IV Risk Assessment and Management

A. Public Perception of Risks

As with any science and technology, biotechnology can bring with it benefits and risks. It is the risks of agricultural biotechnology that have received widespread publicity in the media even though biotechnology has also been applied to health and industrial sectors. Environmental NGOs have been particularly vocal in taking issue with the new technologies derived from or incorporating GMOs. As a consequence, in the public debate biotechnology has become synonymous with GMOs, although they are only one of the many products of biotechnology.

Curiously, biotechnology and GMOs in health-care products now in widespread use (insulin, hepatitis vaccine, medication for cardiovascular disease, etc.) or for industrial purposes such as bioremediation have elicited no such controversy. This can probably be attributed to the lack of benefits to consumers in the first generation of genetically modified (GM) crops. The main focus was on herbicide and insect resistance that benefited farmers, seed producers, and chemical companies. It is expected that the next generation of genetically modified foods will benefit consumers, nutritionally or from taste or storage benefits, and accordingly may be better accepted.

A number of food-related crises in recent years have made consumers particularly sensitive about food safety issues. Health and food safety concerns are again at the forefront in Europe following additional cases of mad cow disease *(bovine spongiform encephalopathy)* and the banning throughout the European Union of blood and bone meal in feed for all animals. These crises have not been caused by GMOs, but by the intensification of agriculture and food production, a fact that appears to have escaped public attention. In Europe in particular, demands have been made for informative food labeling so that consumers may, if they wish, avoid genetically modified foods.

The anti-GMO movement reveals profound mistrust of developments in science and technology and of the forces seen to be driving them. Genetically modified crops such as maize, sorghum, cotton, and canola have been widely grown for the last five years, yet no harmful effects on human health or the environment have been detected. That was

one of the conclusions of the OECD-sponsored conference held in Edinburg, UK, in 2000. However, it is generally agreed that government and the private sector are responsible for monitoring the long-term effects of GMOs on human health and the environment.

B. Potential Risks of Biotechnology

The risks associated with modern biotechnology fall into four categories: food safety, environmental, socioeconomic, and ethical (Table 4.1). Some of these concerns relate to potential risks inherent in modern biotechnology and can be described as technology-inherent (Leisinger 2000). Others are related more to value systems or cultural practices and can be described as technology-transcending.

1. Food Safety Concerns

The potential risks of biotechnology on human health may include toxic reactions, increased cancer risks, food allergies, food contamination, and antibiotic resistance (Table 4.1). There is also concern that GMOs in animal feed might present a health risk for consumers, or for the animal itself. Consumers are also concerned about the long-term health effects of genetically modified foods.

To address food safety concerns, the following safeguards have been adopted by some countries:

(i) Some countries have regulatory procedures, institutions, and infrastructure in place to ensure food safety (OECD 2000). These regulations cover all aspects of the food chain, from farm inputs (including animal feed, feed additives, pesticides, fertilizers, veterinary drugs) through production and processing (including agricultural products, processed food, novel foods, food additives), to transportation, storage, and distribution.

(ii) Formal science-based procedures for risk analysis of food have been adopted by some countries. These continue to evolve with new scientific information about food safety, emerging pathogens, new technology, and consumer demands for a high level of public health protection. Generally,

Table 4.1: Summary of Perceived and Genuine Risks of Genetically Engineered Foods and Crops

Nature of Risk	Type of Risk	Remarks
Food Safety	1. Toxins and poison. In 1998, a scientist in the Rowett Institute found that GE potatoes spliced with DNA from the snowdrop plant (a viral promoter) are poisonous to mammals.	The UK Government's Advisory Committee for Novel Food and Process examined the data and concluded that the experiment was faulty and the conclusions were wrong.
	2. Increased cancer risks. Monsanto's bovine somatotrophin (growth hormone) injected into dairy cows to produce more milk has been reported to cause cancer in human breast, prostate, and colon.	This is not a GM food. In any event, Canada and the European Union have banned its use. A United Nations Food Standard body has not certified its safe use. The hormone is no longer widely used in US.
	3. Food allergies. In 1996, a Brazil nut gene spliced into soybean was reported to induce potentially fatal allergies in people sensitive to Brazil nuts.	The safety assessment confirmed that the protein was an allergen and the development was abandoned. A standard laboratory test has been available to test possible allergenicity in GE products.
	4. Contamination. StarLink, a GE maize variety approved for animal feed but not for human consumption, was found in an ingredient used by some US beer makers and in taco shells in the US in 2000.	The incident was caused by an accidental mix of StarLink with vast amounts of other maize during harvest, storage, and distribution. The contaminated food was recalled and destroyed. A number of quick and cheap tests are available to determine the presence of GM products in food.

Table 4.1: Summary of Perceived and Genuine Risks of Genetically Engineered Foods and Crops *(cont'd.)*

Risks	Type of Risk	Remarks
	5. Antibiotic Resistance. Use of an antibiotic marker gene in the development of GE crops may contribute to the growing public health danger of antibiotic resistance.	There is little or no evidence about this risk yet. But this is an emotive topic, and developers have now replaced the antibiotic marker with a safer marker.
Environmental Risks	1. Increased pesticide residues. Farmers growing GE crops will use as many toxic insecticides and herbicides as conventional farmers, thus increasing pesticide residues in soils and on crops.	This risk is not yet proven statistically. There are reports that farmers growing GE crops resistant to pests and herbicides are able to reduce production cost significantly through the reduced use of pesticides. That was a major reason why farmers adopted GE crops widely in the PRC and the US.
	2. Genetic pollution. Wind, rain, birds, and bees have carried genetically altered pollen into adjoining fields, contaminating the DNA of organic, non-GE crops.	This genetic pollution is not an environmental issue unless the transfer of pollens causes some kind of environmental damage. Pollen contamination has taken place for centuries with or without genetic engineering.
	3. Damage to beneficial insects. Scientists from Cornell University found that pollen from Bt maize was poisonous to Monarch butterflies and may be to other beneficial insects as well.	Monitoring systems have been devised in the PRC and the US to evaluate the long-term effect of GE crops on beneficial insects.

Table 4.1: Summary of Perceived and Genuine Risks of Genetically Engineered Foods and Crops *(cont'd.)*

Risks	Type of Risk	Remarks
	4. Creation of superweeds. GE crops (soybean and canola) resistant to herbicides may transfer their resistance to weeds, turning them into superweeds, which cannot be controlled by herbicides.	This fear has yet to be proven. Scientists are closely monitoring the use of GE crops resistant to herbicides.
	5. Creation of superpests. GE crops (maize and cotton) resistant to pests may transfer their resistance to pests, turning them into superpests which cannot be controlled by pesticides.	As above, this fear has yet to be proven in practice. There is no known mechanism by which pest resistance from a plant may be transferred to an insect pest.
	6. Creation of new viruses and bacteria. Biotechnology could help terrorists to create killer viruses or bacteria, which could be used in biological weapons.	This could happen, even without biotechnology. Terrorists historically have managed to acquire and subvert beneficial technologies to antisocial purposes.
	7. Genetic bioinvasion. By virtue of their superior genes, some GE plants and animals will inevitably run amok, overpowering wild species in the same way that introduced exotic species do.	There is as yet no scientific evidence that such plants and animals can be created through biotechnology.

Table 4.1: Summary of Perceived and Genuine Risks of Genetically Engineered Foods and Crops *(cont'd.)*

Risks	Type of Risk	Remarks
Socioeconomic Risks	1. Terminator technology will render seeds infertile and force hundreds of millions of farmers to purchase more expensive GE seeds and chemical inputs from a handful of global biotechnology and seed companies.	The Monsanto Company has withdrawn the terminator gene from its GE crops following many complaints from farmers.
	2. High concentration of biotechnology research and development in developed countries will widen the income disparity between developed and developing countries, and between large and small farmers.	The public sector in Asia should accord high priority to biotechnology development that address the problems of small farmers.
Ethical Concerns	1. Biotechnology reduces all life to bits of information (genetic code) that can be rearranged at whim by scientists. The creation of the first genetically modified monkey in 2000 brings the possibility of genetic manipulation closer to humans. There is fear that the technique will be used to create "designer babies."	Although most of these ethical concerns relate to non-agricultural biotechnology, they point to the need for the private sector to incorporate work ethics in biotechnology research and development.
	2. There seems to be little ethical concern by the private companies over the use of GE animals to produce therapeutic drugs.	

Bt = *bacillus thuringiensis*, DNA = deoxyribonucleic acid, GE = genetically engineered, GM = genetically modified, PRC = People's Republic of China, US = United States.

Source: Skerritt (2000) and Wolfenbargen and Phifer (2000).

the procedures conform to international standards set by the Codex Alimentarius Commission of FAO.

(iii) Some countries have adopted a variety of approaches to regulate genetically modified foods, either by applying existing food safety measures or enacting new legislation.

(iv) In response to consumer demands, a growing number of countries are introducing labeling. Opinions differ on whether labeling should be mandatory or voluntary, as well as on acceptable tolerance levels and on the type of information to be used. Two labeling issues currently being addressed are segregation and traceability. Segregation relates to the ability to attest to the separation of genetically modified and non-genetically modified crops (as in the case of soybean in processed foods). Traceability means being able to attest to the origins of food products. Traceability is of particular importance in the current controversy related to mad cow disease. Low cost, quick tests are now available to determine the presence of genetically modified products in food.

2. Environmental Concerns

A number of biotechnology applications are not seen to present any new threats to the environment. That is the case with tissue culture, diagnostics, and market-selected plant breeding. On the other hand, there is fear of potential risks from the release of GMOs into the environment. The potential risks of GMOs on the environment may include increased pesticide residues, genetic pollution, damage to beneficial insects, creation of superweeds and superpests, creation of new viruses and bacteria, and genetic bioinvasion (Table 4.1).

To address environmental concerns, some countries have adopted the following safeguards:

(i) Most current biotechnology applications in tissue culture and micropropagation, diagnostics and vaccines, and marker-assisted plant breeding are subject to existing regulations. They include phytosanitary regulations and plant quarantine, varietal certification of seeds, and veterinary product regulations. These regulations usually conform to international standards, guidelines, or recommendations such as those set

by the International Plant Protection Convention or the International Bureau of Epizootics for animal products.

(ii) A number of countries have introduced new requirements and procedures for the environmental release of GMOs. Procedures for hazard identification and risk assessment of GMOs are now well-established in most OECD countries, and in some Asian countries.

3. Socioeconomic Concerns

Modern biotechnology R&D has been conducted in an institutional and economic environment that differs significantly from the development of the earlier Green Revolution technologies. While the latter were essentially the prerogative of public research institutions and philanthropic foundations, developments in biotechnology have been driven essentially as a competitive, commercial endeavor in which powerful private sector actors compete.

The major socioeconomic risk of agricultural biotechnology stems from the fact that the research, development, commercialization, and distribution of new biotechnological products have been carried out mainly in developed countries by a few, large, multinational companies. These companies have focused on temperate crops for large farmers in developed countries. Undertaking R&D on Asia's basic food crops for small farmers in rainfed and marginal areas is of little interest because they see limited returns from such investments (see detailed discussion on this issue in Chapter II, section C). If this trend continues, modern biotechnology will aggravate the income disparity between developed and developing countries, and between large and small farmers. Increased public investments in agricultural biotechnology are necessary to ensure that small, poor farmers have access to biotechnology. Governments must also address the potential gender disparity in the access to technology, and the negative impact specific to women, since no technology is gender neutral. Lessons from earlier agricultural technological changes should be used as a caveat.

4. Ethical Concerns

Ethical issues may stem from the uneven or inequitable impact of an expanding global economy; from the national social, economic, and politi-

cal context; or from individual values. Indeed, it may be difficult to reconcile personal values with what a majority regard as the common good.

One of the ethical concerns raised by biotechnology—and particularly GMOs—is that it is unnatural and an unwarranted tampering with nature. However, seen in historical perspective, most technology developments in agriculture over the centuries have involved, in one way or another, efforts to overcome the vagaries of nature.

C. Risk Management

To address the potential risks of biotechnology in agriculture, there is a need for Asian countries to establish effective biosafety procedures for the development, testing, and release of the technologies. An example on how this should be done is shown in Figure 4.1.

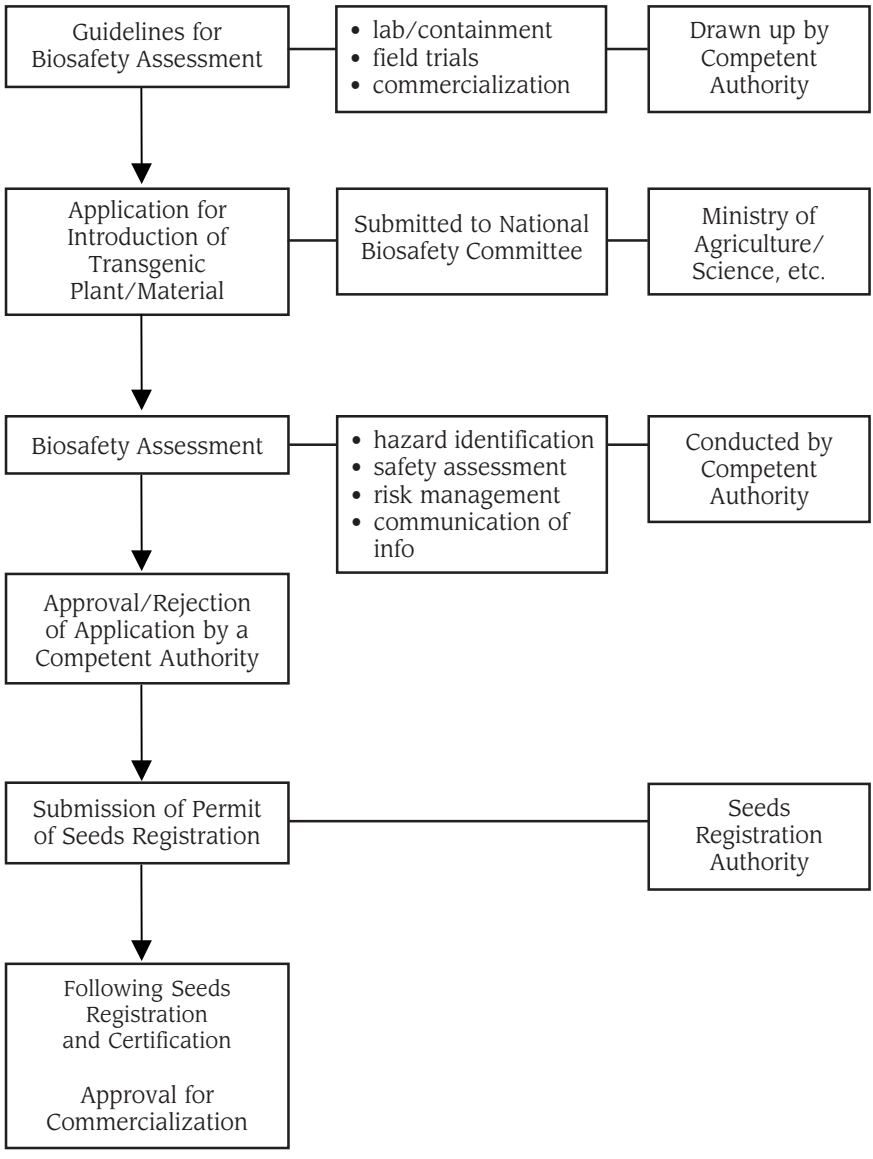
1. Current and Emerging Regulatory Systems for Biotechnology

A growing number of international organizations have become involved in food and environmental safety. Concerted international efforts to develop agreed upon scientific approaches to biosafety date from 1975, when a group of scientists from the United States National Academy of Sciences expressed concern regarding the potential biological risks of rDNA molecules. Efforts to ensure the science-based, case-by-case risk identification, assessment, and management of GMOs have thus been pursued for some 25 years.

In the industrialized world, OECD has been instrumental in forging agreements on scientific principles regarding the safe applications of rDNA organisms in industry, agriculture, and the environment. Since the 1980s, OECD has established guidelines, first for (i) laboratory-based experimentation, then (ii) for small- and large-scale field trials of genetically modified plants and organisms, and finally (iii) for their commercialization and release into the environment or food chain.

During the 1990s, a growing number of international organizations including the United Nations Environmental Programme (UNEP), UNIDO, World Health Organization (WHO), and FAO have become involved in activities related to biosafety. Both UNIDO and UNEP have developed biosafety guidelines. FAO and the WHO are jointly responsible for the Codex Alimentarius Commission, which sets international standards for

Figure 4.1: Procedures for Release/Commercialization



food safety. Codex has set up a new Intergovernmental Task Force on Foods Derived from Biotechnology to develop general principles for risk analysis and to provide guidance on risk assessment.

Other international organizations conducting work on the safe use of biotechnology include the International Centre for Genetic Engineering and Biotechnology, the United Nations Conference on Trade and Development, and, for many aspects of animal as well as human health, the International Bureau of Epizootics.

2. The Convention on Biological Diversity and the Cartagena Biosafety Protocol

Preoccupation with the protection of biological diversity, necessary for sustaining agriculture and food production and, indeed, life itself, became a topic of international debate during the 1980s. As a result, FAO established the International Undertaking on Plant Genetic Resources as a nonlegally-binding agreement for cooperation in the conservation of genetic material. The agreement was based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction. The legally binding Convention on Biological Diversity, which came into force in 1993, encompasses not only plant genetic resources but all living organisms. In contrast to the FAO undertaking, the Convention affirms that States have sovereign rights over their own biological resources.

In January 2000, the legally binding Cartagena Protocol on Biosafety was adopted. This Protocol lays the foundation for a global system for assessing the impact of GMOs on biodiversity. It outlines the obligations of all countries that are signatories to protect biological diversity from the potential risks imposed by living modified organisms resulting from modern biotechnology.

At the heart of the Protocol is the concept of advanced informed agreement to the import of GMOs. This means that an exporting country must inform an importing country of its intention to export. It must also provide information on the GMOs, including an appropriate risk analysis. For its part, an importing country is required to give its informed agreement to the import. This implies that, although signatory states have the right to prohibit the import of GMOs if advanced informed agreement has not been given, they must also be capable of determining the validity of a safety assessment.

In addition, the Protocol advocates the "precautionary approach," described in the 1992 Rio Declaration on Environment and Development as a principle of international environmental law. The Protocol also proposes to establish a Biosafety Clearing-House for collecting, sharing, and disseminating information on risk assessment and management, which is particularly important for developing countries. Thus far, 81 countries have signed the Protocol, including Bangladesh, PRC, Indonesia, Republic of Korea, Malaysia, Philippines, and Sri Lanka.

3. Approaches in Selected OECD Countries

A sample of industrialized countries shows a diversity of approaches to food and environmental safety and in the agencies or ministries that play key roles in the national biosafety system. For example, the US has chosen to develop biosafety capacity within existing institutions (notably the Environmental Protection Agency and the Department of Agriculture). Denmark has designated the National Forest and Nature Agency as the lead agency for biosafety. In Norway, in accordance with the Gene Technology Act, the application of GMOs is subject to ethical and social conditions. A GMO can be approved for use only after the assessment of its benefit to the community and its contribution to sustainable development.

In Australia, apart from the different ministries involved, an Advisory Committee on Genetic Engineering was created some years ago. That will soon be replaced by an office with an enforcement rather than an advisory role. A public hearing must be held before authorization is given to release a GMO. Australia has recently created the Office of the Gene Technology Regulator to operate in the Commonwealth Department of Health and Aged Care.

Japan has based its risk assessment system on the principles and concepts developed by OECD. Different Japanese ministries and agencies have developed guidelines in accordance with their responsibilities on a product-sector basis.

A growing number of countries are introducing guidelines or mandatory measures for labeling genetically modified foods. In the US, formerly strongly opposed to labeling, the Food and Drug Administration has recently been charged with developing guidelines for voluntary labeling of food products to indicate whether or not they contain GMOs. In the European Union, food products containing more than 1 percent GMO must be labeled, stating clearly: "this product contains GMOs." The Australia-

New Zealand Food Standards Council is drawing up a new Food Standards Code. Labeling requirements will be drawn up in accordance with this joint Code. Japan is planning the introduction of mandatory food labeling in April 2001.

The OECD has also played an active role in promoting the harmonization of biosafety procedures among its member countries so that information and data gathered in the course of risk assessment may be mutually acceptable.

4. Emerging Regulatory Systems in Asia

Table 4.2 indicates the status of regulatory systems in a number of Asian countries. A growing number have set up national biosafety systems; others are formulating national biosafety guidelines. Most countries have not yet completed guidelines for commercialization. The PRC is the only country in Asia where transgenic crops have been approved and released for sale. A number of countries are also in the process of introducing food labeling. Indonesia is planning to introduce mandatory labeling in April 2001.

ASEAN has undertaken a number of initiatives aimed at the harmonization of biosafety procedures among its member countries. In 2000 it also conducted a joint workshop with the Ministry of Science and Technology of the PRC to discuss issues related to transgenic plants.

The Asia-Pacific Economic Cooperation has a number of capacity-building and technical cooperation activities in support of risk assessment, risk management, risk communication, and public acceptance. Responsibility rests with its Agricultural Technical Cooperation Experts Group and its Sub-Group on Research, Development and Extension of Agricultural Biotechnology.

Although some Asian countries have regulations in place, weak law enforcement sometimes results in the release of GMOs without proper procedures having been followed. For example, P.T. Monagro Kimia (a subsidiary of Monsanto) released Bt cotton in Indonesia without complying with Indonesian environmental law on safety procedures, environmental assessment, and information disclosure. Law enforcement in Asia needs strengthening to avoid risk to human and environmental health.

Table 4.2: Status of Biosafety in Selected Asian Countries

Country	Responsible Ministry/Agency	Status of Regulatory System			
		Regulatory System in Place	rDNA/ Lab Testing	Field Testing GMOs	Commercialization
China, People's Rep. of	• Ministry of Agriculture (Safety Administration Office for Agricultural Biological Genetic Engineering) • Ministry of Public Health	X	X	X	X
India	• Ministry of Science and Technology (Department of Biotechnology) • Review Committee on Genetic Manipulation • Ministry of Environment and Forests (Genetic Engineering Approval Committee) • Monitoring and Evaluation Committee	X	X	Field testing approved	
Indonesia	• Ministry of Agriculture (Agency for Agricultural Research and Development) • Biosafety and Food Safety Commission	X	X	X	
Malaysia	• Ministry of Science, Technology and Environment • Genetic Modification Advisory Committee • Department of Agriculture	X	X	Field testing for papaya approved	
Thailand	• Ministry of Agriculture and Cooperatives • Department of Agriculture/National Center for Genetic Engineering and Biotechnology • National Science and Technology Development Authority	X	X	X	
Philippines	• National Committee on Biosafety • Department of Science and Technology	X	X	X	Guidelines for plants and plant products ready for approval

Note: X indicates that the countries have complied with the requirements.
Source: Consultants' assessment.

D. International and Donor Support for Biosafety Capacity Building in Asia

A growing number of initiatives are being taken to provide support for Asian countries in developing their capacities to safely manage biotechnology. A representative sample follows.

Following the signing of the Biosafety Protocol, UNEP, through its Global Environment Fund, is preparing a major capacity-building program for developing countries. It will also be responsible for the establishment of the Biosafety Clearing-House.

FAO serves as the secretariat for the International Plant Protection Convention, which has recently established a working group on the Phytosanitary Aspects of GMOs, Biosafety and Invasive Species.

UNIDO has conducted training courses in biosafety in a number of Asian countries. In collaboration with OECD, it has compiled an information source and database (BIOBIN), which provides information on biosafety methods and procedures, and on the status of the regulatory frameworks in individual countries.

OECD has established a network of international organizations with activities related to biosafety to enhance the exchange of information and to facilitate cooperation.

IBS provides a number of services to enhance developing country capacities to manage agricultural biotechnology. It gives short training courses annually for managers of agricultural biotechnology research programs in Asia. Biosafety is a key element in these courses. IBS also provides advice to individual countries.

USAID is involved in a number of biosafety training activities in Asian countries, some of which have been provided by its Agricultural Biotechnology Services Program.

ISAAA is currently setting up a Global Knowledge Center on Crop Biotechnology based at ISAAA's SEAsia Center at Los Baños in the Philippines. ISAAA also organizes capacity-building workshops and training for regulatory officials and scientists from the Asian region.

E. Genetically Modified Organisms: Food and Environmental Issues

In industrialized countries, considerable progress has been made in methods, approaches, and experience in the safe management of GMOs. Overall these methods have proven to be effective, particularly with respect to food safety. The development of a transgenic soybean containing a protein derived from Brazil nuts, potentially useful in animal feed, was abandoned when the safety assessment revealed that the protein was probably an allergen. In response to consumer concerns, antibiotic markers are now being phased out as alternatives are being developed. That despite consensus among national and international regulatory authorities and the scientific community that the markers pose no threat to human health.

Despite acknowledged progress, areas of scientific uncertainty or disagreement persist. New challenges for risk/safety assessment, management, and monitoring will arise as a second generation of food, agricultural, and public health products emerges during this new decade.

Not only are the ranges of organisms and numbers of traits expected to expand, so are the numbers and diversity of geographic and ecological sites in which they are released. These new products will not lend themselves easily to current approaches and methods to risk and safety assessment and to management. This highlights the need for constant review and improvement of assessment principles and procedures, and the urgent need for collection and analysis of ecological data.

Other areas where consensus has not been reached among scientists themselves, or among scientists and policymakers, include (i) the precautionary approach as a method of dealing with scientific uncertainty, and (ii) methods for traceability.

The potential for the development of insect resistance to Bt transgenic crops is another area where the scientific community, industry, and environmental NGOs have not reached consensus. Risk management approaches at the farm level have so far been applied mainly on large-scale, commercial farms where monoculture is practiced. The same approaches may not be effective and, indeed, may not be necessary in the mixed farming systems of Asia.

Efforts to address the issue of resistance to transgenic crops have recently been initiated in Asia. A first International Consultative Workshop on Effective and Sustainable Use of Agricultural Biotechnology in

Integrated Pest Management in Developing Countries was held in November 2000. Organized by IRRI, Zhejiang University, and the International Organization for Biological Control, the workshop tried to determine strategies for the safe deployment of crops such as cotton and rice with novel Bt genes for pest resistance.

Among OECD countries, the continued monitoring of GMOs after release into the natural environment is also an area where opinions differ. On the one hand, it is argued that monitoring should be continued so that unforeseen risk can be managed and ecological impacts can be assessed. On the other hand, it can be argued that the high costs of monitoring are not justified when transgenics have already successfully passed the hurdles of risk identification, safety assessment, and risk management.

It is clear that the potential risks of GMOs may vary by site and over time. Continued research will be necessary to improve data collection and analysis and to modify or devise new risk management strategies as needed.

F. Future Perspective

To date, a number of Asian countries have made substantial investments in biotechnology R&D initiatives. Some public research institutions have reached the stage of field testing of new crop varieties, major research projects are coming to fruition in IARCs in the region, and private companies are also conducting research in the region, or have products waiting to be commercialized and exported to the region. It will be necessary to have biosafety procedures in place to ensure that the benefits of these technologies are realized.

Although many opportunities exist, from donor and other development agencies, in support of capacity building for the safe management of biotechnology, and in setting up national systems, it is the responsibility of national governments to ensure that national regulatory systems are applied, enforced, and monitored. Setting up an effective national regulatory system for the safe management of biotechnology requires substantial resources, both financial and human. It is also a political process and, as such, requires political commitment.

The Cartagena Biosafety Protocol confers both rights and obligations on countries that are signatories. A country is free not to allow the import of GMOs on its territory. At the same time, it has an obligation to

establish a national biosafety system. This means that even if a country decides to ban the import or use of GMOs on its national territory, it will still need to comply with the obligation to develop a biosafety system for the control of such organisms. It is anticipated that UNEP, the World Bank, and United Nations Development Programme (UNDP), through the Global Environment Fund, will contribute funding and technical assistance to developing countries for capacity building in biosafety. Even so, compliance with both the provisions of the Convention on Biological Diversity and the Cartagena Biosafety Protocol will place a heavy burden on some countries.

Apart from obligations under the Biosafety Protocol, if countries wish to control the import or introduction of GMOs on national territory, it will be necessary to have the means of detection in place. Similarly, from the perspective of international trade, when countries export agricultural or food products to countries that either prohibit the import of GMOs or require mandatory labeling for food or food products containing GMOs, the requisite regulatory procedures need to be in place.

The regulatory framework for biotechnology should not, however, be regarded in isolation from the broader policy context of agriculture and the contribution that biotechnology might make in the particular economic, social and environmental context of individual countries. Countries have a range of options in determining policies and priorities for biotechnology. These might range between active promotion of biotechnology approaches, "wait and see," or rejection. Similarly, countries have a range of options in designing and implementing a national biosafety system geared to their particular technical, legal, and institutional realities. For example, a complex and time consuming regulatory system might impose prohibitive costs for local enterprises, particularly start-up companies.

PRC is the only Asian country so far with experience of managing and monitoring new transgenic crops in the field on a large scale. Some countries are gaining experience in field testing, while others have not yet completed biosafety guidelines. Information on socioeconomic and scientific developments in biotechnology and biosafety can be accessed from a number of information sources, including the Biosafety Clearing House mechanism to be provided under the terms of the Cartagena Biosafety Protocol. These sources are especially important for countries such as Cambodia, Lao PDR, and Viet Nam.