VI Issues and Options

A. Policy and Priority Setting

1. Issues

A surprising amount of biotechnology R&D is already being done in Asian developing countries. There have been few studies, however, on the cost-effectiveness of biotechnology R&D in these national programs, and whether priorities are research-driven or demand-driven. On the other hand, countries have a justifiable concern that they will be left behind if not involved in the technology. In establishing policies and priorities, Asian countries should consider that (i) biotechnology requires a high level of capital and specialized technical skills, (ii) the public sector is constrained by inadequate capacity, (iii) the private sector has little interest in investing in technology for poor farmers, (iv) there are potential risks associated with GMO development, and (v) it is difficult to establish an effective biosafety framework.

Some of the broad policy issues relate to capture of benefits. How can the benefits of biotechnology reach poor farmers? That is, how can biotechnology programs be better linked to extension programs? Who will be winners and losers from genetically engineered crops? Will there be a widening income gap between poor farmers and rich farmers who have access to credit to purchase biotechnology-derived seeds?

2. Options

There is a need to assist DMCs in policy and priority setting. Policy setting must be based on informed decisions on appropriate choices regarding the use of new biotechnology applications in agriculture and their prospects for enabling sustainable productivity. The likely impact of biotechnology on poor people, either directly by increasing crop yields and farm incomes or indirectly by improving their environment, should be considered.

There is a need to encourage regional and national coordination of policy on biotechnology (especially of GMOs), and consistent distribution of responsibilities between agencies in different countries. That may be difficult to achieve, but the problems of poor coordination have been highlighted by the European experience (Levidow et al. 1999). If Asian countries are to participate more fully in biotechnology, they will also need to expand their own capacities to undertake biotechnology research linked to the problems of smallholders and marginal farmers.

B. Priorities for Research and Development

1. Issues

Countries have a range of options in determining policies and priorities for investment in biotechnology research. These might range from active promotion of biotechnology approaches, to a wait and see, stance, or to rejection of biotechnology R&D altogether. Whatever the case, technical and policy capacity will still be needed to support international trade and biosafety agreements. Donors, too, have a range of options. Should they focus their biotechnology investment on the more advanced developing countries, where there is more capacity and more likelihood of using the results? In any event, countries need to establish planning for investments based on demand. For example, is excessive emphasis given to plant biotechnology at the expense of animal biotechnology—especially given that the livestock sector is much faster growing? There is a need to establish where biotechnology methods could deliver varieties that conventional breeding cannot. Where either a conventional or biotechnology-based breeding approach could be used to target a particular characteristic, there is the need for comparative economic and risk analyses of the alternative approaches. That should also take into account that many genetic engineering approaches also require conventional crossing and selection to transfer the desired character from the transformed plant into an adapted, elite variety. Many early biotechnology research programs in Australia made the mistake of operating in isolation from breeding and agronomic improvement programs, hindering application of the research. It is important that developing countries do not repeat the mistake.

2. Options

Obtaining a clear view of which crops and characters should be targets for genetic manipulation in Asian developing countries is a critical step, but it has rarely been addressed systematically (Woodend 1994). Research should focus on crops relevant to small farmers and poor consumers in developing countries: cassava, yam, sweetpotato, rice, maize, wheat, millet, and possibly papaya. The limitation is that relatively little biotechnology research is being undertaken on many of Asia's basic food crops or on the problems of small farmers in rainfed and marginal lands. In many cases, Asian countries will need to expand their own national and regional capacity to undertake biotechnology research to address these problems. Once a clear view is obtained on which crops and characters to target, it may make more scientific and economic sense to purchase, license, or import particular elements of technology.

Indeed, there have been a number of successes of crop genetic engineering in developing countries with technology already commercialized or in field trials. These include: insect resistance in maize and cotton and several horticultural crops using genes from Bt and other sources; resistance to a range of viruses in potato (viruses x, y, and leafroll); and ringspot virus resistance in papaya and cucurbits. Rice with resistance to bacterial blight and with increased content of beta-carotene or iron has been produced, as well as tomatoes with elevated lycopene (related to vitamin A).

Support of agricultural biotechnology research is important to developing countries for several reasons. Apart from direct benefits from applications, developing country ownership of IP can be traded for other technology. The existence of active programs in-country can provide a balanced understanding of issues by technocrats who make policy in areas such as biosafety. Some other R&D needs include the following:

(i) One of the most profitable applications of crop biotechnology in the short term to medium term will be through better implementation of molecular markers for selection in conventional breeding programs. That will require closer linkages between biotechnologists and plant breeders in many institutes.

(ii) Engineering of desirable traits in several of the major cereal crops of Asia (e.g., rice, maize, wheat) is being addressed by some of the international networks and through programs at IARCs. Developing country NARSs need to strengthen their ability to adopt the technologies and the germplasm as they are developed by these international initiatives.

(iii) It will be important to identify specific orphan crops and animals with short- to medium-term potential for application of existing biotechnology in developing countries. In some cases, this may best be done through developing more efficient methods of crop improvement or through the use of MAS for complex traits. In others, the most appropriate approach may be through the development of transgenic varieties with specific characteristics such as disease resistance or improved nutritional quality.

(iv) There is a need to ensure that the genomic knowledge of the major food crops in Asia is obtained and is available in the public domain as the basis for the development of new crop varieties for the public good. Such knowledge will underpin the development of the new food crop varieties for Asian agriculture over the next decades. The rice genomics program would be a good model for others (Sasaki 1999).

(v) Apomixis in a wider range of crops has huge potential for simplifying the breeding of adapted genotypes, preservation of hybrid vigor, and improved propagation of crops that currently rely on vegetative propagation. It is also an important tool for the discovery of genes that are potentially important in stress tolerance.

(vi) There is a need to build the capacity of Asian developing countries to undertake laboratory and on-site testing of GMOs. An increasing number of published protocols are available as well as simple, commercial test kits.

C. Intellectual Property Management

1. Issues

Because the private sector invests heavily in, and holds many of the advanced biotechnologies, new discoveries in biotechnology may be protected by plant variety protection, patents, or trade secrets. This raises the issue of IPR. The 1995 Agreement on Trade-Related Aspects of Intellectual Property (TRIP) requires all countries to provide some sort of protection for plant varieties. TRIP requires all signatories to extend IP protection to microorganisms, plant genetic material, and techniques used for genetic manipulation. Although plants and animals, other than microorganisms, may be excluded from patent protection, countries are required to provide protection either by patents or by an effective sui generis system (see details in Appendix 13). Strengthened IPRs will increase the flow of technologies and products from developed to developing countries, and provide new incentives for local research and innovation. But one fear is that industrial nations, using genetic resources originating from developing nations, could develop GMOs or techniques and then restrict developing nations' access to the technology by employing the IPR provision of TRIP. Asian countries need to (i) develop a policy toward IP to protect their own discoveries, (ii) develop an effective approach to cooperation with the private sector in R&D, and (iii) encourage private sector research on products to benefit small farmers in Asia.

IP protection for plant genetic resources are being considered in the context of the Convention on Biological Diversity and renegotiation of the International Undertaking on Plant Genetic Resources of FAO. The issue has also been discussed in the World Intellectual Property Office in the context of traditional resource rights. In addition, environmental aspects of access to genetic resources are being discussed in UNEP and World Trade Organization (WTO). All these discussions are intended to ensure that existing international agreements encourage biotechnology development relevant to Asia's poor while protecting IPR of indigenous peoples.

Most Asian countries are members of the World Intellectual Property Office, have a national patent regime, and are signatories to the Patent Cooperation Treaty and to the Paris Convention. With the exception of the PRC, whose application is pending, most are also members of WTO.

In conformity with TRIP, a number of countries are developing plant variety protection laws and are in the process of joining the International Convention for the Protection of Plant Varieties. These include India, Indonesia, Malaysia, Philippines and Viet Nam. Some countries (Bangladesh, India, Philippines) are currently formulating laws for the protection of biodiversity and community knowledge.

Proprietary interests in biotechnology affect developing countries in several ways, requiring them to consider issues relating to the (i) *licensing in* of technology owned by developed countries or multinational companies, (ii) their *freedom to operate* with their own inventions, and (iii) their ability to commercialize or export products (Maredia et al. 1999). Changes in the last couple of decades in the IP environment in which agriculture operates include the patenting of living organisms in some countries, and establishment of plant variety rights. The protection of target genes and of enabling technologies (e.g., gene regulation, markers for selection, promoter sequences, and transformation technologies) mean that developing country organizations have to be conversant with licensing activities. Among them are technology use agreements, material transfer agreements, and commercial licenses (Mascarenhas 1998). Some alternative strategies to gain freedom to operate can include: (i) inventing around current patents, (ii) redesigning constructs to synthesize genes to reduce reliance on external technical property, (iii) asking IP owners to relinquish claims or provide royalty-free licenses, (iv) ignoring all IP and technical property; or (v) seeking licenses for all IP and commercial property, which is certainly the safest route to building public-private sector cooperation.

Many developing countries, however, use such *inputs* without formal permission. This issue becomes important at the time of commercialization of a technique or process, or release of a variety. By then, it is often too late to change direction or incorporate an alternative piece of technology in a research or breeding program. A recent ISNAR survey of five Latin American countries showed that NARS laboratories used proprietary technologies widely, but in many cases without formal agreements. Most of the proprietary technologies related to plant genetic engineering. They included markers for selection, transformation systems, promoters, and specific genes as well as marker techniques and diagnostics. There was also a lack of knowledge regarding IPRs in both academic and administrative ranks (Salazar et al. 2000).

IP management of biotechnology inventions can be very complex. Kryder et al. (2000) recently reviewed the example of Golden Rice, which is high in pro-vitamin A (beta-carotene). This rice is potentially valuable for those who are too poor to obtain green vegetables. A very large number of proprietary technologies were used to develop Golden Rice. It is a multitransformant, since three genes were introduced into a carotenoid biosynthetic pathway to produce the high beta-carotene levels. Other proprietary technologies included three transformation vectors: *Agrobacterium* transformation, plant regeneration, and DNA amplification. Thus, a country or organization that requires this technology must obtain consent from a wide range of partners.

2. Options

The IPR issue is complex and yet many Asian institutes have focused training only on the technical aspects of biotechnology research, rather than on other areas such as licensing and IP management. Steps required to obtain consent from a wide range of partners for a given technology need to be defined on a case-by-case basis. Therefore, training in IP regulation to facilitate technology transfer in evolving IPR systems, and assistance in developing a clear understanding of TRIP agreements is important. Systems are needed to enable countries to protect their own technology, while minimizing barriers that could hinder technology transfer between countries

The adoption of IPR law by developing countries may make proprietary biotechnologies (seeds and planting materials) more costly. To overcome this problem, the public sector would need to consider buying exclusive rights to newly developed technology and make it available free to small farmers. Alternatively, the public sector and IARCs could invest in biotechnology R&D so that the resulting technology could be made available free to farmers.

D. Public-Private Sector Partnership

1. Issues

Significant increase in biotechnology investment by governments and donor agencies is crucial for achieving food security and poverty reduction. As mentioned earlier, there is insufficient profit motive to induce the private sector to undertake the R&D needed by small farmers. As Byerlee and Fischer (2000) point out, there have been significant market failures in applying biotechnology for the benefit of developing country farmers; therefore the public sector will continue to have an essential role. Because many of the techniques and products of modern biotechnology are privately owned, public agencies need modes of action to operate in an increasingly private sector world. Furthermore, both the public and private sectors have complementary assets needed for biotechnology to be applied to its full potential. Many of the results of biotechnology research will be most easily transferred to poor farmers as seeds in much the same way as the results of the Green Revolution. But this time it is expected that the private sector will have a significant role in dissemination. The private sector, especially seed companies, is becoming more important in several Asian developing countries such as India and the PRC. Similarly, in Europe and North America several seed companies have formed alliances with global life science companies. Several Asian agrochemical and floriculture companies are involved in joint ventures with developed country companies. Thus, in line with ADB's Private Sector Development Strategy (ADB 2000), there is a need to increase the partnership between the public and private sectors.

2. Options

Present involvement of companies in agricultural biotechnology in developing countries in Asia (especially in major crops and large countries) suggests that the motivation is purely commercial. For example, seed for up to half the engineered cotton grown in the PRC has been commercially obtained from Monsanto. In many cases new mechanisms will be needed by which the private sector can assist with technology transfer, extension, and distribution of biotechnology products. That may require some innovative arrangements involving special funds and other financial incentives for private companies. Multinationals also have an incentive to involve themselves in developing country partnerships/philanthropy to counter negative public impressions. Segmentation of markets will be important to allow developing country farmers to access the products of biotechnology under realistic conditions. Brokering groups such as ISAAA, a USAID program, and CGIAR centers have already implemented a range of approaches. These include market segmentation based on crop and growth region, country income level, trade status, or crop variety. In other cases the public sector could offer to buy exclusive rights to newly developed technology and make it available either free or for a nominal charge to small farmers (but on a profit basis to commercial farmers). The private research agency would bear the risks, as it does when developing technology for the market (see details in Appendix 13). The other possibility is for the public sector agency to finance private R&D on orphan crops through competitive bidding.

There is a need to establish whether international organizations and funding agencies should play a brokering role in the dissemination of agricultural biotechnology. A neutral broker can have advantages. For example, ISAAA claims that its comparative advantages are cosponsorship by public and private sector institutions, independence, and neutrality (lack of financial interest in the technology). Funding agencies (e.g., USAID) have also served as brokers between public agencies and private companies. Centralization of technology transfer offices for agricultural biotechnology in individual countries would facilitate brokering agreements, and inspire greater confidence in the private sector.

Other biotechnologies such as micropropagation of plants through tissue culture, and production of biofertilizers, biopesticides, and selected vaccines may be suitable for small- and medium-sized private companies in developing countries. Such companies could take technology directly from local research institutes. There are many successful examples of this already. Such enterprises can create employment in rural areas and deliver affordable and useful products to farmers.

E. Biosafety

1. Issues

Biosafety concerns relate either to food safety and human health or to the environmental impact of genetically modified crops. There is also a broader ethical concern as to whether genetically modified foods are unnatural, and whether the use of the technology encourages the narrow control of agriculture by a few (multinational) corporations. One of the key principles in biosafety guidelines is that of *substantial equivalence* as the approach to identify differences between biotechnology-derived and traditional foods (Miller 1999). The main environmental risks relate to the (i) potential loss of genetic diversity in cropping systems; (ii) potential transfer of genes from herbicide-resistant crops to wild relatives, creating superweeds; (iii) ability of herbicide-resistant crops to act as weeds in rotation crops; (iv) escape of transgenes, especially antibiotic resistance markers to soil bacteria; (v) vector recombination to create new viruses; and (vi) with Bt toxins, insect resistance to the toxin and the effect of the toxin on nontarget organisms.

The need for developing countries to have functioning biosafety systems has strengthened since the adoption of the Cartagena Protocol on Biosafety in January 2000. The Protocol establishes a framework for regulating international trade in transgenic crops. Three major components of the Protocol have implications for individual countries as users, developers, and exporters of GMOs:

(i) International shipments that "may contain" transgenic food products must be so labeled. This applies only to large-scale shipments; it does not affect labeling requirements on consumer products, which are determined by each country.
(ii) Governments may use the *precautionary principle* to bar import of a transgenic product even in the absence of conclusive evidence that the product is not safe. The Protocol does not, however, override other international agreements, including WTO, which requires that import decisions be science-based.
(iii) To assist countries in making import decisions, a database will be established to make available uniform information on transgenic crop varieties.

The need for harmonization of regulations is not just an issue for developing economies in Asia, but also for developed countries. For example, Levidow et al. (1999) report on how difficult it has been for European countries to harmonize regulatory criteria despite an expressed position of using science-based criteria. Countries disagree on the amount of scientific evidence required to resolve uncertainties such as in the recent approval processes for Bt insect-resistant maize and herbicide-tolerant canola.

2. Options

Countries have a range of options in designing and implementing national biosafety systems geared to their technical, legal, and institutional realities and in adapting the system to local needs, priorities, and capacities. There is a need to assess the adequacy and effectiveness of biosafety procedures for the testing, release, import, production, and use of GMOs in Asian countries.

Regulatory systems must be flexible to allow for either increased scrutiny or relaxation of controls (e.g., for containment of field trials) based on available scientific evidence. Harmonization of regulations between agencies is important. But it may be simpler and less expensive to embed biosafety regulation within existing institutions rather than to build new ones. Australia's approach has been to develop national policies and regulations for trade in GMOs within the country's existing regulatory framework. Thus, governments could be helped to build the infrastructure to manage GMOs within the context of developing a quarantine policy, managing sanitary and phytosanitary issues, and assessing risk and environmental impact. Collaboration between quarantine/regulatory officials and environmental policymakers should be strengthened.

An area of potential concern is the lack of verified ecological data on the effects of genetically modified crops under Asian or tropical conditions. Governments and international agencies should be supported in participatory field studies on the ecological impact of first-generation of genetically modified crops such as insect-resistant cotton and rice. These assessments should involve local communities in the evaluation of the new technologies.

The likelihood that Asian developing countries and their agricultural export customers will adopt the labeling of food containing genetically modified products needs to be assessed. Several countries have introduced labeling systems or are considering them. In some cases, industry has expressed concerns about the extra costs involved in testing, ingredient tracing, and labeling. Several options for labeling have been proposed. They include (i) labeling based on the presence of detectable transgenic DNA or protein only; (ii) special labeling for GMO-free foods; (iii) labeling all foods derived from GMOs; and (iv) labeling foods or any food ingredients produced with GMOs (e.g., meat from animals fed with transgenic crop residues). It will be important to establish the impact of such labeling on the production, distribution, marketing, and exports of genetically modified foodstuffs.

F. Fostering Better Public Awareness

1. Issues

The future of biotechnology lies in public awareness and acceptance; good technology alone is not enough. For example, although nuclear power provided low-cost electricity for many countries, there has been substantial disadoption in recent years. The news media in several Asian developing countries regularly report on biotechnology and the controversy surrounding GMOs. Some aspects of the debate are similar to that in Australia, in which the controversy is seen as one of technocrats encouraging the use of biotechnology versus the average person who is unsure of the benefits. European countries, especially, are seen to have the luxury of excess food production. The need to alleviate poverty or enhance food security is not part of their debate. Certain additional issues appear in some developing countries. Some countries such as Thailand are major exporters of processed foods. They are concerned about the attitudes of their export customers toward genetically modified foods.

2. Options

Inclusion of public awareness activities from the onset of a biotechnology program, rather than at its completion, can greatly assist in gaining acceptance. For example, before starting development of a transgenic, insect-resistant, tropical maize in Kenya, CIMMYT consulted with NGOs, farmer organizations, media, and other stakeholders to create a supportive environment. Public awareness programs should be included in the activities of major institutions carrying out biotechnology R&D. That is already done in Thailand and the Philippines, using simple messages in local languages. Again, it will be equally important to involve community groups in the debate, not just scientists or the food industry. Finally, multinational organizations such as Monsanto have recently realized the necessity for developing a strategy to ensure informed public debate about the risks of biotechnology to human health and the environment, and to ensure consumers are fully aware of the true benefits and costs of biotechnology. Such campaigns must recognize that freedom of choice is valid.