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Intermediary Biotechnology Service

A Biotechnology Research Management Study

John Komen  
Gabrielle Persley

## **Agricultural Biotechnology in Developing Countries**

*A Cross-Country Review*

***ISnar***

Research Report

NUMBER

**2**

The mandate of the International Service for National Agricultural Research (ISNAR) is to assist developing countries in bringing about lasting improvements in the performance of their national agricultural research systems and organizations. It does this by promoting appropriate agricultural research policies, sustainable research institutions, and improved research management. ISNAR's services to national research are ultimately intended to benefit producers and consumers in developing countries and to safeguard the natural environment for future generations.

ISNAR offers developing countries three types of service, supported by research and training:

- For a limited number of countries, ISNAR establishes long-term, comprehensive partnerships to support the development of sustainable national agricultural research systems and institutions.
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- For all developing countries, as well as the international development community and other interested parties, ISNAR disseminates knowledge and information about national agricultural research.

ISNAR was established in 1979 by the Consultative Group on International Agricultural Research (CGIAR), on the basis of recommendations from an international task force. It began operating at its headquarters in The Hague, The Netherlands, on September 1, 1980.

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*ISNAR's Research Report series presents the findings of research conducted by the institute and its partners in the areas of agricultural research policy, organization, and management.*



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### **AGROVOC Descriptors**

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biotechnology; organization of research; research; research policies; China; Colombia; Egypt; India; Indonesia; Kenya; Malaysia; Philippines; Thailand; Zimbabwe

### **CABI Descriptors**

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agricultural research; biotechnology; organization of research; research; research policy; China; Colombia; Egypt; India; Indonesia; Kenya; Malaysia; Philippines; Thailand; Zimbabwe

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Intermediary Biotechnology Service

*This report is the first publication in a series of interrelated research-management reports from the Intermediary Biotechnology Service. Forthcoming reports will elaborate on important issues that emerged from the country studies. One report will provide a tool for the decision-making process involved in establishing national biotechnology programs, by analyzing this process at three levels: program scientists, sectoral leaders, and national policymakers. Another forthcoming report reviews the current international debate on intellectual property protection and assesses the policy options available to policymakers in developing countries. A third report will give a detailed overview of international initiatives that have as a common goal the application of biotechnology to tropical agriculture, and reviews the possibilities for national institutions in developing countries to collaborate on these activities.*

## **The Intermediary Biotechnology Service**

The Intermediary Biotechnology Service (IBS) was established by an international group of donor agencies to act as an independent advisor to national programs in developing countries on matters of biotechnology research management and policy. The IBS is headquartered at ISNAR, where it represents a continuation of activities begun in 1988 under a four-year program of ISNAR, the World Bank, and the Australian government, titled *Agricultural Biotechnology: Opportunities for International Development*.

The establishment of the IBS resulted from a recommendation from the Biotechnology Task Force (BIOTASK) of the Consultative Group on International Agricultural Research (CGIAR). BIOTASK conducted an extensive investigation into the problems and potential benefits of applying biotechnology to agricultural research in developing countries. It recommended that a demand-driven, problem-oriented advisory service be established to make available the expertise of advanced biotechnology institutes to the developing countries. The Government of the Netherlands provided funding to implement this recommendation in late 1992.

The IBS is guided by a Steering Committee composed of representatives from client countries, contributing donors, and the implementing agency, ISNAR.

## **Functions**

The current program of the IBS has three main functions:

- to assist national agricultural research systems in developing countries with biotechnology research program management and policy formulation;
- to carry out country studies to identify priority problems amenable to solution through biotechnology;
- to identify international biotechnology expertise and enhance its availability to national programs in developing countries.

The IBS also advises bilateral and multilateral development agencies on biotechnology issues affecting developing countries.

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J.K. and G.J.P.  
July 1993

## **ABSTRACT**

Growing numbers of governments in developing countries are investing in infrastructure and human resources to support national biotechnology programs. At the same time, they are adopting policies to facilitate biotechnology R&D in both the public and private sectors. This report provides a comparative description of the different approaches taken by 10 developing-country governments to stimulate biotechnology research. The experiences discussed include an analysis of the institutional organization adopted, a description as to how the governments of these countries manage the regulatory aspects of biotechnology (biosafety and intellectual property rights), and how they address issues constraining further development of agricultural biotechnology. The basic data came from country studies commissioned as part of an overall study titled *Agricultural Biotechnology: Opportunities for International Development*.

## **ABREGE**

Dans un nombre croissant de pays en développement, les gouvernements investissent dans l'infrastructure et dans les ressources humaines afin d'appuyer les programmes nationaux de biotechnologie. De même, ils adoptent des politiques spécifiques visant le déploiement des efforts de recherche-développement en biotechnologie, dans les secteurs tant public que privé. Le présent rapport décrit en les comparant les diverses approches que suivent les gouvernements d'une dizaine de pays en développement afin de stimuler la recherche biotechnologique. Chacune des expériences rapportées contient une analyse de l'institution de recherche adoptée et une description de la façon dont le gouvernement du pays gère les mesures réglementant la biotechnologie (telles celles qui se rapportent à la sécurité biologique et aux droits de propriété intellectuelle); les auteurs examinent de plus la réaction des gouvernements vis-à-vis des obstacles qui entravent le développement de la biotechnologie agricole. Les données de base de ce rapport proviennent des études de cas menées dans plusieurs pays dans le cadre d'une étude plus ample, intitulée « *Agricultural Biotechnology: Opportunities for International Development* ».

## **RESUMEN**

Un número cada vez mayor de gobiernos en países en desarrollo están invirtiendo en infraestructura y recursos humanos para dar apoyo a los programas nacionales de biotecnología. Asimismo, están adoptando políticas que facilitan la investigación y el desarrollo de la biotecnología tanto en el sector público como en el privado. Este informe proporciona una descripción comparativa de los diferentes enfoques adoptados por 10 países en desarrollo para estimular la investigación en biotecnología en instituciones públicas y privadas. Las experiencias descritas incluyen un análisis de la organización institucional adoptada, una descripción de la manera en que los gobiernos de estos países manejan los aspectos normativos de la biotecnología (bioseguridad y derechos de propiedad intelectual), y el modo como enfocan aspectos limitantes para el desarrollo de la biotecnología agrícola. La información básica proviene de estudios de países, como parte de un estudio global titulado *Biotecnología Agrícola: Oportunidades para el Desarrollo Internacional*.

## ACRONYMS

AARD	Agency for Agricultural Research and Development (Indonesia)
ABSP	Agricultural Biotechnology for Sustainable Productivity
AGERI	Agricultural Genetic Engineering Research Institute (Egypt)
ARC	Agricultural Research Center (Egypt)
ASRT	Academy for Scientific Research and Technology (Egypt)
BBPT	Agency for Technology Assessment and Application (Indonesia)
BCIL	Biotech Consortium India Ltd
BIOTECH	National Institute of Biotechnology and Applied Microbiology (Philippines)
BRC	Biotechnology Research Center (CAAS, China)
BRI	Biotechnology Research Institute (Zimbabwe)
BSU	Bioservice Unit (NCGEB, Thailand)
CAAS	Chinese Academy of Agricultural Sciences
CBN	Cassava Biotechnology Network
CEBC	China EC Biotechnology Center
CIAT	International Center for Tropical Agriculture
CNCBD	China National Center for Biotechnology Development
COLCIENCIAS	Colombian Scientific Council
CRIFC	Central Research Institute for Food Crops (Indonesia)
DBT	Department of Biotechnology (India)
EC	European Community
FRIM	Forest Research Institute of Malaysia
IARC	international agricultural research center
IARI	Indian Agricultural Research Institute
ICA	Instituto Colombiano Agropecuario
ICAR	Indian Council of Agricultural Research
ICGEB	International Center for Genetic Engineering and Biotechnology
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ILRAD	International Laboratory for Research on Animal Diseases
IPR	Intellectual property rights
IRRI	International Rice Research Institute
IUC	Interuniversity Center for Biotechnology (Indonesia)
JICA	Japanese International Cooperation Agency
GATT	General Agreement on Tariffs and Trade
KARI	Kenya Agricultural Research Institute
MARDI	Malaysian Agricultural Research and Development Institute
NACBAA	National Advisory Committee on Biotechnology Advances and Their Applications (Kenya)
NCGEB	National Center for Genetic Engineering and Biotechnology (Thailand)
NCST	National Council for Science and Technology (Kenya)
NSTDA	National Science and Technology Development Agency (Thailand)
OECD	Organisation for Economic Co-operation and Development
PORIM	Palm Oil Research Institute of Malaysia
R&D	research and development

RCZ	Research Council of Zimbabwe
RFLP	restriction fragment length polymorphism
RRIM	Rubber Research Institute of Malaysia
SCBD	Shanghai Center for Biotechnology Development (China)
SIRDC	Scientific and Industrial Research and Development Center (Zimbabwe)
SSTC	State Science and Technology Commission (China)
UNC	Universidad Nacional de Colombia
UNDP	United Nations Development Programme
USAID	United States Agency for International Development

## **EXECUTIVE SUMMARY**

Rapid developments in global agricultural biotechnology are prompting developing-country governments to set up their own national programs in this field. Growing numbers of governments are making investments in infrastructure and human resources to support these programs, and are adopting policies to facilitate biotechnology R&D in both the public and private sectors.

This report is a comparative description of the wide-ranging approaches to, and experiences with, biotechnology in 10 developing countries: China, Colombia, Egypt, India, Indonesia, Kenya, Malaysia, the Philippines, Thailand, and Zimbabwe. It provides a basis for planning and implementing relevant programs elsewhere.

The report analyzes the institutional organization adopted in the various countries, and describes how governments manage the regulatory aspects of biotechnology (biosafety and intellectual property rights) and how they address issues constraining the further development of agricultural biotechnology.

Different countries have taken different institutional and strategic approaches to stimulating biotechnology. The institutional framework that is possible or desirable for a country depends on the size of the country, the strength of its science and technology sector, and its existing research infrastructure. Among the major conditions for productive biotechnology programs are the following:

- close collaboration between new biotechnology and conventional agricultural research (especially plant breeding), to ensure that new techniques are taken through to new products and field application;
- minimal duplication of expensive equipment and services;
- an effective working environment for well-trained scientists and adequate financial resources.

The possible institutional arrangements include

- establishing a national biotechnology agency to coordinate and fund biotechnology within existing institutions and to determine national policies;
- stimulating research at designated centers of excellence;
- creating a national biotechnology institute.

This report discusses the advantages and disadvantages of all three approaches in the context of specific countries.

Approaches to managing two regulatory aspects of biotechnology — biosafety and intellectual property rights — are also examined and compared. Most of the 10 countries are currently developing a suitable national framework for biosafety. These are based on existing national regulatory systems and internationally agreed-upon biosafety guidelines, such as those advocated by the OECD.

The need to introduce legislation which treats biotechnology inventions as intellectual property is under debate in many countries. The effect of such protection on innovation in biotechnology research in developing countries is still not clear and warrants additional study. However, the trend in developing countries is to strengthen intellectual property protection, partly as a result of bilateral negotiations and international trade negotiations.

Lack of financial resources was cited as a major constraint to the growth of biotechnology in most of the country studies. This affects staffing, equipment, and operational budg-

ets. The lack of clear problem definition and priority setting against which to formulate an R&D strategy is also a major limitation in most countries.

External financing of biotechnology research is increasingly being provided by bilateral and multilateral donor agencies and development banks. However, this cannot substitute for fostering local investment. In the long run, biotechnology is likely to require greater private-sector involvement, particularly in marketing and distributing research products. Examples are cited of measures being taken in different countries to encourage the private sector to invest in these downstream activities.

## 1. INTRODUCTION

Rapid developments in agricultural biotechnology\* have stimulated developing-country governments to devise national programs aimed at realizing its potential benefits. Growing numbers of these governments are investing in infrastructure and human resources to support these programs.

Breakthroughs in biotechnology research have often been accompanied by exaggerated claims as to their likely economic impact on agriculture. There are still limits, though, to what can be done with the new technologies. However, an increasing number of new techniques, such as those related to plant cell and tissue culture, improved diagnostic procedures for crop and animal diseases, and the identification and mapping of useful genes, have become valuable tools in agricultural research programs, including those in the developing countries (ATAS 1992; Thottappilly et al. 1992; Persley 1991; Getubig et al. 1991).

This report is intended mainly for policymakers and research managers in public and private agricultural agencies in developing countries. It compares the different approaches taken by 10 developing-country governments to stimulate biotechnology research in public and private institutions. Such a comparative description of experiences from countries with wide-ranging approaches to biotechnology provides a basis for planning relevant programs elsewhere. The experiences discussed include an analysis of the institutional organization adopted, a description as to how the governments of these countries manage the regulatory aspects of biotechnology (biosafety and intellectual property rights), and how they address issues constraining further development of agricultural biotechnology.

The 10 countries reviewed were China, Colombia, Egypt, India, Indonesia, Kenya, Malaysia, the Philippines, Thailand, and Zimbabwe. These were selected to provide a comprehensive representation of the wide range of approaches that can be taken to set up national biotechnology programs.

The basic data came from country studies that were commissioned as part of an overall study titled *Agricultural Biotechnology: Opportunities for International Development*, co-sponsored by ISNAR, the World Bank, and the Australian government. The country studies examined the status of public and private biotechnology activities in each country. They were intended to provide an initial picture of biotechnology policy and research programs in developing countries.

This report highlights the major findings of the country studies. Information from various sources has been used to update them.

Section 2 presents the national programs and institutional framework through which the various governments stimulate the development of biotechnology research. It groups the countries that share a specific organizational structure.

In section 3, attention is given to the management of the regulatory aspects of biotechnology — biosafety and intellectual property rights.

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\* In this report, the term “biotechnology” refers to both “traditional biotechnology” and “modern biotechnology”. In agriculture, the term encompasses not only well-established techniques such as those used in biological pest control and the production of vaccines and biofertilizers, but also more recently available technologies, particularly those associated with recombinant DNA technology; monoclonal antibodies; and new cell and tissue culture techniques.

For the purposes of this report, “agriculture” is broadly defined as the use of the natural resource base to produce crops, livestock, fish and trees.



Section 4 appraises the ways in which different governments address the constraints to further development of biotechnology — in terms of finance, human resources, private-sector involvement, international cooperation, and information.

Finally, section 5 presents the report's conclusions and recommendations.

Table 1 and the boxes highlight particular aspects of biotechnology programs in certain countries. Summary tables at the end of sections 2, 3, and 4 provide cross-country overviews of government programs, regulatory aspects, and constraint-related facets.

The complete country studies are to be published in a forthcoming volume titled *Agricultural Biotechnology: Country Case Studies* (CAB International, UK).

## 2. A COMPARISON OF GOVERNMENT PROGRAMS

Governments in all 10 countries studied have advanced the use of biotechnology in agriculture, industry, and health. However, the means by which they develop and institutionalize their national biotechnology programs differ between groups of countries.

### 2.1 India, China, and Thailand: National Coordinating Agencies

China, India, and Thailand have a strong capability in agricultural research and each has established central agencies to coordinate national biotechnology programs. In this way, biotechnology development has been promoted in various existing institutes, in line with national priorities.

**India:** The Government of India has implemented a broad, centrally coordinated program in biotechnology. The Sixth Five Year Plan (1980–1985) included India's first government document covering biotechnology. Under this plan, the National Board on Biotechnology was established in 1982. Four years later, the board's responsibilities were assigned to a separate department in the Ministry of Science and Technology, the Department of Biotechnology (DBT). The DBT's major tasks are to

- develop integrated plans and programs in biotechnology;
- identify specific R&D programs in biotechnology and biotechnology-related manufacturing;
- support biotechnology infrastructure development;
- facilitate the import of biotechnological processes, products, and technology;
- formulate biosafety guidelines for laboratory research and applications.

The DBT has defined biotechnology programs for agriculture and medicine (see also table 1), with a total annual budget of about Rs. 750 million (approximately US\$ 28 million). By 1991, 216 R&D projects had been approved and were at various stages of implementation. To avoid spreading funds over too many areas of research, the DBT selected product-oriented projects to be included in an Action Plan (1990–1991). The plan is divided into two kinds of projects:

- new activities, including biofertilizers and silk production; and
- ongoing activities, including vaccines, oil palm demonstration projects, increased production of biomass, immunodiagnosics, aquaculture, and embryo-transfer technology.

Agricultural biotechnology research is largely conducted in established agricultural research institutes, coordinated by the Indian Council of Agricultural Research (ICAR). ICAR is responsible for an extensive agricultural research system, including, for example, the Indian Agricultural Research Institute (IARI) in Delhi and the State Agricultural Universities (28 in total). The DBT, therefore, has to provide only limited funding for new infrastructural facilities. Existing institutions are encouraged and partially financed to create new infrastructure. For instance, IARI established the Biotechnology Center, supported by both ICAR and DBT. IARI is also the site of one of DBT's National Infrastructure Facilities, the Blue-Green Algal Collection.

Table 1. *India: Selected Activities in Agricultural Biotechnology Funded by the Department of Biotechnology*

DBT PROGRAMS						
Research and Development	Demonstrations and Product-Based Programs	Manpower Development	Infrastructure Facilities	Biotechnology Information System	Industrial Biotechnology	Biosafety Guidelines and Regulations
<ul style="list-style-type: none"> <li>• RFLP map-ping of rice</li> <li>• wide hybridization of rice</li> <li>• wide hybridization of Brassicas</li> <li>• introduction of <i>B.thuringiensis</i> gene in chickpea</li> <li>• tissue culture pilot plants for propagation of forest trees</li> </ul>	<ul style="list-style-type: none"> <li>• cultivation of oil palm on commercial scale</li> <li>• tissue culture of high-yielding cardamom</li> <li>• biological pest control (pilot plant production units)</li> <li>• biofertilizers</li> <li>• embryo transfer in cattle</li> </ul>	<ul style="list-style-type: none"> <li>• postgraduate and postdoctoral programs</li> <li>• short-term training courses</li> <li>• national scholarships</li> <li>• overseas scholarships</li> <li>• training programs for R&amp;D personnel from industry</li> </ul>	<ul style="list-style-type: none"> <li>• national facility for microbial collections</li> <li>• national facility for blue-green algal collections</li> <li>• national facility for plant tissue culture</li> <li>• genetic engineering units at several universities</li> </ul>	<ul style="list-style-type: none"> <li>• electronic biotechnology information service (BTNet)</li> <li>• data bases on research, information sources, and patents</li> <li>• workshops in bio-informatics</li> </ul>	<ul style="list-style-type: none"> <li>• tissue culture of stress-tolerant sugarcane varieties</li> <li>• <i>in vitro</i> production of bamboo</li> <li>• tissue culture of elite tea varieties</li> </ul>	<ul style="list-style-type: none"> <li>• site visits</li> <li>• regulation of imports of rDNA products</li> <li>• training on biosafety aspects</li> </ul>

**China:** The Government of China created capacity in modern agricultural biotechnology in a similar way to India, drawing on the extensive research capabilities of the Chinese Academy of Agricultural Sciences (CAAS) and adding new infrastructure to existing institutes. For instance, CAAS created the Biotechnology Research Center (BRC) as a focal point for CAAS institutes involved in biotechnology research.

China's long tradition in the use and development of fermentation techniques and its early involvement in tissue culture served as a base for introducing modern biotechnology. The country possesses one of the world's largest research bases for plant tissue and cell culture. The number of research units in the field of tissue or anther culture is estimated at more than 1000. Some 4000 to 5000 science and technology personnel are working in biotechnology-related R&D, spread over many institutes and many crops.

The single most important governmental body for coordinating biotechnology research is the China National Center for Biotechnology Development (CNCBD), whose advisory functions resemble those of India's DBT. It was created in 1983 as part of the State Science and Technology Commission (SSTC), reflecting the high priority accorded to biotechnology in the long-term High Technology Development Program (1986–2000). Its principal function is to provide funds for designated areas of applied biotechnology research — in agriculture, health, and protein engineering. It coordinates all biotechnology R&D activities in research institutes and universities and promotes the exchange of academic information, the training of personnel, and international cooperation.

**Thailand:** In Thailand, the government also decided to coordinate and promote government-funded R&D activities in biotechnology through a central national agency, the National Center for Genetic Engineering and Biotechnology (NCGEB). Established in 1983, the NCGEB is the main coordinating center for R&D projects in biotechnology. It provides support for biotechnology as a complete package, including funding, information, training, linkages to industry, and international linkages. NCGEB supports research in five affiliated laboratories: the Universities of Chulalongkorn, Mahidol, Kasetsart, and Chiang Mai, and the King Mongkut Institute of Technology. Research projects in agricultural biotechnology funded by the center focus on

- tissue culture;
- plant selection and germ plasm conservation;
- biofertilizers;
- pest control;
- rice.

A biotechnology research laboratory is being established by the NCGEB to provide certain core technologies for laboratories throughout the country (see box 7).

In December 1991, the NCGEB, together with the National Metal and Materials Technology Center and the National Electronics and Computer Technology Center, was brought under the guidance of the newly established National Science and Technology Development Agency (NSTDA). This special autonomous organization, outside the normal framework of state enterprises and the civil service, was considered necessary to ensure a broad-based approach to developing science and technology in Thailand. Another objective is to stimulate the involvement of the nation's private sector and foreign institutions.

NSTDA is governed by a board of directors, which is chaired by the Minister of Science, Technology and Environment. It comprises representatives from government agencies and the private sector.

## **2.2 Indonesia and Malaysia: The Multiple Centers-of-Excellence Approach**

Indonesia and Malaysia have not established central agencies with designated budgets for stimulating biotechnology. Instead, national advisory committees coordinate biotechnology research activities at selected centers of excellence. The two countries build upon their well-developed capacities in conventional agricultural research, integrating biotechnology research expertise in existing institutions.

**Malaysia:** In its current Sixth Plan period (1991–1995), Malaysia has emphasized the development of biotechnology, particularly agricultural biotechnology. The government created a National Biotechnology Committee in 1984. This was succeeded in 1991 by the National Biotechnology Working Group whose functions are to

- advise the government on policy issues in research, funding, and incentives to industries;
- monitor new developments in biotechnology;
- facilitate R&D cooperation between research institutions and industry;
- establish a mechanism for funding research activities;
- prepare annual reports on the status and advancement of biotechnology in the country;
- establish guidelines on the code of ethics and safety in all aspects of biotechnology development.

The mandate of the National Biotechnology Working Group covers biotechnology R&D in agriculture, medicine, and industry. The working group's strategy is to promote and coordinate these activities through specific centers of excellence, selected from existing universities and national research agencies. The government provides funding for the development of biotechnology infrastructure at these centers. Examples of centers of excellence active in agricultural biotechnology are

- the Malaysian Agricultural Research and Development Institute (MARDI);
- the Palm Oil Research Institute of Malaysia (PORIM);
- the Rubber Research Institute of Malaysia (RRIM);
- the Forest Research Institute of Malaysia (FRIM).

Research programs at PORIM, RRIM, and FRIM focus on applying tissue culture techniques to their specific mandate crops. MARDI has a much broader mandate and conducts research on rice, cocoa, vegetables, field crops, and ornamentals. In 1990, it strengthened its biotechnology research by establishing a Biotechnology Center within the institute (see box 1). This center promotes research and development from the laboratory scale to the pilot scale, emphasizing the transfer of biotechnology to the private sector.

In addition to the four major agricultural research institutes, several plant biotechnology research programs are carried out in universities, including the University of Malaya, the National University of Malaysia, the Science University of Malaysia, and the Agriculture University of Malaysia.

### **Box 1. Malaysia: The Biotechnology Center at MARDI**

In recent years the Malaysian Agricultural Research and Development Institute (MARDI) has developed a pool of expertise in scientific disciplines related to biotechnology, dispersed among the institute's various commodity divisions. The establishment of the Biotechnology Center consolidates all the resources related to biotechnology R&D activities. Its current activities are organized under the following programs:

- Plant biotechnology:** *in vitro* culture of ornamental and fruit crops;
- Animal biotechnology:** improvement of techniques used in embryo transfer;
- Food biotechnology:** improvement of methods for producing fermented foods and other fermentation products;
- Environmental biotechnology:** bioconversion of agricultural wastes into value-added products such as microbial enzymes, feed, edible fungal proteins, and compost;
- Molecular and cellular biology:** Basic research in crop improvement and diagnostics.

Through its Industrial Development Unit, the Biotechnology Center supports the transfer of laboratory research results to industry. This is done through feasibility studies, field demonstrations, and marketing surveys. The main objectives of the unit are to

- develop joint ventures with private industry;
- support development of prototypes and establishment of pilot plants, as well as assist in the validation of products developed;
- carry out cost-benefit analyses to minimize risk capital investments in the production of value-added products;
- assist with the transfer of relevant technologies from indigenous or international sources and with screening and evaluation of these technologies.

*Source:* Mohamed Tamin, M.S. (1992).

**Indonesia:** The State Minister of Research and Technology of Indonesia appointed three agencies to take the lead in facilitating a national network for biotechnology R&D: for agricultural biotechnology, the Agency of Agricultural Research and Development (AARD) and its Central Research Institute for Food Crops (CRIFC); for medical biotechnology, the University of Indonesia, Jakarta; and for industrial biotechnology, the Agency for Technology Assessment and Application (BBPT).

Primary responsibility for implementing agricultural biotechnology programs lies with AARD. Bogor Agricultural University also has activities in plant, animal, and microbial biotechnology, related to its postgraduate research programs. The Institute of Technology at Bandung, the Indonesian Institute of Sciences, and BBPT are also active in some

aspects of agricultural biotechnology, primarily in the agroindustrial areas of downstream processing and microbial fermentation.

Agriculture has first priority in Repelita V, the five-year development plan covering 1990–1994. Accordingly, the development of biotechnology is emphasized. In 1985, the government paper “Pattern of Development of Biotechnology in Indonesia” outlined ways in which biotechnology should support national development. A sequential four-stage policy for development was proposed in the paper:

Stage 1. The transfer of technology. At this stage, the development of bioindustries is based on direct assistance by foreign parties. Biotechnology skills and processes are imported, with the aim of producing high-value-added goods and services. This stage simultaneously provides opportunities for Indonesia to understand the design and techniques of biotechnology.

Stage 2. The integration of biotechnology in national research programs.

Stage 3. The national development of biotechnology. New Indonesian technology is developed, aimed at enhancing comparative advantages of the nation’s biotechnology industry.

Stage 4. Stimulating local basic research. This supports the continued growth of bioindustries within Indonesia.

The National Committee for Biotechnology was established to implement this policy and to develop guidelines for government regulation of biotechnology including the protection of intellectual property rights. Specifically, the committee has the responsibility for formulating and preparing policies and programs for the national development of biotechnology;

- encouraging R&D and applications of biotechnology;
- enhancing the growth of national and international biotechnology networks;
- guiding human resources development in biotechnology;
- guiding and encouraging the development of industry.

The Department of Education established three Interuniversity Centers on Biotechnology (IUCs) in 1985. These train faculty members from other universities, operate a post-graduate degree program, conduct focused research, and seek linkages to private industry to ensure access to up-to-date research and technology and to enhance the commercial application of university research (see box 2). A five-member Project Advisory Review Board for Biotechnology annually approves all IUC projects.

### **2.3 The Philippines and Egypt: Creating National Research Institutes**

Two of the countries studied, the Philippines and Egypt, have promoted the development of national biotechnology capability by establishing national research institutes.

**The Philippines:** The Government of the Philippines was one of the first to set up a national biotechnology institute. The National Institute of Biotechnology and Applied Microbiology (BIOTECH), located on the campus of the University of the Philippines at Los Baños, was founded in 1979. Its overall objective is to develop technology for establishing and improving microbiology-based industries. Specific aims of BIOTECH are to

- provide direction and support to research in microbiology, genetics, chemistry, and engineering;

**Box 2. Indonesia: The Inter-University Centers for Biotechnology**

**The establishment in 1985 of three Inter-University Centers (IUCs) for biotechnology by Indonesia's Ministry of Education was financed via World Bank loans amounting to US\$ 23 million. The centers aim to train faculty members from other universities, operate a postgraduate degree program, conduct focused research, and seek links with private industry. The three centers are:**

**IUC for Agricultural Biotechnology, at Bogor. This has laboratories equipped for tissue culture, microbiology, molecular genetics, fermentation, and other aspects of biotechnology. Work is under way on *Rhizobium* and *Mycorrhiza* inoculants, tissue culture of potato and other crops, fermentation of agricultural by-products, and waste water treatment.**

**IUC for Industrial Biotechnology, at Bandung. This IUC has three major areas of activity: (1) microbiology and fermentation, (2) enzyme technology, and (3) waste water treatment.**

**IUC for Medical Biotechnology, at Jogjakarta. Located at Gadjah Mada University, this IUC focuses mainly on vaccine production for tropical diseases.**

*Source:* Dart, P.J., I. Manwan, and G.J. Persley (1991).

provide training to support biotechnological and microbiological industries;  
provide scientific advice to government and private agencies;  
utilize and maintain a microbial resource unit;  
link research and industry to facilitate commercial application of laboratory-tested biotechnology processes.

The major research thrusts of the institute are currently  
nitrogen fixation and enhancement of soil nutrient availability;  
biofuel production from agricultural crops and residues;  
food fermentation and feed production;  
special projects on veterinary antibiotics, plant diagnostics, and plant cell cultures for the production of high-value substances.

The Science and Technology Coordinating Council of the Philippines, through its Sectoral Technical Panel on Biotechnology, drew up a biotechnology implementation plan for the period 1991–95. The plan aims to provide R&D support and training, with a view to establishing bioindustries and raising food self-sufficiency. Six projects were identified for implementation during the plan period:

coconut tissue culture;  
production of high-value fats from coconut oil;  
human, animal, and plant diagnostics and vaccines;  
reforestation through tissue culture;  
penicillin production using locally available raw materials;  
treatment of urban waste.



BIOTECH is expected to be a major implementing agency for these projects and to seek collaboration with specialized research institutions, within and outside the Philippines.

**Egypt:** Biotechnology research is promoted in Egypt through national research institutes. The Academy of Scientific Research and Technology (ASRT) is the principal institute assigned responsibility for biotechnology program development across all sectors in Egypt. The Ministry of Agriculture and Land Reclamation has specific responsibility for agricultural applications.

The Agricultural Genetic Engineering Research Institute (AGERI) was set up in 1990 for advanced research in agricultural biotechnology. It is a component of the Ministry of Agriculture's Agricultural Research Center (ARC), which has prime responsibility for agricultural research. AGERI plans to develop training programs and focuses on the development of biotechnology for potato, rapeseed, and tomato (see box 3).

### **Box 3. Egypt: The Agricultural Genetic Engineering Research Institute**

**In 1990 the United Nations Development Programme (UNDP), in conjunction with the Government of Egypt, commissioned the establishment of the National Agricultural Genetic Engineering Laboratory (NAGEL). A group of 15 senior scientists was recruited, and the facility's name has been changed to the Agricultural Genetic Engineering Research Institute (AGERI). AGERI has established a research program focusing on three model crops. In addition, it trains researchers from other institutions, both in Egypt and in other North-African countries. Research projects have started on the following:**

**production of virus-free potato minitubers through tissue culture and genetic engineering;**  
**improvement of rapeseed varieties, using RFLP techniques (the use of special enzymes to map out the genetic structure of an organism's chromosomes, thereby helping breeders to select for desirable traits);**  
**molecular biology and genetic engineering of tomato to develop disease-resistant varieties.**

**New programs are planned for developing insect-resistant cotton varieties through genetic engineering and for improving the protein quality of faba bean varieties.**

In 1990, ASRT proposed setting up a National Institute for Genetic Engineering and Biotechnology, to focus on basic and applied industrial biotechnology. The proposal was made after ASRT carried out an evaluation of the state of the art of modern biotechnology in Egypt. ASRT concluded that although Egypt has expertise in some areas of biotechnology (e.g., tissue culture, fermentation, and embryo transfer), there was very limited theoretical and practical knowledge of, for example, genetic engineering. The national institute was intended to complement this expertise with advanced research on biochemistry and genetic engineering. The proposal, however, has not yet been implemented. Nor is there a specific national program in biotechnology that determines overall priorities within and across sectors. Although ASRT established a National Biotechnology Committee in 1984, the com-

mittee meets on an ad hoc basis and does not provide the level of coordination required to establish a national program.

## 2.4 Kenya, Zimbabwe, Colombia: Defining National Programs

Kenya, Zimbabwe, and Colombia are defining national biotechnology programs and priorities through national committees and planning conferences. These efforts are being undertaken prior to making major investments in biotechnology.

**Kenya:** Until 1992 the focal point for biotechnology coordination in Kenya was the National Advisory Committee on Biotechnology Advances and Their Applications (NACBAA). It was composed of the directors of research institutes under the Ministry of Research, Science and Technology (covering agriculture, industry, health, and the environment), plus representatives from the private sector. The Committee had the responsibility to

- develop a biotechnology strategy for the period to the year 2000;
- assess the expected degree of scientific advancement;
- advise on modalities for handling biotechnology breakthroughs;
- advise on the feasibility of a biotechnology park.

An outline for a national biotechnology program was prepared in 1991 by NACBAA. In its report, the committee recommended national priority areas, the development of regulatory guidelines, and the formation of a decentralized National Biotechnology Enterprise Program. The program would involve the creation of a National Biotechnology Education Center, a Biotechnology Enhancement Fund, and a National Commission for Biotechnology to succeed NACBAA, which was disbanded after completing its task.

The Kenya Agricultural Research Institute (KARI), the lead agricultural research organization in the country, has already adopted the recommendations in this report relating to agricultural biotechnology research. KARI sponsored two national conferences, in 1989 and 1990, on the future role of plant and animal biotechnology in Kenya (see box 4). Some of the recommendations of these meetings have been taken up in the context of the first National Agricultural Research Project (NARP I), through which a consortium of donors, convened by the World Bank, supports the research programs of KARI. The donor members of the consortium include the governments of the Netherlands, the U.S.A., the U.K., and the European Community. As KARI prepares for NARP II, it is now considering how to strengthen its activities in biotechnology.

Significant expertise in biotechnology also exists in the Faculties of Science and Agriculture at the University of Nairobi and at Jomo Kenyatta University. The University of Nairobi intends to establish a biotechnology institute to provide a focus for research and education in this field.

**Zimbabwe:** The prime agency for coordinating biotechnology in Zimbabwe is the Research Council of Zimbabwe (RCZ). Its overall function is to advise the government on issues of science and technology. In its latest National Science & Technology Policy Statement, agricultural biotechnology research is a principal topic.

The major thrust of the biotechnology program proposed by the RCZ is to develop high-yielding crops, food technology, improved horticultural crops, and improved methods of animal breeding, as well as to create a national gene bank. The proposed national program and related issues were discussed at three workshops held in 1991.

#### **Box 4. Kenya: Setting priorities for agricultural biotechnology**

A national conference on plant and animal biotechnology was held in Nairobi in early 1990. In discussions among the participants, priorities for agricultural biotechnology were enumerated, both for plant and animal production. Information from the conference was followed up by consultations with experts working in national research institutions and government ministries. In plant biotechnology, the top 10 priorities were ranked as follows:

1. developing tissue culture procedures for propagating root and tuber crops, maize cultivars, horticultural crops, vegetable oil crops, fruit trees, and floricultural crops, as well as for eliminating pathogens in these crops;
2. applying *in vitro* methods for selecting desirable traits in cell cultures;
3. applying diagnostic methods for the detection of viruses and of bacterial and fungal pathogens;
4. *in vitro* conservation and distribution of germ plasm of standard and recalcitrant plant species;
5. developing molecular markers, such as RFLP markers, for use in plant breeding and selection;
6. transfer of useful genes into plants in order to develop pest and disease resistance;
7. enhancing nitrogen fixation activity in symbiotic and associative microbes;
8. identification and utilization of indigenous plants of potential importance to Kenyan farmers;
9. use of microbes in bioconversion of natural materials for use as plant fertilizers;
10. developing methods for the biological control of insect pests and diseases.

For application in animal production, the priorities were as follows:

1. applying diagnostic tools for the identification of diseases;
2. developing improved vaccines to control selected diseases endemic in the region;
3. identification and cloning of genes for disease resistance and of genes that may confer superior reproductive performance in animals;
4. embryo culture systems, embryo cloning, and *in vitro* fertilization.

Source: Olembo, N. (1991); Mailu, A.M. et al. (1991)

A large part of the nation's biotechnology program is to take place at the new Biotechnology Research Institute (BRI) being established by the RCZ at the Scientific and Industrial Research and Development Center (SIRDC). The BRI is expected to conduct research on maize, millet, sorghum, cassava, groundnuts, and fruit trees, which have special significance for small farmers. Current research and training activities take place mainly at the University of Zimbabwe, largely funded by international donor agencies (see box 5).

#### **Box 5. Zimbabwe: Donor-funded programs in biotechnology**

Two major biotechnology programs in Zimbabwe have been initiated by the University of Zimbabwe, in collaboration with the Free University of Amsterdam in the Netherlands. Both programs are largely funded by the Netherlands Ministry of Foreign Affairs, through its special program, Biotechnology and Development Cooperation.

##### *MSc program in biotechnology*

This training program was launched at the University of Zimbabwe in 1991 and is jointly offered by the faculties of agriculture and science. The duration of the MSc program is two years, on a full-time basis. The total number of students participating in the program is 12. In the first year, students follow three core courses:

- basic microbiology and fermentation
- basic plant biotechnology
- recombinant DNA technology

In addition, each student follows three out of five advanced courses in

- immunology and virology
- advanced fermentation
- enzyme technology
- advanced plant biotechnology
- cloning technology

During the second year of the program, students conduct a research project in a selected area. The Free University of Amsterdam offers fellowships in the various disciplines involved.

##### *Cassava and biotechnology*

A research and training project at the crop science department of the University of Zimbabwe focuses on research-capacity building in Zimbabwe and the genetic improvement of cassava. The goal of the project, covering the period 1992–96, is to optimize *in vitro* regeneration techniques for cassava and to define a cassava genetic transformation methodology. The purpose of genetic transformation research is to achieve virus resistance, in particular to the African cassava mosaic virus. Fellowships for trainees participating in this program are provided by the Free University of Amsterdam, Wageningen Agricultural University in the Netherlands, and the Scripps Institute in the U.S.A.

**Colombia:** The government of Colombia is currently formulating its policy for biotechnology. In 1991, a presidential decree restructured the national science and technology system. It is now headed by a National Council for Science and Technology, chaired by the President of Colombia and composed of ministers, members of the scientific community, and representatives of the private sector. The Colombian Scientific Council (COLCIENCIAS) is the executive secretariat for the national council.

The National Council for Science and Technology coordinates a number of national programs, one of which covers biotechnology. The national biotechnology program has a high-level governing council composed of representatives of government, the scientific community, and business. Responsibility for the program lies mainly with the National Planning Department and with the program's executive secretariat, COLCIENCIAS.

The outline for a national biotechnology program was first published in December 1991. The publication was followed up with a series of seminars and workshops for scientists, business people, and policymakers. A final document was adopted in November 1992. The program has four objectives:

- to create national scientific capacity to develop and master new biotechnology;
- to promote biotechnology development in selected products and processes, to give Colombian products a comparative advantage;
- to encourage the application of biotechnology to the development of low-input production systems;
- to create a legal and institutional framework that stimulates investment in biotechnology and promotes the rapid incorporation of biotechnology into productive processes.

To achieve these objectives the national program will deal with:

- the establishment of research programs;
- improvements to infrastructure and human resources;
- access to international biotechnology, through joint ventures and other cooperation;
- institutional and legal considerations (intellectual property, biosafety, exchange of germ plasm);
- special stimuli for the private sector.

The allocation of funds to specific research projects is very limited, and it is expected that the role of the national program will principally lie in policy formulation, coordination, and the promotion of research collaboration. No new biotechnology research institutes are planned, as a well-developed public research capacity already exists. The most important institute already working on agricultural biotechnology is the Instituto Colombiano Agropecuario (ICA). ICA has an extensive program in food crops (rice, sorghum, beans, and wheat). In addition, a number of universities have agricultural biotechnology programs. The Universidad Nacional de Colombia (UNC), for instance, has a well-equipped biotechnology institute, with programs in agricultural biotechnology, diagnostics, and industrial biotechnology (see box 6).

#### Box 6. Colombia: Research at the Biotechnology Institute

The Biotechnology Institute at the Universidad Nacional was created in December 1987 to unite the efforts of researchers from the Schools of Science, Engineering, Agriculture, and Medicine. It serves as a center for the coordination of research projects carried out at its own and various other laboratories. The central complex includes nine laboratories and a Biotechnology Orientation and Reference Center. The following are some of the research projects in agricultural biotechnology that have been initiated:

*Molecular biology of plant viruses.* This work focuses on the production of potato seed free of the potato viruses X and Y and potato leaf roll virus, which together cause up to 62% of losses in potato production. Work has also been done on the characterization of the citrus tristeza virus, which infects more than 95% of the citrus trees in Colombia.

*Biofertilizers.* The ultimate goal of this project is the setting up of an industrial plant for the production of *Rhizobium* inoculants, as a substitute for chemical nitrogen fertilizers. Currently, a national *Rhizobium* collection is being developed.

*Bioinsecticides.* The bacterium *Bacillus thuringiensis* (Bt) has the potential to control a range of pathogens. A project has been initiated on the control of *Heliothis* spp (bollworm) in cotton plantations, through Bt-based insecticides. This is a joint project of the Biotechnology Institute and the Cotton Federation of Colombia.

Table 2. *Biotechnology Programs by Country*

Country	GOVERNMENT PROGRAM		
	Program	Prime Coordinating Agency	R&D Base
China	• biotechnology priority in Five-Year Plans and long-term High Technology Development Program (1986–2000)	• CNCBD	• SCBD • CAAS
Colombia	• national program formulated	• national biotechnology council • COLCIENCIAS	• ICA • UNC • private sector
Egypt	• national institute (AGERI) • no national coordinated program	• national biotechnology committee • ASRT	• AGERI • ARC • universities
India	• extensive national biotechnology program developed since 1980	• DBT	• research system under ICAR • universities • private sector
Indonesia	• “Pattern of Development of Biotechnology in Indonesia” • centers of excellence designated	• National Committee for Biotechnology	• national centers of excellence • IUCs • AARD
Kenya	• national planning conferences (1989, 1990) • national program developed by NACBAA	• National Council for Science and Technology	• KARI • universities
Malaysia	• priority in current national plan period • centers of excellence designated	• National Biotechnology Working Group	• MARDI • PORIM, RRIM, FRIM • universities
Philippines	• national institute (BIOTECH) • Biotechnology Implementation Plan	• presidential task force	• BIOTECH • universities
Thailand	• priority area of current national plan	• NCGEB • NSTDA	• NCGEB’s affiliated centers
Zimbabwe	• being prepared by RCZ • national institute (BRI) being established	• RCZ	• institutes under ministry of agriculture • SIRDC • University of Zimbabwe

### **3. REGULATORY ISSUES: BIOSAFETY AND INTELLECTUAL PROPERTY RIGHTS**

Besides formulating a national strategy and generating an institutional framework for biotechnology, governments are also responsible for defining the regulatory conditions for research and development. These include both a biosafety system to guide the production and release of genetically modified organisms, and laws regarding the protection of intellectual property rights.

#### **3.1 Biosafety**

Biosafety is defined as the policies and procedures adopted to ensure the environmentally safe applications of biotechnology. A national biosafety system to regulate production and release of genetically modified organisms is considered essential in any country with a biotechnology program.

The production and release of genetically engineered organisms has raised concerns about potential risks to public health and the environment. Assuring compliance with biosafety regulations is therefore important to foster public acceptance and further development of modern biotechnology. Biosafety regulations are also necessary to facilitate access to modern biotechnology generated abroad, as many international institutions and companies will not test genetically engineered organisms unless the tests have been approved by a responsible governmental body.

Most of the 10 countries under review are currently developing a national framework to regulate biotechnology R&D, adapted to their existing regulatory systems. The steps necessary to establish a national biosafety system that builds on existing regulatory experience — such as plant quarantine acts, environmental protection acts, and worker health and safety regulations — are described by Persley, Giddings, and Juma (1992). They recommend the creation of a national biosafety committee to establish policies and procedures governing the use of biotechnology. These should cover both in-country research and the import of new biotechnology products developed elsewhere. The national committee should also coordinate with the biosafety committees set up by individual institutions undertaking biotechnology research in the country.

The guidelines developed by the Organisation for Economic Co-operation and Development (OECD) have been used as the basis for national guidelines in many countries. The OECD guidelines are regarded as the most authoritative set of internationally agreed-upon guidelines currently available and can provide a sound basis for national biosafety systems.

##### **3.1.1 Country Approaches**

Comprehensive national biosafety systems have been set up in India and the Philippines. In each country, they are based on a network of institutional biosafety committees, coordinated by a national biosafety committee.

In India, the Recombinant DNA Advisory Committee of the Department of Biotechnology (DBT) prepared a set of Recombinant DNA Safety Guidelines which cover all areas



of research and large-scale operations involving genetically engineered organisms, excluding humans. The institutional mechanism for implementing the guidelines consists of

- the Recombinant DNA Advisory Committee, under the DBT, to formulate and update biosafety guidelines;
- institutional biosafety committees located at all centers engaged in genetic engineering research and production activities;
- the Review Committee on Genetic Manipulation, under the DBT, to guide the institutional biosafety committees;
- the Genetic Engineering Approval Committee, functioning under the Department of Environment, to review and approve activities involving the large-scale use of genetically engineered organisms and their products in research and development, industrial production, environmental release, and field applications.

In the Philippines, the National Committee on Biosafety and Biosafety Guidelines is a working group composed of representatives of the Department of Agriculture, the Department of Science and Technology, the University of the Philippines, and the International Rice Research Institute. It has prepared biosafety guidelines that include a provision for case-by-case review of proposed releases of genetically modified organisms. A National Biosafety Committee was established in 1990 to oversee the compliance of policies and guidelines in public and private institutions. A network of 39 Institutional Biosafety Committees was created to ensure the implementation of the guidelines at the institutional level. The National Biosafety Committee coordinates with other national agencies involved in regulations, such as the quarantine services and the environmental management bureau. To date, the National Biosafety Committee has approved 15 applications for the importation of, among other things, transgenic cotton tissue and transgenic strains of rice.

Formal biosafety regulations and mechanisms do not yet exist in the other eight countries under study, although the subject is under review in most of them. For instance, the secretariat of Kenya's National Council for Science and Technology (NCST) has been given the responsibility to formulate guidelines on biosafety. In Thailand, a Biosafety Subcommittee was established in 1990 under the National Committee for Science and Technology Development. The subcommittee completed its draft biosafety guidelines in June 1992. Indonesia's National Committee for Biotechnology is preparing national biosafety guidelines that complement existing environmental and plant quarantine acts. The Research Council of Zimbabwe plans to hold a regional workshop on biosafety in October 1993.

### **3.2 Intellectual Property Rights**

Intellectual property rights (IPR) is that area of law concerning patents, copyrights, trademarks, trade secrets, and plant variety protection. To stimulate local innovation and public-private-sector collaboration, and to encourage investment from abroad, clear national policies, regulation, and understanding of IPR are as important as transparent biosafety regulations. However, there are no internationally-accepted guidelines for the management of IPR, and a wide range of opinions exists regarding the utility of IPR.

### 3.2.1 IPR Debated

The protection of IPR is currently the subject of extensive debate in national and international fora. Industrialized countries are generally pressing for stronger protection, although provisions for IPR still vary significantly among them. In many developing countries, it is often feared that strong IPR protection hampers rather than promotes in-country innovation, since most of these rights are granted to foreign institutions. IPR regulations in developing countries often have short protection terms, include strong compulsory licensing provisions (to ensure that national industry has access to new technology), and exclude many products from protection (cf Van Wijk and Junne, 1992).

This situation prevails in most of the countries reviewed in this report. National IPR policies often explicitly dictate against the patenting of *products*, specifically pharmaceuticals, microorganisms, and plant and animal varieties. IPR protection for *processes* that generate novel products is usually permitted.

This situation is changing because, in international negotiations such as those within the General Agreement on Tariffs and Trade (GATT), developing countries are being pressured to strengthen their IPR systems. Bilateral trade negotiations, especially those with the U.S.A., are also adding to these pressures. Protection for pharmaceuticals and computer software is the main theme in these negotiations, but protection for biotechnology innovations is often included. In addition, there is increasing emphasis, especially in the large developing countries, on encouraging technology transfer and cooperation with foreign companies. Upgrading IPR regulations is viewed as a means to this end. As a result of these external and internal influences, a growing number of developing countries have adopted stronger IPR protection systems.

### 3.2.2 Country Experiences

Thailand and China, among other countries, were urged during bilateral negotiations to revise their patent systems. Thailand adopted a new patent act after the U.S. government had withdrawn Thailand's trade benefits under the General System of Preferences. The new act allows for the patenting of pharmaceutical products, food, beverages, and biotechnological inventions. Patent duration is extended and compulsory licensing provisions are restricted. Similar provisions are now included in China's patent laws, after renewal of the Sino-American Science and Technology Agreement was postponed by the U.S. government.

In India, controversy over IPR with the U.S. government led to the postponement of the Indo-U.S. Vaccine Action Program and the Indo-U.S. Science and Technology Initiative. The Government of India agreed to negotiate on revisions to its laws governing IPR in 1988. The current Indian Patent Act of 1970 excludes products in general; methods of agriculture or horticulture; and processes for the treatment of plants to render them free of disease, or to increase their economic value or that of their products. The Government of India has not yet strengthened its IPR legislation, partly due to strong national opposition.

In order to stimulate international technology transfer, Kenya adopted its first patent law in 1989, the Industrial Property Act. Its most important provision regarding biotechnology is to make life forms patentable provided they do not compromise principles of environmental conservation. The Kenya Industrial Property Office has been established to implement the act. Until recently, Kenya had a "dependent patent system", based on British patent law, whereby it registered patents already granted by the British patent office. Al-

though this has now been repealed, it is not yet possible to file patents under the new law, since regulations, forms, and fees have not yet been determined.

Controversy over intellectual property rights will continue to face both developing and industrialized countries. International negotiations, however, aim at harmonizing IPR regulations among industrialized countries, and a growing number of developing countries are adopting stronger IPR regulations. The precise effects of stronger IPR protection on innovation in biotechnology research are still not clear and further study is needed on this theme.

Table 3. *Summary of Regulatory Aspects per Country*

	REGULATORY ASPECTS	
Country	Biosafety	Intellectual Property Rights
China	<ul style="list-style-type: none"> <li>• draft regulations</li> <li>• national biosafety committee</li> </ul>	<ul style="list-style-type: none"> <li>• revised patent law effective as of January 1993; excludes plant and animal varieties</li> </ul>
Colombia	<ul style="list-style-type: none"> <li>• guidelines under consideration</li> </ul>	<ul style="list-style-type: none"> <li>• government increased coverage of patent law in 1992; now includes biotechnology products</li> <li>• plant variety rights under consideration</li> </ul>
Egypt	<ul style="list-style-type: none"> <li>• no biosafety regulations</li> </ul>	<ul style="list-style-type: none"> <li>• no patent protection for biotechnology products</li> </ul>
India	<ul style="list-style-type: none"> <li>• guidelines and institutional mechanism put into operation in 1990</li> </ul>	<ul style="list-style-type: none"> <li>• no patent protection for biotechnology products</li> <li>• plant variety rights under consideration</li> </ul>
Indonesia	<ul style="list-style-type: none"> <li>• guidelines being prepared by NCB's committee on biosafety</li> </ul>	<ul style="list-style-type: none"> <li>• new IPR legislation being prepared</li> </ul>
Kenya	<ul style="list-style-type: none"> <li>• NCST formulating guidelines</li> </ul>	<ul style="list-style-type: none"> <li>• biotechnology inventions protected under 1989 patent law</li> </ul>
Malaysia	<ul style="list-style-type: none"> <li>• guidelines under consideration</li> </ul>	<ul style="list-style-type: none"> <li>• no patent protection for biotechnology products</li> </ul>
Philippines	<ul style="list-style-type: none"> <li>• biosafety system in place</li> <li>• National Biosafety Committee</li> <li>• network of Institutional Biosafety Committees</li> </ul>	<ul style="list-style-type: none"> <li>• no patent protection for biotechnology products</li> </ul>
Thailand	<ul style="list-style-type: none"> <li>• first draft of guidelines finished</li> <li>• Biosafety Subcommittee</li> </ul>	<ul style="list-style-type: none"> <li>• new patent act (1992) protects biotechnology inventions</li> </ul>
Zimbabwe	<ul style="list-style-type: none"> <li>• draft guidelines</li> </ul>	<ul style="list-style-type: none"> <li>• dependent patent system</li> </ul>



## 4. ADDRESSING EMERGING CONSTRAINTS

Besides creating the appropriate institutional and regulatory environment, governments need to address constraints to the future development of biotechnology. The ways in which this is being done in the 10 review countries are discussed below.

### 4.1 Domestic Finance

A shortage of funding was cited as the main impediment to the development of agricultural biotechnology programs in all countries studied. Detailed estimates of current spending are difficult to obtain; but, in general, investment in biotechnology is only a small fraction of total R&D expenditure. The situation is often exacerbated by a lack of foreign currency, which hampers the import of new technology and laboratory supplies. The public sector constitutes the main source of funding. However, governments are also often subject to stringent austerity programs.

It should be noted that this constraint concerns agricultural research in general, not just biotechnology research. Given the financial problems in maintaining conventional agricultural research programs, it is often difficult for governments to support the high priority attached to the development of biotechnology with well-funded programs. For example, the allocation of funds through the Colombian national biotechnology program was reported to be very limited. Between October 1991 and December 1992, about US\$ 800,000 was spent through the program on 15 research projects. The program budget for 1993 is expected to amount to US\$ 2.8 million.

The two largest countries studied, China and India, have relatively well-funded biotechnology programs. It is estimated that the total amount spent by the Chinese government is on the order of US\$ 30 million per year, excluding personnel costs. The principal funding source for basic research is the Natural Science Foundation of China. Two other major funds, the High Technology Fund and the Five Year Plan biotechnology fund, support applied research. The annual budget of India's DBT is about US\$ 28 million. However, in both India and China, these budgets are spread over a large number of projects and institutes.

#### 4.1.1 Attracting External Finance

Additional funding for biotechnology research is often obtained from external sources and may constitute a large share of total funding. All countries under review have links with bilateral and multilateral donor agencies that support biotechnology activities (see also section 4.4.1). The Government of Indonesia, for instance, had several World Bank loans to support both the establishment of the Inter-University Centers (IUCs) and agricultural research in general. The current World Bank Agricultural Research Management Project includes a substantial component of support for agricultural biotechnology. In addition, several biotechnology facilities were built in Indonesia with support from the Japanese International Cooperation Agency (JICA). Additional support for the work at CRIFC on rice biotechnology is being provided through the Rockefeller Foundation's Rice Biotechnology Program.

CRIFC also takes part in a comprehensive collaborative project in Indonesia initiated by the Agricultural Biotechnology for Sustainable Productivity (ABSP) project that is sup-

ported by the United States Agency for International Development (USAID). The project involves several public and private institutions from Indonesia and the U.S.A.

The United Nations Development Programme (UNDP) was a major source of funds for starting biotechnology activities in Egypt. It committed US\$ 3.1 million to set up AGERI. USAID provides support to AGERI to continue its research program (see box 3), totaling about US\$ 1.8 million.

Current funding from the Government of the Netherlands to biotechnology projects in Zimbabwe (see box 5) amounts to about US\$ 1.5 million.

## **4.2 Human Resources**

Another constraint facing all countries studied is the shortage of personnel trained in modern biotechnology. Teaching programs in modern biotechnology are still scarce in most countries, and training in institutions abroad offers only a partial solution and is expensive.

### **4.2.1 Establishing Training Programs**

Secondment of staff from industrialized-country laboratories can be a useful way to initiate a training program. This approach has proved successful in Indonesia. The same approach has been adopted by the Biotechnology Institute of the National University of Colombia, where specialists from other Latin American countries play an important role in teaching short-term courses.

An elaborate training program has been set up in India by the DBT. One of its major components is the Postgraduate and Postdoctoral Teaching Programme, covering basic and applied biotechnology as well as biochemical engineering. The program is complemented by a range of short-term training courses and national and overseas scholarships. About 10% of the DBT's budget is devoted to grants for training.

In Zimbabwe, a biotechnology training program was launched at the University of Zimbabwe in 1991. The faculties of Agriculture and Science jointly offer an MSc biotechnology degree program. Financial support from the governments of Sweden and the Netherlands covers the costs of equipment, supplies, and visits of experts for advanced lectures (see box 5).

Human resource development is a strong element of bilateral and multilateral biotechnology programs and is also offered by many international research institutes (see section 4.4.1). Such services facilitate human resource development and the creation of national training programs.

## **4.3 Private-Sector Involvement**

The domestic private sector is making limited investments in biotechnology R&D in only a few of the review countries. This is a constraint on the conversion of research results into marketable products. Foreign private investment is also mostly absent, as opportunities for commercial activity are limited and strong local partners hard to identify. This is intensified by the perception that the protection of intellectual property rights is too weak. While some large pharmaceutical or food processing multinational companies have manufacturing facilities, they rely mainly on their parent companies to conduct R&D.

Of the 10 countries surveyed, only Colombia and India possess a dynamic national biotechnology-based industry. The Colombian private sector's efforts in this area concentrate on micropropagation for export commodities such as cut flowers, bananas, and coffee. Floriculture companies such as Floramerica — which has strong connections to the U.S. market — have well-equipped laboratories, but only limited local R&D programs. However, these companies have established links to public R&D. Floramerica, for example, collaborates with the Universidad Nacional on plant disease diagnostics.

The Indian biotechnology industry consists mainly of branches of large national enterprises, such as Hindustan Lever, the Southern Petro-Chemical Industries Corporation, and the Tata Group. Besides these, start-up companies are being established, mostly located in Hyderabad. They have strong tissue culture programs, but lack R&D capability.

#### **4.3.1 Stimulating Private-Sector Activity**

Although present government policy in most of the countries studied aims at encouraging the growth of private-sector activities, especially for biotechnology, there are generally no special financial regulations (e.g., preferred credit or tax incentives) to stimulate private-sector investment in biotechnology research. However, in China the government has launched the Torch Program to encourage the establishment of biotechnology enterprises through low-interest loans, tax abatements, and other incentives. A number of biotechnology production units have been set up under the program, mainly in the pharmaceutical sector.

In many of the review countries, government agencies have established mechanisms to promote the transfer of promising technologies from the public to the private sector. Special mechanisms to promote private-sector involvement have been introduced in Thailand and India. A Bioservice Unit, set up in 1992 as a joint operation of Thailand's NCGEB and the Department of Biochemistry of Mahidol University, is charged with coordinating linkages and transferring novel techniques among government institutions and the private sector (see box 7).

In collaboration with several financial and investment organizations, India's DBT established the Biotech Consortium India Ltd (BCIL) in 1991. BCIL's tasks are the identification and commercial application of technologies developed in public institutions. In addition, it provides information (e.g., directories and newsletters) and consultancy services (e.g., business plans). BCIL has already entered into collaborative arrangements with various organizations, mainly for the transfer of effluent treatment technology. It has also sponsored the setting up of two pilot plants for the mass production of biological pest control agents for agriculture.

Pilot-scale production facilities at public institutions can benefit private-sector involvement. In a new R&D area such as biotechnology, the private sector is attracted to new production processes only if they have clear commercial potential. This has proved particularly successful in the Philippines where the national institute BIOTECH is producing vaccines and biofertilizers, which are then marketed by private groups (see box 8).

Similar initiatives exist in Malaysia, China, and Colombia. The Biotechnology Center of the Malaysian Agricultural Research and Development Institute (MARDI) has a special Industrial Development Unit that supports the transfer of results from the laboratory to industry. The China National Center for Biotechnology Development (CNCBD) has invested heavily in the Shanghai Center for Biotechnology Development (SCBD), which will operate as a major center for technology transfer and has the capability of taking a project from



#### **Box 7. Thailand: Core facility for public and private institutes**

**To strengthen the infrastructure for biotechnology R&D, Thailand's National Center for Genetic Engineering and Biotechnology (NCGEB) and the Department of Biochemistry, Mahidol University, supported the setting up of the Bioservice Unit (BSU). It was established as a core facility to provide basic molecular services to researchers from both governmental and private organizations. The BSU currently provides the following instrumentation services:**

***DNA synthesizer.*** The rapid growth of genetic engineering in the past few years has resulted in an increasing demand for synthetic oligonucleotides. Few investigators working in this area have their own synthesizers and therefore have had to rely on overseas companies to obtain oligonucleotides which are expensive. The BSU currently provides custom-made oligonucleotides, analyzed for their quality prior to delivery.

***Fluorescence-activated cell sorter.*** This device can readily perform rapid cell analysis and immune monitoring.

***Capillary electrophoresis.*** With this separation technique, minute amounts of various types of molecules (proteins, peptides, amino acids, and DNA) can be rapidly analyzed.

basic research to the pilot-plant level. One of the objectives of the Biotechnology Institute at the National University of Colombia is to work with private or state-owned industries to promote the transfer of new technology to industry. Joint projects are underway with the Antioquia Banana Growers Union and the Colombian National Federation of Cotton Growers.

## **4.4 International Collaboration**

Collaboration with advanced institutions in foreign countries and with international organizations can supplement the financial resources available for national biotechnology R&D, facilitate access to modern technologies, and provide training opportunities. We do not attempt to summarize here the range of international collaborative arrangements in place in the 10 review countries. Rather, some examples of innovative programs are given in the following section.

### **4.4.1 Mechanisms of Cooperation**

Some bilateral development agencies have established comprehensive biotechnology programs that go well beyond the funding of individual research projects. For example, the special program, Biotechnology and Development Cooperation, of the Netherlands Ministry of Foreign Affairs not only funds research and training projects in its priority countries — Zimbabwe, Kenya, and Colombia — but also supports priority setting and policy making in these countries.

### Box 8. Philippines: Pilot-scale production at BIOTECH

The National Institute of Biotechnology and Applied Microbiology (BIOTECH) is the national center of excellence in biotechnology. It is mandated to develop technologies for goods and services that are cheaper alternatives to conventional products, safer for the environment, and make use of locally available materials. After more than a decade of research, BIOTECH has several technologies that are or will soon be available for dissemination and commercialization.

*Hemosep-WC*, a *Pasteurella* vaccine, protects ruminants like cattle, water buffalos, goats, and sheep against hemorrhagic septicemia and other forms of pneumonic pasteurellosis. The vaccine is produced at BIOTECH and marketed by the Biologics Corporation. A memorandum of agreement was signed between BIOTECH and the project group to produce the vaccine. Initial monthly production in 1991 was set at 25,000 doses. It increased to 100,000 doses per month in 1992 and monthly output in 1993 is projected to be 400,000 to 500,000 doses.

*Mycogroe* is a cheaper but effective alternative to chemical fertilizers for reforestation crops. It consists of *Ectomycorrhiza* in tablet or pellet form. *Ectomycorrhiza* is a naturally occurring soil fungus that maintains a symbiotic association with plant roots, inducing a better absorption of essential nutrients and water. Mycogroe is being marketed by the Los Baños Biotechnology Corporation.

•*Nitro Plus* is a biofertilizer for legumes. It contains *Rhizobium* bacteria, which enter into a symbiotic relationship with certain legumes, concurrently fixing nitrogen from the air. In this way, it is an effective and cheap substitute for chemical nitrogen fertilizer. Nitro Plus is currently produced and distributed by BIOTECH. Clients include Nestlé Philippines, soybean farmers under a national commercialization program, and pastoral land owners.

Another example of a comprehensive effort is the USAID-supported Agricultural Biotechnology for Sustainable Productivity (ABSP) project. ABSP seeks to link public and private U.S. institutions with partners in developing countries. It has established a research program at U.S. institutions, whereby genetic engineering methods are used to achieve pest resistance in food crops that are important in developing countries. Collaborative projects have been launched in Egypt, Kenya, and Indonesia. ABSP is strongly product-oriented, and complements research by analyzing the IPR- and biosafety-related aspects of research and marketing. Human resource development is an important facet of the project. Postdoctoral researchers from developing countries will spend one to three years in public and private U.S. institutions. Internships are being organized for short-term training in biosafety and intellectual property rights.

An important form of international collaboration on agricultural biotechnology research is the links between international agricultural research centers (IARCs) and national research systems. Compared with many national institutes, the IARCs have easy access to

modern techniques and up-to-date information on biotechnology. All IARCs offer specialized training programs. In this way, they provide research and training opportunities to scientists in several of the countries under review. For example, the Biotechnology Research Unit of the International Center for Tropical Agriculture (CIAT, Colombia) is a major source of technical advice for national research programs in Latin America. The presence of the International Rice Research Institute (IRRI) in the Philippines facilitates access to biotechnology for rice improvement in many Asian countries. IRRI is an active member of the Rockefeller Foundation's International Rice Biotechnology Program, together with national institutes including those in India, Indonesia, the Philippines, and Thailand. It is also organizing the Asian Rice Biotechnology Network, supported by the Asian Development Bank, to complement the activities of the Rockefeller program.

Institutes in countries with ongoing biotechnology programs can benefit from direct cooperation with advanced laboratories abroad. For instance, China established the China EC Biotechnology Center to strengthen collaboration between Chinese and European research institutes (see box 9).

Biotechnology research in India has benefitted from the establishment of the International Center for Genetic Engineering and Biotechnology (ICGEB New Delhi component). The Government of India made large commitments to its establishment, for buildings, laboratory equipment, and recurring costs. Benefits are derived from the collaborative research projects initiated by ICGEB and various Indian institutes in state-of-the-art agricultural and medical research. The ICGEB offers free training courses for member countries and can provide laboratory supplies upon request to affiliated research centers.

#### **Box 9. Bridging Europe and China: The China EC Biotechnology Center**

**The China EC Biotechnology Center (CEBC) was founded in 1991 to strengthen scientific cooperation in biotechnology between China and the European Community (EC). The CEBC is financed under the EC's International Scientific Cooperation program. Located at the China National Center for Biotechnology Development, CEBC has two basic tasks:**

- to function as an information-relay center;**
- to monitor the joint biotechnology projects conducted in China under the EC program on International Scientific Cooperation and the Life Sciences and Technologies for Developing Countries program.**

**Joint projects of Chinese and EC research institutions have been initiated in the areas of agriculture, energy, and health. For example, the John Innes Institute (U.K.) and the Shanghai Institute of Plant Physiology conduct collaborative research on the molecular analysis of synthetic pathways involved in product accumulation in legume seeds. In 1992, the CEBC organized a workshop on biological nitrogen fixation. A workshop on transgenic plants has been planned for 1993/94. The center publishes a quarterly journal in English, the *CEBC Newsletter*.**

#### 4.5 Access to Information

Access to up-to-date information on new developments in biotechnology was reported as a major constraint for scientists in the countries under review, except India. In the planning of biotechnology programs, ensuring timely access to information on new scientific and policy-related developments can help avoid duplication of work done elsewhere. However, agricultural library resources are limited in most developing countries. In Kenya, the number of journal subscriptions significantly decreased in the last decade, largely due to shortages of foreign exchange.

Scientific journals on biotechnology are particularly expensive. An interesting initiative in this respect is one by the Government of the Netherlands. It sponsors subscriptions to the abstract journal *AgBiotech News and Information*. About 150 documentation units of research institutions in developing countries receive copies of this journal through the project, which is part of the Netherlands' special program, Biotechnology and Development Cooperation.

India is attempting to improve access to information on biotechnology R&D. The country has a biotechnology information network sponsored by the Department of Biotechnology (see also table 1). There are plans to extend access to this network to other Asian countries through a new UNDP-supported biotechnology network.

Research networks and regional networks play a prominent role in formal (through journals, newsletters, data bases, and directories) and informal (through meetings and workshops) exchange of information. The Latin American Technical Cooperation Network on Plant Biotechnology, for instance, distributes a newsletter and computer data base of its affiliated laboratories. The Cassava Biotechnology Network (CBN), a project at CIAT financed by the Netherlands, recently launched the *CBN Newsletter*, including updates on current cassava biotechnology research, and organizes biannual scientific conferences.

Table 4. *Summary of Constraint-Related Facets per Country*

Country	CONSTRAINTS			
	Finance	Human Resources	Private Sector	International Collaboration
China	<ul style="list-style-type: none"> <li>total amount spent by government estimated at US\$ 30 million annually</li> <li>High Technology Fund</li> <li>Five-Year Plan Biotechnology Fund</li> </ul>	<ul style="list-style-type: none"> <li>Biotechnology Research Center (CAAS)</li> </ul>	<ul style="list-style-type: none"> <li>Torch Program</li> <li>SCBD</li> </ul>	<ul style="list-style-type: none"> <li>China EC Biotechnology Center</li> <li>Rockefeller Foundation Rice Biotechnology Program</li> </ul>
Colombia	<ul style="list-style-type: none"> <li>almost entirely government-funded, through ICA and public universities</li> <li>1993 budget about US\$ 2.8 million</li> </ul>	<ul style="list-style-type: none"> <li>short-term courses at Biotechnology Institute (UNC)</li> <li>universities</li> </ul>	<ul style="list-style-type: none"> <li>micropropagation companies in export crops</li> <li>limited R&amp;D facilities</li> </ul>	<ul style="list-style-type: none"> <li>CIAT</li> <li>participation in regional programs</li> </ul>
Egypt	<ul style="list-style-type: none"> <li>total government spending about US\$ 3 million annually</li> </ul>	<ul style="list-style-type: none"> <li>AGERI</li> <li>National Agricultural Research Program</li> <li>university programs in tissue culture</li> </ul>	<ul style="list-style-type: none"> <li>very limited involvement</li> </ul>	<ul style="list-style-type: none"> <li>large external support for agricultural research (UNDP, USAID)</li> </ul>
India	<ul style="list-style-type: none"> <li>DBT's annual budget about US\$ 28 million</li> </ul>	<ul style="list-style-type: none"> <li>MSc and PhD courses at IARI</li> <li>10% of DBT budget devoted to training</li> </ul>	<ul style="list-style-type: none"> <li>branches of large national enterprises</li> <li>start-up companies in tissue culture</li> <li>limited R&amp;D capability</li> <li>BCIL</li> </ul>	<ul style="list-style-type: none"> <li>ICGEB</li> <li>ICRISAT</li> <li>Rockefeller Foundation Rice Biotechnology Program</li> <li>many bilateral relations</li> </ul>
Indonesia	<ul style="list-style-type: none"> <li>large part of funding comes from outside sources</li> <li>IUCs financed by World Bank loan</li> </ul>	<ul style="list-style-type: none"> <li>IUC programs in training and post-graduate courses</li> </ul>	<ul style="list-style-type: none"> <li>little R&amp;D activity</li> <li>long tradition in fermentation</li> </ul>	<ul style="list-style-type: none"> <li>large financial support from abroad (e.g., JICA, USAID, World Bank)</li> <li>Rockefeller Foundation Rice Biotechnology Program</li> <li>Australia-ASEAN regional biotechnology program</li> </ul>

Table 4. *Summary of Constraint-Related Facets per Country* (continued)

Country	CONSTRAINTS			
	Finance	Human Resources	Private Sector	International Collaboration
Kenya	<ul style="list-style-type: none"> <li>large part from donor agencies</li> </ul>	<ul style="list-style-type: none"> <li>university programs</li> <li>IARCs</li> <li>overseas training</li> </ul>	<ul style="list-style-type: none"> <li>little involvement</li> </ul>	<ul style="list-style-type: none"> <li>IARCs (e.g., ILRAD)</li> <li>many donor-funded projects (Netherlands, USAID, U.K.)</li> <li>World Bank loan to KARI</li> </ul>
Malaysia	<ul style="list-style-type: none"> <li>infrastructure support for centers of excellence</li> </ul>	<ul style="list-style-type: none"> <li>university programs</li> <li>Biotechnology Center (MARDI)</li> </ul>	<ul style="list-style-type: none"> <li>plantation companies active in tissue culture</li> <li>pilot-scale facilities at MARDI</li> <li>food fermentation industry</li> </ul>	<ul style="list-style-type: none"> <li>institutional cooperation with advanced institutes abroad</li> </ul>
Philippines	<ul style="list-style-type: none"> <li>government support mainly through BIOTECH</li> </ul>	<ul style="list-style-type: none"> <li>BIOTECH</li> <li>university programs</li> </ul>	<ul style="list-style-type: none"> <li>fermentation industry</li> <li>pilot-scale facilities at BIOTECH</li> <li>BIOTECH products marketed by companies</li> </ul>	<ul style="list-style-type: none"> <li>IRRI</li> <li>several projects at BIOTECH funded by bilateral donor agencies</li> </ul>
Thailand	<ul style="list-style-type: none"> <li>biotechnology R&amp;D large proportion of overall national R&amp;D budget</li> <li>large part from external sources</li> </ul>	<ul style="list-style-type: none"> <li>well-established biotechnology education system at universities</li> </ul>	<ul style="list-style-type: none"> <li>some activity in micropropagation (floriculture)</li> <li>Bioservice Unit</li> </ul>	<ul style="list-style-type: none"> <li>Rockefeller Foundation Rice Biotechnology Program</li> <li>many donor-funded projects</li> <li>Australia-ASEAN regional biotechnology program</li> </ul>
Zimbabwe	<ul style="list-style-type: none"> <li>government funds for BRI</li> <li>current activity largely financed by donor agencies</li> </ul>	<ul style="list-style-type: none"> <li>MSc program at University of Zimbabwe</li> </ul>	<ul style="list-style-type: none"> <li>no involvement in research</li> </ul>	<ul style="list-style-type: none"> <li>important role of bilateral donors (Netherlands, Sweden)</li> </ul>



## 5. DISCUSSION

In the countries under review, the public sector is the major force in stimulating biotechnology research in agriculture and other areas. Many governments have formulated national programs and installed coordinating agencies. In all 10 countries, applications of biotechnology in agriculture are being driven by public-sector investments and government policies. The key factors influencing the use of biotechnology were found to be

- the institutional foundation and strategic framework provided;
- the regulatory framework;
- financial resources.

These factors are discussed below.

### *Institutional and strategic framework*

Different countries have taken different approaches to stimulating biotechnology. The institutional framework that is possible or desirable depends on the size of the country, the strength of its science and technology sector, and its existing research infrastructure. The following are key requirements for productively operating an agricultural biotechnology program:

- close collaboration between new biotechnology and conventional agricultural research (especially plant breeding) to ensure that new technologies are taken through to new techniques and their field application;
- minimal duplication of expensive equipment and services;
- an effective working environment for well-trained scientists and adequate financial resources.

The possible institutional arrangements include

- a national biotechnology agency to coordinate and fund biotechnology within existing institutions and to determine national policies (e.g., in China, India, Thailand);
- multiple centers of excellence (e.g., Indonesia and Malaysia);
- a new national biotechnology institute (e.g., Egypt and the Philippines).

Countries with a well-developed agricultural research base, such as China, India, and Thailand, have established national agencies to coordinate and finance biotechnology research in existing institutions. These agencies are also the main scientific and policy advisory bodies to the government. A major advantage of this approach is that the national agencies are able to fund biotechnology research in line with the priorities outlined in a national program. A disadvantage is a tendency to support too many projects spread over too many different institutes.

Combining the approach of establishing national coordinating and funding agencies with the multiple centers-of-excellence approach deserves consideration. Investments in additional research facilities, equipment, and human resources can be well targeted in this way, ensuring cost effectiveness. This approach has proved feasible in Indonesia and Malaysia.



A strong case can be made for creating a new central institute if this results in immediate opportunities for training and research in biotechnology. A central laboratory can service the needs of several institutes without the necessity of duplicating equipment and facilities at every institute with an interest in biotechnology. In addition, it can serve as a focal point for information dissemination, national coordination, collaboration between the public and private sectors, and international collaboration. However, if not accompanied by a program outlining national priorities, research in a central institute may become isolated. The multidisciplinary nature of biotechnology and the fact that it comprises a wide range of techniques make it difficult to assign this task to a single institute. Close working relationships with conventional agricultural research programs (such as plant breeding) are essential if research in modern biotechnology is to be taken through to application. Developing a network of centers of excellence on the basis of existing research institutions is, in principle, preferable to establishing a new central laboratory.

#### *Regulatory framework*

An important task for those who set public policy is to define an efficient regulatory framework for biotechnology. The two main areas here are biosafety and intellectual property.

Clear guidelines are needed to ensure the safe use of biotechnology. Most governments are now moving to establish flexible biosafety systems on the basis of internationally accepted guidelines and linked with existing national legislation.

The need to introduce legislation covering intellectual property protection for biotechnology inventions is under debate in many countries. Its effect on innovation in biotechnology research in developing countries is still not clear, warranting additional study. However, there is a trend in developing countries to strengthen intellectual property protection, partly as a result of bilateral negotiations and international trade negotiations within GATT.

Intellectual property management systems tailored to the needs of individual countries are required. The type of system required by a country such as China, with a large national research capacity, will be different from that needed in smaller countries with an interest in importing and using new technologies developed elsewhere.

#### *Financial arrangements*

Insufficient funding is a major constraint in most countries, resulting, most notably, in a lack of well-trained staff in most programs. Many countries suffer from domestic budget constraints. Others have large national budgets but have to support a vast number of projects. In addition, there is little private-sector involvement in biotechnology and insufficient international collaboration in either the public or private sector. This increases the need for careful planning and priority setting before embarking on ambitious programs.

External financing for biotechnology research is increasingly being provided by bilateral and multilateral donor agencies and development banks. This often comprises a large portion of the overall budget for stimulating biotechnology research in developing countries. However, this is no substitute for fostering local investment in biotechnology over the longer term.

To date, industry has been conspicuously absent from the biotechnology arena. It is, in effect, a missing link in commercializing and distributing the products of research. Its involvement is now being actively encouraged. Special mechanisms have been established in some countries to transfer promising technology from the public to the private sector. Many laboratories have established pilot-scale production facilities to demonstrate the feasibility of promising new processes. Finally, the proof of success of a particular approach to promoting biotechnology R&D will be in the products it generates and their usefulness in agriculture and the environment.



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## **ANNEX II: THE ISNAR/WORLD BANK BIOTECHNOLOGY COUNTRY DATA BASE**

Information from 18 country studies has been entered into a computer data base. This provides a consolidated set of data on the status of biotechnology in a particular country, which can be regularly updated. The division of the data base into nine qualitative and quantitative information areas allows for easy cross-country comparison of specific aspects of biotechnology policy and research.

The following information areas were selected according to the terms of reference of the country studies:

1. general country information;
2. government policy including information on national programs, public–sector research, public–private collaboration, human resources management, intellectual property rights, and biosafety;
3. private–sector activities;
4. international collaboration;
5. current applications in the following agricultural subsectors: plant production, plant protection, biofertilizers, animal production and health, diagnostics, and other applications;
6. specific data on national, bilateral, and multilateral programs;
7. institute profiles;
8. bibliographical data on key documents;
9. addresses of contact persons.

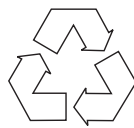
The data base software is a user-friendly package called Q&A which can handle large text fields as well as quantitative data. It combines this function with extensive reporting and word processing facilities. Q&A easily imports or exports data from or to almost any data base or word processing package.

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