased disclosure of safety data because it will erode their competitive position, On the other hand, with the current climate of public skepticism of new technologies and regulatory agencies, increased industry accountability and public disclosure of safety data may be required of business.

. *Congress could liberalize the CBI policy.*

Congress could direct FDA to release data it is currently authorized to release but generally does not. Congress could consider adopting a regulatory policy similar to that used in Canada which would weigh any harm to the company against the public's right to be informed about safety concerns. Current policy considers only the harm to firms. As a last resort, Congress could force the disclosure of health and safety data. Once again the potential harm to the competitive position of companies must be weighed against the public's right to be aware of potential safety risks and to regain public confidence in the regulatory process. Industry probably will object to an easing of CBI policy. Public support, on the other hand, may be equally strong for disclosure.

4. **Genetically modified foods will require a new paradigm for food safety evaluations. Changes in data needs, assay procedures, and sampling methodologies will be required.**

. *Congress could fund the development of new analytical methodologies and assay procedures through the National Institutes of Health (NIH).*

New analytical methods for whole food assessments must be developed if FDA is to determine the safety of genetically modified crops, and to monitor foods once they are marketed commercially. NIH, in coordination with FDA, could provide funding to develop food analytical technologies, These new technologies and assessment procedures would be useful in determining the safety of genetically engineered foods and could also enhance research programs such as the designer foods project (a component of cancer research) and nutritional programs.

. *Congress could provide funds to NIH for the development of databases detailing the normal range of nutritional and toxic components of food.*

Major nutrients and toxic substances in food have been identified, but additional information is needed to assess these food components, such as the quantities at which they normally are present in foods and their chronic impacts on humans. Assessment of such information will be needed to determine whether genetically modified foods present greater safety risks than do foods currently consumed.

. ***Congress*** *could direct FDA and EPA to request that assay procedures developed by firms to detect additives be readily adaptable for use under field conditions.*

Currently, when firms submit a food additive petition or a pesticide registration, they are required to provide an assay method to detect residues or additives in food. Generally, the method provided applies to a single residue and requires sophisticated instrumentation for identification and quantification. Agencies might require multiresidue assay methods that are more readily usable under field conditions than they are today. The residues would have to have some similar characteristics for a multiresidue technology to work. Development of such assay methods may create technical difficulties and are likely to create added costs for industry. However, they would improve monitoring and enforcement activities of regulatory agencies, an issue of particular importance to the public.

5. **Surveys clearly show that consumers desire additional information about the foods they consume. Labeling is a method to provide this information, especially for those concerned about foods produced from biotechnology.**

. *Congress could mandate that all food products containing constituents derived from biotechnology be so labeled.*

This would satisfy the desire of the public to be able to identify foods derived using biotechnology. But it probably would be expensive to provide labels and difficult to verify label information. No generic means exists today to identify whether a food constituent, such as a kernel of corn that will be ground into meal, has been genetically engineered or not, and it is unlikely that such a method can be developed. Consequently, genetically modified products would have to be kept segregated throughout the market to be able to assure the public as to whether their food contains such products or not. This is not now the case for many bulk commodities, such as grains, and entirely new marketing structures would need to be developed. Increased vertical integration of agricultural industries would likely occur. And, significant government resources would be needed to enforce mandatory labeling and the added expense would be passed along to consumers. Thus, guaranteeing that a product does not contain any products derived from biotechnology could become expensive. Based on current research, it is not clear that consumers would be willing to pay that added expense.

. Congress, *through research and extension agencies, could encourage niche markets to be established to satisfy the concerns of those willing to pay higher prices for labeled food signifying that it does not contain genetically engineered food.*

An alternative to passing the high cost of verification along to all consumers is to establish a higher priced niche market for biotechnology-free foods that would satisfy needs of some consumers. Such a market would be similar to the current organically produced food market. Organic produce is higher priced than traditionally grown produce but provides an alternative product to consumers who are willing and able to pay higher food prices. Recent legislation has been enacted to help resolve some problems involved with organic produce such as a lack of a standard definition, grower certification and oversight procedures. Such a policy might also work for biotechnology-free food products, and would have the advantage of passing the extra costs along only to consumers willing to bear them.

Public Sector Research

It is becoming increasingly difficult for the land-grant system to carry out its historic mission. In addition to the increasingly specialized nature of the research conducted, pressures from outside the system are building. Changing political support, resource base, and institutional frameworks combined with the development of revolutionary new technologies will put pressure on the land-grant system to change dramatically.

Historically, political support for the agricultural research system has come from the farm and rural population. For this reason, agricultural research has focused heavily on increasing the productivity of agriculture. However, this traditional base of support has been steadily eroding, and urban groups have put pressure on the system to shift research priorities to such areas as water quality, human nutrition, food safety, and sustainable agriculture.

The development of biotechnology and advanced computer technologies has the potential to revolutionize the way in which agricultural research is conducted, and to provide powerful tools to help address social problems. The scientists who conduct research using these technologies will need a thorough grounding in the basic disciplines that underlie them. Today only a small proportion of academic agricultural scientists have this background. Moreover, for advanced computer technology research to reach its potential, it will need to be identified as a research priority and universities must be encouraged to develop a promotion and tenure system that recognizes more than a publication record for research accomplishments. In addition, multidisciplinary teams involving basic computer sciences, systems design, and traditional agricultural sciences need to be encouraged. To this end, development of nationally recognized centers of excellence, similar to those developed for biotechnology, need to be considered.

In general, agricultural research is underfunded. Estimates of the social rate of return to public-sector agricultural research investments range from 35 to 145 percent, indicating a significant underinvestment in this type of activity by the public sector.

There has also been a slight, but potentially significant shift in the source of funding for agricultural research at land-grant universities (table 1-4). The States, which provide the majority of the funding for research at these universities, have been constrained in spending by the recession of the early 1990s. Few States have increased funds for research and many have cut funding in this area. USDA funding, the second largest single contributor to agricultural research, has remained basically stagnant, barely keeping up with inflation.

Funding from the private sector for university research, on the other hand, has been increasing in the form of industry-supported research, and from the sale of products by universities. Currently, these sources of income represent about 13 percent of the total funding for agricultural research, but have increased by 60 percent since 1982. The product sales category is a potentially lucrative source of funding for universities. Legal and institutional changes have made it easier for universities to capitalize on their research, since now they can retain title to any federally funded technology the university develops. Incentives to privatize the benefits of university innovation could shift the university further toward private funds, especially if public funds do not keep pace with increased needs.

Changing clientele, funding bases, technologies, and institutional structures will create new demands on the land-grant system. Decisions need to be made on how land-grant universities can best serve society in this new era.

Findings

The Uniqueness of Land-Grant Universities—Land-grant universities differ from other universities in their legislated mission to address research on the problems of society. Some argue that the land-grant system has, in part, already abandoned its mission, as agricultural researchers increasingly work for disciplinary laurels rather than society's benefit. Others argue that the system de-

Table 1-4—Total Research Funding for State Agricultural Experiment Stations, Selected Years[a]
(in millions of dollars)

Year	USDA[b]	USDA competitive	Other Federal[d]	State[e]	Industry	Product sales	Other[f]	Total
1982	161.3	5.5	77.8	522.2	57.0	58.5	70.0	952.3
1984	174.9	6.1	81.7	591.4	64.1	61.3	79.8	1,059.3
1986	174.4	11.9	110.8	704.3	78.1	62.9	89.8	1,232.1
1987	175.6	16.8	114.9	732.5	87.4	68.4	104.2	1,299.8
1988	187.0	19.3	115.0	770.0	91.2	77.8	114.1	1,374.2
1989	194.0	21.9	130.4	827.6	101.2	82.4	132.1	1,489.6
1990	203.6	20.0	143.9	877.9	113.8	91.6	145.7	1,596.5

[a]Funding is for the State Agricultural Experiment Stations only and does not include the 1890 universities, the Schools of Veterinary Medicine, or the Forestry Schools. Funding is in current dollars.
[b]USDA includes Hatch, McIntyre-Stennis, Special Grants, Evans-Allen, Animal Health, and miscellaneous other funds administered by the Cooperative State Research Service.
[c]USDA competitive is the USDA competitive grants program.
[d]other Federal includes funding from Federal agencies excluding USDA and includes funding from NIH, NSF, AID, DOD, DOE, NASA, TVA, HHS, PHS, etc.
[e]State is state appropriations.
[f]Other includes funding from nonprofit organizations, and contracts and cooperative agreements administered by USDA.

SOURCE: Inventory of Agricultural Research, Cooperative State Research Service, U.S. Department of Agriculture, Washington, DC, various years.

fines society's problems too narrowly, placing too much emphasis on increasing agricultural productivity and too little on nutrition, environmental, and rural problems among others. Some also argue that too much attention has been given to production agriculture and not enough to postharvest technologies, value-added products, consumer preferences, and agribusiness problems.

No easy answers exist as to what types of research should be conducted with public funds. What is clear, however, is that as the traditional clientele (i.e., farmers) continues to shrink. greater demands will be placed on the system to address the needs of other groups. To be able to do so may require some difficult choices concerning research mix, with some traditional research programs being eliminated and some new programs initiated.

Research Funding Based on Mission Functions—In recent years the land-grant system almost exclusively has embarked on a program to increase public funds through competitive grants. Relatively little attention has been given to securing other types of funding such as Hatch formula funds. This strategy is questionable for the land-grant system in the long run. Research conducted in conjunction with this study suggests that the most appropriate funding policy is a healthy mixture of formula funds and competitive grants. The results indicate that different funding mechanisms may be more appropriate for the different functions or goals of land-grant universities. For example, if the goal is to increase cutting-edge basic research, increased funding for competitive grants might be the best approach. If the primary goal is to enhance research applicable to problem solving or to train future researchers, the more stable and locally controlled Hatch formula funds may be the more appropriate mechanism. The appropriate allocation of these two types of grants depend on the relative priorities given to the three missions of land-grant universities.

Potential Privatization of Research at Land-Grant Universities—Two new sources of research funds are private sector investment and product sales. Constrained and basically stagnant research budgets provide many incentives for universities to increase funding via these mechanisms, but the development has raised many concerns. For example, incentives to privatize university innovations for the benefit of the university rather than society could conflict with the mandated mission of the university. Using public resources to reap private gains raises many ethical questions. Allowing individual researchers to share in the profits of their publicly funded work and encouraging universities to produce consumer products opens the door to potential abuses. Certainly, potential exists for conflicts of interest. There may be financial conflicts if individual researchers are allowed to capture the returns of their innovations. To some extent, this situation already exists in that researchers use public funds to generate new knowledge that can be sold to the private sector in the form of consulting fees. But there is a distinction between providing expertise to potentially multiple clients and having a vested interest in the development of one or several products by companies. Universities also may face conflicts of interest. The credibility of the university may suffer if it is viewed as being too cozy with industry. If public universities are viewed as being more concerned with their own private good than with the public welfare, then the public may not maintain its support for the university.

One underlying principal of scientific research is the free exchange of research results. Concern arises that with increased potential to earn income from research, the results of research will become more proprietary. Moreover, research results may not be freely or readily exchanged if a researcher, university, or industrial sponsor attempts to patent the results or seek additional private-sector funding.

Given the level of underinvestment in agricultural research and the stagnation of public-sector funding for this activity, the extra revenue earned from product sales could provide great benefits for the university and for society. Whether those benefits will be attained will depend on how the revenue generated from commercialized activities is used. The extra revenue could be used to fund socially underfunded research or to enhance the teaching capacity of the university. The new arrangements may enable universities to contribute to economic development in ways not previously possible. Whether or not the funds are used for such purposes will depend on how well university administrators are able to maintain a sense of priority for the overall research and teaching program, and whether they have the administrative skills to keep scarce resources allocated to the proper ends.

Policy Options

1. The new partnership between the public and private sectors potentially can revitalize agricultural research, but could also bias the overall research endeavor and damage the credibility of universities. Research and close monitoring will be needed to understand the changes occurring within the land-grant system and to ensure that they are not undermining the system as a whole.

. *Congress could require the U.S. Department of Agriculture to monitor the increased private-sector, funding of agricultural research and to prepare an annual report for Congress containing the data.*

Currently, little is known about the extent of private-sector funding at land-grant universities and the nature of the relationship between the universities and the private sector. Congress could conduct oversight hearings periodically on this issue. Furthermore, Congress could direct USDA to collect data from the land-grant universities on the extent of public-private collaboration, to prepare an annual report for Congress containing the data, and to provide guidelines on the appropriateness of various public-private sector research collaborations.

. *Congress could direct USDA to require land-grant universities to establish an explicit policy with regard to research sponsored by the private sector and report that policy to Congress.*

The USDA would require each university using private-sector research funds for agriculture to establish a specific policy as to how those funds are used based on a broad policy established by the land-grant system. Establishing an advisory board that includes members of the public in setting priorities for research funded from the private sector might be an effective mechanism. This would help to increase public confidence that the university is using funds to solve problems that confront society.

2. **High rates of return to public-sector investments have been reported by numerous studies, including past OTA reports. This indicates that public sector-research funding is below optimum rates.**

. Congress *could increase public-sector support of agricultural research.*

Increasing public-sector support of agricultural research might help to lessen the pressure on land-grant universities to obtain funds from the private sector. Given the high rate of return on public-sector funding of agricultural research, funding increases probably would prove beneficial.

. *Congress could maintain or decrease public-sector funding for agricultural research.*

Federal funding for agricultural research has been relatively flat for the last 30 years. As a consequence, States have picked up the increased costs of conducting agricultural research. It is difficult for States today to take on an ever increasing share of public supported research. If the Federal Government continues to reduce its contribution to research funding, land-grant universities must look for alternative sources of funding. Private-sector funding from specific industries or individual firms or product sales from technologies developed by the university are the most likely sources of additional research funds. The impact of this shift in support is not known but needs further analysis.

3. **Recent research indicates that public-sector funding mechanisms should be goal oriented.**

. *Congress could* ***appropriate funds for agricultural research through funding mechanisms*** *bused on well-defined agricultural research goals.*

The land-grant system provides teaching, extension, and research functions. Preliminary research suggests that Hatch formula funds are more suited to teaching and extension activities and competitive grants more suited to basic research. By appropriating funds according to goals to be achieved, Congress could improve the effective use of public funds.

. *Congress could maintain the current emphasis* of *increased funds for competitive grants and level or decreased funding of formula and intramural funds.*

Implicitly, this would indicate that Congress places greater emphasis on basic research than on adaptive research, extension, and teaching activities. Evidence does not exist that the lack of basic research is the primary constraint to the ability of land-grant universities to fulfill their historic mission of addressing research aimed at solving societal problems.

. Congress could extend ***competitive grants to extension and teaching curricula development.***

A strong case can be made for formula funding of agricultural research. However, if the only acceptable political form of increased funds is competitive grants, then expanding these grants to include adaptive research, extension and teaching could be considered. Balanced funding of basic research, adaptive research, teaching, and extension would significantly strengthen the land-grant universities and help them meet their multiple missions more effectively.

. *Congress could award* certain competitive grants to ***basic research that clearly shows ties to adaptive research.***

This would be a clear signal that Congress considers the original mission of land-grant universities to be appropriate today. Currently, most grants for basic research are not tied directly to adaptive research. Thus, it is

difficult to differentiate between funding provided by the National Science Foundation (the major funding agency for basic research) and the U.S. Department Agriculture.

4. **The public is increasingly losing confidence in land-grant universities' credibility, and credibility needs to be restored. Development of a more mission-oriented system with increased public input could help to restore confidence in the system.**

The OTA report *Agricultural Research and Technology Transfer Policies for the 1990s* addresses this issue in some detail and provides specific options that suggest changes in the system to make it more mission oriented. Those options are incorporated here by reference. Some of the options were incorporated into the 1990 Food, Agriculture, Conservation, and Trade Act of 1990(1990 Farm Bill).

SUMMARY

Newly emerging biotechnologies and information technologies hold great promise for American agriculture and can provide solutions to many problems. In the decade of the 90s, however, public concerns about the environment, food safety, industry structure, and institutions will focus on these emerging technologies. Whether these technologies will be accepted and flourish, or stagnate, will depend in large measure on how U.S. public institutions resolve the complex problems of regulatory oversight and on whether scientists and policy makers can allay public concerns about biotechnology in particular.