A 2020 Vision for Food, Agriculture, and the Environment
2020 VISION

BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

OVERVIEW

GABRIELLE J. PERSLEY AND JOHN J. DOYLE

FOCUS 2 • BRIEF 1 OF 10 • OCTOBER 1999

Today, almost a billion people live in absolute poverty and suffer from chronic hunger. Seventy percent of these individuals are farmers—men, women, and children—who eke out a living from small plots of poor soils, mainly in tropical environments that are increasingly prone to drought, flood, bushfires, and hurricanes. Crop yields in these areas are stagnant and epidemics of pests and weeds often ruin crops. Livestock suffer from parasitic diseases, some of which also affect humans. Inputs such as chemical fertilizers and pesticides are expensive, and the latter can affect the health of farm families, destroy wildlife, and contaminate water courses when used in excess. The only way families can grow more food and have a surplus for sale seems to be to clear more forest. Older children move to the city, where they, too, find it difficult to earn enough money to buy the food and medicine they need for themselves and their young children.

As these detrimental social and environmental changes are occurring in the developing world, a revolution in biotechnology and associated information technology is improving the health, well-being, and lifestyle of the privileged and creating more wealth in a few rich countries. Can this revolution also be harnessed to serve the food and nutrition needs of the world's poor? What are the opportunities, problems, and risks involved with the new technologies and can they be managed? The last question is particularly pressing in light of the current controversy between the United States and the European Union over genetically modified foods. The benefits and risks of biotechnology weigh differently for food in areas of food surplus than they do for life-threatening diseases in those same areas.

OPPORTUNITIES

In 1998 the global market for biotechnology products (see box for definition of terms) totaled at least US$13 billion. About 80 products, most of them medically related, are on the market or nearly ready for it. In recent years, the fruits of two decades of intensive and expensive research and development (R&D) in agricultural biotechnology has begun to pay off. Approximately 28 million hectares of land were planted with 40 transgenic crops in 1998. Most of these crops were new varieties of cotton, corn, soybean, and rapeseed. Developing countries held 15 percent of the area planted with the transgenic varieties.

Most biotechnology-based solutions for agriculture are likely to be delivered in the form of new plant seeds or new strains of livestock. These solutions continue the tradition of selection and improvement of cultivated crops and livestock developed over the centuries. The difference is that new gene technology identifies desirable traits more quickly and accurately than conventional plant and livestock breeding. Modern biotechnology can also introduce the genes that control desirable traits into plant and animal strains with far greater precision and control than can conventionalmethods.

DEFINITIONS OF BIOTECHNOLOGY AND ITS COMPONENT TECHNOLOGIES

Biotechnology is any technique that uses living organisms or substances from those organisms to make or modify a product, improve plants or animals, or develop microorganisms for specific uses. The key components of modern biotechnology are

- **Genomics: themolecular characterization of all species;**
- **Bioinfomatics: the assembly of data from genomic analysis into accessible forms;**
- **Transformation: the introduction of single genes conferring potentially useful traits into plant, livestock, fish, and tree species;**
- **Molecular breeding: the identification and evaluation of desirable traits in breeding programs with the use of marker-assisted selection;**
- **Diagnostics: the use of molecular characterization to provide more accurate and quicker identification of pathogens;**
- **Vaccine technology: use of modern immunology to develop recombinant DNA vaccines for improving control of lethal diseases.**

Biotechnology applications in agriculture are in their infancy. The first generation of genetically engineered plant varieties have been modified only for a single trait, such as herbicide tolerance or pest resistance. The rapid progress being made in genomics will transform plant, tree, and livestock breeding as the functions of more genes are identified. Breeding for complex traits such as drought tolerance, which is controlled by many genes, should then become common. This is an area of great potential benefit for tropical crops, which are often grown in harsh environments and on poor soils.

To determine if modern biotechnology can benefit the poor in developing countries, policymakers at the national, regional, and international levels need to analyze the problems that are currently constraining agricultural productivity or damaging the environment, assess whether these problems may be solved by integrating modern biotechnology with conventional R&D, and prioritize solutions. This may seem self-evident but such strategic analyses are indispensable for anticipating the potential benefits and risks that may arise while using modern biotechnology to solve specific problems. In addition to analyses, both public and private

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resources for R&D need to be mobilized if the poor in developing countries are to profit from the genetic revolution.

POLICY FRAMEWORK

Modern biotechnology will not solve all the problems of food insecurity and poverty. But it could provide a key component to a solution if given the chance, and if steered by a set of appropriate policies. These policies should guide (1) increased public investments in R&D, including that in modern biotechnology; (2) regulatory arrangements that inform and protect the public from any risks arising from the release of genetically modified organisms (GMOs); (3) intellectual property management to encourage greater private-sector investment; and (4) regulation of the private seed and agricultural research sector to protect the interests of small farmers and poor consumers in developing countries.

Public-sector R&D. Pro-poor policies can help expand agricultural R&D, including traditional and modern biotechnological research, in order to solve problems of particular importance to the poor. The problems of orphan commodities (important subsistence food and/or tropical export commodities that hold little commercial interest for the private sector) require particular attention. Given the high rates of return, more public support for agricultural R&D should be encouraged in most developing countries. Additional public financial support for R&D at the national, regional, and international levels would help to develop public goods the poor can afford.

Biosafety. The term biosafety describes a set of measures used to assess and manage any risks associated with GMOs. Such risks may transcend or be inherent in the technology and need to be managed accordingly. Technology-transcending risks emanate from the political and social context in which the technology is used. They include concerns that biotechnology may increase the prosperity gap between the rich and the poor, and may contribute to a loss of biodiversity. Ethical concerns about patenting living organisms and moving genes between species also fall into this category.

The principles and practices for assessing and managing technology-inherent risks are well established in several countries. They take into account the nature of the organism, the familiarity of the product, any distinguishing features of the process by which a product was produced, and the environment into which it will be introduced. A science-based assessment of these factors on a case by case basis, and identification of any concerns expressed by stakeholders, enable regulators to find out what risks may be associated with a particular product and to make appropriate recommendations. A regulatory system that enjoys the confidence of the public and the business and farming communities is essential for the effective use of biotechnology. The current and proposed international agreements that govern movements of GMOs also contribute to biosafety.

Intellectual Property Management. The purpose of intellectual property management is to protect local inventions and enable access to technologies developed elsewhere. Trade-related intellectual property rights (TRIPs) are a matter of ongoing concern within the World Trade Organization. The present patent system favors those countries that have a strong innovation base. Despite much effort, no satisfactory system exists to recompense traditional owners and improvers of germplasm. The lack of intellectual property protection also constrains private-sector investment in developing countries.

The Private Sector. The participation of the private sector is critical to the development and delivery of new biotechnology products. The enabling environment to encourage private-sector participation includes a regulatory system that accurately informs the public of the benefits and risks involved in the use of new technologies; a legal framework for protecting intellectual property; adequate infrastructure for power, transport, and telecommunications; a fair tax system and investment incentives; a skilled workforce, including a well-supported university sector; public funding for R&D; and incentives to establish innovative public-private collaboration and joint ventures at the national and international levels.

DELIVERING SOLUTIONS FOR THE POOR

The successful application of modern biotechnology to the problems that cause undernourishment and poverty could be called a biosolution. The delivery of new biosolutions to the problems of food security and poverty will require continual policy development and actions at the national, regional, and international levels. These efforts will involve the following five areas: (1) determining priorities and assessing relative risks and benefits in consultation with the poor, who are often overlooked while others decide what is best for them; (2) setting policies that benefit the poor and that minimize technology-transcending risks that adversely affect the poor; (3) establishing an environment that facilitates the safe use of biotechnology through investment, regulation, intellectual property protection, and good governance; (4) actively linking biotechnology and information technology so that new scientific discoveries worldwide can be assessed and applied to the problems of food insecurity and poverty in a timely manner; and (5) determining what investments governments and the international development community will have to make in human and financial resources in order to ensure that biosolutions to the problems of food security reach the poor. ■

For further information, see John J. Doyle and Gabrielle J. Persley, New Technologies: An International Perspective, in *Investment Strategies for Agriculture and Natural Resources: Investing in Knowledge for Development*, ed. G. J. Persley (Wallingford, U.K.: CABI, 1998); and Ernst and Young, *Bridging the Gap*, 13th biotechnology industry annual report, 1999 (available through www.ey.com).

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

BIOTECHNOLOGY AND FOOD AND NUTRITION NEEDS

RICHARD FLAVELL

FOCUS 2 • BRIEF 2 OF 10 • OCTOBER 1999

Biotechnology can make life better for the poor in developing countries by producing higher than usual yields with less inputs, higher yields in a wider range of environments, better rotations to conserve natural resources, and more nutritious harvested products that keep much longer in storage and transport. Improved animals can resist diseases more effectively, have carcass structures that carry higher weights safely and healthily, have more efficient weight gains, and offer better quality meat and other products.

Because plants and animals evolve to fit their environment, and not to serve human needs, men and women have practiced breeding and selection since the earliest times to produce more useful strains of plants and animals. The deployment of new genes and combinations of genes, therefore, is and always will be the basis for plant and animal improvement. Logically, the scientific case for using the new gene technology to improve plants and animals is overwhelming. This improvement process needs to continue in order to sustain today's and tomorrow's world in ways that achieve greater benefits and cause less harm to the planet's resources.

THE BENEFITS AND RISKS OF BIOTECHNOLOGY

The application of biotechnology research to agriculture is in its infancy. However, the incorporation of novel genes has already produced plants that are more tolerant to drought and salt stresses, toxic heavy metals, and pests and diseases. Seeds with greater nutritional value have been produced by increasing the levels of essential amino acids, vitamins, and bioavailable iron. Genetic alterations have reduced overripening and postharvest losses of fruits. Given time and resources, the potential for improving all crops through these methods is enormous. The impact of biotechnology on food production, postharvest losses, and the nutritional value of food could improve the livelihoods of millions of poor people (see table).

But just as with natural evolution and breeding through the ages, gene changes through biotechnology can produce problems as well. Breeding to improve one characteristic can have negative effects on another. Breeding also modifies the concentration of beneficial or harmful ingredients, because it changes the internal chemistry of organisms. Common genes in our cultivated crops could become more commonplace in wild relatives by outcrossing and subsequent selection, leading to possible disturbance of existing ecosystems. New plants or animals may generate husbandry practices that damage the environment. New strains could reduce biodiversity in agriculture.

These sorts of issues are well known to breeders and farmers all over the world. They are increasingly becoming a matter of public debate in many countries. The benefits and risks associated with improved plants and animals are frequently perceived differently from place to place. Local decisions should prevail but be consistent with globally accepted, science-based criteria and international agreements. Most current discussions about the benefits and risks of the new gene technology, however, are based on the first transgenic crops of today. Instead, a strategic, long-term view of needs and opportunities is required that looks beyond these initial products. Relevant scientific knowledge and understanding and the genes available to meet needs are evolving rapidly. Soon the scientific base underpinning plant and animal breeding will be extraordinarily different from that of the past.

NEW, ALREADY AVAILABLE TRAITS THAT COULD HELP FOOD PRODUCTION IN THE POOREST COUNTRIES IF TRANSFERRED INTO THEIR CROPS

- **Beta carotene enrichment to correct vitamin A deficiency**
- **More nutritious oils, starches, and amino acids**
- **Better fatty acid profiles**
- **Better digestibility for animals**
- **Delayed overripening of fruits and vegetables**
- **Bacterial and fungal disease resistance**
- **Insect resistance**
- **Virus resistance**
- **Salt tolerance**
- **Aluminium and manganese tolerance.**

Source: Salamini 1999 (see suggestions for further reading).

THE NEW GENOMICS

Within the next year the full DNA sequence of every gene required to produce a plant will become known as a result of a large international effort. This will be a historic landmark for crop breeding. As a next step, scientists will interpret gene structures and patterns of expression in each organism. This integrated knowledge of large numbers of genes is called genomics. Once a gene has been identified in one species its functional relative can be found in other species to aid breeding of any crop. Descriptions of the human and mouse genes will serve as models for farm animals.

The means of inserting new genes into plants has been demonstrated for a large number of species, including several of

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the world's major crop species. Although the procedure is still inefficient and expensive for many species, stable varieties of soybean, maize, canola, and potato are now in large-scale agricultural production. The technical hurdles clearly are not insurmountable. Creating transgenic plants with large numbers of novel genes may not be easy, but the considerable benefits versus risks provide incentives for continued research.

Knowing the sequences of most genes in a plant or animal chromosome and the chromosomal segments containing them is opening up new opportunities for determining and manipulating the genetic variants present in a particular strain. But this new technology will prove useful to plant improvement only if it is integrated into plant breeding procedures. Breeding programs in the developing world, therefore, will need to absorb this technology via integrated links with public and private institutions that have shown success with the new methods. The international agricultural research centers have begun to stimulate the creation of such links for crops produced by the poor.

Securing the Benefits of Genomics for Developing Countries

Genomic databases for some of the major crops of the developing world—maize, wheat, rice, and soybean—are being developed rapidly and competitively in the public and private sectors of the North to make improved cultivars. How and when can all this knowhow and improved germplasm be made available to the developing world? There is no simple answer to this question, just as similar questions about diffusion of technology and knowhow have had no simple answers in the past. As always, the answers depend on a host of local circumstances, institutions, attitudes, and finance. Many developing countries have started programs to benefit from the new gene technology. Governments, philanthropic agencies, and the private sector are funding technology transfer initiatives. The institutes of the Consultative Group on International Agricultural Research are also playing a role. New, multifaceted approaches to technology transfer urgently need to be developed to reflect the proprietary nature of some of this technology. Such approaches should be driven by the needs of the poor, whenever benefits are greatest and risks low.

Germplasm Conservation

Genes and gene combinations selected in the past in nature and by humans will remain the vital source of germplasm improvement. They must be conserved in seed banks, but also *in situ* when possible and strategically essential. Genomics can play a key role in conservation because it can determine which genes and chromosome segments are duplicated, which are unique, and how easy it will be to recreate the various combinations of chromosome segments in modern breeding programs. Genomics, therefore, needs to be applied on a large scale to germplasm collections. And as the technology becomes faster and cheaper to use, new, long-term international initiatives involving the public and private sectors are required to generate the appropriate knowledge databases.

THE FUTURE PATH

Plant and animal breeding will become increasingly integrated programs of the life and social sciences. The life sciences will be based on huge databases of genes and the practical knowledge of how to analyze and change their presence, activity, and role in whole organisms. This extraordinary revolution in the ways of understanding germplasm, coupled with the means of making additions and changes to plant and animal genomes, can and should have a large impact on the efforts to improve plants and animals for food production.

The gathering and provision of so much sophisticated information in computerized databases, by both the private and public sectors, and the patenting of genes and germplasm require a new paradigm for using biotechnology to improve germplasm, especially in the poor countries where food needs are most urgent. This paradigm requires public and private partnerships among advanced genomics specialists, breeders, and scientists knowledgeable about the germplasm upon which the world depends for food. The fruits of such partnerships should serve environmental sustainability and the needs of diverse consumers, with all relevant groups playing a role as stakeholders. International agreements and an effective regulatory framework for the validation of new strains for agriculture are urgently needed. The benefits and risks associated with each product need to be evaluated locally and in the context of global standards.

Although debates continue to flair in the media about the contribution that biotechnology should make to our crops and livestock, they are often fueled by errors of fact and political agendas having little to do with the needs of agriculture, the environment, and the poor peoples of the world. The features and limitations of current biotechnology products and systems also tend to distort the debate. Discussions should revolve around a long-term strategic view based on what the technology can deliver and what the needs of the world will be over the next millennium. It would be unethical to condemn future generations to hunger by refusing to develop and apply a technology that can build on what our forefathers provided and can help produce adequate food for a world with almost 2 billion more people by 2020. ■

For further information, see Francesco Salamini, North-South Innovation Transfer, *Nature Biotechnology* 17 (Supplement A, 1999): 11-12; Florence Wambugu Why Africa Needs Agricultural Biotech, *Nature* 400 (No. 6739, 1999): 15-16; and Clive James, *Global Review of Commercialized Transgenic Crops: 1998*, ISAAA Brief No. 8 (Ithaca, N.Y.: International Service for the Acquisition of Agribiotech Applications, 1998).

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BIOTECHNOLOGY AND ANIMAL VACCINES

W. IVAN MORRISON

FOCUS 2 • BRIEF 3 OF 10 • OCTOBER 1999

Supplies of livestock products in developing countries must increase to meet growing demand from burgeoning populations and rapid urbanization. Because of competition for land use, the necessary growth in livestock output will have to come in great part from improvement in the efficiency of production systems. Disease is one of the major factors contributing to poor livestock productivity in developing countries. This is particularly true for Sub-Saharan Africa, where animal losses due to disease are estimated to be US$4 billion annually, approximately a quarter of the total value of livestock production. Tsetse fly-transmitted trypanosomosis and tick-borne diseases are the most important livestock disease problems in this region. Therapeutic agents are available for some of these diseases, but problems remain. Chemotherapy, for example, is impractical as a primary means of disease control, because costs are high and intensive application can create drug-resistant organisms. Controlling arthropod vectors to prevent diseases, particularly tick-borne diseases, has proved difficult to sustain because of cost, the need for well-developed infrastructure, and the emergence of resistance to the chemicals used. Vaccination offers a potentially more effective and sustainablemethod of disease control.

OPPORTUNITIES PRESENTED BY NEW BIOTECHNOLOGY AND IMMUNOLOGY

Vaccines developed using traditional approaches have had a major impact on the control of foot-and-mouth disease, rinderpest, and other epidemic viral diseases that affect livestock. But there are many other important diseases, notably parasitic diseases, for which attempts to develop vaccines have been unsuccessful. Rapid advances in biotechnology and immunology over the last two decades have created new opportunities to develop vaccines for parasitic diseases. Initial optimism in the early 1980s that vaccine products would quickly emerge from applications of recombinant DNA technology has not been fully realized. Subsequent experience has demonstrated that, unlike traditional approaches to vaccine development, effective exploitation of recombinant DNA technology requires knowledge of the target pathogens and the immune responses they induce, and an understanding of how immune responses can be manipulated. Since the early 1980s a series of fundamental discoveries in immunology have led to a detailed understanding of how the immune system processes and recognizes pathogenic organisms, and the different ways that immune responses control infections. This new knowledge is directly relevant to all stages of vaccine development, from identification of the genes or proteins that need to be incorporated into a vaccine, to the design of a vaccine delivery system that will induce a particular type of immune response. These advances, coupled with further developments in the application of DNA technology, now provide a strong conceptual framework for the rational development of new vaccines.

USE OF BIOTECHNOLOGY TO DEVELOP CANDIDATE VACCINES

Two main approaches are being pursued to develop vaccines using recombinant DNA technology. The first of these involves the deletion of genes that determine virulence of the pathogen, thus producing attenuated organisms (nonpathogens) that can be used as live vaccines. With current technology, this strategy is more appropriate for viral and bacterial diseases than for parasites. Attenuated live vaccines have been developed for the herpes viruses that cause pseudorabies in pigs and infectious bovine rhinotracheitis in cattle. A number of candidate *Salmonella* vaccines have also been produced.

The second strategy is to identify protein subunits of pathogens that can stimulate immunity. This is the preferred approach to many of the more complex pathogens. It requires knowledge of the immune responses that mediate immunity. This knowledge helps identify the relevant target proteins. The strategy can be illustrated by the approach the International Livestock Research Institute (ILRI) (incorporating the former International Laboratory for Research on Animal Diseases) took to develop a vaccine against *Theileria parva*, the parasite that causes East Coast Fever in cattle in Africa. Studies of immune responses to the parasite have revealed antibody responses to the tick-derived infective stage of the parasite, as well as cell-mediated immune responses against the parasite stages that reside within cattle cells. A parasite protein recognized by the antibody response and the corresponding parasite gene have been identified. Protein expressed from this gene, when used to vaccinate cattle under experimental conditions, has been shown to protect a proportion of animals against parasites. Identification of the parasite proteins recognized by the cell-mediated immune responses presents a greater challenge, but a number of recently developed methodologies for this purpose are now being applied to the problem. It is worth emphasizing that these novel approaches to develop a vaccine for East Coast Fever would not have been possible without the strategic research that had been devoted to understanding the immunology of the disease.

An additional novel strategy developed to vaccinate against blood-sucking parasites involves the use of components of the gut wall of the parasites that are not usually exposed to the host's immune system. Antibodies induced by the vaccine are ingested by the tick during feeding, causing destruction of the gut wall

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and death of the parasite. This strategy has been used successfully to develop a vaccine against the one-host tick *Boophilus microplus*.

Recent rapid advances in pathogen-genome sequencing promise to be of enormous benefit for developing attenuated pathogens and for identifying proteins suitable for use as vaccines. Complete genome sequences are now available for a growing list of human bacterial pathogens. Completion of the sequences of the human malaria parasite, *Plasmodium falciparum*, is expected within a year. These developments will undoubtedly have an impact on vaccine development strategies.

NEW VACCINE DELIVERY SYSTEMS

Live, attenuated vaccines stimulate immune responses similar to those induced by the parent pathogen and usually provide long-lasting immunity. Vaccines using killed organisms require incorporation of adjuvants (agents that enhance immunity-giving characteristics), and the immune responses they induce are usually more limited and of shorter duration than those induced by live vaccines. Co-administration with adjuvants is also a standard method used with subunit proteins but may be ineffective in some cases. Advances in biotechnology have provided a number of alternative vaccine delivery systems for subunit proteins that overcome these shortcomings and offer some of the advantages provided by live vaccines. Two of the most promising approaches are the use of attenuated organisms as live vectors and vaccination with DNA.

Live-vectored vaccines incorporate a gene encoding a subunit protein into the genome of an attenuated organism, which itself may be in use as an attenuated vaccine. The protein is then produced when the organism replicates in the animal. A vaccine containing a rabies virus gene has been used to protect foxes against rabies. An attenuated strain of sheep and goat pox virus containing rinderpest virus genes has been shown to protect cattle against rinderpest. Although this system offers little advantage over the conventional rinderpest vaccine, it illustrates the potential of the vector for delivery of other proteins.

The use of DNA for vaccination is based on the discovery that injection of genes in the form of plasmid DNA can stimulate immune responses to the respective gene products. This occurs as a result of the genes being taken up and expressed by cells in the animal following injection. Stimulation of immune responses and partial protection have been reported for a number of pathogen genes in livestock species, but none of these has yet led to a fully effective vaccine.

The live-vector and DNA vaccination systems could be manipulated further to enhance the immunity-conferring characteristics of the gene products. Experimental studies have demonstrated that these systems have enormous potential for developing vaccines that induce appropriate and enduring immune responses.

PROSPECTS FOR VACCINES AGAINST TICK-BORNE DISEASES

The tick-borne parasitic and bacterial diseases (theileriosis, heartwater, babesiosis, and anaplasmosis) that affect cattle in tropical and subtropical regions constitute a major focus for vaccine development because of their substantial impact on livestock production. Early observations showed that animals that recovered from these diseases subsequently remained immune. These findings encouraged the view that vaccination should be possible. Indeed, various protocols for vaccinating with live organisms (either with attenuated organisms or by infection and treatment) were shown to be effective for theileriosis and babesiosis, but their use in developing countries was limited because of the complex infrastructure required to produce and distribute live parasites. Although new vaccines have not yet been produced for these diseases, encouraging progress has been made in identifying new candidate vaccines. The recent development of an efficient culture system for *Cowdria ruminantium*, the bacterium that causes heartwater, has led to immunization experiments with inactivated bacteria that have yielded promising results. A protein from the infective stage of the *Theileria parva* parasite has also been shown to have protective properties, and advances in understanding of the immunology of this parasite have led to the development of screening procedures to identify proteins recognized by protective cell-mediated immune responses. Proteins from both stages of the parasite will probably need to be used to produce a robust vaccine against East Coast Fever. Similar studies of the immune responses of cattle to the organisms causing babesiosis and anaplasmosis have resulted in the identification of a number of proteins, some of which give protection under experimental conditions.

CONCLUSION

There is good reason to believe that vaccines will be produced against some or all of the major animal diseases, given the necessary scientific and financial resources. However, the complexity of the problems that are being addressed should not be underestimated. The opportunities presented by advances in biotechnology can only be exploited effectively if there is a thorough understanding of the biology of the target pathogens and the diseases they produce. Such an approach requires substantial investment in strategic research. For understandable reasons, current funding policy in the developing countries strongly emphasizes tackling the problems that will yield practical benefit in the short term. In determining future policy, policymakers and funding bodies must not lose sight of the substantial benefits that can be gained in the longer term by investing in strategic research on vaccine development. ■

For further information see N. Mowat and M. Rweyemamu, eds., *Vaccine Manual: The Production and Quality Control of Veterinary Vaccines for Use in Developing Countries*, FAO Animal Production and Health Series No. 35 (Rome: Food and Agriculture Organization of the United Nations, 1997); D. J. McKeever and W. I. Morrison, Novel Vaccines Against *Theileria parva*: Prospects for Sustainability, *International Journal of Parasitology* 28 (1998): 693-706; and *Parasitology Today* 15 (No. 7, 1999), special issue on vaccines for tick-borne diseases.

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

THE ROLE OF THE PRIVATE SECTOR

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FOCUS 2 • BRIEF 4 OF 10 • OCTOBER 1999

Until now developing countries have had free access to conventional, nonproprietary technology through public institutions and international institutes such as the international agricultural research centers (IARCs) sponsored by the Consultative Group on International Agricultural Research (CGIAR). The advent of modern biotechnology has changed this situation because most of the new biotechnology products are proprietary and largely owned by the private sector. How can the private sector contribute to sustainable economic growth in developing countries through the development and marketing of safe transgenic crops?

One of the important goals policymakers have for the next millennium is to develop a global food security strategy that harnesses the considerable potential offered by transgenic crop technology. One way they can achieve this goal is by establishing novel and equitable partnerships with the private sector. These partnerships must address threemajor global challenges: feeding a growing world population; reducing and ultimately eradicating poverty; and protecting the biodiversity and natural resources in tropical forests and fragile ecosystems by increasing food productivity in input-efficient, sustainable systems on the more fertile arable lands.

PRIVATE-SECTOR COMPARATIVE ADVANTAGES

Extensive consolidation in the 1990s within the private sector through takeovers, mergers, and alliances has resulted in an unprecedented concentration of agri-biotechnology research and development (R&D) resources in a small number of major multinational corporations. This situation has given the multinational private sector a number of comparative advantages: a critical mass of R&D resources for funding long-term and speculative projects; economies of scale in relation to global markets; development costs that can be amortized over the long term; and expertise inmarketing and distribution of seed.

THE GROWTH OF TRANSGENIC PRODUCTION

Between 1995 and 1998 the value of the global market in transgenic crops grew from US$75 million to US$1.64 billion. A total of nine countries, five industrial and four developing, grew transgenic crops in 1998. The industrial countries—Australia, Canada, France, Spain, and the United States—contained about 85 percent of the 28 million hectares sown with transgenic crops. Argentina, China, Mexico, and South Africa cultivated the remaining 15 percent of land. Argentina devoted the largest area to transgenic crops in the developing world: 4.3 million hectares in 1998; 60 percent of its soybean areawassownwithtransgenicvarieties.

TRAITS IN COMMERCIAL TRANSGENIC CROPS, 1998

Crop	Million hectares	Share of the transgenic area (percent)
Herbicide-tolerant soybean	14.5	52
Bt corn	6.7	24
Insect-resistant/herbicide-tolerant cotton	2.5	9
Herbicide-tolerant canola	2.4	9
Herbicide-tolerant corn	1.7	6
Total	27.8	100

Source: James 1998 (see suggested readings).

The dominant traits in the transgenic crops grown in 1998 are listed in the table. The benefits of this first generation of crops are better weed and insect control, higher productivity, and more flexible crop management. These benefits accrue primarily to farmers and agribusinesses. The broader benefits—a safer environment through reduced use of pesticides—contribute to a more sustainable agriculture and better food security.

THE IMPACT ON DEVELOPING COUNTRIES

After in-country evaluation, Argentina, Brazil, China, and Mexico are growing transgenic varieties of cotton, maize, soybean, and tomato for commercial purposes. The traits these new varieties confer are insect resistance (cotton, maize) herbicide resistance (soybean), and delayed fruit ripening (tomato). Combinations of traits and crops presently being field-tested in developing countries include virus-resistant melon, papaya, potato, squash, tomato, and sweet pepper; insect-resistant rice, soybean, and tomato; disease-resistant potato; and delayed-ripening chili pepper. Other desirable traits to be developed include greater efficiency in the use of fertilizers, pesticides, and water.Molecular hybridization could increase the productivity of several crops, including the two major staples, rice and wheat, by 15 to 20 percent. A World Bank panel has estimated that transgenic technology can increase rice production in Asia by 10 to 25 percent in the next decade.

The next generation of crops with improved output traits could confer nutritional benefits to millions who suffer from

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malnutrition and deficiency disorders. A gene encoding for beta-carotene/vitamin A has been incorporated into rice and can enhance the diets of the 180 million children who suffer from the vitamin A deficiency that leads to 2 million deaths annually. Similarly, a gene that increases iron levels in rice threefold is a potential remedy for the iron deficiency that affects more than 2 billion people and causes anemia in about half that number.

The Nuffield Council on Bioethics recently concluded that a compelling moral imperative exists to make transgenic crops available to developing countries that want them to combat hunger and poverty. Creative partnerships between developing countries, CGIAR centers, and the private sector could provide the institutionalmechanism for sharing the new technologies.

ALLIANCE WITH THE PRIVATE SECTOR

Developing-country governments could provide incentives to public institutions, nongovernmental organizations, and local private companies in developing countries to acquire appropriate biotechnology applications from external private-sector sources. This technology could be used to meet the needs of both the larger commercial grower and the resource-poor farmer. Several technology transfer organizations and development agencies already have facilitated donations of proprietary products by multinational companies to increase the productivity of subsistence crops.Muchmoreispossible.

Equitable joint ventures between public- and/or private-sector entities from developing countries and private-sector entities in developed countries should be assigned high priority. These ventures can accelerate the adoption of tested technologies by farmers. Developing countries typically will contribute adapted germplasm and the external private sector will provide the proprietary gene that enhances the product. Building trust between parties to ensure equity remains the key challenge. Independent, honest-broker institutions can help build trust to achieve the mutual objectives of both the developing countries and the private sector. Both parties can make in-kind contributions to initiate projects and they can agree on their respective returns after the economic value of the enhanced product has been evaluated in the field. Similar strategic alliances could also apply to germplasm developed by the IARCs.

Joint ventures with multinational agri-biotechnology companies also have great potential for both the public institutions and local private companies in developing countries. They are particularly attractive to the latter, which normally lack the R&D and capital investments to develop their own technology. Joint ventures offer the opportunity to license the technology and gain experience with its use and distribution. The latter activity is one of the weakest links in the chain of crop production in developing countries. Development agencies should also consider participating inmorejoint-venture pilot projects.

THE ROLE OFGOVERNMENT

Governments must provide the enabling environment for local and international companies to operate competitively in a transparent and effective regulatory system that instills confidence and trust through the participation of the science, public, and business communities. The role and responsibility of government fall into four areas:

Government Incentives for R&D. Government should develop a national strategy for biotechnology, with specific priorities for crop biotechnology. These priorities should include the development of applications that will improve the productivity of the orphan crops of resource-poor farmers that the private sector normally does not invest in because of inadequate returns. Investment incentives, such as favorable tax consideration for R&D, venture capital, and repatriation of foreign exchange, are needed to expedite an effective national strategy. A national strategy should also include support for local public- and private-sector capacity in biotechnology; a vigorous program for acquiring and transferring technology from external sources; and commodity prices and an orderly market that provide incentives for farmers to adopt new technologies in order to enhance productivity and sustainability.

Public Awareness. Crop biotechnology directly affects nutrition, the food that consumers eat, choice and labeling of products, the environment, and the ethical concerns of special interest groups. Governments must establish a public awareness program from the outset that effectively communicates with citizens about the rationale for decisions and the risks and benefits of crop biotechnology. The program should also encourage public participation in the decisions regarding the use of transgenic products.

Regulation of Biosafety and Food Safety. Regulations should be science-based; transparent; harmonized with international protocols, domestic legislation, and import-export requirements; and implemented by credible institutions.

Intellectual Property (IP). This issue affects patents, plant variety protection, seed certification, and access to biodiversity. Protection of IP provides the economic incentive to the private sector. With appropriate antitrust laws, enforceable IP protection encourages competition and leads to more products for farmers. More than 140 countries have already signed the TRIPs (Trade Related Intellectual Property Rights) agreement, which is intended to harmonize global seed-related IP issues. IP is often the major constraint to technology transfer. Honest-broker institutions can assist developing countries in this area. ■

For further information see Clive James, *Global Review of Commercialized Transgenic Crops: 1998*, ISAAA Brief No. 8 (Ithaca, N.Y.: International Service for the Acquisition of Agri-biotech Applications, 1998); Clive James, *Progressing Public-Private Sector Partnerships in International Agricultural Research and Development*, ISAAA Brief No. 4 (1997); and AgBiotechNet, CAB International, http://www.cabweb.org (then click on the AgBiotechNet link).

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

DISENTANGLING RISK ISSUES

KLAUS M. LEISINGER

FOCUS 2 • BRIEF 5 OF 10 • OCTOBER 1999

Food security remains an unfulfilled dream for more than 800 million people unable to lead healthy and active lives because they lack access to safe and nutritious food. The fight to achieve food security for this growing population has to take place on many fronts. Technology is one such front and genetic engineering and biotechnology one interdependent option within that front. Biotechnology clearly can solve agricultural problems that traditional technology either cannot solve or can solve in a far more costly manner. But confusion surrounds the perception of risk associated with biotechnology. Whether this new technology promises to be the key technological paradigm in the fight for food security depends on how its risks are perceived, disentangled, and addressed.

TECHNOLOGY-INHERENT RISKS

Current public debate about the "gene revolution" often suffers from a failure to differentiate between risks inherent in a technology and those that transcend it. This differentiation is of utmost importance in any attempt to reason out the risks arising from biotechnology.

Although modern biotechnology has demonstrated its utility, concerns exist about the potential risks posed by genetically modified organisms. Most countries with biotechnological industries have sophisticated legislation in place intended to ensure the safe transfer, handling, use, and disposal of such organisms and their products. Risks disallowed in industrial countries should not be exported to developing countries. If biotechnological procedures are used in developing countries, state-of-the-art quality management that takes local ecological conditions into account must be put into effect along with the well-documented principles and practices of proper risk assessment. Such risk assessments allow governments, communities, and businesses to make informed decisions about the benefits and risks inherent in using a particular technology to solve a specific problem.

Unfortunately, discussion of inherent risk has become mixed up as biologists, legal experts, and ethicists poach on each other's turf. An orderly discussion would keep these voices to their areas of expertise. Decisionmaking and quality management issues should also be kept distinct: The scientific project level (laboratory safety, measurement standards, assessment of technological alternatives, and so on) should remain separate from the national policy level (accountability issues, legal frameworks, and intellectual property rights, for example), which, in turn, should be disentangled from the international level (vulnerability to substitution, international assistance, and so on). The best minds should work on each level and find ways to achieve overall consensus about how to dealwithrisk.

TECHNOLOGY-TRANSCENDINGRISKS

Technology-transcending risks emanate from the political and social context in which a technology is used. In developing countries these risks spring from both the course the global economy takes and country-specific political and social circumstances. The most critical risks have to do with three issues: aggravation of the prosperity gap between North and South, growth in the disparity in income and wealth distribution within societies, and loss of biodiversity.

Aggravation of the Prosperity Gap

Biotechnology makes it possible to produce tropical agricultural goods in the laboratory at a more competitive price than under traditional developing-country conditions. Vanilla, cocoa, sugar, and tropical vegetable oils are examples of tropical export commodities under the potential threat of being replaced by products produced more cheaply elsewhere. If genetically engineered products do substitute for tropical agricultural exports, the wide gap in prosperity between North and South may well grow. The solution to the problem lies in a concerted international endeavor to diversify the production structure in vulnerable countries and not in interventions against the market. Governments of the countries in danger should improve governance and undertake more appropriate long-term structural planning. The international development community should support diversification efforts.

The prosperity gap may also grow if the North does not adequately compensate the South for exploiting its indigenous genetic resources. Private enterprise and research institutes could gain unremunerated control of the genes of plants native to the developing world, use them to produce superior varieties, and then sell the new varieties back to developing countries at high prices. The basic question of whether the owners of biodiversity should be remunerated has been clearly and positively answered by Article 19 of the Rio Convention on Biological Diversity and by the virtually unanimous consensus of institutions engaged in biotechnological development. But the technical details of how compensation should operate for specific nations remains unclear.Whoshouldcompensate whom for what and for howmuch needs unequivocal regulation.

Income and Wealth Disparities in Developing Countries

The growing disparities in the distribution of income and wealth in poor societies serve to undermine the substantial contribution biotechnology can make to the welfare of farmers and to national agricultural development. Disease-resistant cassava, millet richer in protein, and rice enriched with vitamin A and tolerant to stress can contribute to prosperity and thus enhance food security

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only if these technologies, along with social advances, come within the reach of the broad mass of the population, male and female. Whether this happens and how long it takes to happen depend on the political will to create the appropriate national development framework.

Contemporary reviews of the effects of the Green Revolution show that in countries where small farmers had access to agricultural extension services, land, inputs, and credit, they were able to benefit much more and earlier than smallholders producing without the aid of a favorable agricultural development framework. Like the Green Revolution, genetically engineered crop varieties are a land-saving technology. As such they can be of particular importance to those who have little or only marginal land. Whether the potential benefits become reality for small farmers is not a question of technology but of the social quality of development policy. The economic and social impact of biotechnology can only be as good as the sociopolitical soil in which new varieties are planted. Solutions to food insecurity, therefore, ultimately have to be found in the domain of good governance.

But the private sector, which has taken over more and more of biotechnology research, also has to do its share. As important aspects of plant research continue to be patented, they will become too expensive for poor farmers in developing countries. In order to avoid preventing or disturbing research for the poor, the private sector should make the results of its research available for free or on favorable conditions. In this way cutting-edge research can be used to aid those who, for reasons of poverty, do not yet participate inmarkets.

Loss of Biodiversity

The reduction of biodiversity is the third key technology-transcending risk. Diversity diminishes not because farmers grow genetically modified foods, but because the political will to conserve diversity does not always exist. It is precisely because farmers find new varieties more remunerative that the number of food crop varieties has diminished over the last 100 years. But the fact that farmers replace inferior varieties with superior varieties does not at all have to translate into a loss of biodiversity. Varieties that are under pressure of substitution can be preserved from extinction through in vivo and in vitro strategies. Improved governance and international support can also limit loss of biodiversity.

The immense reduction of biological diversity due to the destruction of tropical forests, conversion of native land to agriculture, replacement of wild lands with monocultures, overfishing, and the other practices used to feed a growing world population is far more significant than the loss of biodiversity due to the adoption of genetically modified crop varieties. To slow down the continuing loss of biodiversity, the main battlefield must be the preservation of land andwaterresources.

CONCLUSIONS

Assessing the contribution that genetic engineering can make toward fighting hunger in developing countries is not "simply" an academic task involving facts and figures and rational evaluation. The interpretation of data is subject to the interests and value judgments of a variety of stakeholders. Identical information can lead some to consider agricultural biotechnologies to be among the most powerful and economically promising means of ensuring food security, and others to perceive them as a threat to development in poor countries. The notion that there is no such thing as one reality seems prevalent in discussions of biotechnology, as it does in discussions of allmajor social issues.

Apart from the issue of plurality of opinion is the issue of balance. The media are more likely to take up wild stories about the creation of monsters and scientists who lack morals than to dwell on stories about slow but steady progress toward the creation of pest-tolerant rice. When the Federal Institute of Technology in Zurich recently informed the world that it was possible to genetically modify rice so that it contain vitamin A and iron, an achievement of potentially immense benefit to poor, malnourished people, no media echo occurred. But when news broke that larvae of the Monarch butterfly were damaged in a genetically modified crop experiment not representative of natural conditions, the story was taken as clear evidence that genetic engineering causes incalculable harm to biodiversity.

Because we live in a world of heterogeneous social systems, with a multitude of value judgments and interests, we should expect differing evaluations. On the one hand, the use of biotechnology leads to obvious and significant benefits in the form of increased production and productivity, enhanced environmental sustainability, and improved food safety and quality. On the other hand, biotechnology involves a number of economic, social, and ecological risks. But it should be emphasized that these risks are not a consequence of the technology per se. They arise from particular social settings, transcending the nature of the technology employed within those settings.

Because food insecurity stems from the combined effects of a number of factors, the challenge lies in strategies that tackle all problems comprehensively. Policies must ensure that a development-friendly environment exists and that biotechnology is oriented toward the needs of the poor, particularly smallholders. These small farmers could thereby become indispensable to an overall development effort. New agricultural technologies can only contribute one stone to the complex mosaic of development. But without the yield-increasing innovations of biotechnology, world food security will remain elusive. ■

For further information, see Klaus M. Leisinger, Ethical and Ecological Aspects of Industrial Property Rights in the Context of Genetic Engineering and Biotechnology, paper prepared for a 1997 conference in Interlaken, Switzerland; and Klaus M. Leisinger, *Sociopolitical Effects of New Biotechnologies in Developing Countries*, 2020 Vision Discussion Paper 2 (Washington, D.C.: IFPRI, 1995).

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

SAFE USE OF BIOTECHNOLOGY

CALESTOUS JUMA AND AARTI GUPTA

FOCUS 2 • BRIEF 6 OF 10 • OCTOBER 1999

Use of biotechnology in sectors such as agriculture and medicine has produced a growing number of genetically modified organisms (GMOs) and products from them. The rapid diffusion of transgenic crops illustrates the pace at which biotechnology is transforming the commercial landscape (see figure). The potential ecological, human health, and socioeconomic effects of such use have become the focus of widespread debate at national and international levels. These debates are rooted in different cultural approaches to risk acceptance and management, and their outcomes will reshape existing policies and institutions dealing with the safe use of biotechnology.

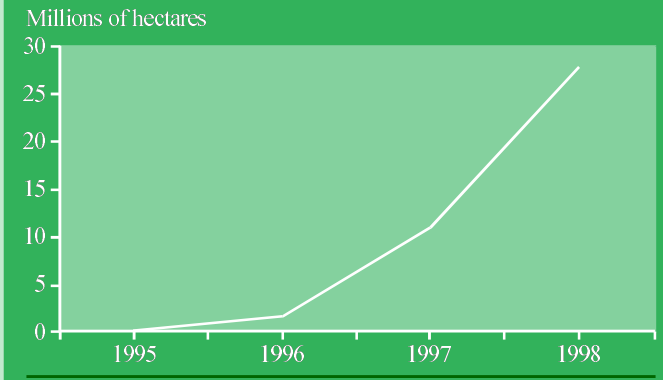
PRACTICES, PRINCIPLES, AND EXPERIENCES

Efforts to ensure the safe use of biotechnology to date, especially in the United States, include undertaking scientifically based, case-by-case hazard identification and risk assessment; regulating the end product rather than the production process; developing a regulatory framework that builds upon existing institutions rather than establishing new ones; and building flexibility into biosafety systems to reduce regulation of products perceived to be low-risk. Biosafety risk assessment focuses on characteristics of the organism being assessed, intended use of the organism, and features of the recipient environment. The concept of substantial equivalence between new and traditional products has been used as a basis for determining what safety tests are needed before putting a genetically modified product on the market and whether product labeling is required.

Given that risk assessment and management decisions have been based on experience gained with a particular organism, its intended use, and its receiving environment, familiarity has emerged as a key biosafety principle in some countries. Although familiarity cannot be equated with safety, it has provided the basis for applying existing management practices to new products. Furthermore, case-by-case and step-by-step risk analysis underpin the use of familiarity to assess and manage risk. The Organisation for Economic Cooperation and Development (OECD) recommends this approach to biosafety and the U.S. regulatory system relies on it.

Partly in response to negative public reaction to growing use of genetically modified crops in agriculture, some countries, especially in Europe and recently Japan, have introduced labeling for some or all biotechnology-based products. The perceived need to base biosafety policies on the precautionary principle has also justified labeling. This approach acknowledges that not enough may be known about the long-term adverse effects of GMOs. It thus requires prior evidence that biotechnology-based products are safe for human health and the environment.

GLOBAL AREA OF TRANSGENIC CROPS (EXCLUDING CHINA), 1995 98



Source: C. James, *Global Review of Commercialized Transgenic Crops: 1998*, Brief 8 (Ithaca, N.Y.: International Service for the Acquisition of Agri-biotech Applications, 1998).

TOWARD AN INTERNATIONAL BIOSAFETY PROTOCOL

As a reflection of the need to regulate potential risks posed by transnational transfers of GMOs, efforts are currently under way to negotiate a legally binding biosafety protocol under the Convention on Biological Diversity. Lack of agreement on a number of critical issues prevented the adoption of the protocol in Cartagena, Colombia, in February 1999. The centerpiece of the draft protocol is an advance informed agreement (AIA) procedure to be followed prior to the transboundary transfer of GMOs (called living modified organisms or LMOs in the protocol). Exactly which categories of LMOs will be covered under this AIA procedure remains a subject of disagreement. All agree that LMOs that will come into contact with the environment of an importing country should be covered under the AIA, in order to assess for potential adverse impacts on biodiversity. A key point of disagreement centers on whether LMOs that are "intended for food, feed, or processing" rather than for deliberate release into the environment should also be covered under the AIA. LMOs not intended for release into the environment are called commodities. A group of major agricultural exporting countries (the Miami group, including Argentina, Australia, Canada, Chile, the United States, and Uruguay) argues that agricultural commodities should be excluded from the AIA procedure because they cannot pose a threat to biological diversity. These countries point out that providing detailed information on LMOs in bulk agricultural

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commodity shipments is not feasible, because genetically modified and nonmodified seeds commingle and no direct business link exists between seed growers and exporters. Other countries, especially developing countries, call for all first-time transfers of LMOs, including commodities, to be covered by AIA. This is seen as necessary in order to monitor entry of LMOs, as well as to assess human health impacts. These countries also point out that the "intended use" of LMOs for processing (rather than for planting) cannot always be guaranteed once the organisms have entered a country's borders.

Negotiators also disagree on whether decisions taken under AIA should be based upon sound science or precaution. Those calling for sound science note that reliance upon the precautionary approach could result in discriminatory or unjustifiable barriers to international trade in LMOs. Those favoring precautionary approaches note that unambiguous scientific evidence of harm relating to LMOs may not be forthcoming in the short term. They argue, therefore, for precaution in the face of scientific uncertainty, in order to ensure that genetically modified products are safe for human health and the environment. Another key conflict involves the exact nature of the relationship between a country's obligations under the protocol and its rights and obligations under World Trade Organization (WTO) agreements. A standoff on this issue was one of the main reasons for the deadlock in Cartagena. Countries also disagree about whether issues such as socioeconomic effects of LMOs, liability and compensation, and pharmaceutical products should be included in the protocol. Further negotiations are under way in an attempt to finalize a protocol in 2000–2001.

CAPACITY REQUIREMENTS AND THE ECONOMICS OF REGULATION

Biosafety measures cannot be effectively implemented without adequate institutional and human capacity at the national level. In most countries with regulatory regimes, existing institutional arrangements have been adjusted to accommodate biosafety needs. Many developing countries are now in the process of developing biosafety regulations. In some poorer countries, discussions about the introduction of these regulations have been accompanied by concerns about their expense. As a way to address these concerns, the last decade has seen an increase in the number of formal and informal programs aimed at creating human resource capacity for biosafety regulation. The programs have focused on risk assessment and regulatory oversight. Training, workshops, seminars, and technical meetings have helped to build capacity in biosafety. International organizations have played a key role in supporting such activities. The draft biosafety protocol also identifies capacity building as a key area for international cooperation.

PUBLIC PARTICIPATION AND AWARENESS

Current public debate on the commercialization of agricultural biotechnology products, especially in Europe, has underscored the importance of public participation in risk assessment and decisionmaking pertaining to GMOs. The rapid pace of technological change and the wide-ranging nature of the perceived effects of biotechnology necessitate much greater public participation in policymaking. A number of industrialized countries have launched programs aimed at including the public in technology assessment and decisions involving the use of biotechnology in agriculture. The issue is not simply one of providing scientific information to the public, but rather of building trust between science and society. Intermediary programs and institutions concerned with the social aspects of biotechnology could be established to build such trust. While informed and effective public participation remain crucial requirements in this arena, the need to maintain confidentiality about proprietary commercial information constrains the nature and extent of this participation. Where the boundary should lie between privately and publicly held information pertaining to GMOs continues to be an area of debate in determining the appropriate level of public participation in decisionmaking.

INFORMATION EXCHANGE AND EXPERIENCE SHARING

For information without proprietary constraints, national and international agencies are increasingly using modern communication technologies, such as the internet, to disseminate information on regulations and risk assessments of genetically modified organisms. While such communication technologies are important mechanisms for sharing information and experiences, and their use is likely to grow in the future, excessive reliance on them could prevent those countries with the least capacity and the greatest need for risk-related information from having timely access to the latest knowledge about biosafety. Measures adopted to complement information dissemination through the internet include the establishment of biosafety clearing houses within national and international agencies. The use of such intermediary institutions as bridges for sharing information and experience between various sections of society and across countries needs to be enhanced. In particular, intermediary institutions could facilitate the task of monitoring risk assessments and decisions pertaining to biotechnology products as an important means of accumulating knowledge. While a number of national agencies have begun monitoring activities, the results of these efforts have not been consolidated into global biosafety assessments. Such assessments could be useful in disseminating the lessons learned about different genetically modified organisms and in facilitating experience and information sharing among countries. ■

For more information see John Doyle and Gabrielle Persley, *Enabling the Safe Use of Biotechnology: Principles and Practice* (Washington, D.C.: World Bank, 1996); G. Tzotzos, *Genetically Modified Organisms: A Guide to Biosafety* (Wallingford, U.K.: CABI, 1995); and Aarti Gupta, *Biosafety in an International Context* (Cambridge, Mass., U.S.A.: Harvard University, 1999), available at http://environment.harvard.edu/gea.

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

INTELLECTUAL PROPERTY MANAGEMENT

JOHN H. BARTON

FOCUS 2 • BRIEF 7 OF 10 • OCTOBER 1999

Intellectual property protection has contributed in a most important way to the development of the current biotechnological revolution in agriculture, and to the institutional restructuring accompanying that revolution. The intellectual property issues, options, and necessary actions vital to developing nations seeking to benefit from the safe application of biotechnologies are outlined below.

FORMS OF PROTECTION

Beginning in the mid 1900s, nations began to offer Plant Variety Protection (PVP, also known as Plant Breeders' Rights) to breeders. Under PVP a breeder could obtain protection for a new variety, provided it was novel, distinct, uniform, and stable. The protection gave the breeder the exclusive right to market the variety, although farmers were able to reuse their seed and breeders had the right to use protected material in producing new varieties. In 1991 treaty revisions permitted nations to prohibit farmers from reusing harvested seeds, and gave breeders certain rights over material bred from protected materials and stronger rights over products grown with protected seeds. This system of protection is governed by an international agreement and organization, UPOV (French acronym for International Union for the Protection of New Varieties of Plants).

Beginning with the famous decision of Diamond v. Chakrabarty in 1980, the United States, and later Europe, moved to grant regular patent rights covering plants. More than 400 patents mentioning rice and biotechnology were issued in the United States in 1998 (compared to 12 in 1988). The United States, but not Europe, will grant a regular patent on a variety—with the probable implication that the material cannot be reused by farmers or used by third parties for further breeding. The United States and probably Europe also grant patents on all plants of a particular species into which a specific new gene has been inserted by biotechnological means. In this sense it is possible to patent a gene, which typically involves legal claims over the isolated gene and DNA sequences, over the genetic engineering tools that use those sequences, and over plants that have been transformed with such tools. The rights of the patent holder do not extend to plants in which the genes occur naturally. The United States and Europe have also granted patents on wide categories of transgenic plants, for example, all transgenic cotton or soybean. Many other nations as well grant patents on processes for genetic transformation of plants. Which of these patents will be valid has yet to be resolved by litigation. Agricultural biotechnology companies sometimes also keep information about crop plant genomes confidential under a form of trade secrecy. These firms can then market the information to other firms.

Although many developing countries have been hesitant about adopting such forms of intellectual property protection, the Trade Related Intellectual Property Rights (TRIPs) agreement, negotiated as part of the Uruguay Round, requires all members to make patents available in all fields of technology. However, members may exclude from patentability plants and animals other than microorganisms and the processes used for the production of plants and animals that are essentially biological. All members must provide an effective *sui generis* system for the protection of plant varieties. Not surprisingly, the moves by industrial countries to protect the products of biotechnology have led developing countries to seek to protect the genetic sources of those products. Developing-country efforts culminated in the 1992 Convention on Biological Diversty. This agreement made it clear that nations could enact legislation prohibiting the export of genetic resources unless arrangements were made to share the benefits of financial returns from the exported resources.

IMPLICATIONS OF PROTECTION

The trend toward intellectual property protection has had several important structural consequences. First, and probably most important, private-sector research has radically increased, driven in part by the possibility of profits supported by intellectual property rights. Moreover, private-sector industry has greatly centralized. What was once an industry in which small seed breeders played a major role has now become a global oligopoly dominated by five leading firms (AgrEvo, DowElanco, DuPont, Monsanto, and Novartis). Intellectual property litigation may be part of the explanation for this oligopolization. Firms began suing each other in large numbers during the first seasons in which transgenic seeds began to be used significantly in the United States. The various patents that had been issued were so broad and so numerous that there were many plausible cases of mutual reciprocal infringement. The easiest way to settle some of the disputes was through merger–and a wave of mergers occurred beginning about 1996 and continuing into 1999. Some of the mergers can also be explained by the desire of firms to have access to the basic research capabilities held by other firms. Moreover, as investment in product development increases, firms need a larger, strongermarketing capability.

Although the force of the trend has yet to become clear, it is likely that intellectual property rights will also significantly

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affect international trade patterns. Specific varieties of ornamental and specialty crops have already gained consumer recognition but are, at the same time, protected by PVP. The result is that a country wishing to grow a variety for export must have in place the legislation that gives confidence to the rightholder licensing the particular variety to farmers. This competitive use of variety and intellectual property rights can be expected to increase in light of the large number of new markets and applications for genetically modified crops. It may even become a response to the lowering of more formal trade barriers.

ISSUES AND OPTIONS FOR POLICYMAKERS

These trends raise a number of issues for policymakers, both those directly involved in agricultural research and those working from a broader governmental perspective. Officials making decisions about publicly funded agricultural research must first consider whether to modify research foci in order to complement the work carried on in the private sector. The private sector will probably do well at adapting crops (maize, wheat, and rice, for example) that middle-income farmers will use in middle-income nations. Private industry probably also will do well at research on crops exported to the developed world. On the other hand, the private sector will pay little attention to the needs of the poorest farmers, and it may not be as environmentally sensitive as publicly funded institutions. The public sector, therefore, has an important role to play in areas that complement private-sector activity. Moreover, if mergers reach the point where competition within the private sector is weak, the public sector should ensure that good public varieties can compete with private varieties so that farmers face reasonable choices. Such choices should be made available even if there are objections that public-sector activity is cutting into private-sector profits.

Because the private sector will hold many of the advanced technologies, the publicly funded agricultural research community must also develop an effective approach to cooperation with the private sector in research and product development. National systems may need to distribute their new varieties by obtaining intellectual property protection for them and licensing them to a private firm. As public budgets shrink, the public sector could obtain income from licensing its technology. But the returns from such activity are likely to be small, and ultimately the local farmer and consumer will pay the royalty. Even so, the public sector may need to obtain intellectual property protection in order to have bargaining chips to protect its freedom to distribute its own research products to farmers. The private sector may not readily make technologies available to the poor.

International political pressure is likely to ensure that national governments make an effort to comply with TRIPs. But such efforts should mean more than simply passing TRIPs-compliant legislation. It may be possible to design compliance in a way that benefits national agriculture. For example, should the inventive step requirement for issuing a patent be as low as it is in the United States or Europe? When should product patents be issued as opposed to process patents? What kind of freedom for experimental use of genetic material should be protected? Moreover, the intellectual property legislation must be supplemented with appropriate training in the courts, law firms, and law schools, so that the law can be used effectively and nations can enjoy thoughtful debate on the law. Effective legislation for managing intellectual property rights for products of government research also must be passed. In light of the cost of operating these systems, as many of these institutions as possible should be created at the regional rather than the national level.

Governments must also represent their interests in the global negotiations that affect this body of international law, negotiations that are likely to be initiated in a new international trade round. Realistically, the fundamental standards and compromises of TRIPs are unlikely to change. But a real possibility exists that an antitrust code can be negotiated. This would almost certainly benefit developing nations. The kind of concentration occurring in the agricultural biotechnology industry need not be allowed and should be controlled by global mechanisms. In the face of the concentration that exists, a strong competition-based argument can also be made for restricting the exercise of intellectual property rights to the extent needed to allow new firms to enter the industry. In new trade rounds or other negotiating contexts, developing nations could seek ways to use the intellectual property system to encourage research for their needs. U.S. Orphan Drug legislation already grants special privileges, including market protection, to encourage private-sector research on diseases with too few victims to attract investment. Might the developed world have similar arrangements for products that benefit the developing world?

To accomplish these goals, developing nations must mobilize their legal and scientific human resources. Thoughtful, capable people will be needed for defining national policy, representing the national interest in negotiations with multinational firms, assisting national exporters to deal with developed-world market barriers, and negotiating in international trade, agricultural, and intellectual property fora. These people will face policy questions that combine issues of science with issues of intellectual property, competition law, and international trade. Their success will be indispensable to the success of developing-country agriculture. ■

For further information, see J. Barton, W. Lesser, and J. Watal, Intellectual Property Rights in the Developing World, prepared for the Rural Development Department of the World Bank, June 1999; F. Erbisch and K. Maredia, eds., *Intellectual Property Rights in Agricultural Biotechnology* (Wallingford, U.K.: CABI, 1998); and W. Siebeck, ed., *Strengthening Protection of Intellectual Property in Developing Countries; A Survey of the Literature*, World Bank Discussion Paper No. 112, 1990.

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

RESEARCH POLICY AND MANAGEMENT ISSUES

JOEL I. COHEN, CESAR FALCONI, AND JOHN KOMEN

FOCUS 2 • BRIEF 8 OF 10 • OCTOBER 1999

Biotechnology provides new opportunities for achieving productivity gains in agriculture. The application of modern biotechnology to agricultural research systems in developing countries, however, involves new investments, changes in resource allocation, and new responsibilities for policymakers, research managers, and scientists. The new responsibilities include determining the benefits and risks of biotechnology applications in a particular country, identifying the key productivity constraints, and deciding the extent to which a national research agenda should embrace biotechnology. Government officials, institute directors, and scientists assuming these responsibilities play a crucial role in setting policies and research agendas and developing regulatory capacity for agricultural biotechnology. Their task is difficult because public budgets for agricultural research are severely constrained inmostdeveloping countries.

Given these difficulties and responsibilities, the key question national agricultural research systems (NARS) have to face is, How are biotechnology programs best initiated and integrated with ongoing, conventional agricultural research and national priorities? This process of integration cannot succeed without taking into account the characteristics particular to biotechnology, including high development costs; new demands on human, financial, and managerial resources; opportunities for international collaboration; the challenge of negative public perception; biosafety; and intellectual property rights.

UNDERSTANDING NATIONAL CONTEXTS FOR BIOTECHNOLOGY RESEARCH PROGRAMS

Policymakers devising strategic approaches for the use of biotechnology in agriculture need to determine what resources are required within the context of national capabilities. In 1998 the International Service for National Agricultural Research (ISNAR) conducted surveys of biotechnological research in national agricultural research systems in Mexico, Kenya, Indonesia, and Zimbabwe. The study included information on relevant programs or institutions; human, physical, and financial resources; and the types of biotechnology research undertaken. The data covered the period from the mid to late 1980s to the mid to late 1990s for the 34 public and private organizations surveyed.

The survey shows that advanced research techniques are being used only in a few public-sector organizations. Most organizations remain in the early stages of developing the capacity for biotechnology research. Themajority of agricultural biotechnology research focuses on crops; only a small amount focuses on livestock. Although expenditures on biotechnology research grew annually in all four countries, the percentage of biotechnology expenditures in total agricultural research expenditures remains small. The number of researchers grew faster than expenditures, resulting in a 7 percent annual decrease in expenditures per researcher (in three countries). The public sector accounts on average for 92 percent of total expenditures on biotechnology in the four countries. Against this background of limited capacity and financial resources for biotechnology research, it becomes even more important to stimulate informed decisionmaking regarding future investments.

POLICY ANDMANAGEMENT ISSUES

Special efforts have to be made to assist individuals who manage research programs or institutions in which agricultural biotechnology is becoming increasingly important. Specialized courses have been developed to enhance themanagerial capacity and competency of directors and managers in public research organizations, with an emphasis on building a strategy, setting priorities, managing biosafety and intellectual property, coping with funding issues, ensuring product delivery, and accessing information to assist decisionmaking. Some of these issues are discussed below.

Defining a Clear Research Agenda

Governments deciding whether or not to invest in agricultural biotechnology need to determine where the most pressing needs and priorities lie and if biotechnology can meet those needs and fit those priorities. The key step is to identify the constraints in agriculture that conventional research has not been able to overcome and the recent scientific discoveries that offer new ways out of the constraints. A number of other issues also require special attention: (1) making sure that national capacity can assess the available information on new developments in biotechnology, the performance of biotechnology products in other countries, and the potential application of new developments to national priorities; (2) ascertaining the cost of research and development (R&D) and the infrastructure required; (3) ensuring that regulations are in place for assessing the risks new products may pose to human health and the environment; (4) managing intellectual property rights; and (5) creating the delivery systems that will get new products to farmers and consumers.

Priorities ultimately need to be set by incorporating the perspectives of economists, policymakers, scientists, and end users. ISNAR has applied this multidisciplinary approach to determine priorities for the Chilean National Program on Agricultural and Forestry Biotechnology.

Managing Proprietary Technology and Intellectual Property

Some form of intellectual property rights protects most biotechnology processes and products, many of which are owned by

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private-sector companies. Public, national, and international agricultural research organizations working in and with developing countries also develop and use protected materials. The legal and management implications of using proprietary biotechnologies and disseminating products resulting from them are complex.

ISNAR has conducted surveys to determine the extent to which proprietary research inputs are used at seven international agricultural research centers and in national agricultural research organizations in five Latin American countries. The surveys show that proprietary technologies and materials that are protected through intellectual property rights have made important contributions to the research programs of the institutes involved. The increasing use of proprietary materials also means greater reliance on licenses, material transfer agreements, and other legal agreements. Both national and international public research institutes therefore require suitable institutional and legal frameworks for managing intellectual property. With such legal expertise, research organizations can protect inventions when necessary and use them to negotiate access to and use of proprietary technologies owned by others.

Ensuring Environmental Responsibility

Effective biosafety systems foster the safe use of biotechnology. The four major elements of effective biosafety systems are (1) written guidelines that clearly define the structure of the system, the roles and responsibilities of those involved, and the review process; (2) the regulatory authorities themselves, who should comprise an in-country cadre of well-trained individuals, confident about their decisionmaking ability and about the support of their institutions; (3) an information system that enables the biosafety evaluation process to be based on up-to-date and relevant scientific information and the concerns of the community; and (4) feedback mechanisms for incorporating new information and revising the regulatory system as needed. This four-pronged approach stresses the dynamic, flexible nature of biosafety systems and the need to build capacity and competence among those responsible for theirmanagement.

Assessing Funding Implications

Research in agricultural biotechnology has to be conducted over the long term and without interruption. Uncertain funding, therefore, can severely disrupt the research process. Reasons reported for funding constraints include (1) implementation of fiscal austerity policies, (2) lack of understanding of biotechnology among decisionmakers, (3) insufficient research impact, (4) dependence on funds from a single source, particularly government or donors, and (5) lack of political and financial support from agribusiness and from farmers and their organizations.

Political support can be built for public-sector funding by documenting and publicizing research impacts, developing strong and articulate client organizations that have political influence, building closer relations between biotechnology leaders and policymakers, and broadening the funding base to include environment and commerce departments. Strategic alliances between public- and private-sector entities can also expand the financial resources for agricultural biotechnology research. The development or promotion of institutional mechanisms such as competition for funds, joint ventures, collaborative research, research levies, and contract research can facilitate public-private sector interaction.

Ensuring Product Delivery

Decisions about the generation of products and their delivery to users must be considered at an early stage of a research program. These decisions need particular attention in R&D programs involving biotechnology, because product diffusion is affected by factors such as the costs of large-scale production, biosafety evaluation and risk assessment, and public acceptance of the final product. Collaboration or joint ventures between the private sector and public institutes or universities is essential for successful product delivery. In some cases, specialized national or international organizations have facilitated technology transfers from the public to the private sector that have led to the diffusion of new products. A number of products can also be expected from several joint international initiatives now at the R&D stage. The relationship between the public and private sectors in product development and delivery should be strengthened, specifically in the areas of product price regulation and registration; onfarm demonstrations, pilot production facilities, and science parks for start-up companies; and procurement and distribution of planting material.

WHAT COMES NEXT?

The application of biotechnology to food and agriculture requires that potential benefits and risks to society be made clear. Developing countries urgently need to acquire further managerial, analytical, and technical strengths in order to build a strong national capacity for understanding and analyzing these issues. Public institutions play an essential role in formulating the agenda and priorities for the use of biotechnology. They should also ensure environmental safety, contribute to public awareness, and collaborate with the private sector on product development and diffusion. Consequently, the need for the public and private sectors to share information does not diminish; rather, its urgency increases. The relation of new products to current farming practices and the agroecosystems that sustain them is an important area for further research.

It is through such work that national investments in research and human resource development will contribute meaningfully to the agricultural needs of developing countries over the coming decades. ■

For further information see J. I. Cohen, ed., *Managing Agricultural Biotechnology: Addressing Research Program Needs and Policy Implications* (Wallingford, U.K.: CABI, in press [1999]); and ISNAR's biotechnology website: http://www.cgiar.org/isnar/projects/ibs/index.htm.

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

DEVELOPING APPROPRIATE POLICIES

PER PINSTRUP-ANDERSEN

FOCUS 2 • BRIEF 9 OF 10 • OCTOBER 1999

Modern biotechnology can enhance agricultural productivity in developing countries in a way that further reduces poverty, improves food security and nutrition, and promotes sustainable use of natural resources. But such benefits from biotechnology require policy action on a number of fronts. The small farmer in developing countries faces a variety of problems and constraints. Crop losses due to insects, diseases, weeds, and drought threaten income and food availability. Acid soils, low soil fertility and lack of access to reasonably priced plant nutrients, and other biotic and abiotic factors also contribute to low yields. Poor infrastructure and dysfunctional markets for inputs and outputs, along with lack of access to credit and technical assistance, add to the problems plaguing the small farmer. Solutions to these problems will benefit both farmers and consumers. Although modern biotechnology cannot solve all these problems, it can provide a critical component to the solution if it is guided by appropriate policies. Four sets of policies are particularly important. Each of these is briefly discussed below.

POLICIES TO GUIDE RESEARCH FOR THE POOR

Policies must expand and guide research and technology development to solve the problems of particular importance to the poor. These problems include diets with inadequate levels of energy, protein, and micronutrients, and crop losses due to biotic and abiotic factors. Research should focus on the crops of particular importance to small farmers and poor consumers in developing countries. Bananas, cassava, yams, sweet potatoes, rice, maize, wheat, and millet, along with livestock products, feature most prominently in the diets and production activities of the poor. Except for limited work on rice, bananas, and cassava, little biotechnology research currently focuses on helping the small farmer and poor consumer solve their productivity and nutrition problems. The prediction so often heard that the poor in developing countries are unlikely to benefit from modern agricultural biotechnology in the foreseeable future could well come true—not because the technology has little to offer but because it will not be given a chance.

Allocate Additional Public Resources to Agricultural Research

There are three ways to expand biotechnology research for the benefit of the poor. First, allocate additional public resources to agricultural research, including biotechnology research, that promises large social benefits. Existing national and international agricultural research systems have to be strengthened or new ones built. Low-income developing countries currently invest less than 0.5 percent of the value of agricultural production in agricultural research, compared to about 2 percent in developed countries. Underinvestment is widespread despite high annual economic rates of return from investments in agricultural research. A recent assessment of more than 1,000 research projects and programs found an average annual rate of return of 88 percent. Investments by the private sector are limited to research that permits a large enough profit from the returns. Nonetheless, privately funded research can still generate large benefits to farmers and consumers, as illustrated by a recent study of the distribution of benefits from the use of genetically modified (GM) soybeans in the United States. The private patent holders and private seed companies captured one-third of the total economic benefits, farmers and consumers gained two-thirds. While private-sector agricultural research has increased rapidly in the industrialized countries during the last 10 to 15 years, it currently accounts for a small share of agricultural research in most developing countries.

Convert Some Social Benefits to Private Benefits

Second, expand private-sector research for the poor by converting some of the social benefits of research to private benefits for the private sector. The public sector can entice the private sector to develop technologies for the poor by offering up front to buy the exclusive rights to newly developed technology and make it available either for free or for a nominal charge to small farmers. The amount of the offer could be determined on the basis of expected social benefits, using an annual rate of return normally expected from agricultural research, for example, 60–80 percent. The risk of failing to develop the specified technology would rest with the research agency, just as it does when technology is developed for the market. The public sector offer would come due to the research agency that first develops the technology, but only when the technology is developed, tested, and made available. Both private- and public-sector agencies could participate in this research. Opportunities for collaboration between multinational life science companies and public-sector agricultural research agencies in both developing and developed countries might increase the probability of success. With necessary refinements, the arrangement proposed here should be of interest to international development assistance agencies. This proposal builds on a similar idea that Jeffrey Sachs of Harvard University proposed for developing vaccines for tropical diseases.

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Protect Intellectual Property Rights

The third way to expand biotechnology research to help the poor is to protect the intellectual property rights of a private research agency that develops a particular technology, for example, seed with infertile offspring, or that contracts directly with the farmer, in both cases forcing the farmer to buy new seed every season. This would make it easier for the private sector to recuperate the incomes needed to justify the research. But seeds with infertile offspring may be inappropriate for small farmers in developing countries because they pose large risks to food security. Existing infrastructure and production processes may not be able to keep fertile and infertile seeds apart. Small farmers could face severe consequences if they planted infertile seeds by mistake. Monitoring and enforcing contracts that prohibit large numbers of small farmers from using the crops they produce as seed would be expensive and difficult to do.

POLICIES TO PROTECT AGAINST HEALTH RISKS

GM foods are not intrinsically good or bad for human health. Their health effect depends on their specific content. GM foods with a higher content of digestible iron are likely to benefit consumers with iron deficiencies. But the transfer of genes from one species to another may also transfer characteristics that cause allergic reactions. Thus, GM foods need to be tested for allergy transfers before they are commercialized. It was precisely such testing that avoided the commercialization of maize with a Brazil nut gene. GM foods with possible allergy risks should be fully labeled. Labeling may also be needed to identify content for cultural and religious reasons or simply because consumers want to know. Finally, labeling may be required to identify the production process itself when that, rather than any specific health risk, interests consumers.

Failure to remove antibiotic-resistant marker genes used in research before a GM food is commercialized presents a potential although unproven health risk. Recent legislation in the European Union requires that such marker genes be removed before a GM food is deemed safe for consumers. Risks and opportunities associated with GM foods should be integrated into the general food safety regulations of a country.

POLICIES TO ADDRESS ECOLOGICAL RISKS

Effective national biosafety regulations should be in place before modern biotechnology is introduced into a country's agriculture. Such regulations should be country-specific and reflect relevant risk factors. The ecological risks policymakers need to assess include the spread of traits such as herbicide resistance from genetically modified plants to plants (including weeds) that are not modified, and the build-up of resistance in insect populations. Seeds that produce infertile offspring may be an effective solution to the risk associated with cross pollination but, as mentioned earlier, they may be inappropriate for small farmers. The approach used to develop terminator seeds, however, offers great promise for the development of a seed that will avoid the spread of new traits through cross-pollination. The seed would contain the desired traits, such as pest resistance or drought tolerance, but each trait would be activated only after treatment with a particular chemical. Without treatment, the seed would maintain its normal characteristics. Thus, if a farmer planted an improved seed, the offspring would not be sterile; rather they would revert back to being normal seeds (before improved traits were introduced). The farmer would then have the choice of planting the normal seed or bringing back the improved traits by applying a particular chemical. Contrary to the terminator gene, this approach complies with the principle of doing no harm.

Both food safety and biosafety regulations should reflect international agreements and a society's acceptable risk levels, including the risks associated with not using modern biotechnology to achieve desired goals. The poor should be included directly in the debate and decisionmaking about their desire for technological change, the risks of that change, and the consequences of no or alternative kinds of change.

POLICIES TO REGULATE THE PRIVATE SECTOR

Recent mergers and acquisitions have resulted in increasing concentration among companies engaged in biotechnology research. The outcome of this growing concentration may be reduced competition, monopoly or oligopoly profits, exploitation of small farmers and consumers, and successful efforts to gain special favors from governments. Effective antitrust legislation and institutions to enforce the legislation are needed, particularly in small developing countries where one or only a few seed distribution companies operate. Effective legislation is also required to enforce intellectual property rights, including those of farmers to germplasm, along the lines agreed to within the frameworks of the World Trade Organization and the Convention on Biological Diversity.

CONCLUSIONS

Modern biotechnology research may help reduce poverty, improve food security and nutrition, and make the use of natural resources more sustainable, only if it focuses on the problems and opportunities poor people in developing countries face and only if appropriate policies accompany it. Modern biotechnology is not a silver bullet, but it may be a powerful tool in the fight against poverty and should be made available to poor farmers and consumers. ■

For further information, see Per Pinstrup-Andersen, Rajul Pandya-Lorch, and Mark W. Rosegrant, *World Food Prospects: Critical Issues for the Early 21st Century*, 2020 Food Policy Report (Washington, D.C.: IFPRI, 1999); Per Pinstrup-Andersen, Modern Biotechnology and Small Farmers in Developing Countries, *Research Perspectives* (IFPRI newsletter), vol. 21, no. 2, 1999; and Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (London: Nuffield Council on Bioethics, 1999).

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BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES

LETTER TO A MINISTER

GABRIELLE J. PERSLEY

FOCUS 2 • BRIEF 10 OF 10 • OCTOBER 1999

With the upsurge of media interest in biotechnology and public concern about the release of genetically modified organisms (GMOs) into the environment and their use in food, many a minister is seeking information from his or her advisers about the issues involved, about the role and responsibilities of government, and about the contribution government should make to a balanced debate on the problems, opportunities, and challenges arising from modern biotechnology.

The response of a government will be influenced by a country's size, wealth, location, and culture; by societal views on the use of science and technology; and by the size and the strength of the science, technology, and business sectors in a country. It will also be influenced by the importance of food and agriculture in the economy, by the extent to which a country exports or imports agricultural commodities; and by the seriousness of its problems in food insecurity, poverty, and population growth.

Although the advice to ministers will vary from country to country, and possibly even from ministry to ministry within a government, many issues are similar for all countries. For the issues that cut across both countries and governments, a hypothetical group of advisers may respond to the minister in the following way:

Dear Minister,

Re: *Safe Use of Biotechnology*

You have sought our advice about whether our country stands to benefit from the new developments in biotechnology, what the risks are, and how we should respond to concerns expressed by advocacy groups and the public about the use of these new technologies.

Background

Modern biotechnology stems from the new developments in the science of genetics during the past 30 years that have given us a far greater understanding of the genetic basis of all life. These developments enable us to identify, isolate, transfer, and use the specific genes that control individual traits in an organism. In agriculture, this improved ability to modify and control the genetic endowment of crops, trees, animals, fish, and microbes continues the practice of genetic improvement farmers have carried out over the centuries by crossing and selecting better plants and animals. This traditional practice of improvement was formalized as the science of genetics in the early part of this century, after an Austrian monk, Gregor Mendel, postulated a set of rules to explain the inheritance of biological characteristics in all living organisms. The subsequent continuum of discoveries about the genetic foundations of life (a field of knowledge sometimes referred to as biosciences or life sciences) forms the basis of modern biotechnology, which encompasses new gene technologies. The biotechnology industry developed in the 1980s, as a result of powerful new discoveries in biology and the patents and other forms of intellectual property rights given to inventors to protect their discoveries. The granting of intellectual property rights led to an explosion of private investment in the biosciences in the last 20 years.

The value of the global market for biotechnology-based products in 1998 came to approximately US$13 billion. About 80 new products are ready or almost ready for market. The greatest number of modern biotechnology applications appear in health care, where they offer new hope to patients with AIDS, genetically inherited diseases, diabetes, influenza, and some forms of cancer. New biotechnology-based processes are now used routinely in the production of most new medicines, many diagnostic tools, and new medical therapies. In agriculture, new transgenic varieties of some 40 different crops were grown on 28 million hectares worldwide in 1998, mainly in Argentina, Australia, Canada, China, France, Mexico, South Africa, Spain, and the United States. Fifteen percent of this area was in developing countries.

Almost all the biotechnology-based products currently on the market have been developed for sale in industrial countries, as these are the markets that will generate the returns on the substantial R&D investments on which the industry is based. A small number of global life science companies, some venture capitalists, and many small biotechnology companies, mostly in the United States and Europe, are flourishing in biotechnology-based businesses. The commercial biotechnology sector has shown only limited interest in applying modern biotechnology to the problems of food security and poverty in developing countries because, under present arrangements, commercial firms would find it hard to recoup their investments.

It is therefore the responsibility of governments to ensure that developing countries benefit from the judicious and safe use of modern biotechnology. We need to assess the potential benefits and risks of the new technologies and position ourselves to use the new discoveries from home and abroad to reduce food insecurity and poverty. We must mobilize the expertise and resources of both

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the public and private sectors nationally and internationally to address the specific problems that damage human health, constrain agricultural productivity, and threaten the environment. This strategy of using modern biotechnology as a component of our overall policy to foster sustainable economic development and improve the livelihoods and well-being of the poor will require good governance and political skills and leadership of a high order. It will also require some new policies and actions by government. These are outlined below:

Proposed Policies and Actions

1. *Develop coherent and consistent policies*: Take a government-wide approach to policy development in biotechnology so that we are consistent in our principles and practices. This will enable us to maximize the advantages from applications of modern biotechnology and minimize any risks to human health, the environment, and the economy. Risks may stem either from the technology itself, thereby creating a food safety issue, or from outside of it, thereby aggravating the gap between rich and poor or reducing biodiversity because of the way the technology is applied. At the international level, consistency will help us develop coherent negotiating positions and meet international obligations to the international treaties we have signed such as the Convention on Biological Diversity and that of the World Trade Organization (WTO).
2. *Establish desired priorities and outcomes*: Define clearly the desired outcomes from public investments in R&D, including those in biotechnology; identify the priorities to be addressed; and ensure that these priorities are consistent with the government's efforts to improve the livelihoods of our people. In determining priorities and assessing the relative risks and benefits of using various technologies, we should consult with all stakeholders, including the urban and rural poor, who are often overlooked while others decide what is best for them.
3. *Ensure the safe use of biotechnology*: Build an efficient and transparent regulatory system for biotechnology-based products that meets international standards and enjoys a high degree of public confidence. Ensure that it has the necessary public funding and skilled personnel to do its job. Its responsibilities are twofold: (a) to assess any risks associated with the release of new products developed either in-country or abroad, and (b) to provide accurate information to the public about the risks and benefits of modern biotechnology. Suitable product labeling (for example, with information about potential allergens) will enable consumers to make informed choices.
4. *Manage intellectual property*: Enact legislation as necessary to establish an intellectual property regime consistent with our legal obligations under the WTO. This will ensure that our farmers and entrepreneurs benefit from local inventions and will encourage the introduction, evaluation, and use of overseas inventions as appropriate.
5. *Encourage private-sector investment*: Elicit greater investment by local and overseas investors in biotechnology-based industries through a fair tax regime and other financial incentives.
6. *Increase support for public sector R&D*: Increase public financial support for agricultural R&D, including the use of modern biotechnology, at the national, regional, and international levels. Additional support will help develop public goods that the poor have access to and can afford. Despite agricultural R&D's demonstrated high rates of return, most developing countries and development agencies underinvest in it.
7. *Support education and public awareness*: Improve education in science and technology at all levels, so that the country will have a highly skilled workforce and informed public debate about the relative merits of various technologies, including biotechnology.
8. *Establish and maintain infrastructure*: Support the development and maintenance of the infrastructure necessary both to encourage investment in biotechnology-based industries and to ensure that products are delivered to those who need them. The infrastructure required includes roads and systems for telecommunications, power, water, and international air and sea transport.
9. *Monitor overseas technology developments and encourage international collaboration*: Analyze developments in technology in this rapidly moving field on a regular basis. We should assess the potential of currently available technologies and keep abreast of new developments overseas so that we can mobilize the best available technology to solve our specific problems. If we mobilize new scientific developments creatively, in consultation with the various sectors of our society, and with the help of international collaboration as appropriate, we can improve the livelihoods of those who suffer from food insecurity and poverty in this country.

Conclusion

In the next millennium regions, countries, companies, consumers, farmers, investors, and entrepreneurs of all kinds will find a way to benefit from the powerful new developments in modern biotechnology and to manage the risks inherent in or associated with them. We must be among these innovators and users, otherwise immense opportunities will pass us by.

Respectfully, ■

For further information see Gabrielle J. Persley, *Beyond Mendel's Garden: Biotechnology in the Service of World Agriculture* (Wallingford, U.K.: CABI, 1990); Ernst and Young, *European Life Sciences 99*, sixth annual report (London: Ernst and Young International, 1999); and Gabrielle J. Persley, Global Concerns and Issues in Biotechnology, *HortScience* 32 (1997): 977 979.

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