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Agricultural Biotechnology: Global Challenges and Emerging Science

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In global terms, increases in world food production have more than kept pace with the increases in the global population to date. Although the world agricultural growth rate has decreased from 3% in the 1960s to 2% in the past decade, the aggregated projections show that, given reasonable initial assumptions, world food supply will continue to outpace world population growth, at least to 2020. Worldwide, per capita availability of food is projected to increase around 7% between 1993 and 2020 (IFPRI, 1997). Therein lies a paradox.

The first aspect of the paradox is that despite the increasing availability of food, approximately 800 million people out of the global population of 6 billion are food insecure. They dwell among the 4.5 billion inhabitants of Asia (48%), Africa (35%) and Latin America (17%). Of these 800 million people, a quarter are malnourished children (IFPRI, 1997).

Children and women are most vulnerable to dietary deficiencies. Dietary micronutritional deficiencies accompany malnutrition. Vitamin A deficiency is prevalent in the developing countries and it is estimated that over 14 million children under 5 years of age suffer eye damage as a result. Up to 4% of severely affected children will die within months of going blind and even mild deficiencies can significantly increase mortality rates in children. Iron deficiency affects 1 billion people in the developing world, particularly women and children and its effects are compounded by common tropical diseases.

The second aspect of the paradox is that food insecurity is so prevalent at a time when global food prices are generally in decline. Over the period 1960–1990, world cereal production doubled, per capita food production increased 37%, calories supplied increased 35% and real food prices fell by almost 50% (McCalla, 1998).

The basic cause of the paradox is the intrinsic linkage between poverty and food security. Simply put, people's access to food depends on income.

Poverty is both a rural and an urban phenomenon. Over 1.3 billion people in developing countries are absolutely poor, with incomes of US$1 per day or less per person, while another 2 billion people live on less than US$2 per day (World Bank, 1997). Most live in the low-potential, rain-fed rural areas of the world. With increasing urbanization, a higher proportion will be living in the cities of the developing countries by the mid-21st century. Ensuring their access to sufficient nutritious food at affordable prices is also an important component of global food-security strategies. Agricultural research needs to respond to both of these challenges, so as to improve the livelihood of families who live in rural areas and ensure the increased availability of nutritious food at affordable prices for the urban dwellers.

Global Challenges

The most important global challenges are as follows:

- Reducing poverty, especially in rural areas.
- Improving food security and reducing malnutrition.
- Providing sufficient income for the rapidly increasing numbers of urban poor.
- Mobilizing new technologies for environmentally sustainable development.

The global problems facing agriculture are described by Swaminathan (2000):

- First, increasing population leading to increased demand for food and reduced per capita availability of arable land and irrigation water.
- Secondly, improved purchasing power and increased urbanization leading to higher per capita food grain requirements due to an increased consumption of animal products.
- Thirdly, marine fish production is becoming stagnant.
- Fourthly, there is increasing damage to the ecological foundations of agriculture, such as land, water, forests and biodiversity, as well as climate change.
- Finally, while dramatic new technological developments are taking place, particularly in biotechnology, their environmental and social implications are yet to be fully understood.

World food production challenge

Production trends

As a result of the green revolution, yields of maize, wheat and rice in developing countries doubled between 1961 and 1991. In Africa, the annual increase in yield per hectare for maize, wheat and rice (1.3%) is less than a third of that achieved in Asia (4.5%). This presents a significant opportunity to raise cereal production in Africa through yield increases. Food-animal production in developing countries increased by 15% in the 1980s, whereas the global increase was 24%.

Consumption patterns

Demand for food in developing countries is met by both local production and imports. Currently developing countries are net importers of 88 million tons of cereals per year at a cost of US$14.5 billion. In Africa, the current annual production shortfalls of cereals, met by imports, is about 21.5 million tons. It is predicted that these shortfalls will increase tenfold by 2025. Since the 1970s, the developing countries have been increasingly large net importers of milk and meat (except pig meat).

Future food demands

There will be a global demand for 40% more grain in 2020, with most of the demand coming from developing countries. This will include a doubling in demand for feed grains in developing countries. Net cereal imports by developing countries will almost double to meet the gap between production and demand (IFPRI, 1997).

Future challenges

The food production increases over the past 40 years have been achieved largely by increasing productivity of cereals, expanding the area of arable land and massive increases in fertilizer and pesticide use. To meet the production challenges of the next decades, there is a need to:

- Increase biological yields of the major food crops.
- Improve productivity of livestock.
- Improve nutrient content in the diet, especially of women and children.
- Intensify agriculture, since land for agriculture is increasingly scarce.
- Manage natural resources in a sustainable way.

Environmental trends

- The intensification of agriculture in the favourable areas has come at the cost of damage to the environment, with increasing salinity problems in irrigated areas and damage to human health and wildlife due to misuse of pesticides.
- Decreasing water availability for agriculture is one of the most important trends over the last decade. There is a need for more efficient use of water in agriculture, including the development of water-saving and drought-tolerant genotypes and more efficient water-management practices.
- Pressure on land from urbanization and industrialization increases. There are limited prospects for expanding the land available for agriculture, except by moving into forests or marginal areas. The latter have poor soils and little irrigation and are prone to drought.

- Deforestation and loss of biodiversity are caused by the clearing of land for logging in areas of terrestrial mega-biodiversity. The use of modern plant varieties also threatens the loss of landraces of crops.
- Natural disasters pose a continuing threat and the long-term effects of climate change are unknown.

Trade and competitiveness trends

- Increasing trade: one option for obtaining the necessary purchasing power for food is through increased interregional and international trade.
- Increasing competitiveness: the declining prices for agricultural commodities suggest a need also to increase the productivity of agricultural exports and to develop new value-added products for export.
- Product quality needs to meet the certification and food safety standards of importing countries.

Food security strategies

While there is a need for further intensification of agricultural production to meet projected demand for food, intensification strategies must change in order to avoid an adverse environmental impact and reverse the effects of past practices (Pinstrup-Andersen and Cohen, 2000). Strategies to achieve the needed increases in food supply over the next 25 years include the following:

- Sustainable productivity increases in food, feed and fibre crops in both irrigated and rain-fed areas.
- Reducing chemical inputs of fertilizers and pesticides and replacing these with biologically based products.
- Integrating soil, water and nutrient management.
- Improving the nutrition and productivity of livestock and controlling livestock diseases.
- Sustainable increases in fisheries and aquaculture production.
- Increasing trade and competitiveness in global markets.

The challenge now is how to use new developments in modern science, including biotechnology, together with new information and communications technology and new ways of managing knowledge to make complex agricultural systems more productive in sustainable ways.

As Swaminathan (2000) says,

> we need to examine how science can be mobilized to raise further the biological productivity ceiling without associated ecological harm. Scientific progress on the farms, as an ever-green revolution, must emphasize that the productivity advance is sustainable over time since it is rooted in the principles of ecology, economics, social and gender equity and employment generation.

Promethean Science

The pace of change in modern science led Persley (2000) to term it 'Promethean [daringly original and creative] science', acknowledging both its risks and benefits. The term stems from the Greek Titan, Prometheus, who legend says introduced fire to humans. Biotechnology, like fire, carries with it benefits and risks, depending on its use (see also Serageldin and Persley, 2000).

Modern science encompasses new developments in the biological, physical and social sciences. In the biological sciences, discoveries over the past 20 years allow much greater understanding of the structure and function of human, animal and plant genes. At the same time, new discoveries in the physical sciences underpin the revolution in information and communications technologies. For example, the use of geographical information systems enables characterization of agroecosystems and also offers means by which new technologies can be customized to the needs of particular agroecosystems. The biological and physical sciences also interact in new ways. For example, the ability to analyse large volumes of data is a critical component of various genome projects that are mapping all the genes in an organism, as in the Human Genome Project (Doyle and Persley, 1998).

There have also been new developments in the social sciences that underpin community participation in technology development and evaluation (sometimes termed agroecological methods). Participatory methods developed in the social sciences can help in the understanding of the problems and the researchable issues, particularly of small farmers operating in marginal environments. They may also be used to clarify the concerns of people in rural and urban communities in regard to the deployment of new technologies, including the products of biotechnology.

It is the successful integration of all branches of modern science and traditional knowledge that is required to develop knowledge-intensive solutions to the problems of rural communities. These solutions need to be not only technically feasible but also socially acceptable. Indeed, the potential value of modern science to agriculture and the environment will not be realized without major additional efforts involving all stakeholders, including civil society, farmer cooperatives, producers, consumers, governments and development agencies.

Scope of biotechnology

Biotechnology broadly defined refers to any technique that uses living organisms or substances from these organisms to make or modify a product, improve plants or animals or develop microorganisms for specific uses. Biotechnology consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology (for example, food fermentation and biological control), through to novel and continuously evolving techniques of modern biotechnology (Fig. 1.1).

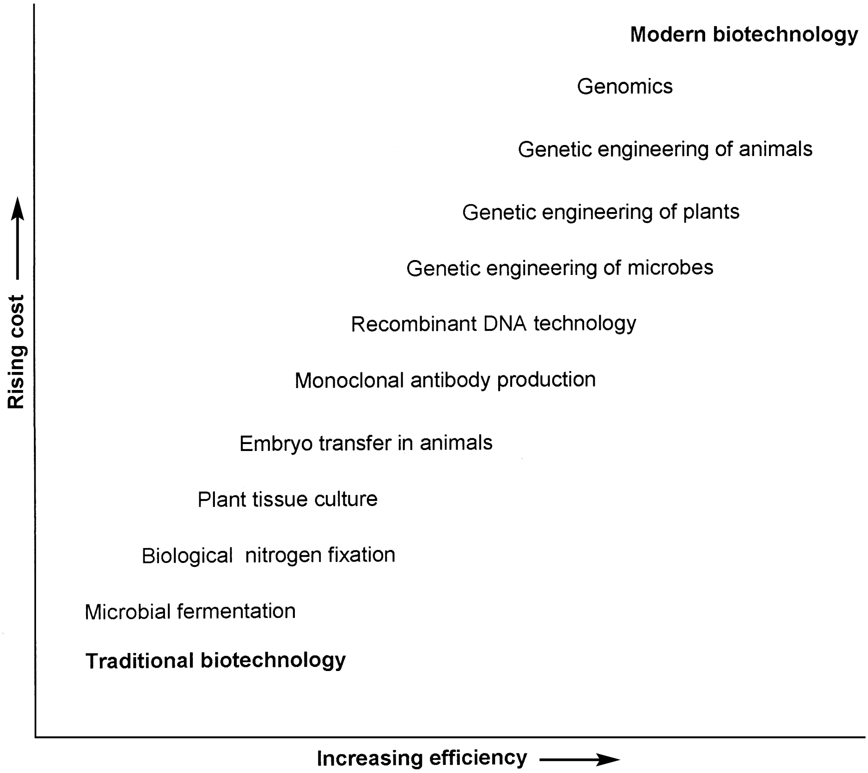

Fig. 1.1. Gradient of biotechnologies (from Persley, 1990; Doyle and Persley, 1996).

During the 1970s scientists developed new methods for precise recombination of portions of deoxyribonucleic acid (DNA), the biochemical material in all living cells that conveys the instructions that govern inherited characteristics, and for transferring portions of DNA from one organism to another. This set of enabling techniques is referred to as recombinant DNA technology or genetic engineering. Modern biotechnology currently includes the various uses of new techniques of recombinant DNA technology, monoclonal antibodies and new cell and tissue culture methods.

Over the past two decades the number of significant advances made in modern biotechnology has increased dramatically. It is this increase in the use of new techniques for understanding and modifying the genetics of living organisms that has led to greatly increased interest and investment in biotechnology. This has been accompanied by increasing concerns as to the power of the new technologies and the safety of their use, both to human health and to the environment.

Evolution of Modern Genetics

Mendel's laws of genetics were rediscovered in 1900. Mendel had published his original work on inheritance patterns in pea in 1865, but it took 35 years for others to grasp their significance. Since 1900, we have witnessed steady progress in our understanding of the genetic make-up of all living organisms, ranging from microbes to humans. A major step in human control over genetic traits was taken in the 1920s when Muller and Stadler discovered that radiation can induce mutations in animals and plants.

In the 1930s and 1940s, several new methods of chromosome and gene manipulation were discovered and used in plant improvement. These included the use of colchicine to achieve a doubling in chromosome number, commercial exploitation of hybrid vigour in maize and other crops, use of chemicals such as nitrogen mustard and ethyl methane sulphonate to induce mutations and techniques such as tissue culture and embryo rescue to get viable hybrids from distantly related species.

The double-helix structure of DNA, the chemical substance of heredity, was discovered in 1953 by James Watson and Francis Crick. This, combined with the development of recombinant DNA technology, triggered explosive progress in every field of genetics. Today, there is a rapid transition from Mendelian to molecular genetic applications in agriculture, medicine and industry.

This brief review of genetic progress from 1900 to 1999 (see Swaminathan, 2000) stresses that knowledge and discovery represent a continuum, with each generation taking our understanding of the complex web of life to a higher level. It would therefore be unwise to either adopt or discard experimental tools or scientific innovations because they are either old or new. Just as it took 35 years for biologists to understand fully the significance of Mendel's work, it may take a decade or more to understand fully the benefits and risks associated with living modified organisms (LMOs), including genetically improved foods (Persley and Siedow, 1999).

The gene revolution

The 1990s have seen dramatic advances in our understanding of how biological organisms function at the molecular level, as well as in our ability to analyse, understand and manipulate DNA molecules, the biological material from which the genes in all organisms are made. The entire process has been accelerated by the Human Genome Project, which has invested substantial public and private resources into the development of new technologies to work with human genes. The same technologies are directly applicable to all other organisms, including plants and animals. The first complete sequence of a plant genome – the flowering plant *Arabidopsis thaliana* – is now completed (Arabidopsis Genome Initiative, 2000). The rice genome is also very close to completion. The new scientific discipline of genomics has arisen, which has contributed to powerful new approaches to identify the structure and functions of genes and their applications in human health, agriculture and the environment. These new discoveries and their commercial applications have helped to promote the biotechnology industry, mainly in North America and Europe.

Commercial Applications of Agricultural Biotechnology

The greater specificity in the handling of genes since the 1970s has meant that inventors could protect their discoveries by means of patents and other forms of intellectual property rights (IPR). This has led to an explosion of private investment in the biosciences, leading to what has been called a biotechnology revolution. Most modern biotechnology applications are in health care, where they offer new hope to patients with AIDS, genetically inherited diseases, diabetes, influenza and some forms of cancer. Biotechnology-based processes are now used routinely in the production of most new medicines, diagnostic tools and medical therapies. The global market for these products is approximately US$13 billion.

New developments in agricultural biotechnology are being used to increase the productivity of crops, primarily by reducing the costs of production by decreasing the needs for inputs of pesticides and herbicides, mostly in crops grown in temperate zones. The applications of agricultural biotechnology are developing new strains of plants that give higher yields with fewer inputs, can be grown in a wider range of environments, give better rotations to conserve natural resources and provide more nutritious harvested products that keep much longer in storage and transport, and continued low-cost food supplies for consumers.

Private industry has dominated research, accounting for approximately 80% of all R & D. Consolidation of the industry has proceeded rapidly since 1996, with more than 25 major acquisitions and alliances, worth US$15 billion.

During the past decade, the commercial cultivation of transgenic plant varieties became well established, particularly during the latter part of the decade. In 1999, it is estimated that approximately 40 million ha of land were planted with transgenic varieties of over 20 plant species, the most commercially important of which were cotton, maize, soybean and rape-seed (James, 1999). The value of the global market in transgenic crops grew from US$75 million in 1995 to US$1.64 billion in 1998.

The traits these new varieties contain include insect resistance (cotton, maize), herbicide resistance (maize, soybean) and delayed fruit ripening (tomato). The benefits of these new crops are better weed and insect control, higher productivity and more flexible crop management. These benefits accrue primarily to farmers and agribusinesses, although there are also economic benefits accruing to consumers in terms of maintaining food production at low prices. Health benefits for consumers are also emerging from new varieties of maize and rape-seed with modified oil content and reduced levels of potentially carcinogenic mycotoxins. The broader benefits to the environment and the community through reduced use of pesticides contribute to more sustainable agriculture and improved food security.

Other crop/input trait combinations currently being field-tested include virus-resistant melon, papaya, potato, squash, tomato and sweet pepper; insect-resistant rice, soybean and tomato; disease-resistant potato; and delayed-ripening chilli pepper. There is also work in progress to use plants such as maize, potato and banana as mini-factories for the production of vaccines and biodegradable plastics.

Several large corporations in Europe and the USA have made major investments to adapt the new discoveries in the biological sciences to commercial purposes, especially to produce new plant varieties of agricultural importance for large-scale commercial agriculture. The same technologies also have important potential applications to address problems of poverty reduction, food security, environmental conservation and trade competitiveness in developing countries (Tzotzos and Skryabin, 2000; US National Academy of Sciences, 2000).

Scientific advances

Further scientific advances will probably result in crops with a wider range of traits, some of which are likely to be of more direct interest to consumers – for example, by having traits that confer improved nutritional quality in food. Crops with improved output traits could have nutritional benefits for millions of people who suffer from malnutrition and deficiency disorders. Genes have been identified that can modify and enhance the composition of oils, proteins, carbohydrates and starch in food/feedgrains and root crops. A gene encoding β-carotene/vitamin A formation, for example, has been incorporated experimentally in rice. This is being evaluated for the feasibility of using vitamin-A enriched rice to enhance the diets of the 180 million children who suffer from vitamin A deficiency. Similarly, introducing genes that increase available iron levels in rice threefold is a potential remedy for iron deficiency, which affects more than 2 billion people and causes anaemia in about half that number.

Applications of biotechnology in agriculture are in their infancy. Most current genetically engineered plant varieties are modified only for a single trait, such as herbicide tolerance or pest resistance. The rapid progress being made in genomics may enhance plant breeding as the functions of more genes and how they control particular traits are identified. This may enable more successful breeding for complex traits, such as drought and salt tolerance. This would be of great benefit to those farming in marginal and rain-fed lands worldwide, because breeding for such traits, has had limited success with conventional breeding of the major staple food crops.

Applications of Biotechnology for Poverty Reduction and Food Security

Breakthroughs in modern science have led to rapid progress in understanding the genetic basis of living organisms and the ability to use that understanding to develop new products and processes useful in human and animal health, food and agriculture and the environment. The adoption of modern biotechnology is most advanced in human health, where many new drugs, diagnostics and vaccines are based on the use of new biotechnology.

The applications developed from the new methods in biotechnology place them within the continuum of techniques used throughout human history in industry, agriculture and food processing. Thus, while modern biotechnology provides powerful new tools, these tools are used to generate products that in most cases fill similar roles to those produced with more traditional methods.

In agriculture, there is now increasing use of modern molecular genetics for genetic mapping and marker-assisted selection as aids to give more precise and rapid development of new strains of improved crops, livestock, fish and trees. Other biotechnology applications, such as tissue culture and micropropagation, are being used for the rapid multiplication of horticultural crops and trees. New diagnostics and vaccines are being widely adopted for the diagnosis, prevention and control of fish and livestock diseases.

Harnessing the full power of the genetic revolution requires going beyond these early applications of modern biotechnology and recognizing the power of the new revolution in genomics and associated technologies as aids for genetic improvement. The new technologies enable greatly increased efficiency of selection for useful genes, based on knowledge of the biology of the organism, the function of specific genes and their role in regulating particular traits. This will enable more precise selection of improved strains. These techniques may be used for more efficient selection in conventional breeding programmes. They may also be used for the identification of genes suitable for use in the development of transgenic strains (Serageldin and Persley, 2000).

The most striking differences between the techniques of modern biotechnology and those that have been used for many years lie in the increased precision with which the new techniques may be used and the shorter time required to produce results. For example, modern biotechnology enables plant breeders to collaborate with molecular biologists and transfer to a popular and highly developed crop variety one or two specific genes needed to impart a new characteristic, such as a specific kind of pest resistance.

The advantages of the new techniques of modern biotechnology are that they speed up plant and animal breeding, offer possible solutions to previously intractable problems and difficult targets, such as drought tolerance, and

Table 1.1. Illustrative applications of biotechnology to the goal of poverty reduction.

			Biotechnology applications (1–6)						
			1	2	3	4	5	6	7
Poverty reduction objective	Constraint	Target	Microbial fermentation/ biocontrol/ biofertilizers	New diagnostics/ vaccines	Tissue culture/ micropropagation	Molecular markers and MAS	Genetic engineering/ transgenics	Genomics	Examples
Increasing rural incomes	Lack of clean seed/ planting material	Vegetative crops and trees	Bio-pesticides	Plant disease diagnostics	Cardamom				India
					Potato				Vietnam
					Banana				Kenya
Sustainable production in resource-poor areas	Drought	Cereals				Maize		Drought tolerance in cereals	AMBN/ CIMMYT
	Pests	Maize				Insect resistance			
	Acid soils	Aluminium tolerance				Aluminium tolerance			
More nutritious food	Vitamins	Rice					Vit. A rice		IRRI
	Micro-nutrients	Rice				Iron			India China

Notes:
1. Traditional biotechnology applications, such as microbial and food fermentation.
2. New diagnostics and vaccines based on molecular applications.
3. New methods for tissue culture and micropropagation of planting material.
4. Use of molecular markers in marker-assisted selection (MAS) in conventional plant and animal breeding.
5. Genetic engineering to produce transgenic plant and/or animal strains, containing new specific gene(s) controlling a particular trait.
6. Genomics: understanding the physical structure of the genome and, in functional genomics, the function of specific genes.
7. Specific global examples where new biotechnologies are being developed.

AMBN, Asian Maize Biotechnology Network; CIMMYT, Centro Internacional de Mejoramiento de Maiz y Trigo; IRRI, International Rice Research Institute.

Table 1.2. Illustrative applications of biotechnology to the goal of food security.

			Biotechnology applications (1–6)						
Food security objective	Constraint	Target	1 Microbial fermentation/ biocontrol/bio-fertilizers	2 New diag-nostics/ vaccines	3 Tissue culture/ microprop-agation	4 Molecular markers and MAS	5 Genetic engineering/ transgenics	6 Genomics	7 Examples
Meeting demand predictions for staple foods	Pests/ diseases	Rice	Rice FAO/IPM programme				Bacterial blight (Xa1)	Rice genome	ARBN/ IRRI China
	Abiotic stresses	Salinity/ drought tolerance in cereals				Cereals/ drought tolerance	Salinity tolerance (mangrove gene)	Cereals	India China ICRISAT CIMMYT
Increasing livestock	Diseases	Cattle/pigs/ sheep		FMD					Thailand
	Productivity	Dairy cattle			Embryo technology				India
Increasing fish/aqua-culture	Diseases	Shrimp viruses		Molecular diagnostics					Thailand
Increasing vegetables/ fruits	Pests/ diseases	Tomato/ potato	BW biocontrol agent		Potato (Vietnam)	BW-resistant varieties			AVRDC Vietnam
		Papaya					Papaya ringspot virus		ISAAA Asian regional network

Notes: 1–7: see Table 1.1.
FAO, Food and Agriculture Organization; IPM, Integrated Pest Management; ARBN, Asian Rice Biotechnology Network; IRRI, International Rice Research Institute; ICRISAT, International Crops Research Institute for the Semi-Arid Tropics; CIMMYT, Centro Internacional de Mejoramients de Maiz y Trigo; FMD, foot and mouth disease; AVRDC, Asian Vegetable Research and Development Center; BW, bacterial wilt; ISAAA, International Service for the Acquisition of Agribiotech Applications.

Table 1.3. Illustrative applications of biotechnology to the goal of environmental protection.

			Biotechnology applications (1–6)						
Environmental objective	Constraint	Target	1 Microbial fermentation/ biocontrol/bio-fertilizers	2 New diag-nostics/ vaccines	3 Tissue culture/ microprop-agation	4 Molecular markers and MAS	5 Genetic engineering/ transgenics	6 Genomics	7 Examples
Pesticide Reduction	Pesticide misuse	Cotton					Bt cotton		China
		Rice				Insect resistance	Bt genes		IRRI
		Vegetables	Bt as bio-pesticide						Malaysia
Efficient water use	Drought/ salinity	Maize, rice, sorghum				Molecular markers		Cereal genes for drought tolerance	China CIMMYT/ IRRI/ICRISAT
Reduce deforestation				Identify diversity sources	Rapidly growing fuel wood				CIFOR/ ICRAF/ IPGRI

Notes 1–7: see Table 1.1.
Bt, *Bacillus thuringiensis*; IRRI, International Rice Research Institute; CIMMYT, Centro Internacional de Mejoramiento de Maiz y Trigo; ICRISAT, International Crops Research Institute for the Semi-Arid Tropics; CIFOR, Centre for International Forestry Research (Indonesia); ICRAF, International Centre for Research in Agroforestry; IPGRI, International Plant Genetic Resources Institute (Rome).

Table 1.4. Illustrative applications of biotechnology to the goal of increasing competitiveness.

			Biotechnology applications (1–6)						
			1	2	3	4	5	6	7
Objective	Constraint	Target	Microbial fermentation/ biocontrol/ biofertilizers	New diagnostics/ vaccines	Tissue culture (tc)/ microprop- agation	Molecular markers and MAS	Genetic engineering/ transgenics	Genomics	Examples
Sustainable productivity exports	Yield/quality	Coconut				High lauric acid			Philippines
		Banana			Banana tc		BBTV resistance		India China Vietnam
Food safety and quality control	Pesticide residues	Food exports		Certify export quality					
Value-added exports	Product quality	Bamboo			Bamboo tc				China Vietnam

Notes 1–7: see Table 1.1.
BBTV, banana bunchy-top virus.

enable the development of new products. These products may include more nutritious food with higher levels of vitamins and minerals, crop varieties with improved tolerance to pests and diseases that require less pesticide use, and vaccines that protect livestock against lethal diseases.

Because modern biotechnology provides powerful new techniques and the number and variety of new products is so great, it is important to provide appropriate regulatory mechanisms to ensure that products produced by the use of new techniques are as safe as the products of traditional biotechnology. This is especially so when these products are LMOs that might interact with the environment. The applications of modern biotechnology to agriculture, particularly the development of transgenic crops and other LMOs, are the subject of public debate as to the safety and efficacy of the new products.

A number of applications of biotechnology are being used in Asia, Africa and Latin America to address specific problems in crop and livestock production, fisheries and forestry. There are also opportunities for their expanded use to contribute to poverty reduction, food security, environmental conservation and trade competitiveness (Tables 1.1–1.4). The range of applications includes new biocontrol agents for pest and weed control, improved diagnostics and vaccines for fish and livestock diseases, higher-quality and disease-free planting material (e.g. banana, potato, sweet potato), new varieties of rice and maize selected using molecular markers for drought and salinity tolerance, and transgenic varieties of selected crops.

The most commercially widespread of the new transgenic crops are cotton varieties containing one or more genes from the bacterium *Bacillus thuringiensis* (Bt) for insect resistance. Insect-resistant, transgenic cotton varieties were grown by some 3 million small-scale farmers on at least 0.3 million ha in China in 2000.

The applications of the new developments in biotechnology could contribute more to strategies to achieve future poverty reduction and food security if they are better targeted on issues that affect poverty and food security and if they are also accompanied by political will, appropriate public policies, public and private investments in technology development and product delivery and, importantly, regulatory frameworks that generate both consumer and commercial confidence (Persley and Doyle, 1999).

Agricultural Biotechnology in Selected Countries

Asia/Pacific

China, India, Indonesia, Pakistan, the Philippines and Thailand are committed to the use of modern biotechnology in agriculture and are investing significant human and financial resources in this policy and have done so over the past decade.

China sees the greatest challenge as the use of biotechnology to increase food production and improve product quality in an environmentally sustainable manner. China has moved quickly to develop new biotechnologies. Over 103 genes have been evaluated for improving traits in 47 plant species. The crops include rice, wheat, maize, cotton, tomato, pepper, potato, cucumber, papaya and tobacco. A variety of traits were targeted for improvement, including disease resistance, pest resistance, herbicide resistance and quality improvement. Approximately 50 genetically improved organisms (GIOs) have been approved for commercial production, environmental release or small-scale field testing in China. In a few cases, new genetically improved varieties have been approved for large-scale commercial production. Genetically improved plant varieties, mainly of insect-resistant cotton, were grown commercially by some 3 million farmers on at least 0.5 million ha of land in China in 2000 (Zhang, 2000).

India has devoted considerable public resources to infrastructure and human resource development in biotechnology. Current efforts are aimed at applications to improve agricultural productivity; bioremediation in the environment; medical biotechnology for the production of new vaccines, diagnostics and drugs; industrial biotechnology; and bioinformatics (Sharma, 2000; see also Sharma, this volume). R & D priorities in agriculture include new regeneration protocols for rapid multiplication of citrus, coffee, mangrove, vanilla and cardamom. Yield of cardamom has increased 40% using tissue-cultured plants.

Over the past two decades, *Indonesia* has placed high priority on biotechnology. The government designated three national biotechnology centres to coordinate R & D in agriculture, medicine and industrial microbiology. Applications of biotechnology in agriculture are primarily the responsibility of the Agency for Agricultural Research and Development (AARD). A national committee on biotechnology advises the minister in developing guidelines for government policy in the promotion of biotechnology. In recent years there has been an extensive training programme within Indonesia and abroad to upgrade skills of scientists involved in biotechnological research.

Crop improvement efforts using modern biotechnology started in *Pakistan* in 1985, when a training course was held on recombinant DNA. Work is now concentrated on chickpea, rice and cotton, where there is some private-sector investment. Field evaluation of LMOs is hampered by lack of biosafety regulations. The government controls field testing, multiplication, distribution and biosafety issues. The country lacks policy and regulations regarding IPR and patents involving biotechnology (see Zafar, this volume).

The Philippines began their biotechnology programmes in 1980 with the creation of the National Institutes of Molecular Biology and Biotechnology, with a focus on agricultural biotechnology. In 1997, the Agriculture Fisheries Modernization Act recognized biotechnology as a major means of increasing agricultural productivity. The Act provided for a budget for agricultural biotechnology of almost US$20 million annually for the next 7 years (4% of the total R & D budget), an increase from US$1 million per year. In 1998, five high-level biotechnology research projects were funded by government: development of new varieties of banana resistant to banana bunchy-top virus and papaya resistant to ringspot virus; delayed ripening of papaya and mango; insect-resistant maize; marker-assisted breeding in coconut; and coconut with high lauric acid content. Public concerns about the safety of LMOs have been vocal in the Philippines and this is constraining the commercial use of modern biotechnology in agriculture (de la Cruz, 2000).

Thailand is focusing on the applications of biotechnology to traditional foods, fruits and export commodities. R & D priorities are to raise production and cut costs by using new biotechnology to address problems on crops such as rice, sugar cane, rubber, durian and orchids. An early success in Thailand has been in the application of biotechnology to the development of new molecular diagnostics for the diagnosis and control of virus diseases in shrimps. These diseases cost the shrimp export industry over US$500 million in lost production in 1996 (Morakot, 2000).

Five of these countries have regulatory systems in place at the national and institutional level to govern R & D programmes and commercial developments where appropriate. Intellectual property management was considered to be a difficult issue for all six countries.

Latin America and the Caribbean

The main challenges in relation to agricultural biotechnology are: management of intellectual property for both major and minor crops; assessment of several research options, not only a molecular approach, in assessing how best to tackle problems and challenges to improve agricultural productivity; identification of beneficiaries; prioritization of work on favoured and/or marginal areas; use of GIOs as indicators of environmental damage; and need to monitor the behaviour of GIOs in the environment after release. The ecological research effort for monitoring GIOs is needed to satisfy public concerns about the behaviour of GIOs in the environment, and needs to focus on the following key questions. What are the specific concerns? How to do it? Who will do it? Who will pay for it?

In *Brazil*, many lines of R & D are benefiting from the application of biotechnology tools such as marker-assisted plant and animal breeding, genomic mapping of several species including sugar cane, embryo transfer applied to different animal species, genetic resources characterization and conservation, and use of genetic improvement to introduce new traits, such as papaya resistant to papaya ringspot virus and beans resistant to golden mosaic virus. The issues of field testing of genetically improved plants need to be addressed. Tropical agriculture is very different from the temperate fields where most of the new genetically improved products have been tested. Protocols are required for field trials, risk assessment (environmental and food safety), registration of products and public acceptance. The need is urgent, because these are constraints that will intensify as GIOs become an integral part of the research agenda in the region (Sampaio, 2000).

In *Costa Rica*, there is particular interest in using the tools of biotechnology to characterize and conserve biodiversity (Sittenfeld *et al.*, 2000). Costa Rican institutions have developed some innovative partnerships for bioprospecting, which could serve as a model for other countries. In agriculture, pesticide use increased threefold between 1993 and 1996 on crops such as banana, coffee and rice. Much of this pesticide is used to control banana diseases, where pesticide use is a health risk to field workers and an environmental risk to land, water and animals. Biotechnology-based solutions are urgently needed to replace chemical control of banana diseases. Recent discoveries in regard to understanding and managing the development of fungicide resistance in the black Sigatoka pathogen are leading to a 10–15% reduction in fungicide use on banana (a potential saving of some US$10 million per year). On rice, new virus-resistance genes are being introduced into local rice varieties.

Coffee continues to be the major export crop for *Colombia*, though its importance has declined as exports of other commodities (e.g. banana, sugar, beef, cut flowers) have increased. Agriculture now accounts for 19% (estimated in 1999) of Colombia's gross domestic product (GDP). There are extensive national efforts in many areas of biotechnology, which are aimed at delivering benefits to the rural areas while also maintaining a healthy environment and sustainable national agriculture.

Africa

The major challenge for *Kenya*, *Zimbabwe* and *Egypt* is the persistent poor performance of agriculture in Africa generally, which is leading to a food crisis. The issues concerning many countries are how to improve food security, increase productivity, conserve biodiversity, reduce pest management costs and deal with increasing urban migration. Specific issues related to biotechnology are how to develop institutional capacity for risk assessment and management, to access information on developments in biotechnology elsewhere that may have application in Africa and to develop the necessary human resources and infrastructure.

Several success stories are coming out of Africa, where biotechnological approaches have contributed to the solution of specific problems, reduced the cost of pest control and created new employment opportunities in towns and villages. They include the wide adoption by farmers of rapid multiplication of disease-free banana plantlets in Kenya; use of new genetically improved pest-resistant cotton by small farmers in South Africa; and use of new vaccines against animal diseases in Kenya and Zimbabwe (Chetsanga, 2000; Ndiritu, 2000; Njobe-Mbuli, 2000).

Some of the problems and constraints identified include: lack of awareness of the benefits and risks associated with modern biotechnology; lack of capacity in some countries to deal with assessing these benefits and risks and in regulating the use of modern biotechnology; high investment costs associated with biotechnological innovations; and increasing concerns being expressed in the media about the potential negative impacts of biotechnology and the need for public awareness of the issues.

In sub-Saharan Africa the need is both to improve awareness and institutional capacity to develop biotechnology-based products and, perhaps as importantly, for African stakeholders, scientists and policy-makers to articulate an African agenda and to participate in critical global debates on trade and economic growth (Njobe-Mbuli, 2000).

One of the major targets for biotechnology in *Egypt* is the production of transgenic plants conferring resistance to the biotic and abiotic stresses that are causing serious yield losses in many economically important crops in the country. The Agricultural Genetic Engineering Research Institute (AGERI) was established in 1990 with the aim of mobilizing the most recent technologies available worldwide to address problems facing agricultural development (Madkour, 2000).

The challenges identified were the need to increase agricultural productivity, while preserving the fragile natural resource base in the region and the need to conserve the rich indigenous plant and animal species. The opportunities include: using modern biotechnology to develop crop varieties tolerant to biotic and abiotic stresses, especially drought and salt tolerance; improving the nutritional quality of agricultural commodities; producing biofertilizers and biopesticides; and improving the availability of soil nutrients.

The main constraints are inadequate financial resources, lack of qualified personnel, poor infrastructure and insufficient regional and international collaboration. There is also a lack of clear strategies, policies and regulatory frameworks to guide the use of modern biotechnology in most countries of the region.

Risks and Benefits in the Use of LMOs

Public concerns about the use of LMOs lie in four major areas: food safety, the environment, socio-economic and ethical issues. First, in relation to food safety, there are concerns about assessing the risks of genetically modified (GM) foods to human health and understanding potential benefits of new GM foods to consumers. Secondly, in relation to environmental effects, the concerns relate to assessing the risks and benefits of releasing LMOs into the environment and the effects such releases may have on the environment. These may be direct effects, such as on biodiversity, or indirect, through changing agricultural practices that affect the environment. LMOs released for agricultural purposes may be plants, trees, livestock, fish and/or microorganisms.

Given the rapid pace of new developments in agricultural biotechnology, many consumers are seeking further information about the potential effects of biotechnology on their food and their environment. The media have sensed that this is an issue high in public consciousness and are actively promoting widespread debate on how we should best use the discoveries of modern genetics. This is one of the most important public debates of the new millennium, because its resolution will have global implications for food and raw material production for the rest of this century (Johnson, 2000).

Food safety and human health

Risk factors. There are several areas of public concern with regard to potential human health risks of GM foods. These relate to understanding the potential of proteins and/or other molecules in GM foods to cause allergic reactions, to act as toxins or carcinogens and/or to cause food-intolerance reactions among the population. Methods of testing and evaluating these types of risks have been established for food and these are being applied to GM foods so as to detect any increased risks associated with particular foods (Lehrer, 2000).

A recent consultation between the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) reported that 'the Consultation was satisfied with the approach used to assess the safety of the genetically modified foods that have been approved for commercial use'. The US Food and Drug Administration (FDA) has also stated that 'we have seen no evidence that the bioengineered foods now on the market pose any human health concerns or that they are in any way less safe than crops produced through traditional breeding'.

Although no instances of harmful effects on human health have been documented from GM foods, that does not mean that risks do not exist as new foods are developed with novel characteristics. GM foods should be assessed on a case-by-case basis, using scientifically robust techniques, so as to ensure that the foods brought to market are safe for human consumption.

For example, any protein added to a food should be assessed for its potential allergenicity, whether it is added by genetic engineering or by manufacturing processes (Lehrer, 2000). Allergenicity can be raised in foods either by raising the level of a naturally occurring allergen (e.g. in groundnuts) or by introducing a new allergen. More than 90% of the food allergens that occur in 2% of adults and 4–6% of children are associated with eight food groups. These include Crustacea, eggs, fish, groundnuts, soybean, tree nuts and wheat. These foods merit close attention when examining GM foods for the potential for increased risk of allergenicity (Lehrer, 2000). There is also a need to assess the allergenic potential of unknown proteins, such as those produced by Bt genes in plants. It was the presence of a heat-tolerant Bt protein in Starlink maize that caused the US FDA to withhold approval for its use in human consumption, as the FDA scientific advisory panel considered that this protein posed a moderate allergy risk.

Antibiotic resistance. There are also concerns about the risk that the antibiotic-resistance genes used as selectable markers in GM plants may transfer to microorganisms that are human pathogens, adding to the increasing problem of antibiotic resistance in human pathogens. This problem is the result of widespread use of antibiotics in human and animal health. WHO, the Organization for Economic Cooperation and Development (OECD) and FAO have assessed the antibiotic-resistance markers used in transgenic crops as being safe. The risk of transfer of an antibiotic marker from a GM food to a human pathogen is considered remote. Nevertheless, the use of these antibiotic markers is being phased out. Other selectable markers that can be removed from the plant in the development phase are replacing them (Escalar, 2001).

Risk assessment

The International Life Sciences Institute (ILSI) has developed a decision tree that provides a framework for risk assessment in foods (Lehrer, 2000). It uses the following criteria, that an introduced protein in a food is not a concern if: (i) there is no history of common allergenicity; (ii) there is no amino acid sequence similar to those of known allergens; (iii) there is rapid digestion of the protein; and (iv) the protein is expressed at low levels. For example, these risk assessment techniques were used to test the safety of increasing the protein content in soybean by introducing a protein from Brazil nut. However, food allergy tests showed that this transferred a potential allergen to soybean. Hence, further development of this GM high-protein soybean ceased.

The techniques for assessing the potential for allergenicity, toxicity and carcinogens in food are well established and should be readily able to be used by trained professionals in many countries (Metcalf *et al.*, 1996; Lehrer, 2000). Given increasing global concerns about food safety, all countries will need to have in place food-safety regulations and the human and institutional capacity to be able to ensure the safety of their food supply (World Bank, 2000).

Benefits to human health

The risks in GM foods need to be weighed against the benefits. The next generation of GM foods is likely to include a number of functional foods that offer some nutritional benefits to consumers. Human health benefits of GM foods lie in the potential for introducing traits that enable factors such as the following:

- Improved nutritional quality of foods (e.g. higher vitamin content, lower fat content).
- Reduced toxic compounds in food (e.g. cassava with lower levels of cyanide).

- Crops grown with lower levels of chemical pesticides, thus reducing pesticide residues in food.

Labelling

A key concern of consumers is being able to identify those foods that may contain allergens and other potentially harmful substances. Those who have allergic or food-intolerant reactions to particular foods can avoid them. Others may wish to avoid certain foods on health, ethical or religious grounds. Informative food labelling, whether mandatory or voluntary, could be used to provide information about specific products and enable consumers to make informed decisions about their use, in terms of both risks and potential beneficial effects (Skerritt, 2000).

International developments

As a result of an international conference on the safety of GM foods, the OECD (2000) noted the need for the following:

- Factual points of departure as to where there is agreement and disagreement on human health risks.
- Benefits versus risks, which differ for different countries and environments.
- Management of genetic modification technologies.
- The role of stakeholders and consultative processes.
- An international programme of activities to inform the public debate and policy-making, including a possible international panel to review scientific evidence on the benefits and risks of the applications of new biotechnologies in food.

The International Council of Scientific Unions (ICSU) has initiated a review of the scientific basis of assessing risks and benefits of GM foods, as a contribution to the ongoing debates, nationally and internationally.

Environmental risks and benefits of LMOs

In regard to the risks and benefits of LMOs in the environment, public concerns are based on the premise that, when LMOs contain genes introduced from outside their normal range of sexual compatibility, these organisms may present new risks to the environment. Present recombinant DNA technology enables such genetic modifications to be made to introduce new and potentially useful traits into plants, trees, microorganisms, livestock and fish.

The most widespread new LMOs released in the environment are GM crops, with some 44 million ha being cultivated commercially, in 15 countries. Most of this area (68%) is planted in North America with GM maize, cotton, potato, rape-seed and soybean, modified with new genes for insect resistance and/or herbicide tolerance and virus resistance (James, 2000). Among emerging economies, China has at least 0.5 million ha, mainly of transgenic cotton with insect resistance, being grown by some 3 million farmers.

The concerns about the impact of LMOs on the environment are about the risks of both direct ecological effects and indirect environmental effects due to changing agricultural management practices brought about by the use of LMOs. The applications of biotechnology may offer means that enable agriculture to sustain yields while minimizing the adverse environmental effects of agricultural intensification. Yet there is a perception that some of the present generation of GM crops, especially the new herbicide-tolerant and insect-resistant crops developed for extensive agricultural systems, may present yet further risks to biodiversity in present agricultural systems (Johnson, 2000).

Some of the claims for the potentially harmful effects of currently cultivated GM crops on the environment include the following:

- The use of genes from Bt as a source of resistance to insect pests may lead to 'super' pests.
- The use of crops with resistance to glyphosate (Round-Up) may lead to greater use of broad-spectrum herbicides.
- Virus-derived genes used as a source of virus resistance in crop plants may lead to new viruses with potential to kill native plants.

Governments, research organizations and companies must respond to these claims and other concerns and have in place the means to scientifically assess and report on the risks and the benefits to the environment of LMOs (Cook, 2000).

There is a need for science-based risk assessments for plants and other organisms (livestock, fish, trees and microbes) that are intended for use in agricultural and other managed environments. There is also an urgent need for ecological research and developing agreed standards and protocols to enable the continuing monitoring of the behaviour of LMOs after experimental (small-scale) and commercial (large-scale) releases into the environment. Such data would then feed back into risk assessments, so as to inform future decisions on the development and management of LMOs being developed for agricultural purposes.

A recent review of the scientific literature reveals that key experiments on both the environmental risks and benefits of genetically engineered plants are lacking. (Wolfenberger and Phifer, 2000). The complexity of ecological systems presents considerable challenges to designing experiments to assess such risk and benefits.

The US National Academy of Sciences (NAS, 1987) released one of the earliest studies on the safety of LMOs in the environment. Its four conclusions were as follows:

- There is no evidence that unique hazards exist either in the use of recombinant DNA techniques or in the transfer of genes between unrelated organisms.

- The risks associated with the introduction of recombinant DNA-engineered organisms are the same in kind as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques.
- Assessment of the risks of introducing recombinant DNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it will be introduced (product), not on the method (process) by which it was modified.
- There is an urgent (and ongoing) need for the scientific community to provide guidance for both investigators and regulators in evaluating planned introductions of modified organisms from an ecological perspective.

Thousands of field trials conducted with GM crops over the past decade support these conclusions by NAS in this and subsequent reports (NAS, 1987; NRC, 1989, 2000; Cook, 2000).

GM plants in the environment

Cook (2000) reported on an approach to science-based risk assessment for plants intended for use in agricultural or other managed environments. In addressing the risks posed by the cultivation of plants in the environment, five environmentally related safety issues need to be considered (OECD, 1993). These issues are the potential for:

- Gene transfer, meaning the movement of genes from a crop through outcrossing with wild relatives to form new hybrid plants.
- Weediness, meaning the tendency of a plant to spread beyond the field where first planted and establish itself as a weed or invasive species.
- Trait effects, meaning effects of traits that are potentially harmful to non-target organisms.
- Genetic and phenotypic variability, meaning the tendency of the plant to exhibit unexpected characteristics.
- Expression of genetic material from pathogens, such as the risk of genetic recombinations following mixed virus infections.

Gene flow and transfer of traits to other species. Gene transfer is an issue when crops are being grown in areas close to their wild relatives, with whom they are able to cross to form interspecific hybrids. Natural hybridization occurs within 12 of the world's 13 most important food crops and their wild relatives (the exception being banana, since cultivated banana is infertile). Thus, the world's major cereal crops (maize, wheat, barley, sorghum), oil-seeds (rape-seed, soybean and groundnut) and root and tuber crops (cassava and potato) can cross with their compatible wild relatives. Such wild relatives occur in the centres of diversity of these crops (see map of the centres of origin and diversity of the world's major food crops in Serageldin and Persley (2000)). Natural hybridization may occur at low frequency when pollen blows or is otherwise transported from crops to wild relatives in the vicinity. Such gene flow and interspecific crosses cannot occur in crops whose centres of origin and diversity and closest wild relatives are on other continents (e.g. maize in Europe, since its centre of origin is in Mexico).

Recent research confirms that genes introduced into some GM crops may spread into related native species (Chevre *et al.*, 1997). This is not unexpected since genes have long been known to move from conventionally bred crops to wild relatives, at low frequency. For example, in the UK, such hybrids occasionally occur between oil-seed rape (*Brassica napus*) and native species, such as wild turnip (*Brassica rapa*). Published studies on the gene transfer issue are dominated by rape-seed (Wolfenberger and Phifer, 2000), whose centre of origin is in Europe.

The difference is that genes inserted into GM crops are often derived from other phyla, giving traits that have not been present in wild plant populations. The concern is that these genes may change the fitness and population dynamics of hybrids formed between native plants and related GM crops, eventually back-crossing genes into the native species. The importance of pollen transfer from GM crops to wild relatives is not that it occurs but whether the resulting hybrids survive and reproduce and introgress genes back into the native population.

The issue is not so much the rate of gene flow (on which there has been much research), as the impact that this might have on agriculture and the environment (on which there has been very little research). Conventional plant breeding, using techniques such as mutagenesis and embryo rescue, also produces new genes in crops, about which we also know very little regarding their behaviour in the wild (Johnson, 2000).

Weediness. There are risks that GM plants could have negative impacts on natural ecosystems by increasing weediness by two routes. First, the GM plants could establish self-sustaining populations outside cultivation themselves. The concern is that these plants may become invasive weeds that out-compete wild populations and thus lead to further decreases in biodiversity in native plant habitats. Weeds having tolerance to a range of herbicides could also emerge (Johnson, 2000).

Secondly, novel genes from GM crops could be introduced into their wild relatives by pollen spread and the survival and reproduction of the resulting hybrids. This may have a negative impact on the wild plant population if new genes are introgressed back into the wild plant population. For this to happen, the new genes must increase the plants' fitness to survive and reproduce in the wild.

Transfer of certain genes, such as resistance to insects, fungi and viruses, may increase the fitness (ability to reproduce) of any resulting hybrids. If hybrids acquired insect resistance from GM crops, they could damage food chains dependent on insects feeding on previously non-toxic wild plants. Not only would there be a direct effect, for many insects are entirely dependent on single plant species, but acquisition of resistance in wild plants would probably change their population dynamics, increasing the risks of their invading agricultural land and natural ecosystems.

Many geneticists would argue that most 'foreign' genes introduced accidentally from GM crops to crop/native plant hybrids would decrease their fitness in the wild, leading to rapid selection of these genes out of the population (Johnson, 2000). A recently published 10-year study by Imperial College in the UK on the fitness of GM plants to survive in the wild supports this hypothesis. GM maize, rape-seed and sugar beet (all with herbicide tolerance) and potato with insect resistance were compared with conventionally bred crops. All four GM crops were out-competed by their conventionally bred relatives (Crawley *et al.*, 2001). Thus, in this experiment, the genetic modifications in these species for herbicide tolerance and insect resistance made them less competitive and less fit to survive in the wild. Plant breeding tends to reduce rather than increase the weediness characteristics of crop plants (Cook, 2000).

Trait effects. Trait effects are those that are harmful to non-target organisms. For example, plants modified to produce pesticidal proteins, such as Bt toxins, may have both direct and indirect effects on populations of non-target species. One group of Bt toxins primarily targets Lepidoptera (butterflies and moths, particularly the European corn-borer) and the others affect Coleoptera (beetles). The effects of Bt toxin-producing plants on non-pest species among these insect groups may vary widely, depending on sensitivity and the concentration of Bt in transgenic plants and environmental conditions.

Laboratory experiments demonstrated that the larvae of monarch butterflies (a relative of the European corn-borer) were susceptible to pollen from Bt maize when ingested in large amounts (Losey *et al.*, 1999), but the actual ecological significance of this laboratory experiment was not clear. Subsequent field experiments in several locations in North America found that there were no significant differences between butterfly survival in areas planted with Bt maize and those planted with conventional crops (Henderson, 2000).

In assessing trait effects, such as those of Bt crops, on non-target species, it is important to compare the potential risks of Bt crops with the present effects of chemical pesticide use in risk assessments.

Genetic and phenotypic variability. This is the tendency of a plant to exhibit unexpected (pleotropic) characteristics in addition to the expected characteristics. This trait is well known from conventional breeding, but becomes an identifiable hazard only if the variability leads to one of the other safety issues, such as greater weediness or a greater tendency for out-crossing.

Expression of genetic material from pathogens. Another potential hazard would be the possibility of recombination of a virus gene expressed by the plant with genes from another virus infecting that plant. This risk would be similar to the risk of genetic recombinations following mixed virus infections that occur in nature.

Genetic modification of native species. There is some experimentation on genetic modification of native species (e.g. *Eucalyptus* in Australia). These developments greatly increase the risks of gene transfer because GM native organisms will be completely cross-fertile with native species. There is also a risk that GM varieties of native plants would be fitter than native species and colonize natural ecosystems, with unpredictable results (Johnson, 2000).

Biotechnology and biodiversity. Risks to biodiversity and wildlife are important issues in particular environments. Careful assessment is necessary of the risks associated with the creation of new selection pressures coming from the introduction of GIOs into the environment. These new selection pressures may have profound effects on the delicate balance of life. Of special concern is the potential impact on biodiversity of GIOs as selection pressures wield influence in the species composition of the ecosystem. These concerns merit further study, especially on the behaviour of GIOs in the open environment. The framework for strategic planning in the deployment of GIOs should be formulated with sustainability as the primary concern (Johnson, 2000; Platais and Persley, 2001).

Ecological research. There are concerns that the science needed to be able to assess these ecological risks is not being undertaken (Johnson, 2000). At the moment we do not know what effect escaped genes might have on natural and farmland ecosystems. This lack of science is disturbing, given the commercial pressure for the introduction of GM crops into the landscape (Johnson, 2000). There is clearly a need to set up effective monitoring systems to detect gene transfer and research to assess its ecological impacts. Research in this area would be in the interests of both the industry and the environment as it would yield data that would form a scientific basis for regulatory decisions.

There may also be scientific options that could be used in future generations of GM crops that would mitigate some of the ecological risks. For example, it may be possible to include in GM crop plants inbuilt mechanisms, such as pollen incompatibility, to prevent gene flow. Another means to ensure genetic isolation is to make sure that, wherever possible, plants used for transformations are unrelated to native species and edible crops within the intended market territory. This principle would influence the choice of which plants companies choose as platforms for biomedical and industrial product transformations (e.g. higher starch production, vaccine production in plants). If gene technology is to become a standard technique for plant breeding, genetic isolation of crops from the rest of the living environment may become normal practice, as will the removal of marker genes for antibiotic resistance (Johnson, 2000).

GM crops and agricultural intensification

The prospect of gene transfer causes concern for crops that have wild relatives in the same geographical area. Perhaps of greater importance is the fact that management of some GM crops would be very different from conventional intensive agriculture or organic farming.

In the USA, GM herbicide-tolerant (GMHT) crops are grown under a regime of broad-spectrum herbicides applied during the growing season. Farmers report almost total weed elimination from GMHT crops, which include cotton, soybean, maize, sugar beet and oil-seed rape. Recent research in the UK confirms that weed control in GM beets and other GMHT crops is likely to become much more efficient. These results are hardly surprising, since this is the main purpose behind the technology.

This GMHT system will soon be available, at least experimentally, for many agricultural crops, including vegetables. Broad-spectrum herbicides used on commercial scale GMHT crops during the growing season may be far more damaging to farmland ecosystems than the selective herbicides they might replace. Using these herbicides in the growing season may also increase the impact of spray drift on to marginal habitats and watercourses. It is not the volume of herbicides that is the issue but their efficiency and impact on wildlife. When insect resistance and herbicide tolerance are combined in the same crop variety, there may be few insects capable of feeding on the crops and few invertebrates and birds would be able to exploit the weed-free fields (Johnson, 2000).

The use of more effective pesticides (including herbicides) over the past 20 years has been a major factor in causing serious declines in farmland birds, arable wild plants and insects in several European countries. Pesticides not only have direct toxic effects on wildlife but they also enable modern crop-management changes to take place.

Besides the aesthetic and scientific reasons for conserving biodiversity within and around agricultural crops, there is another important utilitarian reason for wanting to do so. There is a danger of losing the food-chain links between native species and crop systems. This link is vital for preserving the function of biodiversity to deliver early warning of dangers in crops or the chemicals used to manage them.

There is some evidence that the use of GM crops with insect resistance in North America is reducing the volume and frequency of pesticide use on cotton, maize and soybean (Wolfenberger and Phifer, 2000).

In addition, the future development of new crops with improved tolerance to abiotic factors (such as drought, salinity, frost) and the advent of 'pharmed' crops used to produce vaccines and industrial products may also change crop-management practices. They may either increase or decrease demand for arable land in the long term. They may also put further pressure on natural biodiversity on marginal land.

The problem with assessing the environmental impact of these changes in management is that the regulatory system and the public have little scientific data on which to assess the real risks and potential benefits from adopting GMHT crop systems. In the UK, 27 field-scale experiments are in place to try to answer some of these important questions (Johnson, 2000). Research is urgently required to make the ecological consequences of using GM crops clearer. Information from such research can then be used by regulators to make more informed and publicly defensible decisions about whether GM crops should be commercialized and under what conditions.

Future R&D strategy

There are some promising new developments in R & D that may assist in the design of future GM crops that would have clear benefits to the environment and that would mitigate some of the environmentally damaging effects of agricultural intensification (Johnson, 2000).

- Securing fungal resistance in adult plants by 'switching on' resistance genes that are active in the seed, but not currently in adult plants. This seems to be an elegant and safe use of biotechnology that could lead to significant reductions in fungicide use.
- Achieving insect resistance by altering physical characteristics of plants, perhaps by increasing hairiness or thickening the plant cuticle. This could reduce insecticide use, without using in-plant toxins.
- Altering the growing characteristics of crops (for example, shortening the growing season or changing the timing of harvests) offers the prospect of allowing more fallow land and less autumn planting. The recent discovery of dwarfing genes could be a significant step towards the production of higher-yielding and more reliable spring-sown cereals.
- Developing crops (including trees) that can tolerate high levels of natural herbivory and yet remain viable.
- Preventing out-crossing by engineering pollen incompatibility and other mechanisms into crops. This could significantly reduce the risk of spread of GM traits into native species.

Many of these traits could simply be transferred from one crop variety into another or be accomplished by switching on or off genes already present in the plant. Such transformations are likely to be more acceptable to the public than moving genes between phyla. The consequences of short-circuiting genetic distance between species, which has been maintained over long periods of time and geographical isolation, are not yet well enough understood to be able to assess the risks (Johnson, 2000).

Biotechnology and the new science of genomics, which is giving new insights into how genes function, offer a whole new range of options for how to use land. For the first time, it may be possible to design crops to suit the land and the purpose rather than having to adapt land and purpose to suit the crop. These could become important components of sustainable farming systems that combine yield increases with environmental sustainability. This is also important for developing countries where biotechnology may be able to offer new solutions to old problems of crop pests and disease in locally adapted crops, rather than trying to export conventional, chemically based agriculture with its damaging effects on biodiversity and the wider environment.

Regulatory systems

Food safety and biosafety regulations should reflect international agreements and a given society's acceptable risk levels, including the risks associated with not using biotechnology to achieve desired goals.

The principles and practices for assessing the risks on a case-by-case basis are well established in most OECD countries and several emerging economies. These principles and practices have been summarized in a series of OECD reports published over the past decade or more. National, regional and international guidelines for risk assessment and risk management provide a basis for national regulatory systems. Biosafety guidelines are available from several international organizations, including the OECD, United Nations Environment Programme, United Nations Industrial Development Organization and the World Bank.

Regulatory trends to govern the safe use of biotechnology, to date, include undertaking scientifically based, case-by-case hazard identification and risk assessments; regulating the end-product rather than the production process itself; developing a regulatory framework that builds on existing institutions rather than establishing new ones; and building in flexibility to reduce regulation of products after they have been demonstrated to be of low risk.

All sections of society should be included directly in the debate and decision-making about technological change, the risks of that change and the consequences of no change or alternative kinds of change.

Ethical Issues

In regard to ethical issues, it is important to pursue a dialogue on ethical issues to clarify moral and ethical issues of concern and how they might be addressed in different societies. The ethical challenges include the role of science – its risks, benefits and impact on society. Moral and ethical standards are used to develop laws governing some aspects of biotechnology (e.g. in medicine, laws governing human cloning).

A major ethical concern is that 'genetic engineering' and 'life patents' accelerate the reduction of plants, animals and microorganisms to 'mere commercial commodities, bereft of any sacred character'. All agricultural activities constitute human intervention into natural systems and processes, and all efforts to improve crops and livestock involve a degree of genetic manipulation. Continued human survival depends on precisely such interventions.

Intellectual Property Management

Many R & D programmes face the challenge and opportunities of managing intellectual property. Partnerships are critical to effective management and investment in intellectual property protection.

- Learning to manage IPR is a critical issue for many countries and institutions.
- Intellectual property management includes clarifying the role of institutions, developing an inventory of intellectual property, developing ownership of intellectual property where appropriate, undertaking technology transfer and marketing the intellectual property.
- Human resource development is a major need in this area.
- Benefit sharing with holders of indigenous knowledge and genetic resources is an important issue that must be addressed.

It is most important to build up human resource capacity in IPR for scientists, managers, policy-makers and society as a whole. Societal changes are reflected in changing IPR requirements and further changes are likely to result from continuing international negotiations on IPR and finding ways to reflect the contribution of indigenous knowledge.

Public/private-sector roles

In order to maximize the use of modern molecular knowledge, both public- and private-sector research is required to bring innovation and choices to farmers and consumers. The private sector is likely to focus on those areas of opportunity that will repay their investment in innovation. The public sector must maintain the freedom to operate in an era of increasing proprietary technology. In developing countries, the public sector will need to develop technologies that meet the needs of the non-commercial sector, including the needs of resource-poor farmers and urban consumers.

Future Actions

There is a need for more investment in public research in national agricultural research systems (NARS) and the international agricultural research centres (IARCs), to develop appropriate technologies and products that address the objectives of poverty reduction, food security, sustainable natural resources and/or trade competitiveness in developing countries. This needs to be done in partnership with the private sector (especially local companies). Farmers and consumers must be actively involved in articulating their problems and driving the R & D agenda. Partnerships and dialogues with NGOs and civil society are also needed to reach consensus as to appropriate technology choices.

There is also need for the following:

- More public and private R & D investments in targets that affect the livelihoods of the poor and that are perceived to benefit both farmers and urban consumers.
- The start-up of local companies to commercialize and distribute new technologies, including the continuing importance of local seed companies in the distribution of new plant varieties.

- Innovative mechanisms to stimulate more R & D on the problems important to the rural and urban poor, including exploring the feasibility of tax concessions in OECD countries and a global competitive grants facility.
- Exploring new modalities for public/private-sector partnerships, learning from past experience of those already in operation, especially in relation to intellectual property management.

Conclusion

Biotechnology is only one tool, but a potentially important one, in the struggle to reduce poverty, improve food security, reduce malnutrition and enhance the living standards of the rural and urban poor. The uncertainties and the risks are yet to be fully understood and the possibilities are as yet not fully exploited. It is important not to deny people access to new technology that may address their present problems, so long as they are fully informed of the potential risks and benefits and able to make their own choices.

By assessing the current and potential usefulness of modern biotechnologies for the solution of specific problems in agriculture, new ground is being broken in analysing how best to assess and mobilize:

- Rapid developments in science and technology.
- New public policy requirements.
- New institutional arrangements.

The exchange of a wealth of knowledge, information and experience and the sharing of differing perspectives will be valuable in moving ahead with responsible dialogue and debate on the use of the new developments in science and technology for the benefit of society.

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