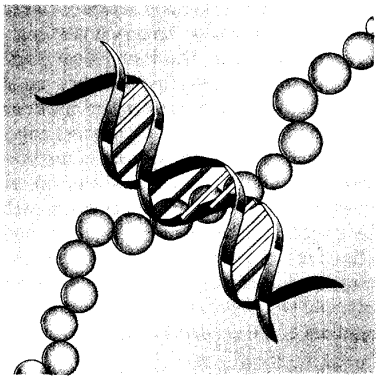
FOCUS ON BIOTECHNOLOGY

Issues and Challenges



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Every generation feels that it lives in uniquely challenging times. Yet every generation somehow finds the tools and means to rise and meet those challenges. In the 1990s, society as a whole—along with agriculture in particular—is facing rapid political and economic change, increased international competitiveness, and growing environmental concerns such as water quality, human health and nutrition, global climate change, and food safety. Fortunately, we have the new tools of biotechnology that offer tremendous potential to help address these issues.

In agriculture, over the centuries, people have sought to improve plants, animals, and microorganisms to produce food and fiber for their needs. The process of genetic improvement is the backbone of agriculture and the foundation of our ability to feed and clothe a growing world population.

Biotechnology offers a powerful, yet precise set of new tools to use in this ongoing endeavor. The last ten years of research and development have led agricultural biotechnology to the very brink of commercialization. Our hard work is about to pay off in terms of new agricultural products in the marketplace — products that could trigger a revolution in the way agriculture is carried out around the world — thanks to a technology that may one day have a greater impact on our lives than any other revolutionary technological advance of the 20th century.

But this emerging potential cannot stand and flourish solely on its own. In the U.S., we have found that a strong, successful biotechnology effort requires three basic support activities: *research*, *regulation*, and *communication*.

The investment in the long-term research required to capitalize on the opportunities of the "new biology" began in the early 1970s at the National Institutes of Health. Indeed, because of these investments, the tools of biotechnology were applied rapidly throughout plant and animal sciences. In 1984, the United States Department of Agriculture (USDA) made its first commitment to "agricultural" biotechnology research. The program has grown from $14 million in 1984 to more than $214 million for the fiscal year 1994.

Like research funding, *judicious regulation* has always been a crucial part of the U.S. biotechnology endeavor. Regulation is necessary in order to respond to the challenge of developing biotechnology to meet broadly accepted societal goals, while at the same time protecting human health and the environment. Those of us working in agriculture feel this challenge particularly keenly.

Realistically, we recognize that the fulfillment of biotechnology's potential is dependent on a thorough understanding by the public and by the research community of not only the science involved, but also the social and economic impacts it brings in its wake. That is why *effective communication* is the other crucial part of our endeavor.

Transgenic Farming

Let me illustrate these two points using a specific technology. One of the most exciting fields of animal biotechnology is the genetic modification of farm animals to produce pharmaceuticals and other valuable products. For example, DNX Corporation in New Jersey has recently announced success in developing transgenic pigs that produce human hemoglobin in their bloodstream. If this product proves functionally normal in humans and produces no untoward reactions, porcine-produced human hemoglobin may be an ideal candidate for a large-scale human blood substitute. Its great advantages would be low cost and the removal of the risk of transmission of AIDS and hepatitis.

Further, a research team in the U.K. has achieved expression of human alpha-1-antitrypsin in the milk of transgenic sheep. A research team in the Netherlands has developed transgenic dairy cattle using a new, *in vitro* method of embryo production. And a research team in the U.S. has achieved transgenic production of variant human tissue-type plasminogen activator in goat milk.

These advances and other contemporary discoveries are beginning to blur the distinction between research in agriculture and research in other life sciences. Indeed, it does not seem too farfetched to imagine a day when a great deal of farm income will be generated from the sale of products that are neither food nor fiber. But this exciting view of the future may be jeopardized if we do not pay attention to the three crucial supports noted above — adequate research funding, judicious regulation, and effective communication.

Research

In the fiscal year 1993 and 1994 budgets, the president announced a biotechnology research program designed to assure the nation a vigorous foundation in science and engineering for the future development of this critical technology. The budget included $4.27 billion for biotechnology in FY 1993 and $4.31 billion in FY 1994. That trend is continuing into the FY 1995 and FY 1996 budgets.

This presidential initiative recognizes the critical role of biotechnology in future technological strength, economic growth, and the health and quality of life for the Nation. The United States has been the world leader in biological research for the past 30 years, providing a foundation for the current U.S. preeminence in biotechnology research. This leadership, however, is clearly being challenged as the field changes and rapidly expands.

Twelve Federal agencies are participating in the biotechnology research program, with biotechnology research efforts in areas ranging from the use of microorganisms to clean up the environment, marine biotechnology, human genome research, and molecular medicine. The largest fraction of the FY 1994 biotechnology research budget supported programs in the Public Health Service, primarily the National Institutes of Health. However, increases in funding over FY 1992 levels

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were proposed for research related to manufacturing, bioprocessing, energy, agriculture, and the environment, and these increases are continuing to the FY 1996 budgets.

Regulation

In the U.S., a regulatory framework is in place for the review and approval of products for commercialization, particularly where clearances are required for the release of certain genetically modified organisms into the environment.

During the past 10 years, we have continued to better define the risks, and hence could lessen the scope of organisms that should receive regulatory oversight. Our 1991 publication "Guidelines For Research Involving Planned Introduction Into The Environment Of Genetically Modified Organisms" — illustrates how this definition of scope should be used in a regulatory system.

Regulation of biotechnology must be based on sound scientific principles, in which intensity of oversight is commensurate with the level of risk. We have three major regulatory goals: 1) to avoid singling out recombinant-DNA technology as representing any more risk than traditional procedures used to modify an organism; 2) to refrain from unduly hindering research with burdensome and unnecessary overregulation; and 3) to provide assurance to the public that there is careful scientific review prior to the release of modified organisms if there is any question as to how they will affect the environment or human health.

In the United States, the USDA Animal and Plant Health Inspection Service (APHIS) reviews applications for field tests of transformed plants that involve a plant pest. From 1987 until October 1994, USDA had issued more than 1140 permits of notification for field tests of genetically transformed plants, and the momentum of field testing is growing. Importantly, scientists who have conducted field tests with organisms produced with biotechnology have not reported any unexpected effects on the environment or public health. And the public has gradually gained confidence that it is being well-protected.

Of course we must have systems which ensure safety. It is equally important to ensure that we do not create a burdensome system of oversight that stifles innovation and requires scientists to provide unnecessary paperwork on projects we already know, through long experience, are really very safe. This is a difficult balance, but we must achieve it if biotechnology is to flourish.

Technology Transfer

Another aspect of regulation involves facilitation of the transfer of technology from the research laboratory to the marketplace— a key factor in the commercialization of biotechnology. In past years, the U.S. has sometimes had difficulty in keeping private firms up-to-date on what public sector research has to offer. Business firms have been slow to take advantage of government research results.

To address this impedement, the U.S. Congress passed the Federal Technology Transfer Act of 1986, which mandates, when appropriate, technology transfer agreements between industry and government research laboratories. These technology transfer agreements, called cooperative research and development agreements (CRADAs), provide the industry cooperator with the first right to exclusive licenses on patented inventions made under the agreement. Also, in carrying out these agreements, government scientists are authorized to work as closely as necessary with private firms to help the companies commercialize technology based on the scientists' research.

Under these agreements, the cooperator either provides funds for specified government research expenses or enters into a memorandum of understanding, which involves no transfer of funds. Of course, the research must be consistent with the government agency's mission.

How well is it working? Since the act was implemented, there have been hundreds of technology transfers between USDA and the private sector. Incidentally, if you own a personal computer you can interface with the Technology Transfer Automated Retrieval System to get the latest update on new research results. Some 400 companies now regularly use the system, which produces an interpretive summary, but does not contain confidential business information.Another example of technology transfer and leverage of Federal funds can be found in the federal/university/private sector relationship at several U.S. universities. These cooperative ventures actively solicit inventions from the faculty and seek to commercialize them.

USDA's Extension Service, located in every county across the United States, is also involved in the ongoing transfer of agricultural technology. Extension has placed biotechnology high on its list of priorities and has instituted programs to keep its own agents up-to-date so they can be more helpful to the industry and the general public.

Patents and intellectual property

In a broader sense, regulation also includes the adequate protection of intellectual property rights— one of the keys to the successful development of the biotechnology industry. Private sector companies will not invest years in research and development if they cannot be assured a fair return once they bring a biotechnology product to market. Thus, we believe that full patent protection of biotechnology products and processes is a prerequisite for realizing their benefits.

However, the industrialized world must take special care to ensure that the benefits of biotechnology reach the developing countries of the world. This will involve special programs for training and technology transfer, not only by governments and international organizations, but also by the private sector.

More and more companies are recognizing their special responsibilities in this area by setting prices that developing countries can afford, establishing joint ventures and subsidiaries in the developing world, and allowing their scientists time to work on projects with counterparts in developing countries. Some companies have even donated improved genetic materials to developing countries. And there are many possibilities for further work that can be done.

Communication to the Public

I believe we can all agree that one goal of regulation is to strengthen public confidence. In order to do that, we must *communicate* to the public that science is being pursued safely and that the products of agricultural biotechnology, like the products of other technologies, meet accepted regulatory criteria.

Effective regulation and communication are two sides of the coin of public acceptance of biotechnology. In my experience, people fear the unknown. Thus, in order to gain public acceptance, nations must ensure that their systems of regulatory oversight are as open as possible. The public must have the maximum opportunity to understand the processes used to ensure its safety and protect the environment. In addition, I believe we all need to improve our ability to communicate effectively with the public about technical issues.

Rarely has a single new technology held such promise for a wide spectrum of benefits— in health, agriculture, energy, and the environment. The impressive breadth and importance of biotechnology research is clearly recognized. When official U.S.-European Community (US-EC)

science policy consultations were set up about five years ago, biotechnology research was the first area chosen for discussions. The US-EC Task Force on Biotechnology Research has held three very productive meetings, and one of the conclusions reached at the meeting in Brussels was to organize a joint workshop on public understanding of biotechnology, which was held in Dublin in March 1992.

Risk Communication

If we are to expect the public to react favorably to new products of biotechnology, risk communication is yet another area that requires attention by the scientific community. Risk assessment research is a central mechanism for addressing public concerns. Consumers no longer just look to the benefits of new products, they also demand to be informed about the risks.

In order to supply consumers with the information they seek, the 1990 U.S. Farm Bill legislation explicitly directs USDA to support biotechnology risk assessment research. Under this legislation, the Secretary of Agriculture is to establish a grant program to fund research on methods to confine introduced organisms, monitor their dispersal, study potential gene transfer, and investigate other areas in which biosafety information may be incomplete. To support this research, USDA has allocated one percent of its biotechnology research funding exclusively for risk assessment work; the funding level was about $1.7 million during the 1994 fiscal year.

All of these activities are ways to step up our efforts to communicate with the public. We hope to do a better job of explaining the promise of biotechnology in addressing many of the issues which are dear to people's hearts— environmental protection, hunger and malnutrition, and food safety. This is a new challenge for the scientific community, but one that we cannot afford to ignore. For without public support, the advancement of science will come to a halt, and society will be deprived of the fruits of our labors.

Conclusion

Biotechnology is an invaluable process for the quick, safe, and precise transfer of specific genetic information from one organism to another, in order to create predictable end results. As such, USDA sees biotechnology as an important component of a balanced, efficient, well-managed, and environmentally responsible agricultural system, which uses the very best of technology and science.

The recent discoveries in the field of biotechnology have made the life sciences some of the most exciting fields of scientific endeavor— especially for those with creativity and vision. We are only beginning to explore the diverse multi-disciplinary applications of these discoveries.

The great British leader Winston Churchill said, "If the human race wishes to have...prolonged... prosperity,...science will do for them all they wish and more than they can dream." Brilliant as he was, Churchill was wrong on this one. Science— in this case, biotechnology— will do nothing for *us*; it is *we* who must do for biotechnology. In the complicated and demanding world in which we live, factors other than the rate of research breakthroughs will influence scientific achievement. Carefully thought out regulation, effective communication, and a commitment to long-term research funding will play equally important roles in the determination of biotechnology's future.

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