Capacity Building in Biosafety of
GM Crops in Asia

Benchmark Document on the Needs and Present Status of the Capacity Building in Biosafety of GM Crops in Asia

FAO Regional Office for Asia and the Pacific
Bangkok

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BACK GROUND

‘Capacity Building in Biosafety of GM Crops in Asia’

The FAO Regional Office for Asia and the Pacific (FAO-RAP), which is implementing the above project assigned the undersigned the task of preparing a ‘Benchmark Document’ on the needs and present status of capacity building through critical comparison of strengths, weaknesses and gaps in the participating countries and the Region, in terms of their capacity building capability with regards to human resources, research and technology development infrastructure, regulations and policies for assessing and managing biosafety risks of GM crops.

In order to obtain base information from the participating countries a detailed questionnaire was prepared, in consultation with Dr. Ginna Geal of the Project Secretariat in Bangkok and Dr. Andrea Sonnino, FAO-SDRR, and sent to the focal points in the participating countries. The responses received from the focal points formed the basis of findings presented in this document. In addition the information retrieved from the following documents, kindly provided by FAO-RAP and FAO-SDRR, was also very useful in preparing the Document.

1. Proceedings of the FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific, March 21-23, 2002, FAO Regional Office for Asia and the Pacific and Asia-Pacific Association of Agricultural Research Institution, Bangkok, Thailand.
2. Proceedings of the First Regional Consultation on Capacity Building in Biosafety of GM crops in Asia, Bangkok, Thailand, 7-10 July 2003, GCP/RAS/185/JPN Doc No. 2, 2003, FAO Regional Office for Asia and the

Pacific and Asia-Pacific Association of Agricultural Research Institution, Bangkok, Thailand.

3. UNEP-GEF Project on Development of National Biosafety Frameworks
4. Country Information in FAO BioDec

The draft document was submitted on February 19, 2004, and discussed and validated at the 2nd Regional Meeting of the Focal Points at Bangkok on March 11 and 12, 2004. The meeting in Bangkok was attended by the Focal Points of all the ten Participating Countries.. Valuable inputs were also provided by Dr. Susumu Kawabe, Dr. Nobuyuki Kabaki, and Dr. Ginna Geal in finalizing this Document.

I warmly thank Dr. Andrea Sonnino, Dr. S. Kawabe, Dr. N. Kabaki, Dr. Ginna Geal and the Focal Points for their valuable help and inputs in the preparation of this document.

May 18, 2004 Anupam Varma

Acronyms and Abbreviations

AARD:	Agency of Agricultural Research and Development
AFMA:	Agriculture and Fisheries Modernization Act
AIA:	Advance Information Agreement
BCABE:	Biosafety Committee on Agricultural Biological Engineering
BCC:	Biotechnology Cooperating Centre
BIOTECH-UPLB:	National Institute of Molecular Biology and Biotechnology, University of the Philippines, Los Banos
BIOTEK:	National Biotechnology Directorate
CBD:	Convention on Biological Diversity
CEMB:	Centre for Excellence in Molecular Biology
CPB:	Cartagena Protocol on Biosafety
CSA:	Chinese Science Academy
CSIR:	Council of Scientific and Industrial Research
DBT:	Department of Biotechnology
DST:	Department of Science and Technology
DAE:	Department of Atomic Energy
DLC:	District Level Committee
ECB:	Expert Committee of Biotechnologists
EPA:	Environment Protection Act
GEAC:	Genetic Engineering Approval Committee
GEF:	Global Environment Facility
GMAC:	Genetic Modification Advisory Committee
GMO:	Genetically Modified Organism
IBC:	Institutional Biosafety Committee
ICAR:	Indian Council of Agricultural Research
ICCP:	Intergovernmental Committee for the Cartagena Protocol on Biosafety
ICMR:	Indian Council of Medical Research
IRRI:	International Rice Research Institute
ITPGR:	International Treaty on Plant Genetic Resources for Food and Agriculture
LMO:	Living Modified Organism
MARD:	Ministry of Agriculture and Rural Development
MAS:	Marker Aided Selection
MoA:	Ministry of Agriculture
MoC:	Ministry of Construction
MoE:	Ministry of Environment
MoEF:	Ministry of Environment and Forestry
MoFAL:	Ministry of Food, Agriculture and Livestock
MoPH:	Ministry of Public Health
MoST:	Ministry of Science and Technology

MoSTE:	Ministry of Science, Technology and Environment
MoSTR:	Ministry of Science and Technology Research
NAFDC:	National Agency for Food and Drug Control
NBC:	National Biosafety Committee
NBFSC:	National Biosafety & Food Safety Committee
NCBED:	National Centre of Biological Engineering Development
NGO:	Non-Governmental Organization
NIBGE:	National Institute of Biotechnology and Genetic Engineering
OEGESA:	Office of Agricultural Genetic Engineering Safety Administration
PCSD:	Philippines Council on Sustainable Development
RARM:	Risk Assessment and Risk Management
RCGM:	Review Committee on Genetic Manipulation
RDAC:	Recombinant DNA Advisory Committee
SBCC:	State Biotechnology Coordination Committee
SEPA:	State Environment Protection Administration
SIQA:	State Inspection and Quarantine Administration
SPS:	Sanitary and Phytosanitary Agreement of WTO
TRIPS:	Trade Related Aspects of Intellectual Property Rights
UNEP:	United Nations Environment Programme
UPLB:	University of Philippines, Los Banos

1. INTRODUCTION

Asia and the Pacific, the seat of some of the worlds oldest cultures, has the distinction of being the most populated region, housing nearly 60% of the world's population, which depends largely on agriculture for livelihood. Since the late sixties, this region has witnessed unprecedented gains in agricultural production, popularly known as the 'Green Revolution', brought about by the introduction of high yielding varieties and improved agronomic practices supported by proactive government policies. It is a fallacy, that in spite of the accelerated growth in agricultural production hunger is rampant in the region with nearly 540 million people going to bed hungry and nearly 200 million children malnourished leading to stunted growth. Moreover, the gains of the Green Revolution have waned. With constantly increasing population and dwindling natural resources - particularly arable land, application of modern developments in molecular biology and biotechnology for achieving sustained growth in agricultural production for ever-green revolution is imperative.

Modern biotechnology has provided hope for not only improving farm productivity but also their quality and processability. Thus making agricultural production more efficient and cost effective. There is, however, a caution. The products of modern biotechnology, especially the genetically modified organisms (GMOs), must be handled with great care to avoid potential risk to human, animal and plant health, and environment. To address the major concerns (Box 1.1), Parties to the Convention on Biological Diversity (CBD) developed a protocol on biosafety – the Cartagena Protocol on Biosafety (CPB) adopted in January 2000

at Montreal. For the effective implementation of the Protocol each country, as a Party to the Protocol, needs to develop adequate human resource and institutional capacity.

Box 1.1: The major concerns in the use of GMOs

- Unintentional introduction of allergens and other anti-nutritional factors in foods.
- Unintentional gene flow: the chance of transgene escaping from GM crops to
  - wild relatives which may become super-weeds
  - Related cultivated species
  - Non-transgenic crops of the same species
- Development of resistance in target pests to the toxins produced by GM crops
- Emergence of new pests (like viruses)
- Adverse effect on non-target organisms
- Transgenic plants may turn weedy

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Aware of the potential of agricultural biotechnology for sustainable development, various countries of the region have launched research and development programmes related to biotechnology, including GMOs. For successful utilization of GMOs and their products the countries need to put in place efficient scientific, institutional and regulatory mechanisms to protect human, animal and plant health, environment and biodiversity as envisaged in CBD and CPB. Harmonization of the regulatory measures is also essential for promoting trans-boundary movement of agricultural goods in the region. To meet this overall objective, the United Nations' Food and Agricultural Organization (FAO) has launched a project, funded by the Government of Japan, on "Capacity

Building in Biosafety of GM Crops in Asia" with the following objectives and expected outputs.

1.1 Objectives

- Strengthening of national capacities in participating countries for the development of human resources, research and technology, legislation, regulations, policies and programmes for biosafety. This includes the assessment and management of potential risks associated with GM crops. GM crops are here to stay as these will create high-value jobs and lead to economic empowerment of the farmers.
- Establishment of an Asian Network on Biotechnology (*Asian Bio-Net)* that will bring together public and private sector institutions and stakeholders for harmonizing biosafety assessment and management standards, guidelines, measures and methodologies. This will be done in compliance with existing international agreements and arrangements for the sharing of information on GM crop-related biosafety experiments at the regional and country level. This will also promote the inter-country exchange and sharing of information, expertise and GM crops.
- Supporting and promoting GM crop research and technology development.

1.2 Expected Outputs

- Development of human resources, research and technology, infrastructure, regulations and policies on biosafety.
- Trained human resources for researching, analyzing and managing potential risks associated with GM crops. This will facilitate transparent, science-based and

objective regulatory and policy decisions and harmonized biosafety regulations regarding the development, trade and commercialization of GM crops.

- Identification of the relative strengths, weaknesses and gaps in participating countries and the region as a whole for meeting the above objective.
- Establishment of the Asian Bio-Net to provide a forum for sustained regulatory collaboration among Asian countries for the safe and judicious use of modern biotechnology.
- Development of national policies on regulation of GM crops in the context of agriculture and trade policies, and consistent with agreed international standards.
- Support for research and technology development for the assessment and management of risks related to GM crops.

The countries which are participating in this initiative are: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand and Viet Nam.

In this 'Benchmark Document', present status and needs of the capacity building for biosafety of GM crops in Asia are presented in the light of strengths, weaknesses and gaps in participating countries and the region as a whole.

2. OVERVIEW

2.1 Convention on Biological Diversity and Cartagena Protocol on Biosafety

The Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety (CPB) are aimed at minimizing the potential risk to human health and environment from the handling and transfer of Living Modified Organisms (LMOs) produced through modern biotechnology; in this document LMOs are referred as Genetically Modified Organisms (GMOs). Biosafety issues related to GMOs have been identified as a major concern both, in the countries with economies in transition and the countries with sound economies. A national biosafety system to regulate production and release of GMOs is essential in all countries promoting modern biotechnology. The regulatory measures, however, require global harmonization. The CBD, which was negotiated under the United Nations Environment Programme (UNEP) and adopted in May 1992, provides an important base in this direction. The CBD was put up for signature at the Earth Summit in Rio de Janeiro, Brazil on June 5, 1992 and it entered into force on December 29, 1993. The Articles 8(g), 19.3 and 19.4 of CBD (Box 1) deal with issues related to biosafety.

The conference of parties of CBD established an ad hoc working group to develop protocols on biosafety to address various biosafety concerns. After intense negotiations between July 1996 and February 1999, The working Group on Biosafety developed the CPB (Annexure I) which was adopted on January 29, 2000. The CPB has been signed by 110 countries and has entered into force since September 11, 2003. Among the countries party to this project the CPB has been signed by six countries (Table 2.1).

Box 2.1: CBD Articles addressing biosafety issues

Article 8 (g): Each contracting party shall, as far as possible and as appropriate establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Article 19.3: The parties shall consider the need for and modalities of a Protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

Article 19.4 Each contracting party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in Article 19.3 above, provide any available information about the use and safety regulations required by that contracting party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the contracting party into which those organisms are to be introduced

The CPB aims to ensuring an adequate level of protection through safe transfer, handling and use GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human, animal and plant health, and specifically focusing on trans-boundary movements. The Protocol establishes an Advance Informed Agreement (AIA) procedure for ensuring that the countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. It also provides a precautionary principles reaffirming principle 15 of the Rio Declaration on Environment and Development, which a government may use to bar import of a transgenic product even in the absence of conclusive evidence that the

product is not safe. This, however, does not override other international agreements, including WTO, which require that import decisions be 'science based'. The Protocol also provides for establishment of a biosafety clearing-house to facilitate the exchange of information on GMOs and to assist countries in the implementation of the Protocol.

Capacity building is a key component of CPB (Article 22). It envisages the following:

- Cooperation amongst the parties in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology required for biosafety.
- Cooperation in capacity-building to include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety.
- The needs of developing country Parties with economies in transition shall be taken fully into account for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the convention.

The CBD recognizes (Article 16, 18 and 19) that technology transfer and cooperation is important for meeting its objectives. Article 16 of the CBD provides for transfer of technologies relevant to the conservation and sustainable use of biological diversity in developing countries on fair and most favorable terms, including on concessional and preferential terms where mutually agreed. A wide range of technologies are relevant for the attainment of CBDs objectives. The technologies required for *ex situ* conservation (such as tissue culture, cryogenic preservation, etc.) are mostly available off the shelf under public domain. However, it is not so in the case of biotechnologies

which may contribute to sustainable agricultural development. Such technologies are proprietary in nature as most of the biotechnologies are protected by patents. Thus, unlike the situation in the past when agricultural research was mainly in the domain of the public sector, now the multi national companies dominate the research and commercial activities related to biotechnology and its application in agriculture, making transfer of new technologies to the developing countries difficult. This, however, highlights the need to build capacity of developing countries not only to assimilate and use such technologies but also to address related biosafety issues. Therefore, capacity building at national level is of paramount importance. Capacity building is specifically required in the following areas to enhance the national capabilities in implementing CPB.

- Strengthening the legislative framework and operational mechanisms for biosafety management.
- Development and improvement in capacity for risk assessment and monitoring.
- Establishment of a biosafety database and biosafety clearing house mechanism.
- Development of centres of excellence and a network for research, risk assessment, and monitoring.

3. PRESENT STATUS OF CAPACITY BUILDING IN PARTICIPATING COUNTIRES

The present status of capacity for risk assessment and risk management (RARM) of biosafety in the participating countries, determined on the basis of presentations made by experts from these countries in (a) FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific[1], (b) First Regional Consultation on Capacity Building[2], (c) the responses received from the focal points[3] in participating countries, and (d) some other connected publications, is briefly presented here:

3.1 Bangladesh

In Bangladesh, which is endowed with diverse terrestrial and aquatic flora and fauna, 9.1 million ha area is used for agriculture. Biological diversity in Bangladesh is threatened by population pressure leading to over exploitation of natural resources, natural calamities like cyclones and floods and agricultural practices like shifting cultivation. Being a member of CBD, Bangladesh has developed biodiversity related programmes, but and has assigned biotechnology a low priority. In the absence of a national policy for utilizing biotechnological advancements, biotechnology in Bangladesh is at an introductory stage. It is largely confined to standardization of tissue culture protocols, micropropagation of different groups of plants, embryo transfer for cattle improvement, and molecular characterization of plants. Use of modern molecular biology

[1] Proceeding of the FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific, March 21-23, 2002, FAO Regional Office for Asia and the Pacific and Asia-Pacific Association of Agricultural Research Institution, Bangkok, Thailand. Pp 91

[2] Proceedings of the First Regional Consultation on Capacity Building in Biosafety of GM crops in Asia, Bangkok, Thailand 7-10 July 2003, GCP/RAS/185/JPN, FAO of the United Nations, pp 41.

[3] Annexure III: Focal Points

and biotechnology, like gene isolation, cloning, expression and characterization, and development of DNA-recombinant vaccines, etc., is rudimentary. Application of biotechnology in fisheries and livestock sectors is even less significant.

3.1.1 Infrastructure

Several public and private sector institutions (Table-3.1) have taken up biotechnology related programmes, but they lack trained human resource as well as the infrastructure essential for up stream biotechnological research. Apart from the constraints , lack of regulatory procedures and financial support have slowed application of biotechnology.

Table 3.1: Institutions engaged in biotechnology research and development in Bangladesh

Sl No.	**Institute**	**Infrastructure (adequate/inadequate)**	**Biosafety committee in position**	**Number of Scientists engaged in biotechnology research**			**Areas of Biotechnology research**
				Ph. D from your country	Ph. D. from other country	M.Sc	
1.	Bangladesh Agricultural Research Institute, (BARI), Gazipur	Inadequate	X	1	4	9	Tissue Culture, Anther culture
2.	Bangladesh Rice Research Institute (BRRI), Gazipur	Inadequate	X		4	2	Tissue Culture, DNA finger printing
3.	Bangladesh Jute Research Institute (BJRI), Dhaka	Inadequate	X		2	1	Regeneration system of jute
4.	Bangladesh Sugarcane Research Institute (BSRI), Ishurdi, Pubna	Inadequate	X		1	1	Tissue culture, Anther culture
5.	Bangladesh Institute of Nuclear Agriculture (BINA), Mymensingh	Inadequate	X		2	4	Tissue culture
6.	Bangladesh Forest Research Institute (BFRI), Chittagong	Inadequate	X		1	2	Tissue culture
7.	Bangladesh Livestock Research Institute (BLRI), Dhaka	Inadequate	X		4	10	Vaccine production, embryo transfer
8.	Bangladesh Fisheries Research Institute (BFRI), Mymensingh	Inadequate	X	3	2		Embryo rescue
9.	National Institute of Biotechnology (NIB), Dhaka	Inadequate					
10.	Bangladesh Council for Scientific and Industrial Research (BCSIR), Dhaka	Inadequate		2	5		Tissue culture
11	Bangladesh Agricultural University, Mymensingh	Inadequate	X	7	6		Tissue culture, Molecular characterization

12.	Dhaka University	Inadequate	X	8	4		Tissue culture, molecular characterization
13	JahangirNagar University	Inadequate		1	1		Tissue culture
14	Chittagong University	Inadequate		2	1		Tissue culture
15	Khulna University	Inadequate		3	4		Tissue culture
15.	Rajshahi University (RU)	Inadequate	X	6	4		Tissue culture
16.	Bangladesh Rural Advancement Committee	Inadequate		2	1		Tissue culture
17.	Biotech Seeds, Rajshahi Private Enterprise	Inadequate					Tissue culture

3.1.2 Biosafety and Regulatory Framework

Bangladesh is a party to CBD, CPB, ITPGR and TRIPS. Biotechnology related activities in Bangladesh are largely confined to areas like tissue culture, which do not require biosafety clearance. However, Bangladesh has developed Biosafety Guidelines and recently a National Technical Committee on Biosafety has also been formed, but the guidelines, organizational structure as well as the composition of various committees need to be revised, in the light of latest developments, to safeguard the interests of the country, particularly in relation to biosafety of GMOs.

The country does not have in place mechanism for regulating import, field evaluation and monitoring of GMOs. A Biosafety Acts is being prepared. The country also plans to establish a National Authority to deal with various aspects of Biosafety. Bangladesh is a signatory to SPS Agreement of WTO, but the National Plant Quarantine Unit is not adequately equipped to check inadvertent introduction of GMOs and hazardous organisms. The country does not have any institutional mechanism for public deliberations of biosafety related issues. At present patent law does not cover biotechnology inventions. The country is preparing Plant Variety and Farmers' Rights Protection Act. Currently, legislations dealing with Intellectual Property Rights and

Biodiversity and Community Knowledge Protection are lacking. Mechanisms for documentation and database development related to GMOs as well as bio-resources are also not existing. The country does not have any regulation regarding the use of GMOs as food.

3.1.3 Requirements for capacity building

Bangladesh has to build capacity for biosafety through trained human resource, development of appropriate infrastructure suitable for developing GMOs and also for RARM, formulating and implementing regulatory mechanisms, developing policies with regards to GMOs, establishing administrative machinery for regulating GMOs, and providing adequate funding for biosafety related programmes. Active participation in the regional cooperation programme will be useful for quick capacity building.

3.2 China

China has given high priority to agricultural biotechnology[4],[5]. Biotechnology related R & D activity is directed to transform agriculture in China through basic and applied research and development of linkage between research institutions and the government. Greater attention is directed for conservation and sustainable use of biodiversity and safety of GMOs.

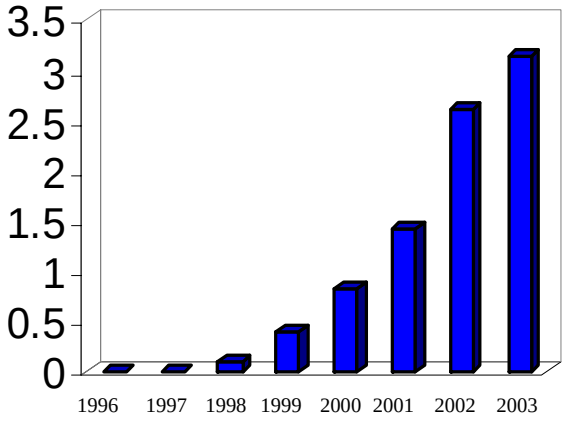
China is a party to the CBD, but it is awaiting ratification of the Cartagena Protocol. For implementing CBD, China Biodiversity Conservation Action Plan has been developed and the country has also published National Biosafety Framework. In 1993 a National Coordinating Group for implementation of CBD was formed. It is composed of 20 departments including Ministry of Environment (MoE), Ministry of Science and

[4] IUCN Capacity building Initiative, National Biodiversity Programme, Asia, China
[5] Huang, J. 2003. Agricultural Biotechnology Development, Policy and Impacts in China. FAO Report

Technology (MoST), Ministry of Agriculture (MoA), Chinese Science Academy (CSA), State Environmental Protection Administration (SEPA), and Ministry of Construction (MoC). Functioning of such a large and diverse group must be a difficult task.

Over one hundred R&D institutions in China are engaged in biotechnology. Many of these institutions are developing transgenic plants with traits like herbicide-, insect- and virus resistance, and quality (nutrient improvement)[6]. A wide variety of genes are being used for developing transgenic crops for various traits (Table-3.2.1). China was the first country in Asia to introduce commercial production of GM crops. A large number of transgenic crops have been approved for field trials, and some (cotton, green pepper, petunia and tomato) are grown commercially (Table-3.2.2). The area under GM crops in China is growing at a fast rate (Fig. 3.2.1). In 2001, nearly 1.4 million ha area was under GM crops.

Fig 3.2.1 Growth of area under transgenic crops in China (million hectares)



The country is also developing transgenic animals (mouse, rabbit, goat, chicken, cattle and pig) and fish; these are at experimental stage. In an attempt to improve efficiency of nitrogen fixation and biocontrol of diseases and insect pests, transgenic

[6] Huang, J. 2003. Agricultural Biotechnology Development, Policy and Impacts in China. FAO Report

microbes have been developed. GM bacteria and rhizobia, with improved nitrogen fixing ability, have been approved for field release.

Table 3.2.1: Genes that are being used in plant genetic transformation

Modified traits	Gene conferring the trait
Virus-resistance	TMV-cp, TMV-rep, CMV-cp, PVX-cp, PVY-cp,RSV-cp, BYDV-cp, BYDY-rep, MDMV-cp, TuMV-cp
Fungal Disease-resistance	Cecropin B, Shiva A, Lysozyme gene, Xa21, Chitinase, Glucanase
Insect- resistance	Truncated cryIA(b), synthetic CryIA(b), CpTI, Pin2, GNA, AHPI
Herbicide-resistance	Bar, tfd A, psb A
Others	Pro A, BADH, mtl D, gut D, barnase, anti-sense ACC, anti-sense PG

Table 3.2.2: Development of transgenic plants in China[7]

Crops	Trait	Status
Barley	-	Experimental
Carrot	Mycobacterium protein	Experimental
Chilli	Virus (CMV, TMV) resistance	Field trial
Chinese cabbage	Virus (TuMV) resistance	Field trial
Cotton	Insect (Lepidoptera) resistance (Bt and CpT1)	Commercial
	Aphid resistance	Field trial
	Fungal (*Verticillium* and *Fusarium*) resistance	Field trial
Green pepper	Virus resistance	Commercial
Groundnut	Virus (PStV)	Field trial
Maize	?	Experimental
	Salt tolerance	Experimental
	High lysine	Field trial
	Insect (borer) resistance	Field trial
Melon	Virus (CMV) resistance	Field trial
Oilseed rape	?	Experimental
Papaya	Virus (PRSV) resistance	Field trial
	Delayed fruit ripening	Experimental
Petunia	Flower colour	Commercial
Populus	Insect (Gypsy moth) resistance	Field trial
	?	Experimental

[7] IUCN Capacity building Initiative, National Biodiversity Programme, Asia, China

Potato	Wilt (bacterial) resistance	Field trial
	Wilt and virus (PVY) resistance	Field trial
	Virus (PVY) resistance	Field trial
Rice	Stem and yellow borer	Field trial
	Salt tolerance	Field trial
	Multiple traits	Field trial
	Blight and virus (RDV) resistance	Field trial
	Virus (RDV) resistance	Field trial
	Plant hopper resistance	?
	Drought	?
Sorghum	Salt	Experimental
Soybean	Soybean moth resistance	?
	?	Field trial
Sugar beet	Abiotic stresses	Experimental
Sweet pepper	Virus (CMV) resistance	Field trial
Tobacco	Virus resistance	Field trial
	?	?
Tomato	Virus (?) resistance	Commercial
	Virus (CMV) resistance	Commercial
	Long shelf life	Commercial
	Cold tolerance	Field trial
Wheat	Wilt (bacterial) resistance	Experimental
	Virus (YMV) resistance	Experimental
	Virus (BYDV) resistance	Experimental

3.2.1 Infrastructure

Most of the biotechnology research including development of GMOs is conducted in 20 leading institutions of the country (Table 3.2.3), which employ 80% of the trained workforce, 85% of research expenditure and 90% of research output.

Table 3.2.3: National key laboratories engaged in biotechnology research in China [8]

S No.	Institute
1.	National Key Lab of Agricultural Biotechnology, China Agricultural University
2.	National Key Lab of Crop Genetic Improvement, Central China Agricultural University
3.	National Key Lab of Tropical Crop Biotechnology, Institute of Plant Protection, CAAS
4.	National Key Lab of Tropical Crop Biotechnology, Institute of Tropical Crops, CATA
5.	National Key Lab of Veterinary Biotechnology, Haerbin Veterinary Institute, CAAS

[8] Huang, J. 2003. Agricultural Biotechnology Development, Policy and Impacts in China. FAO Report

6.	National Key Lab of Freshwater Fish Germplasm and Biotechnology, Changjiang Aquatic Product Institute, CARi
7.	National Key Lab of Membrane Biology & Engineering, Institute of Zoology, CAS, Peking University Qinhua University
8.	National Key Lab of Biochemistry Engineering, Institute of Chemistry and Metallurgy, CAS
9.	National Key Lab of Enzyme Engineering, Jilin University
10.	National Key Lab of Protein & Plant Gentic Engineering, Peking University
11.	National Key Lab of Genetic Engineering, Fudan University
12.	National Key Lab of Plant Molecular Genetics, Institute of Plant Physiology, CAS
13.	National Key Lab of Plant Cell and Chromosome Engineering, Institute of Genetics, CAS
14.	National Key Lab of Fresh Water Ecology and Biotechnology, Institute of Aquatic Biology, CAS
15.	National Key Lab of Molecular Biology, Institute of Biochemistry, CAS
16.	National Key Lab of Preliminary Development of Microorganism Resources, Institute of Microbiology, CAS
17.	National Key Lab of Biological Control, Zhongshan University
18.	National Key Lab of Drought Agro-ecology, Lanzhou University
19.	National Key Lab of Bioreactor, Huadong Science & Technology University
20.	National Key Lab of Microbial Biotechnology, Shandong University

The total number of scientist engaged in biotechnology research in China was more than 1200 in 1999, which forms one of the largest trained work force in the world engaged in biotechnology research. China's total investment in biotechnology research in 1999 was estimated to be around US $ 112 million.

3.2.2 Biosafety and Regulatory Framework

The country has issued several administrative regulations (Table 3.2.4) to manage research, development, environmental release and commercialization of GMOs. The latest effective regulation is that of 2001 (Table 3.2.4).

The Safety Administration Regulation on Agricultural GMOs, established the following management system

1. A joint meeting system, composed of officials from MoA, MoST, SEPA, Ministry of Public Health (MoPH), State Inspection and Quarantine Administration (SIQA), and other related departments. The leading Ministry is MoA.
2. Determination of safety level, on a four point scale, of GMOs.
3. Establishment of Safety assessment system of Agricultural GMOs.
4. System of labeling of GMOs (see Box. 3.1).

Table 3.2.4: Administrative regulations for managing GMOs in China

Regulation	**Year**	**Issued by**
"Safety Administration Regulation on Genetic Engineering"	1993	State Science and Technology Commission
"Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering	1996	MoA
"Safety Administration Implementation Regulation on Tobacco genetic Engineering"	1998	State Tobacco Monopolistic Administration
"Regulation on Approval of New Biological Products",	1999	State Drug Administration
"Safety Administration Regulation on Agricultural GMOs"	2001	State Council of China

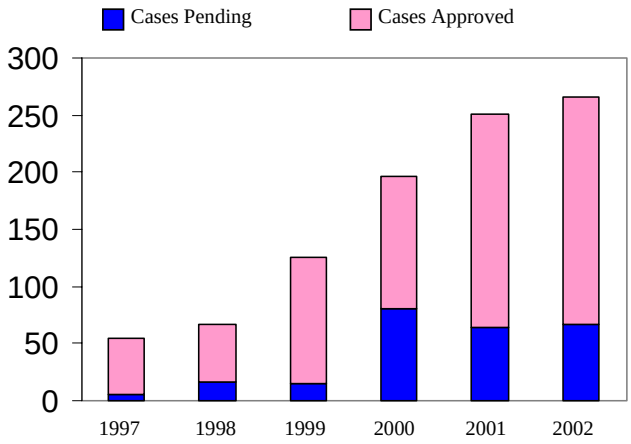
MoST is responsible for research and technology development on biosafety at the national level[910]. The focal point for biosafety protocol is SEPA, through its 'Biosafety Office'. A new division of biosafety management has also been set up at the National Centre of Biological Engineering Development (NCBED). It has the responsibility of new regulations, academic exchange and coordination. MoST is incharge of formulation and implementation biosafety regulations for agricultural biotechnology within MoA, The Office of Agricultural Genetic Engineering Safety Administration (OEGESA) is responsible for implementation of biosafety regulations. A Biosafety Committee on Agricultural Biological Engineering (BCABE), consisting of 58 professional experts as members representing various disciplines and ministries, is responsible for safety assessment and consultation of experimental research, field trials, environmental release and commercialization of GMOs. The cases being approved by the BCABE are gradually increasing (Fig 3.2.2)A 'Biosafety law' is being framed, which will cover all aspects of biosafety, including GMO, invasive alien species, cloning and genetic resources protection.

Box 3.1: Labeling of GMOs and GM products in China

- Genetically modified X X
- Genetically modified X X product (finished product) or Processed with genetically modified X X as raw material
- This product is made from genetically modified X X but no longer contains genetically modified ingredients or The raw materials of this product contains genetically modified X X, but the product itself no longer contains genetically modified ingredients.

[9] IUCN Capacity building Initiative, National Biodiversity Programme, Asia, China
[10] Huang, J. 2003. Agricultural Biotechnology Development, Policy and Impacts in China. FAO Report

Fig. 3.2.2: Cases considered by the BCABE for environmental release of GMOs



Each institute has a biosafety management group. Biosafety management system at the provincial and county levels is also envisaged. There will be 31 biosafety committees and offices at provincial level. This would require enormous resources for capacity building.

3.2.2.1 Biosafety regulations for RARM

The first biosafety regulations were framed by MoST in 1993 to promote R&D of biotechnology in China. The related ministries were asked to frame regulations corresponding to their work, only the MoA framed the regulations. In May 2001, the State Council developed the Safety Administration Regulation on agricultural GMOs. Thereafter, the MoA issued the following detailed rules for implementation in March 2002.

1. Management Rule on the Safety Assessment of Agricultural GMOs.
2. Management Rule on the Safety of Import of Agricultural GMOs.
3. Management Rule on the Labeling of Agricultural GMOs.

These guidelines include important changes covering extra production trial before commercialization, processing of GM food, labeling for marketing, export and import of GMO products, local and provincial level monitoring, and regulating responsibilities. Although China has established biosafety regulations, problems related to monitoring system are weak.

Some attention is also being given to research related to risk assessment through special funding (by MoST, SEPA, MoA, CSA and National Science Foundation of China) of relevant institutes and universities. Researches are directed to study impact on environment, gene flow, and development of models to predict potential effect on environment and formulation of strategies for their management. Special training programme on these aspects would help in building expertise to undertake research on such biosafety related issues.

A 'web-site of biosafety information in China' has been developed to meet the obligation of clearing-house under article 20 of the Cartagena Protocol on Biosafety'. The site requires improvement by making it more interactive and multilingual particularly in the context of present programme.

3.2.3. Capacity Building

Under various programmes, of 'Biosafety Office' of MOA, China organized more than 30 workshops, attended by officials and scientists from China and other countries, covering the following broad areas:

- Policy in R&D
- Policy in Safety Management and Trade
- Advances in biotechnology

- Principles, procedures and methodology for risk assessment and management of GMOs.
- Biosafety legislation and implementation
- Capacity building on legislation and technical guidelines.
- Environment Protection.
- Capacity building is also required in relation to IPRs, particularly for human capacity development and financial resources to manage issues related to IPR, particularly in relation to complexity and number

Overall, China has the largest biotechnology programme supported by the public sector in Asia. It has developed capacity in the following area for the risk assessment and management of GMOs.

- Legislation
- Technical guidelines
- Risk assessment
    - Infrastructure
    - Trained human resource in various disciplines like molecular biology, population genetics, ecology, taxonomy, microbiology, virology, botany, zoology, entomology, pathology, biochemistry etc.
- Basic research on development of parameters for risk assessment
- Database development and management

But all these areas need further strengthening and improvements. Apart from these the country has to build capacity for developing methodologies for monitoring of environmental impact of GMOs and development of technologies for prediction through

computer modeling and management of adverse effect of GMOs on environment. The country also requires training of managers and professionals dealing with regulatory measures, and for developing information clearing house for effective exchange of information.

3.2.4 Public Awareness

Public awareness about biosafety of GMOs is created through print media, TV and radio highlighting socio-economic and environmental issues including potential risk of GMOs. However, in China NGOs are less effective compared to some other countries of the region.

3.3 India

In India, biotechnology has been recognized as an important tool for socio-economic development since 1982, when the country established a National Biotechnology Board. In 1986, a separate Department of Biotechnology (DBT) was established to deal with all matters connected to biotechnology research and application. Apart from DBT, biotechnology research in the country is also supported by Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Department of Atomic Energy (DAE), University Grants Commission and Private Sector Organizations.

National environment policy strives to achieve a balance between development and conservation. Recognizing the need for having a strong regulatory mechanism, to minimize the potential risks to the environment that can be caused by GMOs, the

Government of India notified rules and regulations in 1989, under the Environment (Protection) Act, 1986, for the manufacture, use/import/export and storage of hazardous micro-organisms/genetically engineered organisms or cells for governing such biotechnology products. These have been supplemented by guidelines, which are regularly updated so that these remain in tune with the developments in modern biotechnology. The country has established well defined regulatory authorities from the central level to the district level. Non-compliance of these regulations, including non-reporting of the activity in this area, attract punitive actions provided under the EPA. The National Development Plan of India identifies biosafety research and capacity building as an important national priority.

3.3.1 Infrastructure

Various institutions working under CSIR, DBT, ICAR and UGC have identified new genes, developed drug delivery systems, diagnostics, recombinant vaccines and computational biology. The country has built a strong infrastructure for biotechnology research in 35 agricultural universities, more than 200 general universities and more than 500 research institutions. Research activities on GMOs has significantly increased. The key institutions engaged in the development of transgenic crops in the public and private sectors are listed in Table 3.3.1 and 3.3.2.

Table 3.3.1 Major institutes in India engaged in transgenic research in the Public Sector[11]

S. No.	Institute	Crop	Transgene(s)	Objective	Status
1.	Central Tobacco Research Institute	Tobacco	Bt toxin gene Cry 1A(b) and Cry1C	To develop plants resistant to *H.armigera* and *S.litura*.	Field trial
2.	Bose Institute, Calcutta	Rice	Bt toxin genes	To develop plants resistant to lepidopteran pests. .	Green house testing
3.	Tamilnadu Agricultural University, Coimbatore	Rice	Reporter genes like *hph* or *gus A* and GNA gene	To determine transformation efficiency	Transgenic plantlets
4.	Delhi University, South Campus, New Delhi	1. Mustard/ rape seed	1. *Bar,Barnase-Barstar*	1. Develop CMS system	1. Field testing
		2. Rice	2. Abiotic stress tolerant genes (codA, cor47, hsp1)	2. Develop plants for abiotic stress tolerance	2. Transgenic plantlets
		3. Cotton	3. Cry 1A(c) gene	3. Insect resistance	3. Green house testing
		4. Wheat	4. Abiotic stress tolerant gene (*hva* 1) Insect resistance (Pin II)	4. Abiotic and insect resistance	4. Transgenic plantlets
		5. Brinjal	5. Abiotic		5. Transgenic

[11] Adapted from: Manju Sharma, K.S.Charak and T.V.Ramaniah (2003). Agricultural biotechnology research in India: Status and Policies., Current Science, 84(3):

			stress tolerant genes (*adc, mtlD, imt I*) Fungal resistance (glucanase)	5. Abiotic and fungus resistance	plantlets
5.	Central Potato Research Institute, Shimla	Potato	Bt	To develop plants resistant to lepidopteran pests.	Green house testing
6.	AAU, Jorhat, Assam	Chickpea	Bean alpha A1	To generate plants resistant to bruchids.	Transgenic plantlets
7.	Central Institute for Cotton Research, Nagpur	Cotton	Bt. cry gene(s)	To generate plants resistant to lepidopteran pests.	Transgenic plantlets
8.	Centre for Cellular and Molecular Biology, Hyderabad.	Rice	Bar	To generate herbicide-tolerant plants.	Transgenic plantlets
9.	Central Rice Research Institute, Cut tack	Rice	Bt cry1A(b) Xa21	To develop plants resistant to lepidopteran pests, bacterial blight/disease.	Transgenic plantlets
10.	Directorate of Rice Research, Hyderabad	Rice	Xa.21, Cry1A(b)	To generate plants resistant to lepidopteran pests and bacterial and fungal diseases.	Transgenic plantlets
11.	Indian Agricultural Research Institute (Biotechnology Centre), New Delhi	1.Brinjal 2. Tomato 3. Cauliflower	1. Bt. cry 1A(b) 2. Bt. cry 1A(b) 3. Bt. cry 1A(b)	1. To generate plants resistant to lepidopteran pests. 2. To generate plants resistant to lepidopteran pests. 3. To generate plants resistant to	1. Field testing 2. Green house testing 3. Transgenic plantlets

				Platella scylostella.	
		4. Rice	4. Bt cry1A(c),	4. To generate plants resistant to lepidopteran pests.	4. Field testing
		5. Mustard/ rapeseed	5. Arbidopsis annexin gene	5. To generate stress-tolerant plants.	5. Transgenic plantlets
		6. Mustard/ rapeseed	6. Choline dehydrogenase	6. To generate stress-tolerant plants.	6. Transgenic plantlets
		7. Tomato	7. ACC synthase	7. To control fruit ripening	7. Transgenic plantlets
		8. Banana	8. ACC synthase.	8. To control fruit ripening	8. Transgenic plantlets
		9. Tobacco	9. Chitinase, glucanase and RIP	9. To generate plants resistant to fungal attack.	9. Transgenic plantlets
		10. Brassica	10. Chitinase, glucanase and RIP	10. To generate plants resistant to fungi.	10. Transgenic plantlets
		11. Pigeonpea	11. Protease inhibitor and lectin genes	11. To generate plants for insect resistance.	11. Transgenic plantlets 12. Transgenic plantlets
		12. Cabbage	12. Bt.Cry1A(b)	12. To generate plants resistant to P. scylostella.	
12.	Indian Agricultural Research Institute (Virology Centre), New Delhi	1. Tomato	1. Rep of ToLCV	1. To develop ToLCV resistant plants	1. Green house testing
		2. Papaya	2. CP of PRSV	2. To develop PRSV resistant plants	2. Transgenic plantlets
		3. Cucumber	3. CP of CMV	3. To develop	3. Transgenic

			and CGMMV	CMV and CGMMV resistant plants	plantlets
		4. Potato	4. CP of PVY and PLRV	4. To develop PVY and PLRV resistant plants	4. Transgenic plantlets
		5. Tobacco	5. CP of PVY	5. To develop PVY resistant plants	5. Transgenic plantlets
13.	International Centre for Genetic Engineering and Biotechnology, New Delhi	1. Tobacco	1. Bt.cry1A(b)	To generate plants resistant to yellow stem borer.	1. Transgenic plantlets
		2. Rice	2. Gm2	2. To generate plants resistant to gall midge.	2. Transgenic plantlets
14.	Indian Institute of Horticulture Research, Bangalore	1.Muskmelon	1.Rabies glycoprotein gene	1. To develop edible vaccines.	
		2. Tomato	2. Leaf curl virus sequence	2. To generate plants resistant to leaf curl virus.	
		3. Tomato	3. Chitnase and glucanase	3. To generate plants resistant to fungal diseases.	
		4. Citrus	4. CP of citrus triesteza virus	4. To generate transgenic citrus plants resistant to citrus triesteza.	
15.	Madurai Kamaraj University, Madurai	1.Blackgram	1. CP and rep. genes of Vigna mango yellow mosaic virus	1. To develop viral resistant plants.	1. Transgenic plantlets
		2.Rice	2. Chitinase B-1, 3 glucanase and osmotin genes	2. To develop plants resistant to fungal infection.	2. Transgenic plantlets

		3. Coffee	3. Chitnase, B-1, 3 glucanase and osmotin genes	3. To develop plants resistant to fungal infection.	3. Transgenic plantlets
16.	Narendra Dev University of Agriculture, Faizabad	Rice	Cry 1A(b) gene	To generate plants resistant to lepidopteran pests	Transgenic plantlets
17.	National Botanical Research Institute, Lucknow	Cotton	Cry1 E and Cry1C with terminal altered at C end	To develop transgenic resistant to Spodopotera litura and Heliothisis armigera.	Green house testing
18.	Punjab Agricultural Univerisity, Ludhiana	Rice Pusa Basmati	Cry 1Ab, Cry1 Ac	For resistance against yellow stem borer.	Transgenic plantlets
19.	Tata Energy Research Institute, New Delhi.	Mustard	Ssu-maize Psy and Ssu-tpCrtI gene.	To generate plants containing high levels of B-carotene.	Transgenic plantlets
20.	Jawaharlal Nehru University, New Delhi	1. Potato 2. Tomato	1. Lysine obtained from *Amaranthus* plants (*Ama-1)* *2. Oxalate decorboxylase*	1. To develop high lysine containing potato 2. To develop plants with reduced oxalate content	1. Field evaluation 2. Transgenic plantlets
21.	University of Agricultural Sciences, Bangalore.	Rice	GNA gene	To develop edible vaccines.	Transgenic plantlets
22.	International Crops Research Institute for the	Ground Nut	CP and rep. of Indian peanut clump virus ((IPCV)	Development of plants with resistance to IPCV	Green house testing

	Semi-Aried Tropics (ICRISAT), Hyderabad				

Table 3.3.2 Efforts of the private sector in developing transgenic crops in India[12]

Company	Crop	Transgene	Objective
Ankur Seeds Ltd. Nagpur	Cotton	Cry1A(c)	To generate plants resistant to lepidoteran pests
Hybrid Rice International, Gurgaon	Rice	Cry 1A(b), cry9C and bar genes	To develop plants resistant to lepidopteran pests and herbicide tolerance.
Indo-American Hybrid Seeds, Bangalore	Tomato	Alfalfa glucanase and Tomato leaf curl virus genes	To generate plants resistant to viral and fungal attacks.
MAHYCO, Mumbai	1. Cotton	1. Cry1(c)	1. To generate plants resistant to lepidopteran pests.
	2. Cotton	2. CP4 EPSPS	2. To generate plants for resistance to herbicide glyphosate.
	3. Cotton	3. CryX gene	3. To generate plants resistant to lepidopteran pests.
	4. Corn	4. Cry1A(b)	4. To generate plants resistant to lepidopteran pests.
	5. Rice	5.Cry 1A(c), Xa21 and GNA genes.	5. To generate plants resistant to lepidopteran pests, bacterial blight and

[12] Source: Manju Sharma, K.S.Charak and T.V.Ramaniah (2003). Agricultural biotechnology research in India: Status and Policies., Current Science, 84(3):

	6. Mustard	6. CP4 EPSPS	sucking pests. 6. To generate plants tolerant to herbicide.
MAHYCO Research Foundation, Hyderabad.	Rice	Bacterial blight Resistance conferring Xa-21 gene	To generate plants resistant to bacterial blight.
Proagro PGS (India) Ltd. , Gurgaon	1. Brassical mustard 2. Tomato 3. Brinjal 4. Cauliflower 5..Cauliflower 6. Cabbage	1. Bar, barnase barstar 2. Cry1A(b) 3. Cry1A(b) 4. Cry1H/cry9C 5 Bar, barnase, barstar 6. Cry1H/cry9C	1. To develop superior hybrid cultivars. 2. To generate plants resistant to lepidopteran pests. 3. To generate plants resistant to lepidopteran pests. 4. To generate plants resistant to lepidopteran pests. 5. To develop superior hybrid cultivars 6. To generate plants resistant to lepidopteran pests.
Syngenta India Ltd. Pune	1. Cotton 2. Maize	1. Vip-3 gene 2. Cry1A(b)	1. To generate plants resistant to lepidopteran pests. 2. To generate plants resistant to lepidopteran pests.
M/s Rallis India Ltd., Bangalore	1. Chilli	1. Snowdrop Lectin gene	1. Resistance against lepidopteran, coleopteran & homopteran pests,

	2. Bell pepper	2. Snowdrop Lectin gene	2. Resistance against lepidopteran, coleopteran & homopteran pests,
	3. Tomato	3. Snowdrop (*Galanthus nivalis*) Lectin gene	3. Resistance against lepidopteran, coleopteran & homopteran pests

3.3.2 Biosafety and Regulatory Framework

India having ratified to the Biosafety Protocol on 17th January 2003 is committed to meet its obligation under the Protocol. The National Development Plan identifies biosafety research and capacity building as an important national priority. India actively participated in the formulation and negotiation of the Cartagena Protocol.

Ministry of Environment & Forests (MoEF), under the Environment Protection Act (1986), notified the Rules in 1989 for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells. These rules and regulations cover the areas of research as well as large scale applications of GMOs and products made there from throughout India. The rules also cover the application of hazardous microorganisms, which may not be genetically modified. Hazardous microorganisms include those, which are pathogenic to animals as well as plants. The target substances include hazardous natural microorganisms, all genetically engineered organisms including microorganisms, plants and animals.

These rules also define the competent authorities and their composition. Presently there are six competent authorities that is, Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committees (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC),

State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC). The RCGM established under the Department of Biotechnology (DBT) supervises research activities including small-scale field trials, whereas approvals for large-scale releases and commercialization of GMOs are given by the GEAC, established under the Ministry of Environment and Forests. The SBCC's and DBCC's have a major role in monitoring. The Rules also mandate that every institution engaged in GMO research establish an IBSC to oversee such research and to interface with the RCGM in regulating it.

(i) The Recombinant DNA Advisory Committee (RDAC):

This committee constituted by the Department of Biotechnology takes note of developments in biotechnology at national and international levels. The RDAC prepares recommendations from time to time that are suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This Committee prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990, which was adopted by the Government for conducting research and handling of GMOs in India.

(ii) Institutional Biosafety Committee (IBSC)

The IBSC is the nodal point for interaction within the institution for implementation of the guidelines The activities of IBSC include training of personnel on biosafety and instituting health monitoring programme for laboratory personnel. The directives are to carry out medical checks including

pathological tests done periodically on persons involved in the work/experiments on GMOs.

(iii) Review Committee on Genetic Manipulation (RCGM)

The RCGM operates under the Department of Biotechnology. It performs the following functions:

a. To review all approved ongoing research projects involving high risk category and controlled filed experiments
b. To undertake visits of sites of experimental facilities periodically, where projects with biohazard potentials are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.
c. To issue clearance for import of etiologic agents and vectors, germplasm, organelle, etc., needed for experimental work/training and research.

(iv) Genetic Engineering Approval Committee (GEAC):

GEAC functions as a body under the MoEF and is responsible for approval of activities involving large scale trials/ use of hazardous microorganisms and recombinant products in research and industrial production from the environment angle.

(v) State Biotechnology Coordination Committee (SBCC):

SBCC, headed by the Chief Secretary of the State. is constituted in each State where research and applications of GMOs are contemplalocated. The Committee has the powers to inspect, investigate and take punitive

actions in case of violations of the statutory provisions. The Committee coordinates the activities related to GMOs in the State with the Central Ministries.

(v) District Level Committee (DLC):

DLCs are formed in each district (there are about 600 districts in the country) where GMO related activities are taken up. DLC is responsible to report to SBCC regularly on the biosafety aspects of GMO based activities in the district.

The District Collector, who heads the Committee, can induct representatives from State agencies to enable the smooth functioning and inspection of the GMO related activities with a view to ensure the implementation of safety guidelines while handling GMOs, under the Indian EPA.

Thus India has developed an elaborate institutional framework for ensuring biosafety related to research and use of GMOs in the country. However, the structure of various committees has a weakness of limited technical expert advice on scientific components of biosafety issues for arriving at science-based decisions.

India is following a policy of case-by-case approval of transgenic crops. So far approval has been given to commercial release of GM cotton.

India has a strong scientific base for biotechnology research and development. It also has the expertise for safe handling of GMOs through its network of research

institutions. However, country needs to improve Capacity for RARM, and food safety regulations.

3.4 Indonesia

Indonesian archipelago, comprising of 17,508 islands covering an area of 1.9 million square km is one of the centres of mega-diversity. It is the Worlds fourth largest country in terms of population, of which 55% is involved in agriculture. Agriculture accounts for 19% of the GDP and 60% of the non-oil exports. To boost agriculture, biotechnology has been accorded a national high priority since 1985. The National Policy on Biotechnology considers biotechnology to play a key role in the country to cover various areas like disease diagnosis, detection of mycotoxins, biological control of pests and diseases of plants and animals, bio-fertilizers, tissue culture, micropropagation and production of disease free plants, embryo transfer technology for cattle, vaccine production, enzymes, hormones and antibiotics production, conservation of genetic resources, molecular characterization of genetic resources, molecular characterization of pests and pathogens of plants and animals, gene cloning, MAS, genetic transformation of plants and microbes, molecular 'pharming', recombinant vaccines, gene therapy and field testing of GMOs. The country has developed capacity for transformation of a variety of crops for resistance to biotic and abiotic stresses (Table 3.4.1). Molecular assisted breeding using DNA members has been used to develop rice varieties resistant to bacterial leaf blight.

After the economic crisis of 1998, greater emphasis has been given to the application of biotechnology for improved production of food, and traditional medicine, and for value addition to improve agricultural exports. In this direction, application of

embryo transfer technology to increase milk and meat production, diagnostic kits for animal diseases, bio-fertilizers and bio-pesticides, have been emphasized. As a long-term strategy the country also lays emphasis on drug discovery, genomics, germplasm conservation, genetic improvement of crop plants, fish biotechnology and bio-remediation. In livestock, micro satellite technology has been used to determine genetic diversity. Increase in emphasis is also reflected in the funding of biotechnology programmes, both in the public and private sectors.

Table 3.4.1 Status of Transgenic Research in Indonesia

Crop	**Trait**	**Transgene**	**Status**
Cabbage	Resistance to *Alternasia*	Chitinase gene	Transgenic plantlets
Cacao	Resistance to Stem borer	Cry	
	Resistance to pod borer	Transgene plantlets	Gene constructs
Cassava	Starch compositions	Candidate gene	-
Citrus	Resistance to CVPD	Target gene	Sequencing
Chili pepper	Resistance to *Potato virus Y*	Cp	-
Coffee (Arabica)	Tolerance to rust	Chitinase	Transgenic plantlets
Corn	Resistance to Asian Borer	Cry	Transgenic plantlets
Forestry plants	Insect resistance agronomic quality	??	-
Papaya	Virus resistance (PRSV)	Cp antisense	Transgenic plants T1
	Delayed ripening	-	Transgenic plants T1
Peanut	Resistance to *Peanut stripe virus*	Cp	Transgene plantlets
Potato	Resistance to Potato virus Y	Cp	Transgene plantlets
	Resistance to bacterial disease		Transgene plantlets
Rice	Resistance to stem borer	Cry and/or snow drop lectin	
	Resistance/tolerance to blast	Chitinase; anti-fungal genes	Transgenic plants T3

	Resistance to drought	Regulatory gene	Being constructed
	Resistance to tungro disease	Target gene	Being sequenced
Soybean	Tolerance to stem borer	Cry	Transgenic plants T3
	Albumin content		Transgenic plants T3
	Inserted phytohormone		Transgenic plants T3
Sugarcane	Drought tolerance	Candidate gene	Transgenic plants T3
	Stem borer	Cry	-
	Resistance to *Sweet potato feathery mottle virus*	Cp	-
	High sugar content		Transgenic plants

In the public sector, funding of biotechnology programmes increased from about $82.5 million in 1998 to $ 1119.0 million in 2002/03 and in the private sector it increased from $19.8 million to $ 214.3 million. Private non-commercial sector (NGOs) also contributed $35.7 million for biotechnology research.

In 1985, National Commission for Biotechnology was established and in 1994 Indonesia Consortium for Biotechnology was established. Now, Ministry of Research and Technology and the Consortium are arranging national strategy for biotechnology (Indonesian : Rencana Umum Bioteknologi). For research, each ministry/department proposes research statement to National Research Board. Assessment for the proposal is carried out by the Board. In the Agenda 21 Indonesia, The National Strategy for Sustainable Development, published in 1996, five distinct areas related to biotechnology development have been identified. These are: Agricultural Biotechnology, Medicinal

Biotechnology, Environmental Biotechnology, Development of Biotechnology Infrastructure, and Guidelines of Biological Safety. Thus, the country has identified biosafety as an important issue.

3.4.1 Infrastructure

In Indonesia, seven institutions representing both the public and private sector are mainly engaged in biotechnology research (Table: 3.4.2). Most of these Institutions have adequate infrastructure and technical staff mainly trained in Indonesia (Table 3.4.2). Only two institutes, have established IBSC. In addition, biotechnology research is also being carried in the following eight research institutions of the Agency for Agricultural Research and Development (AARD): Central Research Institute for plantation crops (Bogor and Marihat Maiden), Central Research Institute for Industrial Crops (Bogor). Indonesian Sugar Research Institute (Pasuruan), Research Institute of Animal Production (Ciawi, Bogor), Research Institute for Animal Diseases (Balitwet), and Central Research Institute for Fresh Water Fisheries (Jakarta)[13].

Table: 3.4.2 Institutions engaged in biotechnology research and other related activities in Indonesia

S No.	Institute	Infrastructure (adequate/inadequate)	Biosafety committee in position	Number of Scientists engaged in biotechnology research			Areas of Biotechnology research
				Ph. D from your country	Ph. D. from other country	M. Sc	
1	ABIOGRI, Agricultural Research and Development, (GOVT)	Adequate	X	23	1	46	Agricultural Research
2	Centre Research and Development for Biotechnology, IIS (GOVT)	Adequate	X	24	0	16	Agricultural Research

[13] IUCN: Regional Biodiversity Programmes Asia; Indonesia

3	Eyckman Laboratory (GOVT)	Adequate		20	?	14	Medical Biotechnology
4	Gajah Mada University (GOVT)	Adequate		15		10	Medical Biotechnology
5	Bandung Technology Institute (GOVT)	Adequate		21	?	7	Industrial Biotechnology Environmental Biotechnology
6	PT Sinar Mas (PVT)			?		?	Biocontrol Meristem Culture
7	PTP XI (National Estate Company)			1		?	Transgenic crops

3.4.2 Biosafety and Regulatory Framework

Present status of biosafety regulations in Indonesia [14]are briefly given in Table 3.4.3 and mechanism for their implementation is given in Fig 3.4.1

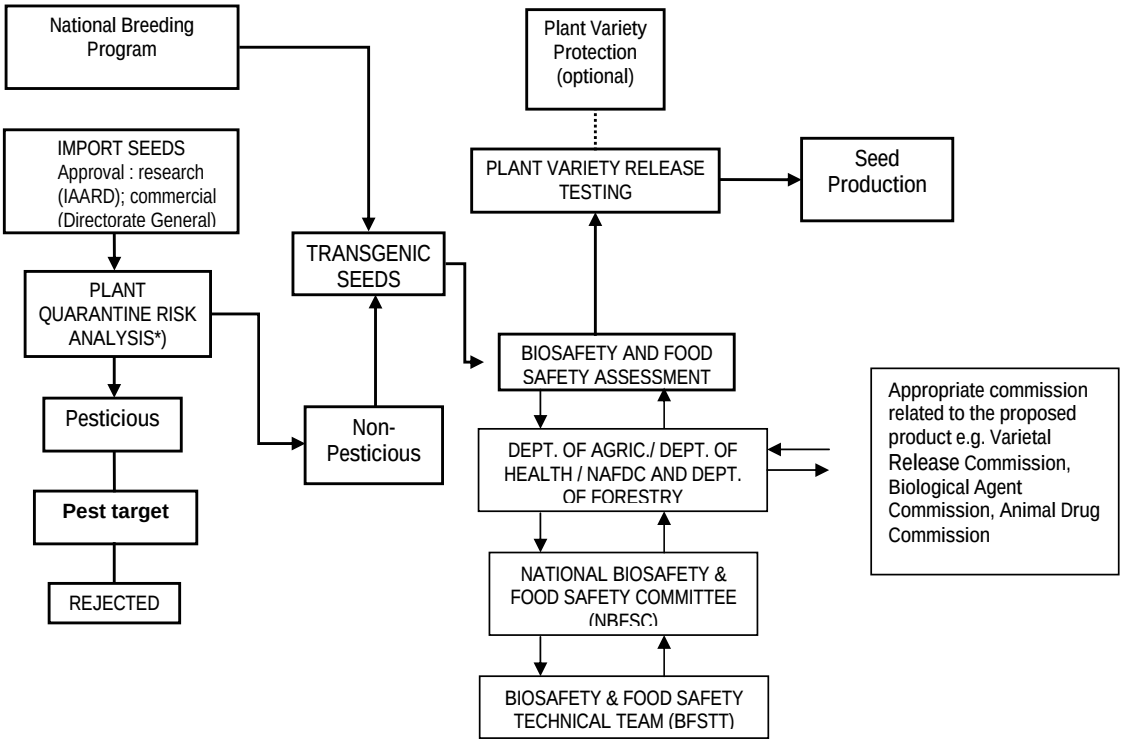
Table 3.4.3: Biosafety regulations in Indonesia

Existing		
Regulations	**Aspects regulated**	**Contents related to biosafety**
Law No 5, 1994	Ratifications of CBD	Risk assessments for biotech products
Law No 7, 1996	Food	Obligation to report and submit food containing *lmo* for food safety analysis by National Agency for Food and Drug Control (NAFDC)
Executive order No 69, 1999	Food labeling	Labeling for packaged products containing *lmo* with threshold limit of 5%
Joint Decree of Minister of Agriculture, Minister of Health, Minister of Forestry And Estate Crops And Minister of State For Food and Horticulture, 1999	Biosafety and Food Safety of Genetic Engineering Products	Procedures and requirements for safety testing, assessment and release of transgenic varieties

[14] Source: UNEP-GEF Project on Development of National Biosafety Frameworks

Law No 12, 1992	Crop culture	Procedure for release of new variety (intended for seed commercialization)
Law No. 29/2000	Plant Variety Protection	Requirement of biosafety and food safety assessment of GM Crops. Agriculture Ministerial Decree No. 737/Kpts/TP/240/9/98. GM crops must be assessed for biosafety before conducting a multilocation test. (As a requirement of plant variety release)

Fig 3.4.1: The existing mechanism, for the release of GMO, as per the Joint Decree of Four Ministries



Indonesia is a party to CBD (but it is awaiting ratification) and it is a signatory to Cartagena Protocol on Biosafety, and the MoE is formulating regulations for its ratification by the Indonesian House of Representatives. In the mean time the provisions of CPB are proposed to be implemented through an executive order, which will replace the current Joint Decree of Four Ministers, which has the following weaknesses:

1. In the existing procedure, there is no provision for compulsory public information and its mechanisms, although in reality before giving the permit Department of Agriculture, arranges Seminars inviting various stakeholders, including NGO.
2. There is no definite timeframe for each step of the procedures, causing difficulties for the proponent in planning their activities.
3. The lack of procedures for research causing difficulties because research proponent have to go through the same procedure as intended commercial release.
4. Some of the membership of the Committee (the Chairman and Co Chairman) are *ex officio*; it may cause bias between political and scientific decisions and also the lack of timeframes and their busy schedules may cause delay in decisions.

The new regulations are aimed at overcoming the above shortcomings by introducing the following features:

1. It is proposed that the National Biosafety Committee (NBC) will be more independent and serving more than one Ministries.
2. The biosafety permit for transgenic organisms intended for release into the environment come from MoE based on the recommendations from NBC and public participation.

3. For GMO to be used directly as food or processing, the permit comes from National Agency for Food and Drug Control (NAFDC), for feed it comes from Department of Agriculture.
4. There are definite timeframes especially for the consultation time (time needed to make decisions after the necessary assessment in laboratory and contained facilities) and flow of the documents.
5. There are procedures for public participation and National Biosafety Clearing House will be established for the purpose as a part of National Biosafety Committee
6. There will be a special procedure for research and development, the permit will be given by the research establishment in each Ministry/Department. For R&D in Agriculture by AARD based on recommendations by the NBC.

For ensuring public participation, strategy of accessibility of information to the concerned stakeholders through electronic media and print media is under consideration. Similarly to address the issues related to liability and redressal, appropriate regulations are proposed to be developed to meet biosafety requirements without hampering biotechnological developments in the country.

Indonesia is a party to the CBD, and signatory to CPB and a member of TRIPS, but not to International Treaty on Plant Genetic Resources for Food and Agriculture, which is under consideration. The country has established a Biosafety Clearing House to facilitate exchange of information on GMOs. The country needs to build capacity in risk analysis and management of biotechnology-derived products as well as a strong public

awareness programme. The existing biosafety framework needs improvement through involvement of all stakeholders.

The country introduced Biosafety Act in 1997, but the institutional mechanism related to biosafety, appears to be diffused as biosafety is apparently under the preview of looked into by several Ministries and Committees, such as, Ministry of Agriculture, Ministry of Health, Agency for Food and Medicinal Regulation, Commission for Biosafety and Food Safety Assessment and Technical Team for Biosafety and Food Safety Assessment. The Ministry of Agriculture deals with biosafety of GM crops, animal vaccines, husbandry and feed; the Ministry of Forestry deals with GM forestry plants; and, Agency for Food and Drug Regulation for GM food.

The country has established a National Biosafety Committee to assist the Regulator Office in assessment of biosafety and/or food safety of GMOs, The Regulator Office also regulates import/export of GMOs. The Commission for Biosafety and Food Safety coordinates field evaluation and monitoring of GMOs. The country permits import of GMOs meeting biosafety requirements and food item containing GMO products are required to be labeled. Indonesia is the first country in the region to permit field release of GM cotton after completing risk assessment.

The Commission of Biosafety and Food Safety Assessment, established in 1997, maintains the database on biosafety and assessment of GMOs and advises the government on the safe release of GMOs. The commission is assisted by a technical team of experts, drawn from various institutes engaged in biotechnology research, in biosafety assessment. The technical team has developed biosafety guidelines specific to plants, cattle, fish and microorganisms.

Indonesia is also signatory of SPS Agreement of WTO, but neither the expertise for its implementation in relation to GMOs is available nor the National Plant Protection Organization adequately equipped to check inadvertent introduction of GMOs and hazardous organisms.

The country has formulated patent laws covering biotechnological interventions. Mechanisms for plant variety protection, trademark protection are also available. There is also a legislation on intellectual property rights. Amongst the hazardous organisms, documentation of invasive species and quarantine organisms has been prepared. Documentation on risk analysis of Bt cotton is also available.

Indonesia is rich in biodiversity, but it needs to develop capacity in genomics to harness full potential from its biodiversity. Bio-prosperity, establishment of microbial culture and germ plasm collection are important targets for research. The genera and species that should be protected require documentation. The country does not have a Biodiversity and Community Knowledge Protection Act.

Food Safety in Indonesia is governed by Food Law (1996) and Regulation for Food Promotion and Labeling (1999), but actual mechanism of ensuring Food Safety needs strengthening. Indonesia has built a reasonably good capacity for developing and utilizing GMOs, but the country needs to develop expertise for GMO risk analysis and biosafety related regulatory measures.. The infrastructure and biosafety framework also require strengthening.

3.4.3 Capacity development

Between 1989-1997, Indonesia had a large number of scientists working in the area of biotechnology. In 1997, there were 247 persons holding M.Sc. degree and 102

holding Ph.D. degree. These scientists, however, are scattered in different institutions, mostly in the public sector.

3.5 Malaysia

Malaysia is blessed with rich natural resources and favourable climate for tropical agriculture throughout the year. The economic crisis of the late 90's and increasing agricultural imports have prompted emphasis on the application of biotechnology to improve agricultural production. It is identified as one of the areas for advancement in the 8th Malaysian Plan (2001-2005). Malaysia is one of the 12 mega-diversity centers as it is home for 150,000 species of invertebrates, 286 mammal species, 736 bird species and 15,000 flowering plant species. It is important to take appropriate safeguards to protect this vast diversity from any adverse effects of GM technology.

3.5.1 Infrastructure

To promote biotechnology, the Ministry of Science, Technology and the Environment (MoSTE) set up the National Biotechnology Directorate (BIOTEK) in 1995. BIOTEK established seven Biotechnology Cooperating Centres (BCC) to coordinate biotechnology research on plants, animals, food, molecular biology, medical, environment/industry and biopharmacy. Biotechnology research is mainly conducted in six institutes (Table 3.5.1)[15]. Recently Malaysia has developed the Biovalley Initiative consisting of three new institutions for research on genomics and molecular biology, neutraceuticals and pharmaceuticals, and agricultural biotechnology. To further promote biotechnology, partnership has been developed with the Massachusetts Institute of

[15] Country information in FAO-BioDec

Technology. Malaysia has taken up programmes to develop transgenic plants for a variety of traits [16](Table 3.5.2). These are mostly at experimental stage.

Table 3.5.1: Research organizations working on biotechnology in Malaysia.

Research Organization	Research Emphasis
Malaysian Agricultural Research and Development Institute (MARDI)	• Disease resistance in rice, chilli and papaya • Delayed ripening in papaya • Floral colour and senescence in orchids
Malaysian Palm Oil Board (MPOB)	• Yield improvement • Improved oil quality • Production of bio-plastics
Rubber Research Institute, Malaysia (RRIM)	• Yield improvement • Disease resistance • Production of high-value proteins
Institute of Medical Research (IMR)	• Medical diagnostic kits • Screening of local herbs for pharmaceutical properties
Universiti Kebangsaan Malaysia (UKM)	• Molecular biology of *Burkholderia pseudomallei* • Antibody engineering • Gene and genome analysis of Anopheles maculates • Molecular biology of protozoan parasites • Molecular studies of *Glomerella cingulata* and its pathogenesis of Cry proteins • Molecular systematic studies of wildlife and domestic animals
Universiti Malaysia Sarawak (UMS)	• Screening of local plants for anti-malarial drug • Genetic studies of high-risk populations on nasopharyngeal carcinoma (nasal cancer) • Transgenic sweet potato with Japanese encephalitis vaccine for pigs

[16] Country information in FAO-BioDec

Universiti Putra Malaysia (UPS)	• Oil palm expressed sequenced tags (ESTs) • Plant transformation • Gene expression • Floral/ meristem/ embryo development • Plant defense stress response

Table 3.5.2: Status of development of transgenic plants in Malaysia

Crop/Plant	Trait	Status
Banana	?	?
Chilli pepper	Virus (?) resistance	Experimental
Eggplant	?	Experimental
Muskmelon	?	Experimental
Oil palm	Fatty acid composition	?
	Biodegradable plastic	Experimental
	?	?
Orchid	Long shelf life	Experimental
	Flower colour	Experimental
Papaya	Virus)PRSV) resistance	Experimental
	Virus resistance and extended shelf life	Experimental
Pepper	Virus (CMV) resistance	Experimental
Pineapple	Tolerance to blackheart	Experimental
Rice	Sheath blight resistance	Experimental
	Virus (RTV) resistance	Experimental
Rubber	Protein content	Experimental
Teak	Improved wood quality	Experimental
Tobacco	?	?
Wingbean	Fungal resistance	?

3.5.2 Biosafety and Regulatory Framework

Malaysia is a party to the CBD and CPB; it is a member of TRIPS and has accession to ITPGR. MoSTE is the focal point for coordinating matters related to biodiversity and biosafety. MoSTE has established a National Committee on Biodiversity and a Genetic Modification Advisory Committee (GMAC) to ensure safety in the use, handling and transfer of GMOs, and to advise the Government about genetic

modification technology and its application. The NBC has established a secretariat to coordinate biosafety related matters.

GMAC has developed 'National Guidelines on release of GMOs into the Environment', which provide a framework addressing biosafety issues like regulation, assessment and managements of risks associated with release of GMOs into the environment. These guidelines also require establishment of Institute Biosafety Committees (IBCs) to ensure adherence to the guidelines in activities related to GMOs. However, the biosafety guidelines are being followed on a voluntary basis[17]. The country has established a biosafety clearing house to facilitate exchange of information on GMOs.

Currently, GMOs are regulated sectorially. For importation of GMOs, the concerned departments work as competent authority. For example permission to import GM plants is given by the Department of Agriculture, and for GM animals, by the Department of Fish and Food by the Ministry of Health. However, approval is given after clearance from GMAC. Monitoring of field releases is done closely by the NBC, GMAC and competent authority.

To further safeguard its biodiversity, GMAC drafted a Biosafety Bill so that a Biosafety Law is put in place in Malaysia. The Bill has been discussed by various stakeholders particularly with regard to policy, scope, labeling, export and contained use. The Bill was to be tabled in Parliament in June 2002. A new law for food and feed will also cover GMOs.

[17] Nair, Helen & Lumi Kalson Abu Bakar (2001). Agricultural Biotechnology in Malaysia. Paper presented at Inst. Workshop in Agricultural Biotechnology for the Poor, ABD, Nahila, 15-17 Jan.

Malaysia has developed expertise for risk assessment and risk management related to GMOs, as the country has allowed field release of transgenic soybean tolerant to glyphosate (Roundup Ready Soybean) , for food, feed and processing. Transgenic papaya modified for delayed ripening (having antisense ACC oxidase cDNA sequence) has been approved for confirmed field release under netted condition. Transgenic oilpalm tolerant to herbicide glufosinate has not been approved for confined field release.

3.6 Pakistan

Agriculture is an important sector of Pakistan's economy with 22.93 million hectares of very fertile land under cultivation. Biotechnology has been given a high priority for improving agricultural crops since 1985. The country has also put in place a national policy on biotechnology. The country has developed biotechnology programmes to address issues related to (a) diagnosis of human, animal and plant diseases, (b) biocontrol of plant diseases, (c) tissue culture to exploit somaclonal variants, and micropropagation of potato and banana, (d) vaccine production, (e) enzymes, hormones and antibiotics production, (f) conservation of microbes, (g) molecular characterization of animals, plants and microbes, (h) molecular characterization of pests and pathogens of animals and plants, (k) genetic transformation of plants and microbes, (l) molecular 'pharming' and development of recombinant vaccines, and (m) field testing of GMOs. The technologies for embryo transfer, production of biofertilizers and virus-free seed potato through tissue culture have shown good economical impact. The country has launched a major programme to develop transgenic chickpea, cotton and rice for resistance to insect pests; transgenic cotton, rice for resistance to fungal and bacterial diseases and transgenic rice for salt tolerance, profuse tillering and short stature. All these

transgenics are at developmental sage (Table 3.6.1). For these programmes the country provides a budget of US$ 18-20 million.

Table 3.6.1 Status of transgenic crop development in Pakistan[18]

Crop	Trait	Status
Chickpea	Insect resistance (Bt gene)	Experimental
	Drought and Salt tolerance with Yeast and *Arabidopsis* Na^+/H^+ antiporter genes	Experimental
Cotton	Diamondback moth resistance with Bt gene	Experimental
	Virus (CLCuV) resistance with Tr AC 1 gene	Field Trials
	Virus (CLCuV) resistance with RNA interference (RNAi)	Experimental
Rice	Bacterial blight resistance with Xa21 gene	Experimental
	Salt tolerance with Yeast and Arabidopsis Na^+/H^+ antiporter genes	Experimental
Sugarcane	Insect resistance with Cry gene	Experimental
Tobacco	Insect (*Helicoverpa armigera* and *Heliothis vericens*) resistance with synthetic spider venom gene	Experimental
	Salt tolerance with Yeast and *Arabidopsis* Na^+/H^+ antiporter genes	Experimental
	Salt tolerance with ArDH chloroplast transformation	Experimental
Tomato	Virus (TLCV) resistance through RNAi	Experimental
	Male sterility through RNAi	

3.6.1 Infrastructure

The major centres engaged in biotechnology are (i) National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad; (ii) Centre for Excellence in Molecular Biology (CEMB), Lahore; (iii) Agricultural Biotechnology Institute, Islamabad; and (iv) National Agricultural Research Centre, Islamabad. Apart from these, 15 other centers are also engaged in biotechnology research. NIBGE is the foremost

[18] Country Information in FAO-BioDec

biotechnology institute. It is adequately equipped and has a group of about 65 scientists, of which 15 scientists hold Ph.D. degrees from different universities in Pakistan and 15 from other countries (Table 3.6.2). Biotechnology research is also being done in several other centers where infrastructure is not adequate for biotechnology research and trained human resource is also limited.

Table 3.6.2: Major institutes engaged in biotechnology research in Pakistan

S No.	**Institute**	**Infrastructure(adequate/inadequate)**	**Biosafety committee in position**	**Number of Scientists engaged in biotechnology research**			**Areas of Biotechnology research**
			/	**Ph. D from your country**	**Ph. D. from other country**	**M.Sc/ M.Phil**	
1	National Institute for Biotechnology & Genetic Engineering (NIBGE), Govt	Adequate	X	15	15	35	Agri, Health, Indust, Env
2	CEMB Punjab Univ. Govt	Adequate	X				Health, Agri, Industry
3	Agricultural Biotechnology Institute	?	?	?	?	?	?
4	National Agricultural Research Centre						
	15 other centres	Inadequate	/		1 to 4		Mostly ??

The following Ministries/Departments deal with biotechnology and related activities in Pakistan: (a) Ministry of Science & Technology Research (MoSTR), (b) Ministry of Food, Agriculture & Livestock (MoFAL), (c) Higher Education Commission (d) National Commission on Biotechnology, (e) Pakistan Council of Science and Technology, and (f) Pakistan Atomic Energy Commission.

3.6.2 Biosafety System and Regulatory Framework

Biotechnology research policy and activities are dealt by MoFal and MoSTR, whereas environmental aspects are the responsibility of Ministry of Environment, Local Bodies and Rural Affairs.

Pakistan is a party to CBD, signatory to CPB, member of TRIPS and has accession to ITPGR. In Pakistan, mechanism to facilitate exchange of information on GMOs has not been created. IBCs are in position in the two main biotechnology research centers i.e. NIBGE and CEMB, but not in the other centers engaged in biotechnology research. The country has established NBC, but it is one of the three committees, which have final authority to allow field experiments and commercial release of GMOs. Currently biosafety related to GMOs falls in the purview of Ministry of Environment, Local Bodies and Urban Affairs.

Pakistan has developed biosafety guidelines in 1999, but Biosafety Act is yet to be formulated. In the absence of the Biosafety Act, the capacity for GMO detection in live/food materials available at NIBGE is not being fully utilized. The mechanism for field evaluation and monitoring of GMOs is also lacking despite production of transgenic crops in the country. This needs to be established. The country does not have a policy for introduction of GMO seeds or GMO for direct use as food, feed or processing.

Pakistan is signatory to SPS Agreement of WTO. Expertise is available for GMO detection at some specialist institutions, but the National Plant Protection Organization is not adequately equipped.

Proposals to amend Patent and Designs Act (1911) and Patent ordinance (2000) to cover biotechnological interventions and use of biotechnology products are pending

enactment. Plant Variety Protection is regulated by Plant Breeders Rights Ordinance (2000), but the Act is awaiting discussion by the Parliament. The country has established Trademark protection, but biotechnology products are yet to be covered. The country has a legislation on intellectual property rights but it does not cover live material. The country does not have a Biodiversity and Community Knowledge Act. However, the process of documenting genera and species requiring protection and the hazardous organisms has been initiated. The country has a good system of variety approval. The environment safety is regulated by Environment Protection Act, but it does not cover GMOs. The food safety system is outdated and poorly equipped. Overall, the development of biosafety regulation in Pakistan is slow.

3.7 Philippines

The Philippines is basically an agricultural country. More than 70% population is directly or indirectly dependent on agriculture, which is practiced in 10.3 million ha. Rice, corn, banana, coconut, sugarcane, pineapple and coffee are the major crops. The country produces 27 million tones of rice and corn, which falls short of the domestic requirement. In 1997, the Philippines launched a modernization initiative for augmenting agricultural production through Agriculture and Fisheries Modernization Act (AFMA).[19]

3.7.1 Infrastructure

Biotechnology research and development was initiated in the Philippines in 1979 with the establishment of National Institute of Molecular Biology and Biotechnology at the University of Philippines, Los Banos (BIOTECH-UPLB). In 1995, biotechnology programme was further strengthened through establishment of three more institutes to

[19] De la Cruz, R.E (2003) Status of Agricultural Biotechnology in the Philippines, Paper presented at the FAO APPARI Expert Consultation on the Use of Agricultural Biotechnology in Asia and the Pacific, Bangkok, Thailand March 31, 2003.

deal with industrial biotechnology, human health biotechnology, and aquatic and marine biotechnology. BIOTECH-UPLB mainly provided leadership in agricultural biotechnology. Some other institutes also engaged in biotechnology R&D (Table-3.7.1), also have adequate infrastructure. In addition UPLB scientists have access to the containment facilities at International Rice Research Institute (IRRI).

Table 3.7.1: Institutes engaged in biotechnology research in the Philippines

S No.	Institute	Infrastructure)
1.	University of the Philippines Los Banos (UPLB)	Adequate
2.	Philippines Rice Research Institute (PRRI)	Adequate
3.	Philippines Sugar Research Institute (PSRI)	
4.	Cotton Research & Development Authority (CRDA)	
5.	Fiber Industry & Development Authority (FIDA)	
6.	Philippine Carabas Centre (PCC)	
7.	Philippines Coconut Authority (PCA)	
8.	Visayas State College of Agriculture	
9.	Benguet State University	
10.	Central Luzon State Univerisity	
11.	Mindanao State University	
12.	Central Mindanow University	
13.	University of Santo Tomas (Pvt.)	Adequate
14.	De La Salle University (Pvt.)	Adequate
15.	Ateneo de Manila University (Pvt.)	Adequate

The focus of biotechnology programmes in the Philippines is on genetic engineering, genomics, diagnostics, and socio and biosafety concerns. Transgenic crops (Table-3.7.2) and fish are being developed for resistance to pests and diseases, abiotic stresses, improved nutrition, improved yields and improved growth. Apart from transgenic crops development, biotechnology is being extensively used in

micropropagation, MAS, genome mapping, germplasm characterization, identification of useful genes, and biofertilizer application in crops. For livestock, biotechnology has helped in developing vaccines, diagnostic kits, and embryo transfer. Molecular diagnostic kits for shrimp diseases, biological control of fish and shrimp pathogens have also been developed. Biodiversity assessment is another area of successful application of biotechnology.

Table – 3.7.2: Transgenic Crop development in the Philippines [20]

Crop	**Trait**	**Status**
Banana	Virus (BBTV) resistance	Field Trial
Coconut	High lauric acid	Experimental
Maize	Insect resistance	Field Trial
Mango	Delayed fruit ripening	Experimental
Papaya	Virus (PRSV) resistance	Experimental
	Delayed ripening	Experimental
Rice	Multiple resistance (fungal, bacterial, insect, salt)	Experimental
Tobacco	Delayed leaf senescence	Experimental
Tomato	Delayed fruit ripening	Experimental

In 1998, nearly 300 scientist holding Ph.D. degree and 350 holding M.Sc. degree were engaged in biotechnology research about 65% of those were at the UPLB. In the Philippines about 0.2% of GDP is budgeted for research of which 4% (about US $ 20

[20] Country information in FAO-BioDec

million) are required to be provided for biotechnology R & D, but in effect about 2% are given. Funding is further supplemented to the tune of US $ 7.5 million form other internal and external sources.

3.7.2 Biosafety and Regulatory Framework

The Philippines is a party of the CBD and signatory to CPB. The Department of Foreign Affairs is the National Focal point. In 1992, the Philippines Council on Sustainable Development (PCSD) was created, which formed a National Biodiversity Strategy and Action Plan. A sub-committee of PCSD, on biodiversity provides forum for discussion on CBD and biosafety protocol. [21]

In 1990, the country established a National Biosafety Committee of the Philippines, by Executive Order No 430, which marked the start of a regulatory regime to ensure biosafety. The NCB of the Philippines developed guidelines for the planned release of GMOs and potentially harmful exotic species. These guidelines cover R & D but do not cover commercial release.

" In 1995, a law was promulgated through Executive Order (EO) No. 247, prescribing guidelines and establishing a regulatory framework for the prospecting of biological and genetic resources, their by-products and derivative, for scientific and commercial purposes, and for other purposes". This is to protect valuable genetic resources, traditional knowledge and practices. The EO's are implemented through Committees using interagency approach.

The National Ethics Committee on Biosafety of the Philippines was also established by an EO. This committee has developed guidelines from

[21] IUCN Capacity building Initiative, National Biodiversity Programme, Risk Assessment and Management, Philippines

biomedical/behavioral research. For accessing technologies/products by public and private sectors, the Philippines has promulgated a law known as IP code, complying with the minimum standards set by the TRIPS Agreement. It also provides patent protection, copy rights, industrial designs and trademarks. Patenting microorganisms is allowed, but not that of plants or animals. Access to biotechnologies is achieved by mutual agreement through the execution of material transfer agreements. Access to biological and genetic resources is covered by EO # 248, complemented by the Department of Environment and Natural Resources.

GMOs introduced or developed in the country are assessed by the NCBP for environmental risks before granting approval. NBC of the Philippines is also mandated to approve R&D activities related to GMOs. Major concerns related to release of GMOs are safety to humans, livestock and the environment and the possibility of contamination of non-GMO relatives. The country has to strengthen existing regulatory measures, trained human resource and infrastructure for appropriate risk assessment and management of GMOs.

3.8 Sri Lanka

In Sri Lanka, biotechnology has been accorded high priority. A medium term plan (5-10 years) has been prepared by an Expert Committee of Biotechnologists (ECB) constituted by the Council for Agricultural Research Policy. The Agricultural Biotechnology Centre has been identified as the national centre for undertaking biotechnological research and production of transgenic plants. The country has put in place a National Policy on Biotechnology. Currently biotechnology related programmes are related to disease diagnosis, biological control, biofertilizers, tissue culture of plants,

embryo-rescue, micropropagation of potato and banana, vaccine production, conservation of plant genetic resources, molecular characterization of pests and pathogens, identification of useful genes, MAS, genetic transformation of plants and development of recombinant vaccines. However, field testing of transgenic plants has not been initiated so far. Funds allocated for biotechnology projects and other related activities are very meager i.e. about US $ 100,000.00.

3.8.1 Infrastructure

All biotechnology related activities are dealt by the Ministry of Science and Technology. Biotechnology research is being carried out by research institutions of the Department of Agriculture and Universities, which do not have adequate infrastructure for biotechnology research. Some private institutions are also engaged in biotechnology related activity. All these institutions are mainly engaged in tissue culture work and MAS. The Institutions in the public sector have technical staff trained up to Ph.D. level (Table 3.8.1). None of these institutions, however, have 'Institutional Biosafety Committee' in position.

Table 3.8.1: Institutes engaged in biotechnology research in Sri Lanka

Institute	**Infrastructure**	**Biosafety committee in position**	**Qualifications of Scientists engaged in biotechnology research**			**Areas of Biotechnology research**
			Ph. D from your country	**Ph. D. from other country**	**M. Sc**	
Dept. of Agriculture	Inadequate	No		X	X	Tissue Culture , MAS
Universities	Inadequate	No		X	X	- Do -
Private	Adequate	No			X	Tissue Culture

3.8.2 Biosafety and Regulatory Framework

Sri Lanka is a party to the CBD and CPB, member of TRIPS, but not of ITPGR. The country has not established a National Biosafety Committee. However, a 'Biosafety framework' is being formulated through UNEP/GEF Funds. There is no policy related to introduction of GMOs for direct use.

All biotechnology programmes of the country are to be monitored and evaluated by the ECB as food, feed or for processing, but importation of GMOs is not permitted. The country proposes to formulate a 'Biosafety Act' to regulate GMOs, with the Ministry of Environment and Natural Resources as the nodal agency. Sri Lanka is also a signatory of SPS Agreement of WTO, but does not have adequate expertise in the Quarantine department to test for GMOs. Patent Laws are also being prepared, and draft regulations for plant variety protection have been prepared. The plant species requiring protection have been documented, but apparently there is no documentation of hazardous organisms. Mechanism for trademark protection is available.

The country has legislations on Intellectual Property Rights and Biodiversity and Community Knowledge Protections Act and the seeds are regulated through Plant Protection Act, Plant Quarantine Act and Seed Act. Food safety is regulated by Food & Drug Administration.

Current biotechnology activities in Sri Lanka are mainly at level 1 dealing with tissue culture and MAS and the hard core biotechnology is yet to take off. The development of Biosafety Act and regulatory mechanism will catalyze biotechnological activity in the country. The country, however, requires training of scientists for developing and RARM of GMOs. Basic infrastructure in the form of laboratories has been built, but it requires modernization and provision for essential equipment required

for biotechnological work. Capacity building in Sri Lanka for reaping the benefits of biotechnological advances require greater resources than available at present

3.9 Thailand

In Thailand, the thrust is on innovative and creative research for improving quality and productivity of agricultural crops. Development of transgenic plants for quality improvement, tolerance to abiotic stresses and resistance to pests and diseases has been accorded high priority. Transgenic plants have been developed in several crop species for a variety of traits (Table 3.9.1). Some of the transgenic lines are being tested in experimental plots.

3.9.1 Infrastructure

The status of infrastructure, human resource and funding of the key institutions working on biotechnology in Thailand (Table 3.9.2)[22] is not available at present. Major biotechnology programmes are based at the National Centre for Genetic Engineering & Biotechnology and Department of Agriculture.

Table 3.9.1: Status of GM crops development in Thailand[23]

Crops	Trait	Status
Cotton	Bollworm resistance	Laboratory
Rice	BB resistance (Xa 21)	Laboratory
Pineapple	HR	Laboratory
Orchid	Virus resistance	Laboratory
Tomato	Virus (TYLCV) resistance	Laboratory
Papaya	Virus (PRSV) resistance	Experimental plot
Pepper	Virus (CVBMV, PepLCV) resistance	Laboratory
Yard long bean	Virus (CpABMV) resistance	Laboratory
Cucurbit	Virus (TMV)	Laboratory

[22] Country information in FAO-BioDec.
[23] Country information in FAO-BioDec, and updated based on the information provided by the Focal Point.

Table 3.9.2: Institutes engaged in biotechnology research in Thailand

S No.	Institute	Infrastructure (adequate/inadequate)	Biosafety committee in position	Number of Scientists engaged in biotechnology research		Areas of Biotechnology research (No. of Lab.)
				P h D	M. Sc	
1	National Center for Genetic Engineering and Biotechnology	A	X	17	7	2
2	Depart. of Agriculture	In	X	10	32	5
3	Depart. of Fisheries	In	X	12	3	1
4	Depart. of Livestocks	In	X	-	-	-
5	Kasetsart Univ.	A	X	27	44	8
6	Mahidol Univ.	A	X	28	47	9
7	Chulalongkorn Univ.	A	-	36	9	3
8	Chiangmai Univ.	In	X	5	7	2
9	Khonkaen Univ.	In	X	27	27	1
10	Maejo Univ.	In	-	-	-	1
11	King Mongkut Ins. of Technology	In	X	-	-	-
12	Songklanakarin Univ.	In	X	3	1	2
13	Private sectors (NGO)	In	X	3	5	-
13 Inst.				168	182	34

3.9.2 Biosafety and Regulatory Framework

The Ministry of Agriculture and Cooperatives is responsible for biotechnology research, and the Ministry of Natural Resources and Environment is responsible for environmental aspect of biotechnology. Thailand is a party to the CBD, and is in the process to ratifying the CPB. Since 1983, biosafety is identified as a national priority. Biosafety Guidelines on Genetic Engineering and Biotechnology for laboratory work, field work and planned release of GMOs, were finalized in 1992. This followed establishment of a National Biosafety Committee and a number of institutional biosafety committees (24). The national legislation related to GMOs is being drafted. However, a number of existing laws in Thailand can be applied for regulation of GM crops in the

country. The relevant ones for the regulation of transgenic plants are Plant Quarantine Act B.E. 2507 (1964) amended B.E. 2542 (1999), Plant Act B.E. 2518 (1975) amended B.E. 2535 (1992) and Plant Variety Protection Act B.E. 2542 (1999). These laws could be utilized in such a way that they could compliment the enforcement of the biosafety guidelines whenever necessary. The Department of Agriculture (DoA) is the competent national authority on environmental release of transgenic plants. The Department of Livestock Development is in charge of commercial release of genetically modified animals and animal feed. The Department of Fisheries is in charge of fish and aquatic animals. The Royal Forest Department is in charge of wild animals. The Food and Drug Administration (FDA) is in charge of food and food products. Major constraints and limitations include insufficient trained human resource and financial resources, and weak regulatory system. Infrastructure also needs strengthening.

3.10 Viet Nam

Biotechnology is identified as an important and essential prerequisite for economic development in Viet Nam. Major focus areas are the application of biotechnology for micropropagation, plant and animal breeding programmes, improving crop and animal production, environmental protection and reforestation[24]. The Government of Vietnam has developed a National Policy on Biotechnology and has increased funding for biotechnology programmes and for developing infrastructure. Major areas covered by biotechnology programmes in Vietnam are related to disease diagnosis, bio-control of diseases, bio-fertilizers, tissue culture including embryo rescue,

[24] Current Status of Bio-safety in Viet Nam, IUCN Biosafety Capacity Building Initiative, Regional Biodiversity Programme, Asia, Viet Nam

micropropagation of tuber crops, fruit crops and forest trees, embryo transfer technology, vaccine production, enzymes, hormones and antibiotic production, conservation and molecular characterization of genetic resources, molecular characterization of pests and pathogens, gene isolation and cloning, genetic transformation of animals, fish, plants and microbes, development recombinant vaccines, and development of drug delivery systems. Six different ministries manage biotechnology related activities.

3.10.1 Infrastructure

Biotechnology research is being conducted at several institutes (Table 3.10.1) of the Ministry of Agriculture and Rural Development (MARD) and various universities. The Institute of Biotechnology and some institutes of MARD are working on the development of GMOs. The status of these developments is not known (Table 3.10.2). Some genes of industrial importance like amylase, pectinase, DNA polymerase, etc. have been expressed in bacterial systems.

Table 3.10.1: The Institutes engaged in biotechnology research in Viet Nam

S. No.	Institute	Infrastructure	Biosafety committee in position	Number of Ph.D. and M.Sc. engaged in biotechnology research**	Areas of Biotechnology research
1	Institute of Biotechnology	Adequate	X	55	Gene, Cell, Microbial, Enzyme Biotechnology
2	Agricultural Genetics Institute	Adequate	X	40	Gene, Cell, Microbial Biotechnology
3	Cuu Long Delta Rice Research Institute	Adequate	X	30	Gene, Cell Biotechnology
4	Vietnam Agricultural Science Institute	Adequate	X	20	Cell, Microbial Biotechnology
5	Institute of Tropical Biology	Adequate	X	20	Gene, Cell, Enzyme Biotechnology
6	Hanoi University of Natural Sciences	Adequate	X	25	Gene, Cell, Protein-Enzyme Biotechnology
7	Hanoi Agricultural University	Adequate	X	15	Plant Cell Biotechnology
8	HoChiMinh City University of Natural Sciences	Adequate	X	20	Gene, Cell, Protein-Enzyme Biotechnology

	Approx. 20 other institutions and labs	Adequate	?	-	Mainly Plant Cell Biotechnology
	Approx. 34 labs of local provinces	Adequate	?	-	Mainly Plant Cell Biotechnology

** only in-country scientists (approximate number)

Table 3.10.2: Status of GM crop development in Viet Nam

Crops	Trait/gene	Status
Cotton	?	?
Maize	?	?
Papaya	Virus resistance (CP or PRSV)	?
	Delayed ripening	?
Potato	?	?
Rice	Bacterial blight resistance (Xa21)	?
Sugarcane	?	?
Sweet potato	?	?

3.10.2 Biosafety and Regulatory Framework

Viet Nam is a party to CBD and CPB, but not to ITPGR and TRIPS. Viet Nam recognizes the importance of biosafety regulations required for GMOs and their release to environment. The biosafety regulations are under consideration of the Government of Viet Nam. These regulations were developed by National Environment Agency of Ministry of Science, Technology and Environment and Agricultural Genetics Institute of MARD. Until the Decree on Biosafety Regulations for GMOs is issued, the institutions dealing with GMOs and their products have established their own biosafety regulations. The country has neither established Biosafety Clearing House nor National Biosafety Committee.

The country does not have a policy on the introduction of GMOs for direct use as food, feed or for processing. The biosafety aspects of GMOs are the responsibility of

Ministry of Natural Resources and Environment; six other ministries (Agriculture, Aquaculture, Science and Technology, Health Finance and Trade) are also associated. Vietnam is not a signatory to SPS Agreement of the WTO, but their National Plant Quarantine Systems is adequately equipped to check inadvertent introduction of GMOs and hazardous microorganisms.

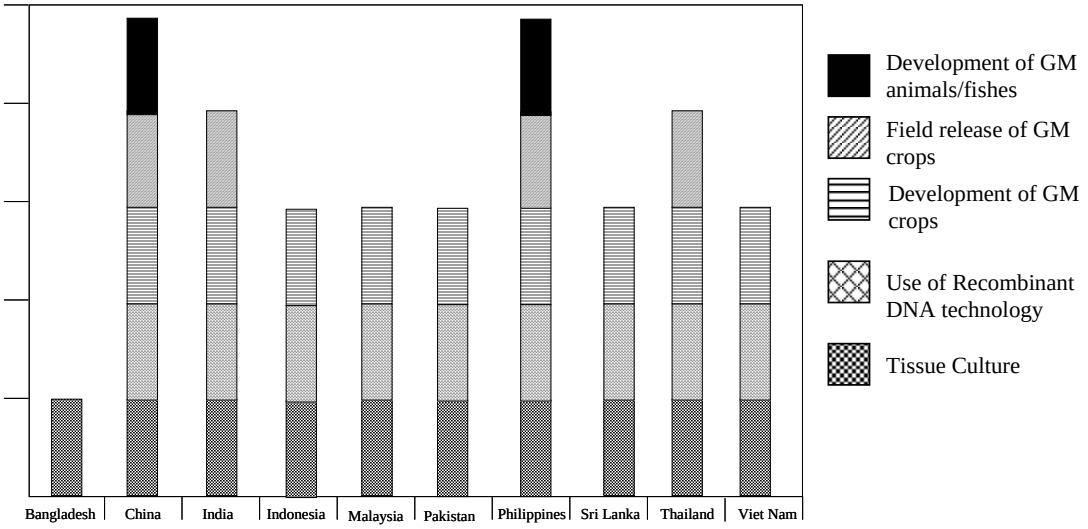
At present, the country does not have a mechanism for public deliberations on biosafety related issues. The country also does not have Patent Laws related to biotechnological interventions and use of biotechnology-derived products. The regulations dealing with Plant Variety Protection are also inadequate. Documentation of endangered species in Viet Nam is inadequate. The country, however, has documented 'hazardous' organisms. The country does not have legislations on 'Intellectual Property Rights', but the country has a Biodiversity and Community knowledge Protection Act. At present the seed regulations of the country do not cover GM crops.

Recently a regulation governing safety of GM foods has been issued.

4. IDENTIFICATION OF NEEDS AND PRIORITIES OF THE PARTICIPATING COUNTRIES

Agriculture is the mainstay of economy of the participating countries in Asia, as 50 to 70% of the population is directly or indirectly dependent on agriculture in different countries of the region. It is, therefore, natural that biotechnology has been accorded high priority in these countries. However, the level of utilization of these technologies varies greatly between the countries (Fig 4.1.1), from the soft biotechnology of tissue culture based micropropagation and biocontrol on the one end, of the spectrum to commercial introduction of GM crops on the other end. Some countries have also developed GM animals and fish for improved quality and improved production. It reflects a great variation in the capacity of the region in utilizing full potential of biotechnology.

Fig 4.1: Status of biotechnology development and utilization in participating countries.

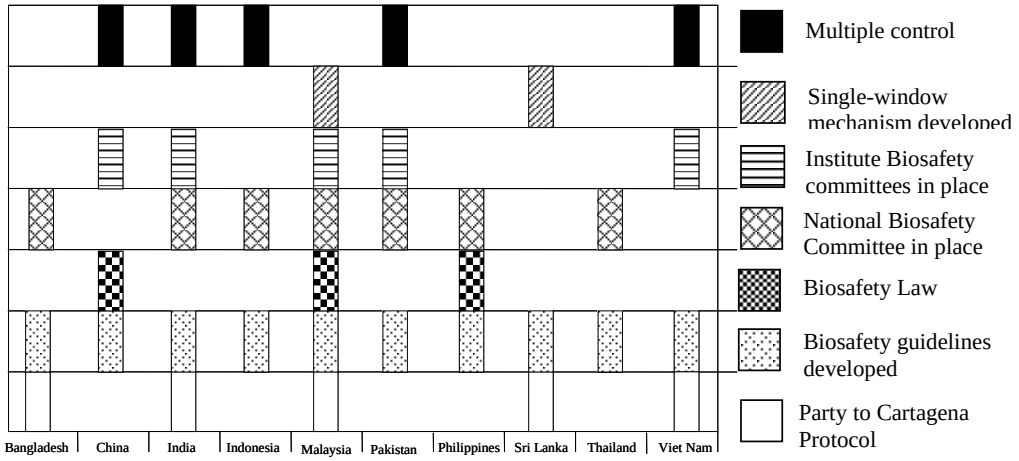


Policy, legislative regulations and mechanisms

Biotechnology has been recognized as the thrust area to improve agricultural production and boost economy of the participating countries. The success of biotechnology application, however, depends on the establishment of a technically sound

national framework for biosafety. This is an important priority, as the Cartagena Protocol on Biosafety is an internationally accepted legal instrument dealing with issues like transboudary movement of GMOs and allowing countries to take informed decisions to import GMOs.

Fig. 4.2: Status of biosafety related regulatory mechanisms in different countries of the region



The countries of the region, however, differ considerably in their status of formulating and implementing regulatory mechanisms to ensure biosafety of GMOs (Fig. 4.2.2). These countries mostly lack unified system to ensure biosafety, which is covered by different ministries and departments. A single window system, for the efficient utilization of GMOs has not been developed in most of the countries. There is an urgent need to put in place biosafety regulatory mechanisms and develop an efficient system for risk assessment and risk management. Irrespective of diversity of participating countries, the regulatory measures related to biosafety would have considerable common features

like scope, objective, institutional structure, application, authorization processes, review, assessment procedures, public awareness, enforcement procedures, etc. The procedures would also have systems to handle advanced informed agreement (AIA) information related to applications for imports; mechanism to review and take decisions; facilities for inspection and monitoring; public information and participation. These would need regional harmonization, without impinging on sovereign rights of individual nations. This will also develop mutual understanding and reduce duplication and improve biosafety.

Harmonization of biosafety procedures will be useful for ensuring safety and efficient implementation regulatory mechanisms. Harmonization would also lead to consensus documentation related to biosafety evaluation of GMOs, which would be valuable in a long term perspective. Such information would also be valuable to the Intergovernmental Committee of the Cartagena Protocol on Biosafety (ICCP) which is the repository of information on biosafety related issues.

4.2 Trained human resource

Some countries in the region are better placed than the others in having a strong group of scientists trained and practicing hardcore molecular biology and biotechnology. However, most of the countries in the region lack the required expertise essential for developing and utilizing GMO, and meeting biosafety requirements. The participating countries also need strengthening of human resource for developing and implementing regulatory mechanism through the training of legal experts, administrators and scientists. Training of active scientists is required in various biosafety related areas like risk assessment and risk management, monitoring, detection of GMOs, biosafety guidelines and regulations.

4.3 Institutional Infrastructure

Infrastructure for research and development related to GMOs varies from country to country. In most of the participating countries it is not adequate to harness the benefits from the fast advancing frontiers of biotechnology. Without a strong infrastructure for R&D, satisfactory implementation of biosafety regulations will not be efficient. Building of appropriate infrastructure for risk assessment and risk management in each country is essential. The Plant Quarantine System in these countries also needs strengthening to check transboundry movement of GMOs to meet SPS requirements.

4.4 Public Awareness and Participation

Article 23 of the Cartagena Protocol is aimed to 'promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of GMOs. But the mechanism of developing public understanding of the benefits of GMOs and associated potential risks is lacking in most of the countries. Participation of NGOs in policy development and creating public awareness is also weak. Public participation is a delicate issue, but a suitable mechanism must be developed for a meaningful public participation, based on creating public awareness and education by airing unbiased views on available scientific information.

4.5 Regional Cooperation

There is an urgent need to harmonize biosafety regulations in the region, which can be achieved by developing an active regional cooperation programme. The Asian Bionet[25] could be an useful starting point, not only for efficient exchange of information related to GMOs, but also for the process of harmonization of biosafety regulations,

[25] Proceedings of First Regional Consultation on Capacity Building in Biosafety of GMO Crops in Asia, FAO of the United Nations, Bangkok 2003. GCP/RAS/185/JPN, Document No. 2 2003 pp 41.

cooperation in risk assessment and risk management and development of database. Information sharing on all aspects of biosafety and documentation of problems related to the crops of common interest will be useful in developing and implementing biosafety regulations. Information sharing on risk assessment and risk management will also be valuable for the participating countries in monitoring and creating public awareness.

4.6 Research needs

Very limited research is ongoing to examine food, feed and environmental safety related to GMOs in the participating countries. This is a priority area to develop capacity and methodologies for risk assessment and risk management on a case-by-case basis of GMOs. R&D programmes are also required for developing standardized methods for GMO detection. It is important to deal with situations of influx of GMOs from countries which may not be segregating GMOs leading to difficulty in proper labeling.

5. CAPACITY BUILDING

Capacity Building is a key component in implementing CPB for safeguarding biosafety concerns of the participatory countries. The areas which require urgent action

are human resource development, infrastructure, formulation and implementation of regulatory mechanisms and policies for optimum utilization of biotechnological development, particularly in relation to GMOs.

5.1 Bangladesh

- *Human resource*
  - Most of the agricultural scientists currently engaged in biotechnology research in Bangladesh received their basic training in tissue culture, genetics and plant breeding, and other related disciplines, but not in molecular biology and genetic engineering. Some of them, through subsequent training programmes, have acquired skills to undertake strategic research in biotechnology, still there is an acute shortage of hardcore molecular biologists and biotechnologists. There is a need for regular upgrading of the skills and knowledge of the scientists to develop capacity through external training programmes, leading to M. Sc. and Ph.D. degrees.
  - Regular training programmes are also required for technical staff who play a valuable role in the development of technologies and their application.
  - There is also a severe shortage of persons trained in the areas of legislation and regulatory affairs, biosafety and risk assessment and management, and negotiations of material transfer agreements. Training programmes in the form of workshops, particularly in relation to biosafety need to be organized for regulatory bodies as well as policy makers. These will be useful in developing policies and regulations and their implementation to ensure biosafety in the country.

- Training programmes related to biosafety of GMOs should be organized for the personnel working in the National Plant Quarantine System.
- Training programmes should be organized for the management scientists and environmental lawyers.
- Training programmes for RARM should be taken up on priority.

- *Infrastructure requirements*
  - Institutes working on biotechnology should be strengthened to undertake research and development programmes related to GMOs.
  - Infrastructure for ecological evaluation and monitoring of GMOs needs to be built. Green house and containment facilities need to be developed for GMO testing.
  - Infrastructure of the National Plant Quarantine System also needs strengthening to build capacity to check inadvertent introduction of GMOs.
  - There is a need to establish an unified system for addressing biosafety concerns.
- *Regulatory Mechanisms*
  - Biosafety guidelines need to be revised.
  - Draft Acts on Biosafety, Plant Variety Protection and Biodiversity, and Community Knowledge Protection need to be finalized and enacted. It is important to stress that in the absence of national legal framework, biosafety programmes would not succeed.
  - A coherent mechanism for coordination between the ministries dealing with biosafety needs to be developed.

- National Committee on Biosafety and Institutional Biosafety Committees need to be established to make biosafety guidelines operational.
- Adequate legislation and food standards for food safety need to be developed.
- Technical assistance needs to be provided.

- *Policies and programmes*
  - An important element is the inconsistency in the learning process as different persons are deputed to meetings and international negotiations, which does not allow continuity in policies and programmes. Persons participating in such meetings represent a particular ministry which may not have control over the institutions involved in biosafety assessment and management. Professionalization of participation in international negotiations will be important in the biosafety context.
  - Bangladesh has necessary width and depth of scientific knowledge to manage the biosafety regulatory process, but policy decisions are required to focus on biosafety issues and undertake research on risk assessment and management issues.
  - There is a need to raise institutional and public awareness on GM food. The objective this programme should be to create awareness about the potential of biotechnology products for social and economic empowerment. The programme can succeed by (a) creating awareness starting from school level, (b) sensitizing the policy and decision makers and (c) active participation of scientific community in discussions related to biosafety.

- *Financial requirements.*
    - Biotechnology research and development needs greater funding and support.
    - Adequate funding needs to be provided to develop and implement regulatory measures.
    - Adequate funding needs to be provided for risk assessment and management of GMOs
    - Additional infrastructural support and funding needs to be provided to the National Quarantine System, as they have to be equipped to check inadvertent introduction of GMOs.
    - Adequate funds for establishing a national unified system or task force efficient development and execution of policies and regulation related to biosafety of GMOs.
    - Funding needs to be provided for regional cooperation.
- *Public Awareness*
    - Bangladesh has strong NGOs. It is desirable to strengthen public sector, private sector and NGO cooperation for developing programmes for Public awareness, education and participation on all aspects of biosafety.

5.2 China

- *Human resource*
    - China has developed a vast trained human resource for biotechnological research and development.
    - There is a need to organize further training programmes for technology development and regulatory framework.

- The personnel working in plant and animal quarantine need to be trained for GMO detection.

- *Infrastructure*
  - China seems to have built world class infrastructure for biotechnology research, including GMO development, but it has to strengthen infrastructure for technology development, database development and management, and scientific technical and institutional collaboration.
  - Special training programmes for scientific risk assessment and risk management are also required.
- *Regulatory mechanisms*
  - The country requires training of legal experts for harmonization of regulatory measures.
  - Training of administrators and professionals dealing with regulatory measures will improve implementation of biosafety regulations.
  - Overall regulatory measures need to be institutionalized to develop a single window system for biosafety regulations and clearances.
  - Regulations regarding GMO labeling and IPR need to be established improved.
  - Information clearing house needs to be developed for exchange of information and data on risk assessment and risk management.
- *Public awareness*
  - It is a sensitive issue. An appropriate system for public awareness, education and participation needs to be developed.

- NGOs need to be encouraged to participate in building public opinion.

5.3. India

- *Human resource*
  - India has well trained scientists engaged in biotechnology research, but there is a shortage of scientists to work on hardcore molecular biology/biotechnology. The country needs to arrange advanced level training in these areas.
  - Training of technical personnel is also essential for efficient biotechnological developments.
  - The country also needs to train legal experts, administrators and professionals responsible for implementing regulatory mechanisms. Considering the large number of district and state level committees, it is an enormous task.
- *Infrastructure*
  - India has built reasonably good infrastructure for work on GMOs at a few centers. Considering the large size of the country, many more centres need to be built. These centres will play an important role in risk assessment and risk management as the country enlarges the scope of use of GMOs in various sectors.
  - Infrastructure for developing databases and their dissemination for generating, delivery and use of knowledge needs to be taken up on a priority.

- The national quarantine system needs to be geared up for implementing biosafety regulations related to GMOs.
- Cooperation, partnership and collaboration between the public and private sector organizations is critical and needs to be strengthened.
- Institutions engaged in biotechnology need to be networked.

- *Regulatory mechanisms*
  - Urgent need is felt in India to put in place an efficient and transparent regulatory framework for testing and evaluation of GMOs. [26]
  - There is a need to establish an independent autonomous body for managing biosafety framework, like a 'National Authority for Biosafety'.

  - There is a need to develop mechanisms to overcome IPR related barriers for successful commercialization of GMOs.
  - Although national rules have been notified to deal with the transgenic crops vis-à-vis the biosafety, there is an urgent need to establish "referral laboratories/institutes" for risk assessment, analysis and risk communication.
  - There is a need to develop mechanisms to overcome IPR related barriers for successful commercialization of GMOs.
  - There is a need to address issues like biosafety, IPR, labeling, redressal etc.
- *Policy*

[26] Highlights of Brainstorming Session on Enabling Regulatory Mechanisms for Release of Transgenic Crops. Trust for Advancement of Agricultural Sciences (TAAS), IARI, New Delhi, October 18, 2003

- A national policy on biosafety risk assessment, management and communication needs to be developed to address biosafety concerns.
- Mechanisms for public awareness, education and participation needs to be established.
- Policy for intra-regional collaboration needs to be developed.

5.4. Indonesia

- *Human resource*
  - Indonesia has built good expertise in plant sciences but lack expertise in animal sciences.
  - Capacity for risk analysis is available to a limited extent. This needs to be strengthened through specialized training programmes.
  - Legal experts also need to improve their capacity related to biosafety issues.
- *Infrastructure*
  - Infrastructure for biotechnology research needs improvement for creating conducive atmosphere for productive research.
  - Private sector needs to be encouraged and strengthened
  - Quarantine system to be strengthened and personnel trained to detect GMOs.
- *Regulatory Measures*
  - Biosafety framework needs improvement to include participation of stakeholders.
  - Appropriate law dealing with biosafety should be put in place.
- *Public awareness*

- Public awareness, education and partnership needs strengthening by training of scientists to address the relevant issues.
- Techniques to be developed for well structured awareness programmes.

5.5. Malaysia

- *Human resource development*
  - Malaysia needs human resource development to deal with various aspects of biosafety, policy formulation, development of regulations and their implementation, risk assessment and risk management and detection GMOs.
  - Advanced training is also required for the molecular biologists for taking part in research programmes related to biosafety of GMOs.
- *Infrastructure*
  - Infrastructure for biotechnology research needs strengthening as some of the institutions engaged in biotechnology research are not adequately equipped
  - System for database management and exchange of information needs to be established.
- *Regulatory Measures*
  - National Biosafety Act needs to be put in place.
  - Protocols for risk assessment and risk management need to be developed in order to develop efficient implementation of biosafety regulation.
- *Public awareness*
  - A structured programme needs to be developed to promote public education and participation.

5.6. Pakistan

- *Human Resource*

- There is a need for a larger number of well trained biotechnologist. Training leading to post graduate degree, from universities in other countries excelling in biotechnology research need to be organized to build a core group of front-line biotechnologists who could take the role of master trainers.
- The country also needs to organize workshops and training courses for hands-on training of scientists and technical personnel engaged in biotechnology research in different institutions.
- Special training courses need to be developed for developing trained human resource to deal with biosafety related issues.
- Inclusion of biosafety in graduate and post-graduate programmes would be useful in creating awareness and arousing interest in the subject.
- Training programmes are also required on specific legal aspects of various biosafety related international treaties and conventions. Such programmes will also be useful in developing guidelines and laws required to ensure biosafety in the country.
- Training workshops for policy makers, legislators, lawyers based on biosafety issues covered by CBD, CPB, SPS, WTO and other international conventions and treaties would be useful.
- Training programmes are required to develop human resource for the National Plant Quarantine System to check transboundary movement of GMOs.

- *Infrastructure requirements*

- Except for a couple of institutions, infrastructure for biotechnology research and implementation of biosafety measures is inadequate. Various institutions/centers engaged in biotechnology research must be adequately equipped to drive full benefit from recent developments in biotechnology
- Infrastructure for biotechnology research by the private sector needs to be promoted.
- Infrastructure for ecological evaluation and monitoring of GMOs needs to be built.
- Appropriate infrastructure is also required for technology development
- The National Plant Quarantine System needs to be strengthened to build introduction of GMOs.

- *Regulatory mechanisms*

- Biosafety Act needs to be put in place at the earliest
- The Acts related to IPR, Trademark, Patents, Plant Breeders Rights, etc need to be harmonized to include biotechnology and GMO related aspects.
- Develop a single window system to address biosafety issues, through an appropriate mechanism to coordinate biosafety related activities of different ministries/departments. This would require capacity building for import/export of GMOs.

- *Policies and programmes*

- Policies and programmes related to biosafety assessment and management of potential risks associated with GMOs need to be urgently developed.

- There is a need to develop standards for regulating GMOs.
- Guidelines need to be developed for biosafety assessment and management
- The guidelines should include suitable measures to minimize potential risks associated with GMOs.
- Methodologies should be developed to appropriately implement above policies and programmes.

- *Financial Resources*

- The country requires appropriate financial support for capacity building for successful implementation of biosafety protocols. The country has given high priority to biotechnology in its IX Five Year Plan
- It is estimated that biosafety capacity building in Pakistan would require about US $ 4 million

5.7. The Philippines

- *Human resource development*
  - The Philippines has a good trained human resource for biotechnology research, but the country needs to introduce advanced level training programmes for improving the capabilities of scientific and technical personnel engaged in biotechnology research.
  - Special training programmes are required for risk assessment and risk management in relation to GMO biosafety.
  - Legal experts need training to upgrade the regulatory mechanisms.
  - Managers and professionals need training to implement biosafety guidelines.

- Trainings are also required for improving the capabilities of personnel working in the quarantine and food safety department for detecting GMOs.

- *Infrastructure*
  - The Philippines has reasonably good infrastructure, but it requires further strengthening, particularly for developing Biosafety Clearing House, regulatory management and the quarantine system. Strengthening of R&D Centres and facilities for technology development will also be useful in harnessing full advantage from the biotechnological development.
- *Regulatory Measures*
  - The country has in place most of the regulatory measures, but these need harmonizing, to avoid overlapping authorities and to promote implementation of biosafety regulations. A single window system needs to be developed.

5.8. Sri Lanka

- *Human resource development*
  - Sri Lanka needs to upgrade its human resource for research and development of GMOs, risk assessment and risk management, development of regulatory measures, data management and information exchange, public awareness, education and participation and regulation of transboundary movement of GMOs and their use in food and feed.
- *Infrastructure*
  - Up-gradation of R&D institution for developing GMOs and associated risk assessment and risk management is urgently required.

- Infrastructure is required for GMO based technology development, to help in commercialization of research efforts.
- Institutional infrastructure also needs to be developed for implementing regulatory measure, information exchange, data management, quarantine system and creating public awareness/participation.

- *Regulatory Measures*
  - The regulatory mechanisms need to be harmonized and implemented.
  - A single window system for dealing with biosafety issues needs to be developed.
  - Policy regarding the use of GMO needs to be developed through wider consultation.

5.9. Thailand

- *Human resource development*
  - In Thailand, some trained human resource is available for R&D, but it has to build human resource for developing regulatory framework and its implementation. Capabilities of quarantine personnel in the detection GMOs also need to be built.
- *Infrastructure*
  - Infrastructure strengthening is particularly required for technology development, risk assessment, risk management, data management, biosafety clearing house, public awareness, quarantine system and biodiversity conservation.
- *Regulatory Measures*

- Regulatory measures related to GMOs are being developed. These need to be quickly put in place.

5.10. Viet Nam

- *Human resource development*
  - Need to strengthen human resource engaged in R&D.
  - Need to develop human resource for developing regulatory measures and implementing them.
  - Train human resource for risk assessment, risk management and detection of GMOs.
- *Infrastructure*
  - Infrastructure for R&D needs strengthening.
  - Need to establish key laboratories for GMO research.
  - Need to establish adequate facilities for GM crops development and risk assessment and risk management
  - Infrastructure for regulatory measures should be built.
  - Infrastructure of quarantine system needs upgradation.
  - Develop infrastructure for information sharing and database management.
  - Adequate resources for biotechnology R&D need to be provided.
- *Regulatory Measures*
  - Need to establish a National Committee on Biosafety and implement biosafety guidelines quickly.
  - Need to develop national policy and legislation on GMOs.

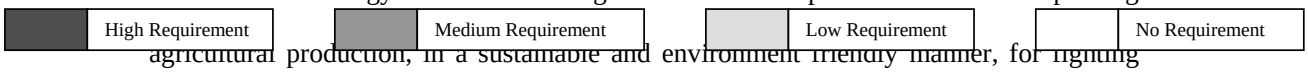
- Create mechanism for public awareness education and participation.

5.11 Capacity building requirement in the region

The participating countries vary greatly in their capacity related to GMO biosafety. The attached matrix (Table 5.11) shows that most of the countries require considerable efforts to build capacity for regulating GMOs. For successful regulation it is imperative to also build capacity for R&D related to GMOs. Some countries in the region have advanced in this direction and can help the other participating countries in quickly developing capacity for developing, harmonizing and implementing biosafety regulations for safe use of modern biotechnology.

5.11.1: Capacity building needs of participating countries

HRD	Research & Development	
	Technology & Development	
	Regulatory Framework	
	Regulatory Management	
	Risk Assessment	
	Data Management	
	Public Awareness	
	Quarantine Personnel	
Infrastructure	Research & Development	
	Technology & Development	
	Regulatory Management	
	Risk Assessment	
	Risk Management	
	Data Management	
	Biosafety Clearing House	
	Public Awareness	
	Quarantine System	
	Biodiversity Conservation	
	Biodiversity Documentation	
	Institutional Collaboration	
	Technology Transfer	
Regulatory	Biosafety Law	
Mechanisms	Biosafety Guidelines	
	Patent Laws	
	Plant Variety Protection	
	IPR	
	Biodiversity and CKP Act	
	Seed Act	
	Food Safety	
	Labeling of GMOs	
Asian Bionet	Information Exchange	
	Intra-regional Collaboration	



Biotechnology has been recognized as an important tool for improving agricultural production, in a sustainable and environment friendly manner, for fighting hunger and malnutrition. The new technology is of a great relevance for the countries participating in the current programme, as a large proportion of population in these countries is directly or indirectly dependent on agriculture. However, for harnessing full potential of biotechnology (particularly GMOs), strengthening of capacities in relation to

human resources, research and technology development, regulatory measures, policies and transparent transfer of technologies is essential. This chapter outlines possible approaches to build capacity in participating countries in the context of Cartagena Protocol on Biosafety.

6.1 Human resource

6.1.1 Most of the agricultural scientists currently engaged in agricultural biotechnology research in the participating countries received their basic training in tissue culture, genetics and plant breeding, and other related discipline, but not in molecular biology and genetic engineering. Some of them, through subsequent training programmes, have acquired skills to undertake strategic research in biotechnology. Thus, there is an acute shortage of hardcore molecular biologists and biotechnologists in most of the participating countries.

6.1.2 It is essential to develop a strong group of hardcore molecular biologists, who would become main resource persons for further generating trained human resource, in each country. To meet this objective, there is a need to arrange training programmes leading to post-graduate degrees at centers of excellence in the area of biotechnology in other countries are needed.

6.1.3 The expertise of the core group, developed by external training programmes, should be utilized by organizing hands-on training programmes of 6 to 12 months. Such training programmes are very useful in quickly developing trained manpower.

6.1.4 Special training programmes in the form of workshops need to be organized to develop capacity for risk assessment and risk management related to GMOs. The participating countries, by and large, do not have the required expertise.

6.1.5 Courses on biosafety need to be introduced in curricula of graduate and post-graduate programmes for (a) creating awareness, and (b) generating interest in the subject.

6.1.6 Regular training programmes should also be organized for technical staff who play a valuable role in the development of technologies and their application.

6.1.7 The participating countries, at present, do not have persons trained in the areas of legislation and regulatory affairs, and negotiations of material transfer agreements. Training programmes for legal advisors, managers and professionals in the form of workshops, particularly in relation to biosafety need to be organized. These will be useful in developing policies and regulations and their implementation to ensure biosafety in the country. Training of legal advisors to operate in research institutions and concerned ministries is also desirable.

6.1.8 Training programmes related to biosafety of GMOs should be organized for the personnel working in the National Quarantine System.

6.1.9 Practical training programmes need to be developed for data management and information dissemination.

6.1.10 Public awareness, education and participation is an essential but sensitive component. Scientists must be trained to professionally organize programmes for public awareness.

6.2 Infrastructure requirements

6.2.1 Infrastructure of institutions working on biotechnology needs to be strengthened to undertake research and development programmes related to GMOs.

6.2.2 Infrastructure for ecological evaluation and monitoring of GMOs needs to be built.

6.2.3 Suitable infrastructure for biodiversity conservation and documentation needs to be built.

6.2.4 Infrastructure of the National Quarantine System also needs strengthening to build capacity to check transboundary movement of GMOs and their products.

6.2.5 Establish an unified autonomous system for addressing biosafety concerns. A possible model is suggested

6.2.6 Establish a biosafety clearing house as a part of unified autonomous system (suggested in 6.2.5) for information exchange and to deal with AIA.

6.2.7 Establishment of system to facilitate private sector participation in biosafety.

6.3 Regulatory Mechanisms

6.3.1 Biosafety guidelines need to be suitably developed and adopted.

6.3.2 Acts on Biosafety, Plant Variety Protection and Biodiversity and Community Knowledge Protection and Seed Act need to be enacted. It is important to stress that in the absence of a national legal framework, biosafety programmes would not succeed.

6.3.3 A coherent mechanism for coordination between the Ministries and Departments dealing with biosafety needs to be developed.

6.3.4 National Committee on Biosafety and Institutional Biosafety Committees need to be established to make biosafety guidelines operational.

6.3.5 Develop adequate legislation and food standards for food safety.

6.3.6 Establish mechanism for harmonization of regulatory mechanisms.

6.4 Policies and programmes

6.4.1 Another important element is the inconsistency in the learning process as different persons are deputed to meetings and international negotiations at different times. Persons participating in such meetings represent particularly ministry which may not have control over the institutions involved in biosafety assessment and management. Policies should be developed to appoint professionals to head the National Biosafety Committee, various working groups and related committees who should also participate in international negotiations.

6.4.2 Policy decisions are required to focus on biosafety issues and undertake research on risk assessment and risk management issues.

6.4.3 Need to raise institutional and public awareness on genetically modified food. The objective of this programme should be to create awareness about the potential of biotechnology products for social empowerment. The programme can succeed by (a) creating awareness starting from school level, (b) sensitizing the policy and decision makers, and (c) active participation of scientific community in discussions related to biosafety.

6.5 Financial requirements.

Adequate funding needs to be provided for capacity building through (a) hands on *in-situ* and *ex-situ* training programmes of short to long-term durations for developing well trained human resource for research and development; (b) workshops to train legal experts, managers and professionals; (c) seminars for exchange of information and ideas; (d) development of infrastructure for research and implementation of biosafety ;regulations; (e) development of infrastructure for unified and autonomous organization for biosafety; and (f) development of active regional collaboration.

6.6 Regional Collaboration

6.6.1 An active regional collaboration, particularly amongst the participating countries, will help in capacity buildings in the region.

6.6.2 Both, the *in-situ* and *ex-situ* training programmes can be organized using the expertise available in the region. The *ex-situ* trainings can be organized in the participating countries, which have taken lead in the development and use of GMOs. Similarly, for *in-situ* training programmes, expertise can be drawn from the participating countries.

6.6.3 Various workshops and group trainings can also be organized jointly for efficient utilization of resources. These will be useful for capacity building for (a) risk assessment and risk management for environment and food safety; (b) electronic data management; (c) developing regulatory measures; and (d) quarantine system.

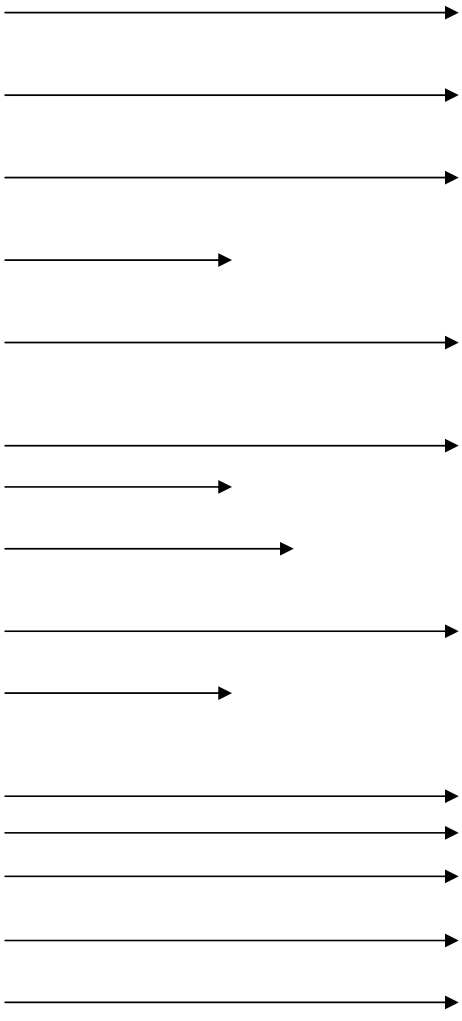
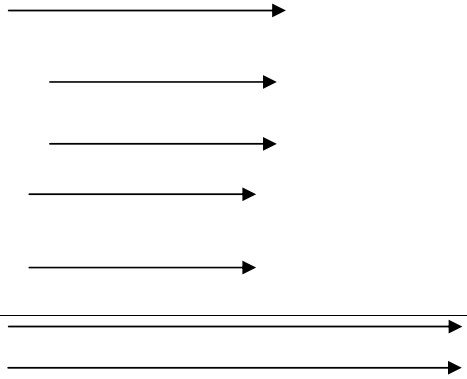
6.6.4 Maximum benefit of an active regional collaboration will be in (a) exchange and sharing of information, (b) development and management of database, (c) harmonization of biosafety regulations and their implementation, (d) confidence building, and (e) cooperative/collaborative research.

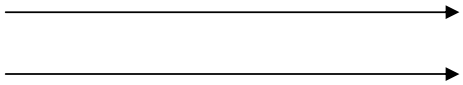
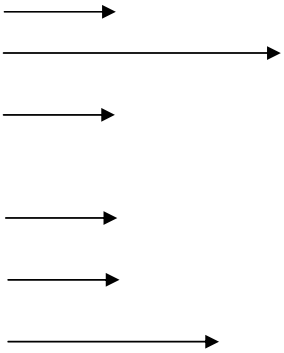
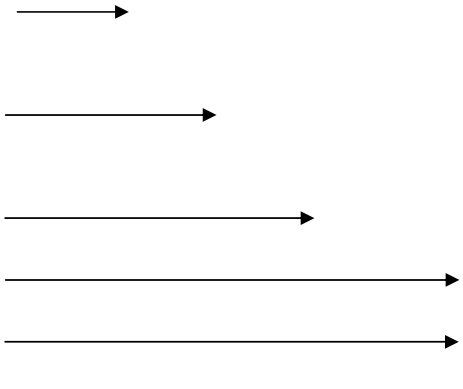
6.6.5 The establishment of Asian-Bionet (or Asia-Bionet), as envisaged earlier, will play a proactive role in capacity building and achieving the overall objective of harnessing biotechnology for improvement in agricultural productivity in a sustainable and environment friendly manner.

6.6.6 The regional collaboration will assist the participating countries in taking well informed decisions and will lead to development of strong base for international cooperation and collaboration in various areas connected with biosafety.

6.7 Time-frame for capacity building

No.	Activity	Year		
		1	2	3
	A. Human-resource development			

	1. *Ex-situ* training leading to M.Sc./Ph.D. degree 2. *Ex-situ* training of six-twelve months for upgrading R&D capacities. 3. *In-situ* training of scientists 4. *Ex-situ* and *in-situ* training of quarantine personnel 5. *In-situ* training of Technical personnel 6. Group trainings • Risk assessment and Risk management • Regulatory measures • Management and implementation of Regulatory measures • Data Management and information dissemination • Public awareness 7. National and Regional Workshops • Risk Assessment • Regulatory measures • Data management and dissemination • Public participation 8. Prepare and update training manuals	
	B. Infrastructure improvement 1. Develop Centres of Excellence (R & D institutions) 2. Ecological evaluation of GMOs 3. Biodiversity conservation 4. Quarantine system 5. Establish unified Autonomous Biosecurity System	

	6. Database management 7. Develop internet based training Centre	
	C. Regulatory Measures 1. Establish guidelines 2. Put in place various Acts 3. Develop coordination between the Ministries dealing with biosafety 4. Establish National Biosafety Committee 5. Establish Institute of Biosafety committees 6. Harmonize regulatory measures in the region.	
	D. Policies and Programmes 1. Develop policies for professionalisation of implementing agencies 2. Develop policies for undertaking research on risk assessment and risk management 3. Harmonization of biosafety programmes 4. Raise institutional and awareness 5. Technology transfer	
	E. Regional Collaboration	
	F. Financial requirements 1. Provide adequate fundings	

7 CONCLUDING OBSERVATIONS

The capacity of participating countries in meeting biosafety requirements related to CPB varies considerably. The requirement for capacity building in some countries like Bangladesh and Viet Nam is greater than the others like China, India and the Philippines, but all participating countries need to improve capacity for safe and fruitful utilization of biotechnology for improving agricultural production in a sustainable and environmentally friendly manner. This document provides a benchmark outline to build capacity in the following areas related to biosafety issues.

1. Development of trained human resource for R&D, formulation and implementation of regulatory measures, risk assessment and risk management.
2. Development and improvement in infrastructure for RD, quarantine and effective implementation of regulatory measures.
3. Development of policies related to biosafety, meeting the needs of individual countries.
4. Development of regional collaboration.