# National Biosafety Framework

## of the Government of the People's Republic of Bangladesh

**Department of environment**
**Ministry of Environment and Forest**
**Government of the People's Republic of Bangladesh**
**Dhaka, Bangladesh**

**NOVEMBER 2006**

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# FOREWORD

(Secretary, Ministry of Environment and Forest)

To Come

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# PROJECT BACKGROUND

The UNEP-GEF Project Number GF/2716-4319 on the Development of the National Biosafety Framework (NBF) of the People's Republic of Bangladesh started in July 2004 and ended in December 2006. The National Executing Agency for the UNEP-GEF project was the Department of Environment under the Ministry of Environment and Forest, Government of the People's Republic of Bangladesh. For coordination and technical advice a National Coordination Committee was formed.

# ACKNOWLEDGEMENTS

The Ministry of Environment and Forest would like to thank all the representatives of the relevant Ministries, Departments, Agencies, Research Organisations and Universities as well as the representatives of the NGOs and the private sectors for their valuable contribution in the preparation of the National Biosafety Framework of Bangladesh. Thanks are also due to Dr. Nizar Mohamed, UNEP-GEP Regional Coordinator for the Asia Pacific region, for his technical support in the preparation of the Framework. Special thanks are also due to the National Technical and Expert Teams who in various ways contributed in the preparation and finalisation of this document.

# EXECUTIVE SUMMARY

The National Biosafety Framework is an outcome of the National Biosafety Development Project in Bangladesh working under the UNEP/GEF Global Project on Development of National Biosafety Frameworks. The project has been assisted by a National Coordination Committee (NCC) consists of members from various agencies and stakeholders.

Bangladesh ratified the Convention on Biological Diversity (CBD) on 20 March 1994 in order to ensure conservation and sustainable use of the country's rich biological diversity. Although Bangladesh is willing to benefit from the latest scientific revolution in modern biotechnology, the country is fully aware of the possible adverse impacts of genetically modified organisms (GMOs) on the environment, biodiversity and human health. Accordingly, Bangladesh ratified the Cartagena Protocol on Biosafety (CPB) on 24 May 2000.

The National Biosafety Framework (NBF) has been developed following an extensive assessment of biotechnology and biosafety in Bangladesh. Surveys were conducted on the current use of modern biotechnology, existing relevant polices, laws and regulations, capacity building activities and existing expertise within the country. The Framework provides the basis for future regulation for the management of GMOs in Bangladesh. The objective of the NBF is two fold. It Give an overview of the existing systems and identifies future needs for an effective and transparent legislation and administrative system.

Based on the gathered information, the NBF has been developed through a multi-stakeholder consultative process. A series of workshops, seminars, and meetings were held to get input from the stakeholders, policy makers, researchers, academics, government and non-governmental organisations. The document was drafted and revised after a national workshop organised by the Department of Environment (DoE). The whole process of the NBF has been technically supported by the UNEP-GEF Regional Coordinator for the Asia-Pacific Region.

The NBF consists of six chapters and several annexes. Chapter 1 deals with introductory issues, such as, background, definitions, and its relationship with the Cartagena Protocol and the Convention on Biological Diversity. Chapter 2 reviews the existing policies relevant to biosafety and proposes a new national policy on biosafety in order to address the issues and concerns arising from the Cartagena Protocol. Chapter 3 examines the existing laws and regulations on biosafety to see how far these are adequate to meet the needs of Bangladesh. It also argues for the adoption of new regulatory regime for biosafety. Chapter 4 proposes the administrative system for handling applications or request for authorisation. Chapter 5 highlights the existing system of monitoring and enforcement and suggests new measures to comply with the Cartagena Protocol. Chapter 6 investigates the effectiveness of the existing mechanisms for and suggests measures to be taken in order to strengthen the existing mechanisms on public awareness, education and public participation.

# ABBREVIATIONS USED IN THE TEXT

| | |
|---|---|
| AIA | Advance Informed Agreement |
| AIS | Agriculture Information Service |
| BARC | Bangladesh Agricultural Research Council |
| BAU | Bangladesh Agricultural University |
| BBCH | Bangladesh Biosafety Clearing House |
| BC | Bangladesh Code |
| BCC | Biosafety Core Comittee |
| BCH | Biosafety Clearing House |
| BG | Bangladesh Gazette |
| BSMRAU | Bangabandhu Sheikh Mujibur Rahman Agricultural University |
| BSO | Biosafety Officer |
| BSWGs | Biosafety Working Groups |
| BT | Biotechnology |
| CAB | Consumer Association of Bangladesh |
| CAN | Competent National Authority |
| CBD | Convention on Biological Diversity |
| CHM | Clearing House Mechanism |
| COP | Conference of the Parties |
| CPB | Cartagena Protocol on Biosafety |
| DAE | Department of Agricultural Extension |
| DDAE | Deputy Director of Agricultural Extension |
| DFO | District Fisheries Officer |
| DHS | Directorate of Health Services |
| DLO | District Livestock Officer |
| DLR | Dhaka Law Reports |
| DLS | Department of Livestock Services |
| DoA | Department of Agriculture |
| DoE | Department of Environment |
| DoF | Department of Fisheries |
| DoH | Department of Health |
| EC | Expert Committee |
| EIA | Environmental Impact Assessment |
| EPC | East Pakistan Code |
| EPO | East Pakistan Ordinance |
| FAO | Food and Agricultural Organisation |
| FBC | Field Level Biosafety Comittee |
| FFP | Food, Feed and Processing |
| GEF | Global Environment Facility |
| GM | Genetically Modified |
| GMO | Genetically Modified Organism |
| GO | Government Organisation |
| HSTU | Hajee Mohammad Danesh Science and Technology University |
| IAS | Invasive Alien Species |
| IBCs | Institutional Biosafety Committees |
| ICT | Information and Communication Technologies |
| IPR | International Property Rights |
| IRRI | International Rice Research Institute |

| | |
|---|---|
| LMO | Living Modified Organism |
| MBG | Medical Biotechnology |
| MBT | Medical Biotechnology |
| MLT | Multi Location Testing |
| MoA | Ministry of Agriculture |
| MoC | Ministry of Commerce |
| MoEF | Ministry of Environment and Forest |
| MoF | Ministry of Food |
| MoFL | Ministry of Fisheries and Livestock |
| MoHFW | Ministry of Health and Family Welfare |
| MoL | Ministry of Law |
| MOP | Meeting of the Parties |
| NBF | National Biosafety Framework |
| NBSAP | National Biodiversity Strategy and Action Plan |
| NCA | National Competent Authority |
| NCB | National Committee on Biosafety |
| NBP | National Biotechnology Policy |
| NECB | National Executive Committee on Biotechnology |
| NGO | Non-Government Organisation |
| NTC | National Technical Committee |
| NTCB | National Technical Committee on Biotechnology |
| NTCCB | National Technical Committee on Crop Biotechnology |
| NTCEB | National Technical Committee on Environmental Biotechnology |
| NTCFLB | National Technical Committee on Fisheries and Livestock Biotechnology |
| NTF | National Task Force |
| NTMB | National Technical Committee on Medical Biotechnology |
| OECD | Organisation of Economic Cooperation & Development |
| PC | Pakistan Code |
| PG | Pakistan Gazette |
| PRSP | Poverty Reduction Strategy Paper |
| R & D | Research and Development |
| RA | Risk Assessment |
| SAAO | Sub-Assistant Agriculture Officer |
| SAU | Sher-e-Bangla Agricultural University |
| SE | Substantial Squivalence |
| SPS | Sanitary and Phytosanitary Measures |
| STRP | Scientific and Technical Review Panel |
| TRIPS | Trade Related Intellectual Property Rights |
| UAO | Upazila Agriculture Officer |
| UFO | Upazila Fisheries Officer |
| UHFPO | Upazila Health and Family Planning Officer |
| ULO | Upazila Livestock Officer |
| UNEP | United Nations Environment Programme |
| WHO | World Health Organisation |
| WTO | World Trade Organisation |

# CHAPTER 1

## 1. BACKGROUND AND INTRODUCTORY ISSUES

### 1.1. The Cartagena Protocol on Biosafety("the Protocol")

The Cartagena Protocol on Biosafety (CPB) was adopted by the international community in Montreal on 29 January 2000 in order to fulfil one of the important objectives of the 1992 Convention on Biological Diversity (CBD): the conservation and sustainable use of biological diversity.

The Convention takes a comprehensive approach to the conservation of biological diversity. It addresses the threats that might arise from the transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology. Article 8(g) of the CBD deals with domestic measures generally. It requires each Contracting Party to take steps to regulate, manage or control the risks associated with the use and release of LMOs resulting from modern biotechnology which are likely to have adverse impacts on the conservation and sustainable use of biological diversity, taking into account the risks to human health.

Article 19(3) of the CBD provides the legal basis for the adoption of the CPB in order to establish an international regulatory regime on LMOs. It obliges the parties to the CBD to 'consider the need for and modalities of a protocol setting out appropriate procedure(s) 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) of the CBD deals with the transfer of LMOs from one Party to another. It requires each Party to provide information on domestic regulations concerning use and safety to any other Party to which a LMO is provided, as well as any available information on the adverse effects which the introduction may have for this party. Article 28 of the CBD mandates Parties to cooperate in the formulation and adoption of protocols.

Accordingly, the Conference of the Parties (COP) to the CBD at its first meeting held in 1994 in Nassau, Bahamas, authorised two meetings to consider the need for and modalities of a protocol on biosafety. A panel of experts met in Cairo in May 1995 and an open-ended Ad Hoc Group of Experts on Biosafety met in Madrid in July 1995. The large majority of delegations present at the Madrid meeting favoured the development of a protocol on biosafety. At its second meeting held in 1995 in Jakarta, Indonesia, the COP decided to establish an open-ended Ad Hoc Working Group on Biosafety (BSWG) to elaborate a protocol on biosafety (Decision II/5). The BSWG was chaired by Veit Koester of Denmark. Six meetings of the BSWG were held between July 1996 and February 1999.

The Sixth and final meeting of the BSWG, held in Cartagena, Colombia, in February 1999, forwarded a draft consolidate text of the Protocol to the first Extraordinary Meeting of the Conference of the Parties (ExCOP) to the CBD for its consideration. However, the ExCOP failed to reach an agreement on certain issues of the Protocol such as the scope of the protocol, LMOs intended for direct use as food or feed, or for processing (LMO-FFPs), the precautionary principle, identification and documentation requirements and the relationship between the

protocol and other international agreements, notably the World Trade Organization (WTO). The final negotiation of these core issues took place at the resumed session of the ExCOP which immediately followed the January 2000 informal meeting in Montreal. Ultimately the Protocol was adopted by the COP to the CBD on 29 January 2000 and entered into force on 11 September 2003.

## 1.2. Bangladesh as a party to the Protocol

Although the Protocol is related to the CBD, it is a separate international treaty. The Protocol with its adoption did not automatically become binding on the Parties to the Convention. According to Article 34 of the Convention, in order to be binding on states, the Protocol is to be ratified by each state separately. Bangladesh signed the Protocol on 24 May 2000 and ratified it on 5 February 2004. According to Article 36 (4) of the Convention, the Protocol came into force for Bangladesh on 5 May 2004, on the ninetieth day after the date of deposit of the instrument of ratification. Bangladesh ratified the Convention on Biological Diversity on 20 March 1994 and for Bangladesh it entered into force on 20 June 1994.

As far as the relationship between international treaties and the national law is concerned, Bangladesh follows dualist approach. It means that international treaties do not automatically become part of the domestic law. An implementing law is needed in order to transform the obligations of treaties into domestic law. Accordingly, if the existing laws are not enough to transform the treaty obligations into domestic law, new laws are to be made. One of the important purposes of this draft framework, as mentioned below, is to review the existing policies and regulatory regime to see how far these are adequate to implement the Protocol's obligations in Bangladesh.

## 1.3. Purposes of the national biosafety framework

A national biosafety framework (NBF) is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the filed of the safe transfer, handling and use of 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 health.

The purpose of description of the NBF is twofold:

(1) Give an overview what has been done in Bangladesh during the NBF Development Project, and what legislation and administrative system are in place in Bangladesh;
(2) Indicate what still needs to be done in order to complete the NBF (i.e. missing legislation that still needs to be drafted/adopted, gaps in administrative or enforcement systems etc).

## 1.4. Definitions used

**Advance informed agreement**: Means a formal agreement between two states or between state and a group of states belonging to a regional economic integration organisation, to transfer any

GMO products thereof, based on information supplied by the exporting state, with the explicit understanding that the information is complete and accurate.

**Contained use**: Means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

**Genetically modified organism (GMO)**: Means any living organism or part thereof which is capable of regenerating itself on its own or in the body/cell of another organism, and whose genetic material has been modified by modern biotechnology in a way not occurring naturally by mating or natural recombination.

**Living modified organism (LMO)**: Means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology and for Bangladesh has the same meaning as GMO.

**Living organism**: Means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

**Modern biotechnology**: Means application of:

(a) In vitro nucleic acid techniques, including recombinant nucleic acid and direct injunction of nucleic acid into cells or organelles, or
(b) Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

**Precautionary approach**: Means that a lack of scientific certainty of the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity, on the environment and human health may be due to insufficient relevant scientific information and knowledge. This shall not prevent a country from taking appropriate steps/precautions with regard to the import of GMOs, in order to avoid or minimise such potential adverse effects.

**Risk assessment**: Means the use of scientific and other appropriate methods to identify and characterise the nature, likelihood of occurrence, and potential magnitude of any hazards, with due regard to the precautionary principle.

**Transboundary movement**: Means any movement of GMOs or biotechnology products, intentional or unintentional, and by any means including gene transfer, across one or more national boundaries.

**Working day**: Means any day other than a weekly holiday(s), and any other day that is a public or a national holiday in the People's Republic of Bangladesh.

## 1.5. Structure of the NBF

This framework report has been structured in accordance with the UNEP/GEF proposed format into six main chapters. Chapter 1 deals with introductory issues, such as, background of the CPB; its relationship with the CBD; ratification of these treaties by Bangladesh; definitions used in this framework; etc. Chapter 2 reviews the existing policies relevant to biosafety and argues for the adoption of a new national policy on biosafety in order to address the issues and concerns of the CPB. Chapter 3 examines the existing laws and regulations on the biosafety to see how far these are adequate to meet the obligations of the CPB by Bangladesh. It also argues for the adoption of a regulatory regime for biosafety. Chapter 4 proposes for administrative system for handling applications on request for authorisation. Chapter 5 highlights on the existing system of monitoring and enforcement in Bangladesh and suggests new measures in the light of the CPB. Chapter 6 investigates the effectiveness of the existing mechanisms for public awareness, education and participation. It suggests measures to be taken in order to strengthen the existing measures on public awareness, education and participation.

A diagrammatic framework for the management of GMOs is shown in Figure 1 below.

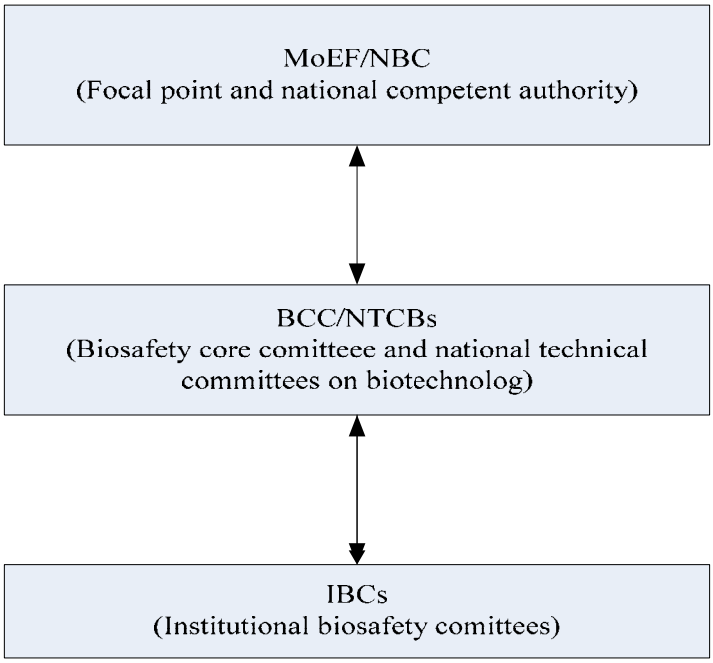



Figure 1. Management for the management of GMOs in Bangladesh

# CHAPTER 2

## 2. NATIONAL POLICY ON BIOSAFETY

### 2.1. National biosafety policy

At present there is no stand-alone national policy on biosafety in Bangladesh to deal with the issues related to the Protocol in a comprehensive way. However, there are some existing policies in relevant sectors which reflect on some of the issues in the Protocol in a sporadic way and these are briefly touched upon below. The policies covered include: (i) Environment Policy, 1992 (ii) National Biodiversity Strategy and Action Plan for Bangladesh, 2004 (iii) National Biotechnology Policy, 2006 (iv) Biosafety Guidelines of Bangladesh, 2006 (v) National Crops and Forest Biotechnology Policy Guidelines, 2006 (vi) National Policy on Fish and Animal Biotechnology, 2006 (vii) National Medical Biotechnology Policy, 2006 (viii) National Guidelines on Medical Biotechnology, 2006.

### 2.2.1. Environment Policy, 1992

The Environment Policy, 1992 is the main document that provides general policy guidance to all relevant sectors with a view to ensuring that their activities take place in environmentally sound way. The major objectives of the 1992 Policy are: (i) to maintain ecological balance and overall development through protection and improvement of the environment; (ii) to identify and regulate activities which pollute and degrade the environment; (iii) to ensure environmentally sound development in all sectors; (iv) to ensure sustainable, long term and environmentally sound use of all national resources.

The 1992 Policy outlines the general policies for all relevant sectors of the country for the realisation of its overall objectives. For example, in the agriculture sector the major policy statements are: (i) all steps taken and technologies adopted for agricultural development and attainment of self-sufficiency in food are to be made environmentally sound; (ii) the application of agro chemicals, artificial materials and inputs which adversely affect the fertility as well as organic properties of the soil and also cause adverse impacts on man and animals are to be regulated.

In the forest, wildlife and biodiversity sector major policy statements are: (i) to conserve, expand and develop forest to sustain the ecological balance and meet the socio-economic needs and realities; (ii) to conserve wildlife and bio-diversity, strengthen related research and help insemination and exchange of knowledge in the concerned area; (iii) to conserve and develop wetlands and protect migratory birds. In the food sector major policy statements are (i) to ensure hygienically and environmentally sound methods for production, preservation, processing and distribution of food; (ii) to prohibit import of food items likely to create adverse impact on the environment and public health.

The 1992 policy emphasises the need for creating widespread mass awareness regarding environmental conservation and sustainable utilisation of all resources. The need for

dissemination of environmental information and public participation is also emphasised in the policy.

The Environment Policy suggests that all laws and regulations related to protection of environment, conservation of natural resources, and control of environmental pollution and degradation should be amended. Whenever is necessary a new law is to be framed. What is important is to ensure proper implementation of all relevant laws/regulations and create wide spread public awareness in this regard. In order to address the global environmental issues the policy advocates for the ratification of all concerned international conventions and protocols.

Thus, the policy statements for the relevant sectors, contained in the 1992 Policy, provide adequate basis for the adoption of additional measures to regulate GMOs in environmentally sound way.

### 2.2.2. National Biodiversity Strategy and Action Plan for Bangladesh (NBSAP), 2004

The National Biodiversity Strategy and Action Plan (NBSAP) provides a framework for the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources of the country. It emphasises the need for cross-sectoral linkages, reflecting the fact that biodiversity conservation in Bangladesh is closely inter-woven with the socio-economic development of the country. The NBSAP also provides a framework for securing necessary environmental conditions to reduce poverty, ensure sustainable development and respond to the implementation of elements of the country's Poverty Reduction Strategy Paper (PRSP).

The major objectives of the NBSAP are: (i) to conserve, and restore the biodiversity of the country for well being of the present and future generations; (ii) to maintain and to improve environmental stability for ecosystems; (iii) to stop introduction of invasive alien species, genetically modified organisms and genetically modified organisms.

According to the NBSAP, threats to biodiversity in Bangladesh arise from loss of habitat due largely to deforestation and inappropriate water and agricultural management, over-harvesting of resources, efforts to increase agricultural productivity, and natural disasters. Underlying causes are predominately related to issues of land tenure and users' rights, and institutional capacity constraints.

Although the strategy considers various threats to biodiversity in Bangladesh, there is no estimation about the nature and extent of threats that GMOs could pose to the conservation of biodiversity in Bangladesh. Of the sixteen strategies developed to shape and direct the actions towards achieving the goals and objectives of the NBSAP, strategy 4 focuses on the adoption of national measures and standards to deal with invasive alien species and genetically modified organisms.

Major actions (short term 0-3 years) suggested by the NBSAP with regard to the alien species and GMOs include: (i) develop national management plans for control and eradication of invasive

alien species (IAS); (ii) support capacity building on identification of invasive species and genetically modified organisms; (iii) develop a national biosafety framework and (iv) locally monitor and prevent the release of IAS and hybrids in aquatic ecosystems. For medium term, (4-7 years): (i) develop capacity building tools and methods for local communities to deal with identification, management and control of invasive species and GMOs and (ii) build awareness of biosafety and bio-piracy issues among local communities and within the Customs Service. For long term (8-10 years): (i) support establishment of monitoring systems for addressing issues of regional and international trade and their impact on movement and/or introduction of invasive species and genetically modified organisms; (ii) support economic and social impact studies on use of genetically modified organisms and alien species. Encourage regional dialogue on sharing of expertise and resources in management of IAS and GMOs.

### 2.2.3. National Biotechnology Policy, 2006

The main goal of the National Biotechnology Policy 2006 is to ensure sustainable development of agriculture-food and other crops, nutrition, health, environment and livelihood of people. The other important goals include strengthening of the national capabilities in modern biotechnology, biosafety and bioethics in order to ensure judicious use of this modern tool for socio-economic development of the country.

The major objectives of the Biotechnology Policy are: (i) to harness judiciously the opportunities of biotechnological applications for enhanced productivity, increased quality and value of products leading to sustained food security, poverty alleviation and health and livelihood improvement; (ii) to take up a detailed inventory of bio-resources in the country in order to promote conservation of biodiversity and sustainable exploitation of bio-resources; (iii) to create congenial environment for encouraging R&D in biotechnology and allied fields through development of infrastructure and through appropriate incentives and regulatory framework for research in modern biotechnology; (iv) to address issues such as, intellectual property rights, biodiversity, biosafety, and bio-ethics with due emphasis on knowledge, innovation and practices of indigenous and local community and (v) to create public awareness on biotechnology by involving all stakeholders to ensure adequate level of protection in the safe handling of this technology.

The Policy identifies the opportunity areas for the application of biotechnology in Bangladesh are: (a) agriculture, food and other crops; (b) fisheries and livestock; (c) forestry and environment; (d) health care and nutrition; (d) biotech products and (e) biodiversity conservation. It contains policy statements on biosafety and bio-ethics. These include (i) management of opportunities and challenges of biotechnology viz., productivity, sustainability, biosafety, access, benefit-sharing and trade be ensured through appropriate mechanisms; (ii) guidelines, acts and regulations will be formulated for development and management of biotechnology, biosafety, bioethics, biodiversity & environment protection to ensure human rights as well as social, cultural, ethical and economic perspectives of the country. For the effective implementation of the policy a National Task Force (NTF) has been formed with the Prime Minister in the chair. It is responsible for generating and allocating need-based resources for operating and undertaking various activities through funding support from the government and possible foreign assistance. The Task Force functions as the highest policy making body to give necessary directives for the

development of biotechnology in the country. The National Executive Committee on Biotechnology (NECB), headed by the Principle Secretary to the Prime Minister will be responsible for implementation of the National Policy on Biotechnology to ensure speedy as well as risk free development of the technology as per directives of the National Task Force. An International Biotechnology Advisory Committee will be formed with internationally recognised experts in different areas of biotechnology to advise the government on priority areas of research and development programmes.

### 2.2.4. Biosafety Guidelines of Bangladesh, 2006

The Ministry of Science and Technology formulated the Biosafety Guidelines in 1999 before the adoption of the Protocol on Biosafety in 2000. However, considering the various obligations of the Protocol, the Ministry of Environment and Forest updated the Guidelines and approved by the government in July, 2006.

The biosafety guidelines are applicable to all research and development activities of modern biotechnology conducted in laboratories of the government research institutes, state enterprises, universities, international organisations located in Bangladesh, private companies or non-governmental organisations. The guidelines apply to laboratory and field trial, transboundary movement, transit, handling and use of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The objective of the guidelines is to contribute to ensuring an adequate level of protection in the laboratory, field trial, safe transfer, handling, use and transboundary movement of GMOs as part of modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health.

Chapter II of the guidelines focuses on the institutional arrangements. It provides that the Ministry of Environment and Forest (MoEF) being the competent national authority and national focal point to implement the Protocol shall establish a National Committee on Biosafety (NCB) in order to ensure environmentally safe management of modern biotechnological development. A Biosafety Core Committee (BCC) will be working to assist and accelerate the functions of NCB. In order to ensure safe management of biosafety activities in the laboratories and in the field there shall be committees under NCB, such as Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC) and also there will be designated Biological Safety Officers (BSO) in each research establishment of the country.

Chapter III of the guidelines elaborates on the risk assessment and risk management procedures. Depending on how and where GMOs will be used, specific criteria for risk assessment in five major areas have been suggested. These areas are: laboratory use, field use, direct use of foreign GMOs into the environment, industrial use, products intended to release into the market. Procedures and guidelines for obtaining permission for various dealings with GMOs, such as, laboratory use, field release, release into the market, have also been provided in this chapter.

Chapter IV of the guidelines provides the procedural details for physico-chemical and biological containment in order to avert the adverse impacts of modern biotechnological research works. It categorises the laboratory works into four different biosafety levels such as, work bearing minimum risk, work bearing low risk, work bearing considerable risk and work bearing high risk and describes the precautionary measures that should be taken to avert such risks.

On the basis of the precautionary principle, the guidelines provide a framework for the following aspects: (i) develop acts, rules, standards and scientific database, codes of practice and monitoring capabilities and enforcement manuals for assessing risk in the research and development and release of GMOs into the environment, (ii) provide the basis to ensure safety of the developers and end-users of modern biotechnological products, (iii) promote the development and enforcement of regulations in harmony with national priorities and international approaches and (iv) foster a favourable climate for developing and accelerating innovation and for adopting sustainable biotechnology products and processes.

### 2.2.5. National Crops and Forest Biotechnology Policy Guidelines, 2006

The major objectives of the National Crops and Forest Biotechnology Policy Guidelines, 2006 are: (i) to ensure sustainable development of agriculture and forest; (ii) to harness judiciously the opportunities of biotechnology for enhance productivity, increased quality and value of products leading to sustain food security, poverty elimination and livelihood improvement; (iii) to develop crop varieties resistant to biotech (pest & diseases etc) and abiotic stresses (drought, salinity, flood etc) and (iv) to establish regulatory framework for biosafety, field trials, Intellectual Property Rights (IPR) and Trade Related Intellectual Property Rights (TRIPS) consistent with the national needs and opportunities and requirements.

The policy outlines research priorities such as, strengthening and commercialisation of tissue culture research, introduction, evaluation and testing of transgenic crops, development of transgenic crops, detection of GM crops and products. Key issues and strategic plans include: strengthening and creation of institutions, infrastructure development, human resources development, law making, technology transfer etc.

### 2.2.6. National Policy on Fish and Animal Biotechnology, 2006

Although at present GM fish and animals are not being produced and used in Bangladesh, in view of the opportunities and potentials, Bangladesh can make revolution in fisheries and livestock productions through the use of biotechnology.

The objectives of the National Policy on Fish and Animal Biotechnology, 2006 are to promote: (i) acquisition of knowledge and skill on animal and fish biotechnology and (ii) development of biotechnology tools in the field of fisheries and livestock, subject to optimum safety and acceptability.

The policy covers a comprehensive overview of global and national development and narrates the key policy issues as well as strategic guidelines for successful implementation of the policy, including research & development priorities in the field of fish and animal biotechnology. The

policy suggests that all biotechnological research and applications should be governed by regulations on biosafety and ethics. The policy notes;

'Such products (GM fish, animals, and microorganisms) must not be released in the nature without proper evaluation for their safety with regard to human, animal or fish health. Research for development and tests for evaluation of such products also should be done in confinement to avoid accidental escape of GMOs in the nature. Therefore, all activities related to the development and evaluation of GMOs should be regulated by the national and institutional biosafety guidelines. Biotechnological research and applications involving human or animal subjects must be governed by national and institutional guidelines on ethics'.

### 2.2.7. National Medical Biotechnology Policy, 2006

The major goals of the National Medical Biotechnology Policy, 2004 includes strengthening of the national capacities in relation to application of modern medical biotechnology and conservation of biosafety, bioethics, and religious, social and cultural values of the people of this country through ensuring judicious use of medical biotechnology and biotechnology as a whole.

The major objectives of the Policy are: (i) to harness judiciously the opportunities of medical biotechnological applications for health and livelihood improvement; (ii) to take up a detailed inventory of medically important bio-resources in order to promote conservation of biodiversity and sustainable exploitation of those bio-resources; (iii) to address issues such as intellectual property rights, biosafety, biodiversity, and bioethics with due emphasis on knowledge, innovation and practices of indigenous and local community and (iv) to create public awareness on biotechnology by involving all stakeholders to ensure adequate level of protection in the safe handling of this technology and also to alleviate wrong perceptions of people regarding use of biotechnology.

The major Policy statements on biosafety and bioethics include: (i) an adequate level of protection will be ensured in the field of safe transfer, handling and use of genetically modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking principally into account risks to human health and environment, (ii) suitable regulatory framework will be established in order to undertake, as well as, to participate as exporter and importer in the national and international trade of biotechnology products: Legislations, rules, guidelines will be prepared for standardisation and registration of medical biotech products (import, production and export); marketing ensuring adequate and prominent labelling; biotech waste disposal; ethical issues, and biosafety guidelines, (iii) the intellectual property rights with respect to medical biotechnology must be in conformation with the general national policies and interests of the Government of Bangladesh and (iv) the policy will promote trading of medical biotechnological products in accordance with principles of Codex Alimentarius, Sanitary and Phytosanitary Agreement (SPS Agreement), and the Protocol.

### 2.2.8. National Guidelines on Medical Biotechnology, 2006

The goals of the guidelines are : (i) sustainable economic & social development through: improving health and nutrition; employment generation; and reduction of poverty, (ii) enhancement of national capacity to compete in medical biotechnology (MBT) related health service & research keeping pace with global standards and (iii) strengthening national capacity in: application of modern MBT; conservation of biosafety & bioethics; and conservation of religious, social & cultural values of our people through ensuring judicious use of MBT & BT.

The major objectives of the guidelines are: (i) to exploit opportunities of MBT for health & livelihood improvement; (ii) to make a detailed inventory of medically important bio-resources to promote biodiversity conservation & bio-resource exploitation; (iii) to conduct genome sequencing of our people to understand overall future national health & nutritional implications and (iv) to address issues such as intellectual property rights, biosafety, biodiversity and bioethics.

The guidelines describe the following strategy on medical biotechnology: (i) due & timely attention to importance of MBT in public, private & NGO sectors through policy response, creation of human resource, infrastructure development, (ii) precautionary approach guided by scientific principles & procedures, (iii) well-resourced effective regulatory system based on the best available scientific expertise & advice, (iv) continued policy advocacy & public awareness activity ensuring transparency & adequacy of information and (v) respect to human rights & privacy issues as well as to people's social, cultural & ethical values.

## 2.3. Need for a stand-alone national policy on biosafety

A separate national policy on biosafety is needed for the following reasons: Firstly, as examined above, sectoral policies make some references to biosafety issues even though their major thrust is to benefit from the application of modern biotechnology in potential areas like crops, forest, fish, animal, and medical sectors. These policies have their own priorities and in most cases there is no explanation as to how the sectoral concerns will be addressed in conformity with the concerns of the Protocol i.e., to ensure adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health. A central national biosafety policy can help establish a relationship and coordination between the core themes of the Protocol and the policy priorities in all relevant areas of the government.

Secondly, sectoral policies do not deal with the issues and concern of the Protocol in a comprehensive way. Many important biosafety issues raised in the Protocol have been either completely ignored or partially addressed in the sectoral policies. For example, neither the goals nor the objectives of the National Biotechnology Policy clearly spell out the need for biosafety measures while emphasising the need for modern biotechnology in the socio-economic development of the country. The vary words genetically modified organisms are missing in almost all policy documents. The need for advance informed agreement (AIA), the right to know of an importing state, has been completely ignored in these policies. Most of the existing relevant policies have no reference to precautionary approach enshrined in Article 15 of the Rio

Declaration on Environment and Development, 1992.A separate national policy on biosafety should therefore, be adopted to reflect on the issues and concerns of the Protocol in a comprehensive way.

Thirdly, although the biosafety guidelines have been updated to reflect the biosafety issues, which have risen in the Protocol but a policy is different from guidelines. While a policy provides an entire framework of action, guidelines deal with procedural matters. Guidelines are supplementary to, but not substitute for, a policy. The biosafety guidelines propose for the establishment of various committees and describe their powers and functions. The guidelines also provide detailed procedures for risk assessment and risk management. Now, a separate national policy on biosafety is needed to outline the framework within which the guidelines will operate.

Fourthly, existence of so many related polices on biotechnology and their occasional reference to biosafety might lead to confusion. A central policy on biosafety could provide a comprehensive picture about the country's biosafety objectives and measures. This could help avoid confusion and misunderstanding about the country's status on biosafety issues.

Fifthly, although the sectoral policies, examined above, have their own agenda, they have emphasised the need for the adoption of biosafety measures including the adoption of separate laws and polices. These recommendations provide enough justification for the adoption of a separate national policy on biosafety highlighting the regulatory measures needed for this purpose.

Lastly, a separate national biosafety policy is needed for Bangladesh to demonstrate the country's highest level of commitment to the biosafety issues. It will affirm that Bangladesh shows adequate respect to the concerns of the international community as expressed in the Caratagena Protocol, 2000. This will help improve the country's image in the international community.

## 2.4. National policy on biosafety

### 2.4.1. Policy statements on biosafety

(i) Recalling that Bangladesh is committed to the obligations of the Protocol on Biosafety, 2000; (ii) Recognising the importance of protecting environment, biodiversity and human health from the adverse impacts of GMOs resulting from modern biotechnology and (iii) Realising the need for developing our own capabilities in biosafety through research, development and training; (iv) realising the importance to establish linkage with the biosafety issues among relevant policies of the government so that any confusion is avoided.

### 2.4.2. Scopes and objectives of the national policy on biosafety

Bangladesh is committed to the obligations of the Protocol and the country's willingness to cooperate with the international community in all matters relating to biosafety under the Protocol. So, the objectives of the national biosafety policy should be in conformity with the objectives of the Protocol and to be adopted in order to address the issues and concerns raised by the Protocol to which Bangladesh is a party. Following objectives could be suggested for the proposed

national biosafety policy: (1) to adopt measures to ensure adequate level of protection in the field of the safe production, transfer, handling, use, export, import, research and all other possible dealings with genetically modified organisms and products thereof that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health; (2) to incorporate precautionary approach in the decision making process relating to biosafety; (3) to provide an effective institutional framework for national decision making, networking, monitoring in matters relating to biosafety; (4) to strengthen institutional, scientific and technical capacities of the country to deal with biosafety issues where necessary in cooperation with local, regional and international organisations, agencies, institutions either public or private; (5) to take into consideration socio-economic and ethical issues in decision making process relating to biosafety; (6) to promote public participation, accountability and transparency in all matters relating to biosafety; and (7) to adopt new policies, laws and regulations or where necessary amend existing policies, laws, and regulations in order to implement the obligations of the Protocol in Bangladesh and the decisions of the Conference of the Parties/ Meeting of the parties to the protocol in Bangladesh.

### 2.4.3. Priority areas of capacity building for biosafety in Bangladesh

National Biosafety Policy has already been formulated with a view to reduce the threats arising from the application of modern biotechnology in agriculture, such as, crops, fisheries, animal, and livestock; food, medical and in the industrial sectors. Bangladesh has to build capacity at various levels for efficient implementation of biosafety policies and regulatory regime and in order to find out the existing capacity in biotechnology a survey was conducted results of which are presented in Annex 1 of this document. Strengthening of administrative procedures, regulatory aspects, modernisation of capable laboratories for GMOs research, development of GMO related risk assessment, management and communication systems, human resource development, capacity building for public education and awareness and providing adequate fund for biosafety issues are priority areas for future action plan. International and regional cooperation, arrangement, agreement will speed up country's capacity building for biosafety issues. Short, medium and long term plans/measures could be described to achieve the objectives of the national biosafety policy that might include law-making, capacity building and awareness-development among the target groups etc.

The biosafety guidelines of Bangladesh have been drawn out to safeguard the interests of Bangladesh in relation to biosafety regarding work on GMOs and their introduction into the country. These guidelines are meant to compliment and mutually support national policies and legislation. A great deal of attention has been paid to scientific details to establish a non-binding legal status and therefore the guidelines lack the force of law for compliance and enforcement.

In order to oversee the biosafety aspects of biotechnology related activities it is important to have a full-time member secretary of the NCB. Provisions should also be drafted to prohibit a person to serve on the NCB in circumstances where there is conflict of interests. No member may be involved in review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Section 3.3 of the biosafety guidelines mentions that 'in the absence of a regulatory regime any violations of the provisions of the guidelines carries a penalty by the concerned ministry by stopping the work immediately and forfeiting the government grants/funds.' However it is a non-binding legal status and hence it lacks the force of law for compliance and enforcement purposes. It is an extremely poor substitute for a legally binding biosafety regime. It is therefore very important to draft legally binding regulations instead of opting for non-binding guidelines.

Provisions have been made in the guidelines for the constitution of Field Level Biosafety Committee (FBC) however details are required about the manner in which the trial release of a GMO is to be undertaken. It is therefore important that Bangladesh formulate guidelines for field testing of GMOs. The guidelines will need to include detailed mechanism for crop-wise monitoring.

The guidelines also do not specify the authority that will be responsible for handling applications for the field trial of GM crops. The NCB will not receive any applications. The applications will be received by competent authorities. Depending on the type of GMOs the competent authorities of relevant ministries will handle these applications. The comments highlighted here have been made with the intention of putting in place a sound biosafety regime in the country.

# CHAPTER 3

## 3. REGULATORY REGIME ON BIOSAFETY

### 3.1. Introduction

This chapter deals with the regulatory regime on biosafety. A regulatory regime on biosafety is comprised of all the legal instruments, such as, laws, acts, regulations, decrees, orders, guidelines etc that are relevant to the regulation of GMOs and the products thereof, including the institutional arrangements for implementing those regulations (UNEP-GEF toolkit module, part-i, p. 24). A regulatory regime is needed in order to ensure adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account risks to human health.

As a party to the Protocol, Bangladesh is required to implement the obligations of the protocol into her domestic legal system. It is worth mentioning here that, at present there is no separate domestic law in Bangladesh that deals with the use, transfer, handling and transboundary movement of GMOs as required by the Protocol. However, under the project of NBF, a legal survey has been conducted to identify laws that are relevant to biosafety in Bangladesh. The survey reveals that there are good numbers of individual laws that are relevant to biosafety in Bangladesh. This chapter reviews these laws under certain headings and sub-headings, such as, agriculture, fisheries, forestry, etc for convenience. This chapter also examines the possibility of developing regulatory regime for biosafety in Bangladesh, provided the existing laws are found to be inadequate to deal with GMOs. The impacts of the new law on the existing sectoral laws and regulations, and the cross-cutting issues that might arise from the overlapping, have also been examined in this part.

### 3.2. Laws and regulations in scope of biosafety

There are no specific laws and regulations to manage GMOs in Bangladesh but there are statutes relating to biodiversity and in some instances biosecurity in general and these are summarised in the table below and details are provided in Annex 2. In respect of GMOs, Bangladesh has developed biosasfety guidelines and these guidelines are expected to form the basis of the regulatory framework and hence are reflected in the proposed administrative and management system outlined in this document.

**The summary table of existing laws and regulations with potential relevance to biosafety**

| Laws & Regulations | Scope | Responsible agency | Status |
|---|---|---|---|
| Constitution of Bangladesh | Regulates powers and functions of the Government | The Government | Adopted 1972 |
| The Destructive Insects and Pests Act | Regulates quarantine measures of plant and plant | Plant Protection Wing | Adopted 1914 |

| | | | |
|---|---|---|---|
| | products | | |
| The Seeds Ordinance | Regulates seeds quality | Seeds Wing | Adopted 1977 |
| The Seeds Rules | Regulates seeds quality | Seeds Wing | Adopted 1988 |
| The Agricultural Produce (Grading and Marking) Act | Regulates grading and marking of agricultural produce | Department of Agriculture | Adopted 1937 |
| Bangladesh Agricultural Research Institute Ordinance | Regulates agricultural research activities | Ministry of Agriculture | Adopted 1976 |
| Bangladesh Rice Research Institute Act | Establishes the BRRI | Department of Agriculture | Adopted 1973 |
| The Fish and Fish Products (Inspection and Quality Control) Ordinance | Regulates inspection and quality control of fish and fish products for export | Department of Fisheries | Adopted 1983 |
| The Fish and Fish Products (Inspection and Quality Control) Rules | Regulates inspection and quality control of fish and fish products for export | Department of Fisheries | Adopted 1997 |
| The Protection and Conservation of Fish Act | Regulates fish protection and conservation of pubic fisheries | Department of Fisheries | Adopted 1950 |
| The Protection and Conservation of Fish Rules | Regulates protection and conservation of public fisheries | Department of Fisheries | Adopted 1985 |
| The Marine Fisheries Ordinance | Regulates conservation and development of marine fisheries | Department of Fisheries | Adopted 1983 |
| The Marine Fisheries Rules | Regulates conservation and development of marine fisheries | Department of Fisheries | Adopted 1983 |
| The Private Fisheries Protection Act | Regulates private fishery rights | Department of Fisheries | Adopted 1889 |
| The Fisheries Research Institute Ordinance | Regulates fish related research activities | Ministry of Fisheries and Livestock | Adopted 1984 |
| The Forest Act | Regulates conservation activities in public forest | Department of Forest | Adopted 1927 |
| The Private Forest Ordinance | Regulates conservation activities in private forest | Department of Forest | Adopted 1959 |
| The Bangladesh Animal and Animal Product Quarantine Act | Regulates quarantine activities of animals and animal products intended for export and import | Department of Livestock | Adopted 2005 |
| The Bangladesh Wildlife (Preservation) Order | Regulates wildlife conservation activities | Department of Forest | Adopted 1973 |
| The Livestock Research Institute Ordinance | Regulates livestock research activities | Department of Livestock | Adopted 1984 |
| The Pure Food Ordinance | Regulates manufacture and sale of foods for public consumption | Department of Food | Adopted 1959 |
| The Pure Food Rules | Regulates the manufacture | Department of | Adopted 1967 |

| | | | |
|---|---|---|---|
| | and sale of foods for public consumption | Food | |
| The Bangladesh Standards and Testing Institution Ordinance | Regulates standards, testing, metrology, quality control, grading and marking of goods | Ministry of Industries | Adopted 1985 |
| The Merchandise Marks Act | Regulates marks on merchandise | Ministry of Industries | Adopted 1889 |
| The Drugs Act | Regulates import, export, manufacture, distribution and sale of drugs | Ministry of Health and Family Welfare | Adopted 1940 |
| The Drugs Rules | Regulates import, export, manufacture and sale of drugs | Ministry of Health and Family Welfare | Adopted 1946 |
| The Patents and Designs Act | Regulates registration and protection of inventions and designs | Ministry of Industries | Adopted 1911 |
| The Patents and Designs Rules | Regulates registration and protection of inventions and designs | Ministry of Industries | Adopted 1933 |
| The Bangladesh Environment Conservation Act | Establishes the Department of Environment | Department of Environment | Adopted 1995 |
| The Environment Conservation Rules | Regulates the EIA procedure | Department of Environment | Adopted 1997 |
| The Environment Court Act | Regulates the powers and functions of the Court | Department of Environment | Adopted 2000 |
| Proposed regulatory mechanism for biosafety | To manage GMOs | Department of Environment | To be drafted |

### 3.3. Need for a separate biosafety law in Bangladesh

The preceding discussion reveals the followings facts: Firstly, there is no separate law to deal comprehensively with the adverse impacts that might arise form the use, handling, transfer and transboundary movements of GMOs as required by the Protocol. Secondly, sectoral laws and regulations are mostly old, whereas the ideas of GMOs and their possible threat to biodiversity, environment and human health are relatively new. Thirdly, sectoral laws and regulations have their own priorities; they were not adopted to address the possible threats of GMOs. Fourthly, some of the provisions of the sectoral laws and regulations might be relevant, as examined above, but the scope is limited. They do not provide a comprehensive regulatory regime for biosafety in Bangladesh. For example, the Destructive Insects and Pests Act, 1914 and the Destructive Insects and Pests Rules, 1966 regulate only import, export and transit of plant and plant products. They do not regulate use, transfer, handling, contained use, direct release etc of plant and plant products which could be GM plant or plant products. Lastly, there are several institutions with overlapping jurisdictions that might create confusion and delay in the regulation of GMOs. For example, the Seeds Ordinance, 1977 and the Seeds Rules, 1988 regulate the quality, sale and distribution of seeds in Bangladesh. Seeds Wing performs this job. But in order to import seeds, further permission is needed from the Plant Protection Wing. If such seeds are used as foods than

other institutions, for example, Department of Food and BSTI will come to play their role in it. Poor coordination among various institutions with undefined jurisdictions might create problems in the regulations of, say, GM seeds and its adverse impacts on environment, biodiversity and human health.

There are three alternative ways of implementing the obligations of the Protocol in Bangladesh: Firstly, to amend the existing relevant sectoral laws and regulations; secondly, to amend one or two major laws highly relevant to the regulations of GMOs in potential areas, for example, seeds, plant and plant products and thirdly, to make a completely new comprehensive law on biosafety.

It is, however, suggested that making a new law with overriding force, would be preferable to amending more than existing thirty relevant laws, administered by almost fifteen Government Ministries/Departments. Furthermore, amending one or two sectoral laws would implement the obligations of the Protocol partially, leaving considerable area unregulated. It is therefore, recommended that a separate law should be put in place in order to implement the obligations of the Protocol in a comprehensive way.

Making a new law might create overlapping provisions. For example, importation of plant requires a permit and a phytosanitary certificate. Importation of GM plant under a new law might also require a permit and a phytosanitary certificate. Making a new law might again create contradictory provisions. For example, under the Destructive Insects and Pests Act, a director or a deputy director may issue a permit for the importation of plant. But a new law might require that a permit for the importation of GM plant may be issued by the National Competent Authority on biosafety.

The problems of overlapping or contradiction may be resolved by making a new law with overriding force. This means that the new law will apply in suppression of all other relevant laws and regulations. For this purpose the new law has to make following declaration: Notwithstanding any provisions contained in any other laws and regulations, the provisions of this (new) law will apply in all matter relating to GMOs. However, such a law should be fairly comprehensive.

### 3.4. Separate biosafety regulatory regime

It is noted that the following regulatory regime is indicative only at this stage and its hierarchy in terms of an independent act or under an existing act like Environment Conservation Act 1995 will be determined after consultation with legal experts and stakeholders. An act or rule, whatever it may be, shall be framed in order to regulate the development, field test, general release, import, export, use, transfer, handling and transboundary movements of GMOs that might pose threat to biodiversity, environment and human health. It may be noteworthy that under the present constitutional arrangement in Bangladesh (Article 65 of the Constitution), a rule may be made by the relevant administrative organs of the government in exercise of the power of legislation delegated under an Act of the Parliament. The Environment Conservation Act, 1995 is such an Act of the Parliament. Under section 20 of the Act, the Parliament has delegated necessary rule-making power to the Ministry of Environment and Forest. Therefore, necessary technical rules on biosafety may be made under section 20 of the 1995 Act.

For a rule-making under an Act requires mandate, the purposes of the 1995 Environment Conservation Act are wide enough to authorise rule-making on biosafety. The purposes of the 1995 Act, as stated in the preamble, are 'to provide for the conservation, improvement of environmental standard and control and mitigation of the pollution of the environment'. The rule-making power under section 20 is wide also. Section 20(1) provides, 'The Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act'. Thus in order to achieve the purposes of conservation of biodiversity, and improvement of environmental standard necessary rules may be made to regulate the use, handling, transfer, export, import etc of GMOs that might have adverse impacts on biodiversity and the environment.

Presently, passing an Act of Parliament is a time consuming and a complex task, whereas rules may be made under the supervision of the Ministry of Environment, in consultation with the stakeholders in more informal settings, providing necessary scope for public participation and public consultation in the law making process. Rules can be amended more easily than an Act of Parliament. An Act of Parliament can only be amended by another amending Act of Parliament. But rules can be amended by the relevant administrative organs with the approval of the higher authority of the Government.

Finally, biosafety regulation requires a flexible mechanism so that international decisions under the Protocol can be implemented as and when necessary. Rules could provide that flexibility in operation.

## 3.5. Proposed biosafety regulatory regime

### 3.5.1. Scope and justification

A Regulatory regime to manage production, development, use, handling, transfer, sale, contained use including field test, general release, export, import, transit, research and any other dealings with GMOs is required. Notwithstanding any thing contained in any other laws and regulations, the provisions of the proposed regulatory regime will apply in all matters relating to GMOs.

### 3.5.2. Objectives

The objectives of the regulatory regime include the following.

(i) To ensure, in accordance with the precautionary approach, an adequate level of protection in the field of production, development, use, handling, transfer, sale, contained use including field test, general release, export, import, transit, research and any other dealings with GMOs resulting form modern biotechnology that may have adverse effect on the environment, biodiversity, and human health.

(ii) To establish a transparent and predictable decision making process relating to GMOs and related activities, including environmental risk assessment, social impact assessment, conditions of monitoring and enforcement, and provision for penalty and redress.

### 3.5.3. Title of the proposed regulatory regime for biosafety

The title of the proposed regulatory regime can be the Biosafety Rules, 2007.

**Exten**t: these rules extend to the whole of Bangladesh.

**Coming into force**:

These rules shall come into force at once, or, say, on the first day of June, 2007 or from the date of notification in the official Gazette, etc.

**Definitions**

A number of key terms should be defined for the purpose of clarity. For example, 'Act', 'Deal with GMOs', 'Biosafety', Biosafety Guidelines', 'Genetically Modified Organisms' etc.

In these rules, unless there is anything repugnant in the subject or context -

a. 'Act' means the Environment Conservation Act, 1995.

b. 'deal with GMOs' means (a) conduct experiments with GMOs; (b) make, develop, produce or manufacture GMOs; (c) breed GMOs; (d) propagate GMOs; (e) use GMOs in the course of development or manufacture of a thing that is not GMOs; and (f) grow, raise or culture GMOs etc.

c. 'Biosafety' means the mechanism developed through law, policy and procedures to ensure the environmentally sound application of biotechnology.

d. 'Biosafety Guidelines' means the Biosafety Guidelines of Bangladesh, 2006 updated by the Ministry of Environment and Forest and approved by the Government of Bangladesh.

**Institutional set up**

The institutional set up, powers and functions described in the Biosafety Guidelines of Bangladesh, 2006 may be followed in preparing these rules. For example**,**

Establishment of National Committee on Biosafety (NCB): The Government shall, by notification in the official Gazette, establish a National Committee on Biosafety.

The powers of the NCB may include: (a) to draft and adopt policies, guidelines, action programme, legislations to ensure adequate level of protection from the GMOs that might have adverse impacts on the environment, biodiversity and human health; and (b) to cooperate with foreign, national and international bodies on biosafety.

The functions of the NCB may include: (a) to establish standards and procedures for risk assessment and labeling of GMOs; (b) to issue license/permit for the use, transfer, handling, import, export, contained use, direct release or commercial release of GMOs, etc.

Similarly, other committees such as, Biosafety Core Committee (BCC), National Technical Committee on Biosafety (NTCB), Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC), Bangladesh Biosafety Clearing House (BBCH) shall be established and their powers, functions shall be clearly described.

**Prohibition and authorisation requirements**

A system of licensing might be established in order to regulate all the dealings with GMOs. A simple approach could be adopted for this purpose in Bangladesh. For example, following provision may be considered.

a. No person shall, import, export, develop, field test, use in containment, release into the environment, sell, purchase, use, transfer, handle, or in other way deal with any GMO without a prior license from the National Committee on Biosafety (NCB).
b. Applications seeking license for any dealing with GMOs shall be submitted in conformity with the requirements of the Biosafety Guidelines for that particular dealing and confirm the accuracy of the information provided.
c. A licensee shall notify the National Committee on Biosafety and the National Technical Committee of Biosafety of any change in or addition to the information already submitted.

'The Biosafety Guidelines' should be defined in the definition clause for the purpose of clarity. The Guidelines may be included in the Annex to the Rules. This approach will help avoid inclusion of detailed technical requirements in the text of the law. Moreover, requirements of the Guidelines may be changed by amending the Annex only.

**License with conditions and revocation of license**

It may be necessary that a license should be issued on condition so as to ensure adequate level of protection to biodiversity, environment and human health from the adverse impacts of GMOs. The rules may require as follows.

a. All grants of license may be subject to terms and conditions regarding use, handling, transfer, develop, field test, use in containment, release into the environment, export, import, labelling, submission of information, lay out of the enterprise, or any other condition deemed appropriate by the National Committee on Biosafety.
b. The National Committee on Biosafety may revoke a license at any time provided (i) there is a new information as to the harmful effects of GMOs; (ii) GMOs cause such damage to the environment, biodiversity or human health as could not

be envisaged at the time of granting license and (iii) no compliance of any condition stipulated by the National Committee on Biosafety has taken place.

**System for handling request for license/permit to deal with GMOs**

A multiple window system for handling request for license/permit to deal with GMOs should be established as it is compatible with the present administrative decision making system of the Government. Applicant should file the application with required information set out in the Guidelines to the National Technical Committee (NTC) of the respective Ministry of the Government. The NTC may send it to the respective expert committee for technical report. With the findings of the report and the comments of the NTC, the application should be sent to the NCB for final decision.

Application requirements should vary depending on the type of dealing asked for: contained use, field test, import for direct use as food, feed or processing. For example, an application for direct release of GMOs to the environment may be subjected to the following requirements.

a. A person shall not develop, field test, use in containment, release a GMO to the environment directly without the written permission of the NCB.
b. A person wishing to release a GMO directly to the environment shall submit to the NTC an application describing the activity for which the approval is sought.
c. An application shall include the following.
    i. Information set out in the……Schedule.
    ii. Risk assessment as set out in the ……Schedule.
    iii. A sworn declaration that the information contained in the application is factually correct and true.
    iv. Any other additional information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

### 3.5.4. Confidential information

It is important for the assessment and evaluation of GMO applications that the public and the scientific community have a right to be informed of and comment on applications. It is also important that information on the effects on the environment or people should be available for this purpose. Information submitted in support of an application is normally in the public domain and may therefore be requested by members of the public.

An applicant may request that specified information be treated confidential. If the responsible agency accepts the request, it will not be able to divulge the information to other parties that can gain undue advantage. However, if the concerned agency rejects the request for confidentiality the applicant will be given the choice to withdraw the application with the confidential information. It is therefore important that the NCB establish procedures for managing confidential information and decide, on a case-by-case basis, whether it accepts as confidential the information designated as confidential by the applicant.

### 3.5.5. A deliberate or unintentional release into the environment

A deliberate or unintentional release of GMOs should not be allowed under the rules. The NCB on the recommendation of the NTC may allow deliberate release of GMOs into the environment in special cases. Unintentional release of GMOs that might have adverse impacts on the environment, biodiversity and human health should be informed to the persons/authorities designated by the rules for immediate remedial actions.

This unintended GMO release situation may require emergency action and it is proposed that the regulatory mechanism will have provision for rapid action for emergency situations. It is noted that there can be at least two types of emergencies. Firstly, an emergency arising from an unintentional release of a GMO into the environment, and secondly, it may be necessary to use a GMO for bioremediation in cases of a national emergency such as an oil spill or an epidemic. It is therefore proposed that the regulatory system allows for a rapid approval to manage emergencies.

### 3.5.6. Packaging, labelling, and transport

The rules should make specific requirements for packaging, labelling, and transport of GMOs. The details of such requirements may be included in an Annex to the rules.

### 3.5.7. Offences and penalties

Violation of any of the rules, or conditions attached in the license, etc should constitute an offence. If rules are made under the 1995 Environment Conservation Act, the offences should be punishable under the Act itself.

### 3.5.8. Jurisdiction of environmental courts

The Environmental Courts should have jurisdiction to try the offences or to award damages or to provide civil remedies arising from the illegal dealings with GMOs under the Biosafety Rules.

# CHAPTER 4

## 4. ADMINISTRATIVE SYSTEM

An administrative authority/system is required to handle applications, notifications or requests for authorisations for activities, such as use, development, field test, use in containment, or release GMOs into the environment. Such systems also include administrative functions, risk assessment, decision making, public participation, monitoring and enforcement, placing in the market as well as intentional introduction into the environment, and handling GMOs and their products and a system is proposed for their management.

### 4.1. A system to handle notifications or requests for authorisations

#### 4.1.1. Introduction

The Ministry of Environment and Forest (MoEF) is the designated National Focal Point according to the Ptotocol. The Protocol also requires the designation of national competent authority or authorities responsible for performing the administrative functions in implementing biosafety activities within the country generally and the regulations in particular to ensure that GMOs and their products are appropriately assessed and managed in a transparent and consistent way in order to contribute to the sustainable development and better use of modern biotechnology for the well being of the people of Bangladesh. Therefore, transparent procedures are required for receiving applications, evaluation, decision making and implementation. It is also required to have a mechanism for monitoring, enforcement and a system for providing information to the stakeholders as well as public awareness and participation. Earlier, Bangladesh has developed biosafety guidelines and that guidelines have recently been revised in the light of the CPB. These guidelines have formed committees to implement the biosafety activities in Bangladesh. These biosafety guidelines could be a basis for the NBF.

#### 4.1.2. Administrative structure of NBF

The effective operation of a regulatory framework for biosafety depends on the legislative and administration system, national policy on biosafety as well as the international obligations of the country. According to the biosafety guidelines different committees are proposed for the implementation of the NBF in Bangladesh. MoEF establishes the NCB as the national competent authority to manage all aspect of work involving GMOs. A biosafety core committee (BCC) shall assist the NCB in order to ensure safe management of biotechnology activities in the laboratories and in the field as well as during the commercialisation of biotech products. There shall be other committees under the NCB, such as institutional biosafety committee (IBC) with designated biological safety officers (BSO) in each research establishment, and field level biosafety committee (FBC). The composition, functions and responsibilities of these committees are given in the biosafety guidelines.

There are provisions for a number of National Technical Committees (NTC), and according to the scopes and requirements, these technical committees will be formed under the guidance of the

different ministries. Such technical committees will assist the NCB in receiving, handling and evaluating the applications for specific type of GMOs.

A few technical committees have already been formed for respective ministries and more are to be formed for other relevant ministries. The technical committees already formed are: National Technical Committee on Crop Biotechnology (NTCCB) for the Ministry of Agriculture, National Technical Committee on Medical Biotechnology (NTMB) for the Ministry of Health and Family Planning, National Technical Committee on Fisheries and Livestock Biotechnology (NTCFLB) for the Ministry of Fisheries and Livestock.

Technical committees are yet to be formed are: National Technical Committee on Food Biotechnology (NTCFB) for the Ministry of Food, National Technical Committee on Environmental Biotechnology (NTCEB) for the ministry of Environment and Forest.

According to their requirements, the respective Ministry will select members for these National Technical Committees and these committees will be supported by a secretariat for processing applications and evaluating the risk assessment and risk management issues as well as monitoring and enforcement considerations on a case-by-case basis and will advise the NCB accordingly.

The following outlines the proposed system for handling applications for the development of GMOs in contained facilities and for processing or field test, and for general release. It is anticipated that powers for the oversight of these activities will be provided in the proposed regulatory regime and the NCB will develop and put in place effective administrative procedures in a transparent manner.

### 4.1.3. System for handling applications and issuing permissions for containment use

Presently there is no fully operational system in place to handle GMO applications. But, in one or two cases the process followed for permissions to work with GMOs is shown in Figure 2. Recently, permissions have been given by MoEF/NCB for conducting research under containment condition in case of fugal resistant GM Potato. National Technical Committee on Crop Biotechnology (NTCCB) at the Ministry of Agriculture received the application from Bangladesh Agricultural Research Institute. After preliminary screening the application was transferred to the Technical Core Committee of NTCCB. The core committee is a part of the NTCCB and examines biosafety as well as characteristics of the organism of the material under consideration. The application was transferred by BARC to NTCCB with the comment of the core committee. Following the decision of NTCCB, the application was forwarded to MoEF for final approval within stipulated 45 working days.

The flow chart for current system of handling applications and issuing permissions under containment is shown in Figure 2.

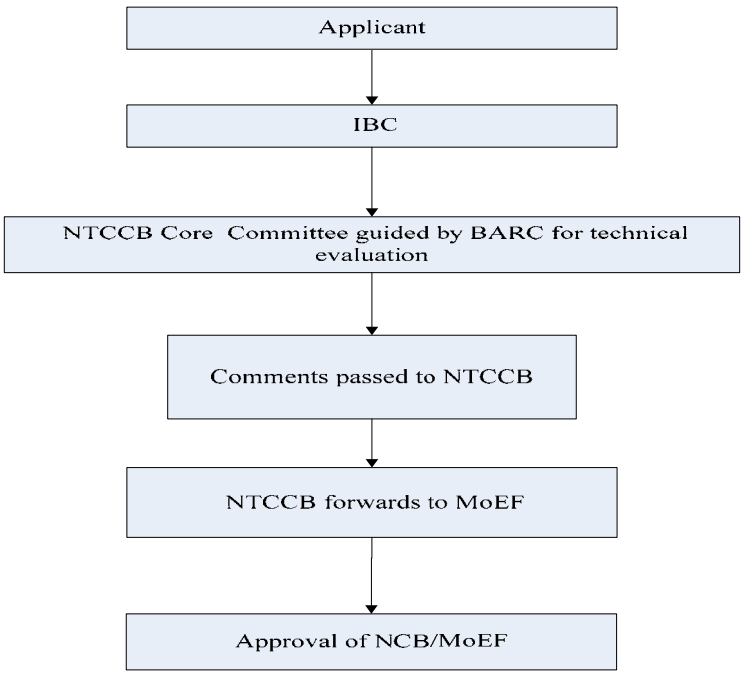



Figure 2. Flow chart for existing system of handling applications and issuing permissions under containment

### 4.1.4. Proposed procedures for handling applications for permit

Under the proposed administrative system of regulatory framework, NCB acts as a National Competent Authority (NCA). In addition, relevant Ministry will be forming National Technical Committees (NTC) to handle applications.

The existing system for handling applications for work under containment has been described in section 4.1.3. Under the proposed system National Technical Committee (NTC) will receive all applications and with the NCB process them.

Following permits of different categories will be given depending on the type of application only after receiving satisfactory information on risk assessment.

(1) Permit to develop or work under containment.
(2) Permit to field test.
(3) Permit to import for direct use as food, feed or processing.
(4) Permit to import into containment for research and development.
(5) Permit to release into the environment with or without condition.

The applicant will provide all the required information/documents and submit the application to the relevant NTC. After receiving the application the NTC will issue a receipt and register the time it received the application. The application will then be forwarded to an Expert Committee

(EC) formed by the respective NTC. The EC will perform the required technical evaluation of potential effects on people and the environment. The EC should have expert members in the field of biosafety both for environmental release and toxicological review. The evaluation of the application will be on a case-by-case basis. After evaluation, the expert report will be provided to the relevant NTC. NTC will forward the positively evaluated applications to the NCB for final approval and to issue permit. In case of any application considered unsuitable for forwarding it to the NCB the NTC will inform the applicant of its conclusion. Before issuing any permit the application may be evaluated through BCC. The NCB will finally approve the application and issue necessary permit within 45 days of receiving the application.

### 4.1.4.1. Proposed application process for development in containment laboratories or greenhouses

The flow chart for evaluation of project proposals for work under containment is presented in Figure 3.

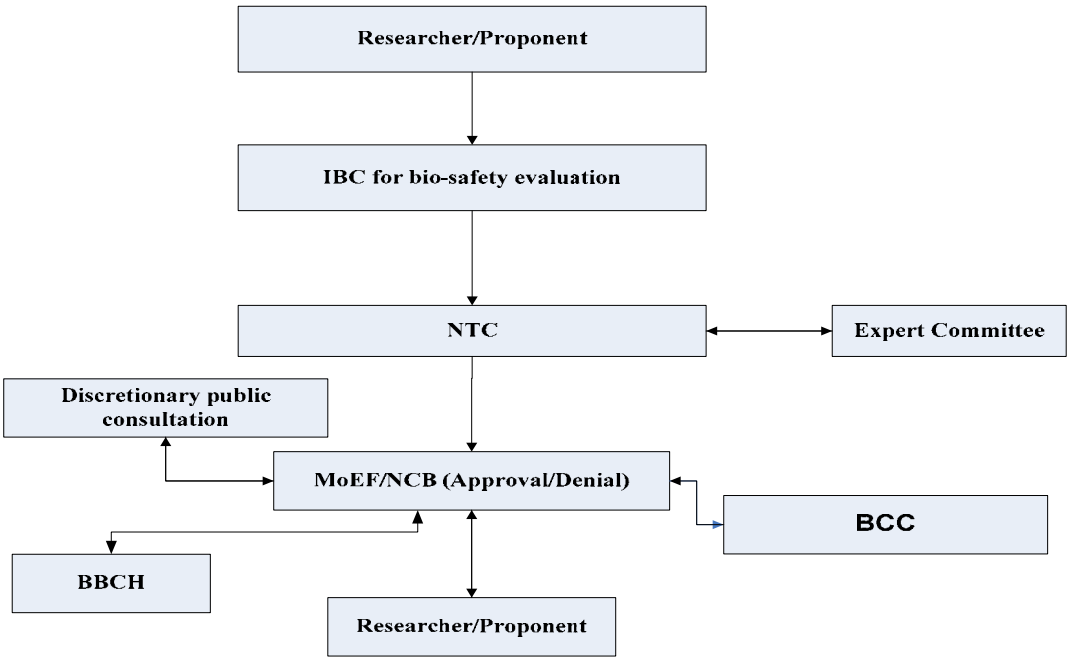



**Figure 3. Flow chart of procedures for evaluation of applications for work under containment (laboratory and greenhouse)**

### 4.1.4.2. Proposed procedure for permit to field test

After contained testing, the applicant need to apply to the respective NTC for an approval to field test. The NTC will evaluate the data generated through contained use in consultation with expert committee and filed level biosafety committee. The applicant may apply for the direct field testing if the applicant can provide satisfactory data of earlier contained use. The issuing of the approval depends on the satisfaction of the NTC.

Flow chart for receiving approval for field testing of project proposals is presented in Figure 4.

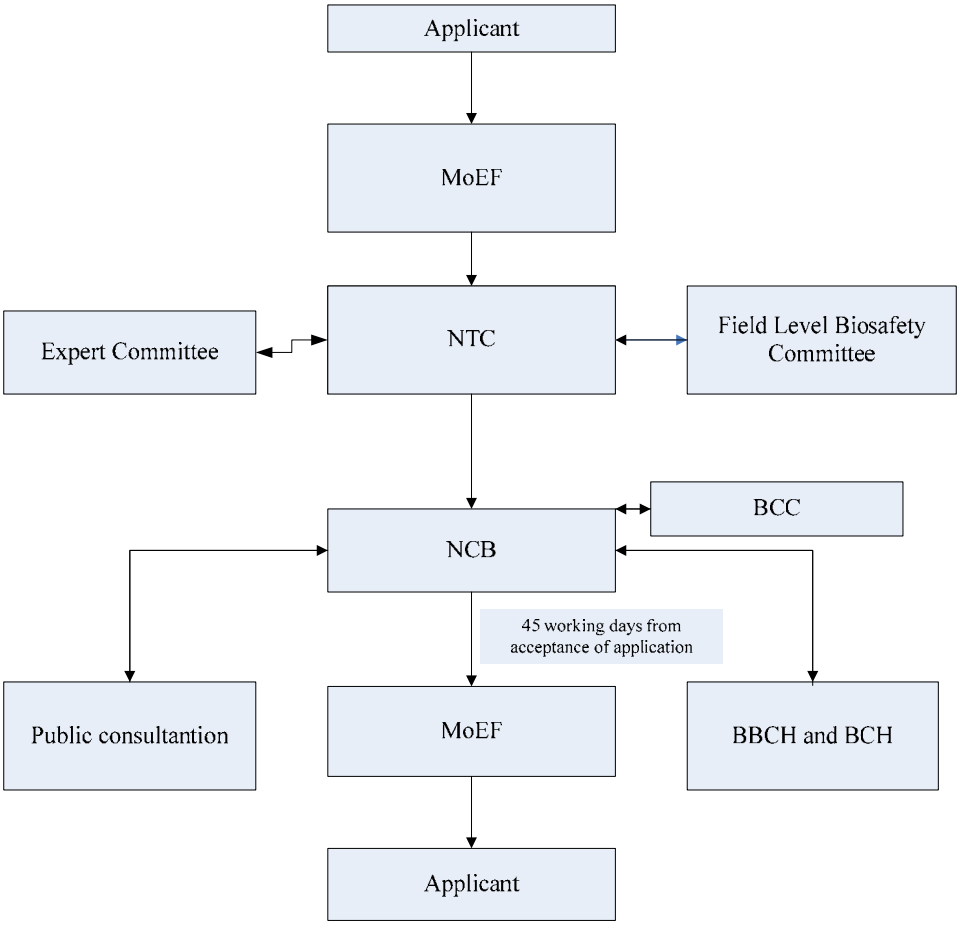



Figure 4. Flow of procedures for evaluation of proposals for field testing or general release into the environment.

### 4.1.4.3. Proposed procedure for permit to import for direct use as food, feed or processing or for import into containment for research and development

In according with the Protocol, a party may take decision to use GMOs as foods or feeds or processing under its domestic regulatory framework. In Bangladesh guidelines on safety of GM foods is not yet established. Matters relating to health and productivity of livestock themselves could be handled by the Ministry of Livestock and Fisheries. On the other hand, those matters relating to human health as a result of livestock fed with GM feed, and food products derived from GMOs could be covered by the Ministry of Food and Ministry of Health. Final approval for commercialisation will be an integrated judgment over these two processes. Figure 4 shows process of approval of GM foods/feeds. It is noted that for import into containment for research and development appropriate institutions will be consulted and discretionary powers will be provided in the regulatory regime for the NCB to publicly notify applications for import into containment that it thinks would have significant public interest (see also Chapter 6). Other applications that will not warrant public notification will be processed through the unnotified procedure and will not require public consultation and will take less time and effort before a decision is reached.

Any person whose application has been denied or whose permit has been withdrawn may appeal in writing to the appropriate authorities within 30 working days of receipt of the written notice. The appeal should clearly state all the facts and reasons to show that the permit was wrongfully withdrawn or denied. All appeals including application documents shall be referred back to NCB for final comments, suggestions, and decision.

Four copies of the permit will be issued. The applicant will retain one copy. The other three can be presented at a) port of entry, b) exporting organisation, and c) collector of customs if required.

A person who is issued a permit should comply with conditions specified in it. Non-compliance with the conditions shall be the ground for revocation of the permit. It will remain revoked until such time that the specified conditions are fully complied with.

It is noted that when genetically modified grain is processed, after processing it is no longer a living organism, e.g. flour and oil from processed maize and therefore the use of that oil or flour should be considered under the existing food regulatory system of the concerned ministry. Those GMOs that are to be consumed as food, e.g. papaya, should need a general release approval and during that assessment the GMO's all potential effects including human health effects need to be considered by the NCB with input from the relevant ministries.

### 4.1.4.4. Information requirement

The biosafety guidelines provide information that would be required for certain activities in accordance with the Protocol and these are annexed in Annex 3 of this document.

### 4.1.4.5. Summary timeframe for decision making

In accordance with the Protocol, the timeframe for processing application is summarised in the table below. It is anticipated that in Bangladesh the timeframe under normal circumstances is to

be the maximum unless a time extension became necessary. It is also expected that many applications falling into low risk contained research and development will be processed in much less time than noted in the table below and such instances would be identified in the regulatory regime in the future.

| | **Activity** | **Timeframe** |
|---|---|---|
| 1 | Acknowledgement of receipt | 90 working days |
| 2 | Communication of decision | 270 working days from the date of acknowledgement |
| 3 | Information of decision to the BCH | 15 working days |
| 4 | Notify an applicant of a change in decision regarding a transboundary movement | 30 working days |
| 5 | Party of imports' response to changed decision on transboundary movement | 90 working days |
| 6 | Notification of unintentional transboundary movement likely to have significant adverse effect | Immediate |

## 4.2. Risk assessment, management and risk communication

### 4.2.1. Introduction

As a per Article 15 of the Protocol, each contracting party should established a system to regulate, manage or control the risk associated with the use and release of modern biotechnological products which may have potential adverse impacts on environment and on human and animal health.

It is expected that more GMOs and other food products will be introduced into the market over the next few years. Therefore, Bangladesh as a party to the Protocol needs to have an effective institutional setup and harmonised mechanism of risk assessment and management of modern biotechnology products to reduce hindrance and to ensure fair practice for smooth movement of products of modern biotechnology.

Several international organisations have addressed the issues related to safety assessments of novel foods and in the present context, genetically modified plants and microorganisms (OECD, 1993; WHO, 1995, FAO, 1996; EC, 1997; Codex Alimentarius Commission). Thus, if Bangladesh adopts those harmonised global guidelines, Bangladesh would move toward a global harmonised approach for addressing risk assessment and management for modern biotechnology products.

### 4.2.2. Risk assessment

Risk assessment can be defined as a process of evaluation, including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to humans or the environment following exposure under defined conditions to a risk source(s). A risk assessment comprises hazard identification and characterisation. A hazard is the potential of an identified source to cause an adverse effect.

**General consideration of risk assessment**

1. Risk assessment should be carried out in a scientifically sound and transparent manner on a case-by-case basis taking into account expert advice and the guidelines developed by the international organisations (WHO1995; FAO, 1996; EC, 1997; Codex Alimentarius Commission).
2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an accepted risk.
3. The results of certain risk assessment tests (e.g., toxicological study) done at a qualified laboratory and accepted by the National Competent Authority of a developed country may be accepted without repeating the tests. However, all agronomical trials (confined greenhouse/field trials) must be conducted/repeated in Bangladesh.
4. For environmental release of GMOs, risk assessment should address all relevant environmental issues and could include an analysis of the potential benefit of the GMOs.
5. In accordance with the Protocol, a Party may take decision to use GMOs as foods or feeds or processing under its domestic regulatory framework.
6. Bangladesh would follow recent guidelines of Codex Alimentarius Commission for food as working Principles for food safety assessment.
7. Socioeconomic issues in the risk assessment and management need to be considered.

Detail considerations for risk assessment are in Annex 4.

### 4.2.3. Basic principles and methodology

The risk assessment strategy for GMOs and products seeks to deploy appropriate methodologies and approaches to compare the GMOs and products with their non-Genetically Modified counterparts. The underlining assumption of this approach is that traditionally utilised organisms and products have gained a history of safe use for consumption by humans or animals and for the application in agricultural and environmental or industrial processes. These organisms and products can serve as a baseline for the environmental and food/feed safety assessment of GMOs. Based on that, the concepts of substantial equivalence (SE) were developed and further elaborated by WHO/FAO for the assessment of the environmental and food safety of GMOs respectively. This comparison is the starting point of the safety assessment, which then focuses on the environmental or food/feed safety, and nutritional impact of any intended or unintended differences identified. Based on the country need, Codex principles for the risk analysis (Codex Alimentarius Commission) could deal with identified differences when it is used for human and animal consumption.

### 4.2.4. The concept of substantial equivalence

The concept of substantial equivalence is based on the idea that an existing organism used as food/feed with a history of safe use, can serve as a comparator when assessing the safety of the genetically modified food/feed. Application of this concept, also denoted as comparative safety assessment, serves the purpose of identifying similarities and potential differences between the GM crop-derived food/feed and the non-GM counterparts, which should subsequently be assessed regarding their toxicological and nutritional impact on humans and animals. The first step of the approach is the comparative analysis of the molecular, agronomic and morphological characteristics of the organisms in question, as well as their chemical composition. Such comparisons should be made between GM and non-GM counterparts grown under the same regimes and environmental conditions. The outcome of this comparative analysis will further structure the second part of the assessment procedure, which may include further specific safety and nutritional testing.

### 4.2.5. Risk management

In accordance with the Protocol, countries should develop appropriate measures in managing risks associated with the GMOs. This is the process of measuring or evaluation of the risks and developing and implementation of strategies to manage the risk followed by monitoring and reviewing the risk mitigation measures.

**Evaluation of risk**: This includes the processes of interpreting, comparing, judging the significance of and deciding the tolerability of the risks that are identified and estimated during risk assessment.

**Development and evaluation of risk mitigation process**: This is the process of identifying, evaluating the efficacy and feasibility and selecting appropriate measures in order to reduce the risk associated with GMOs and their products. Risk managers should take into account the uncertainties identified during risk assessment and implement appropriate measures to manage these uncertainties. Risk management measures may include, as appropriate, food labelling for marketing approvals or post marketing monitoring.

**Implementation:** Proper actions are taken following the risk assessment decision on acceptance or refusal of the introduction of GMOs and their products. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include analytical methods, reference materials and the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post market monitoring.

**Identification and labelling:** Any GMO or products thereof shall be clearly identified and labelled. Such identification shall specify the relevant traits and characteristics in sufficient detail for purposes of tractability.

### 4.2.6. Risk Communication

Risk communication establishes an interactive dialogue between the regulator and stakeholders to provide open, transparent and consultative risk-based management of GMOs. Risk communication should include-

- Transparent safety assessment and risk management decision making processes that should be fully documented at all stages and open to public scrutiny.
- Reports prepared on the safety assessment and other aspects of decision making process should be made available to the interested parties.
- Should include responsive interactive consultation process. The views of all interested parties should be sought and relevant food safety and other issues that are raised during consultation should be addressed during the risk analysis process.
- The availability of information on existing laws, regulations, and guidelines is important and the BBCH in conjunction with the BCH should serve as the channel through which national authorities or stakeholders will be informed about final decision regarding notifications and domestic use (including marketing) of GMOs that may be subject to transboundary movement for food, feed or rendering.

The BBCH should provide the information on the following.

- National contacts.
- National coordinating committee.
- Roster of experts.
- National laws and regulations on biosafety notifications, decisions and declarations.
- Bilateral, regional and international agreements related to biosafety.
- Latest announcements and events including safety assessment and management.
- Publications.

# CHAPTER 5

## 5. MONITORING AND ENFORCEMENT

### 5.1. Introduction

Monitoring and enforcement system is a part of the risk management procedure for biosafety and is usually carried out after an approval and start of an activity and may range from a simple surveillance to detailed monitoring that may involve sampling, testing, analysis and reporting to the respective authority for any action if necessary. Supervision and inspection is to be carried out by inspectors appointed by the NCB.

### 5.2. Principles of monitoring and enforcement system

A procedure for monitoring and reporting could be a part of the conditions under which an approval is given, and the person responsible for monitoring activities may be required to comply with a specific monitoring plan. This will depend on the results of the risk assessment analysis on a case-by-case-basis. The number of inspectors will be different depending on the case concerned. Specific experience and inspecting methods related to the activities of the GMOs should be clearly defined by biosafety committees of relevant organisations under the umbrella of the NCA. Based on the outcome of risk assessments, general and specific supervision system should be enforced clearly identifying what needs to be monitored, how this should be done and how the data will be used. Effective monitoring requires the availability of appropriate methodology prior to the commencement of monitoring program and the monitoring advisers need to be clear in their mind about what they are looking for.

### 5.3. Objectives of monitoring

Monitoring is systematic measurement or observation of the effects of GMOs over time. The aim of monitoring is to find out direct, indirect, immediate, delayed or unforeseeable harmful effects of GMOs to the environment generally, humans, plants, or animal health to confirm the assumptions made in risk assessment. The data obtained by such monitoring can be used to impose additional conditions or to maintain, renew or withdraw an approval. Depending on the GMO released, monitoring will have to focus on specific areas such as effect on endangered species, presence of super weeds, presence of insect resistance, impact on soil microorganism, and impact on man and animal health. The areas to be focused on include the following.

- Field trials of GMOs if they are allowed for environmental release.
- Contained use and reporting of risk to NCB and appropriate competent authority belonging to different ministry(s).
- Deliberate release to the environment of GMOs.
- Impact of GMOs on biological diversity.
- Commercial use and placement on the markets of GMO products.
- Impacts on human and animal health
- Illegal transboundary movement of GMOs and their products.

## 5.4. Administrative system for monitoring and enforcement

The NCB will be directly responsible for the execution of the regulatory regime and it is the mandate of the NCB to establish a well organised sustainable national, regional and institutional network for surveillance of risk regarding safety of GMOs. An effective monitoring plan includes the following three main parts:

1. **The monitoring strategy**
    - Identification of the potential effects to be monitored as indicated from the risk assessment regime.
    - Background information pertinent to a particular GMO.
    - Baseline status of the receiving environment.
    - Timeframe and frequency of data collection.
    - Assignment of responsibilities.

2. **The monitoring methodology**
    - Identification of the relevant parameters to be monitored, as indicated by risk assessment.
    - Place and area to be monitored.
    - Approaches for sampling and analysis including detection methods.

3. **The design of the monitoring plan**
    - Be undertaken on a case-by-case basis.
    - Take into account the characteristics of GMOs.
    - Incorporate specific monitoring provisions focusing on adverse effects identified in the risk assessment and general surveillance for unanticipated adverse effects.
    - Be conducted for a period of time long enough to detect immediate or delayed effects which were identified during risk assessment.
    - Make use of established routine surveillance procedure where appropriate.
    - Identify who will carryout the various monitoring tasks and who is responsible to ensure that the monitoring plan is carried out.
    - Ensure that data are analyzed and used to determine future risk management strategies.
    - Ensure that there is a route by which applicant and competent authority will be informed of any adverse effects.
    - Ensure appropriate mitigation measures if significant adverse effects are noticed.
    - Ensure appropriate methods for public information of monitoring results.
    - Risk management plans in case of accidental releases.
    - Auditing of the monitoring regime on a case-by-case basis.

In choosing the monitoring method and the sampling and detection techniques, attention should also be given to the following.

- Flexibility.
- Applicability and practicability.

- Repetitiveness.
- Investment cost.
- Convenience.
- Transparency.
- Consistency.

## 5.5. Regulatory basis of monitoring and enforcement

Regulatory basis for monitoring and enforcement is necessary and therefore it is important that appropriate provisions are made in the regulatory regime for an effective monitoring and enforcement system. Provisions for enforcement shall include punishment for any illegal activity involving GMOs such as research, development, use in containment, field testing, production, release, import and export, handling, and transport of GMOs etc.

## 5.6. Monitoring and enforcement within the institution

Under the present biosafety guidelines, all institutes/universities engaged in work with GMOs are required to have an IBC with appropriate expertise to evaluate and monitor the biosafety aspects of their work. Where an institution intends to become involved in planned field release, members of the IBC should collectively have the range of expertise necessary to supervise research and assess GMO research programs. The IBC shall have the following functions.

(1) To assist the head of the institution in providing for an effective and efficient system of monitoring and evaluation in the institution.

(2) To enforce all biosafety regulations in the institute, review works conducted by the institutions and recommends research proposals for considerations by the NCB.

(3) To notify the project chief/proponents/investigator about the results of the review. Review at least once in every year, the work or assessment reports on potential risks being conducted at the institution as well as review laboratory records on regular basis to ensure that requirements of the guidelines are being fulfilled.

(4) To formulate and adopt emergency plans covering accidental spills and personnel contamination resulting from lab and fieldwork. Report immediately to the appropriate official in the concerned organisation and to the NCB any significant problems with the implementation of the guidelines and any significant research-related accidents or illness.

(5) To maintain records of approved project proposals for genetic manipulation work and the Committee's assessment Undertake risk assessment in cooperation with research teams if necessary to determine the appropriate containment and biosafety conditions.

(6) To prepare specific contingency plan after undertaking risk assessments and reviewing project proposal. Monitor the containment features and working conditions within the laboratories, plant glass houses and animal houses of the institute to ensure that various facilities are maintained at the required standard.

Each institution shall designate at least one scientist as BSO. It shall be the duty of the BSO to monitor the compliance of the guidelines at the institution level. BSO has to report regularly to the Chairperson of IBC on any matter regarding biosafety applications in the institution. The IBC monitor the progress of the work and reports to NCB any significant unforeseen occurrence regarding the work.

## 5.7. Monitoring and enforcement by the NCB

The NCB represents the most important component of the regulatory regime and therefore the following powers and functions are designated to it in order to ensure proper monitoring and enforcement of work with GMOs.

(1) Review all existing projects and research.

(2) Review, monitor and recommend measures to minimise potential risks that may result from, development, import, contained use, field trial and release of GMOs.

(3) Instruct the respective authority to ensure implementation of biosafety measures related to all activities involving GMOs.

(4) Prepare different forms for all GMO related activities and to develop containment standards, guidelines, code of practice and other documents for the effective management of all GMO activities.

(5) Provide advice and assistance to the IBC and FBC and other relevant committees on the risk and safety aspects of their work. Inspect and certify all laboratories and facilities engaged in high-risk genetic manipulation work.

(6) Cooperate with other national authorities dealing with import of live organisms, to formulate uniform guidelines for identification, inspection and regulation of transgenic species, exotic organisms and others.

## 5.8. Monitoring and enforcement by the BCC

The BCC shall perform the following functions.

Monitor the implementation of biosafety guidelines, policies, acts and rules as complementary to the NCB; provide technical comments or recommendations to NCB or the government on policy, legal and technical issues of biosafety as and when requested for and BCC shall arrange annual inspection and evaluation of performance of all the laboratory engaged in research & development (R&D) of GMOs.

## 5.9. Follow up actions for monitoring and enforcement under the NBF

Efficient monitoring and proper enforcement of violation of Laws on Biosafety will build confidence on the users of the products of 'modern biotechnology'. Regular inspection and improvement, if there be any change in the international sector on surveillance techniques should be brought up by the NCA for changes. Bangladesh will sign MoU with UNEP-GEF and will regularly update information based on the changes of database of its country through the BCH. The follow up actions for monitoring and enforcement may be considered as follows.

a. The infrastructure for the monitoring and enforcement shall have to be established.
b. The experts and personnel carrying out monitoring and enforcement (ME) shall have to be trained.
c. The technical methods of monitoring and enforcement shall be provided.
d. The monitoring parameters and criteria shall be identified and the relevant rules of monitoring, inspection and enforcement shall be produced.

## 5.10. Auditing of monitoring and enforcement activities

It is proposed that the NCB will have the auditing role for all monitoring and enforcement activities to ensure that they are carried out to fulfil their intention of managing potential effects.

## 5.11. Liability and redress

Although no specific provisions are mentioned for liability and redress it is anticipated that existing provisions would be applicable in any unlikely event raising the liability and redress issues.

# CHAPTER 6

## 6. PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

### 6.1. Introduction

Consideration of public awareness, education and participation lies in the Protocol whereof, the contracting party shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs in relation to the conservation and sustainable use of biological diversity and risks concerned to human health. The party shall ensure that public awareness and education encompass access to information on GMOs identified in accordance with the Protocol. Article 23(2) and 23(3) of the protocol implies that the party shall consult the public in the decision making process regarding GMOs and shall endeavour to inform the public about means of public access to the BCH. The development of genetic engineering, biotechnology and GMOs is relatively new in Bangladesh compared to that of developed countries and even in comparison with some ASEAN countries. Available documents and records show that the awareness and extent of knowledge on genetic engineering, biotechnology, and GMOs among people are relatively low. Since the issue is new, initiatives would be undertaken from the very beginning on public awareness, education and people's participation. Therefore, the mechanisms for public awareness, education and participation formulated under this NBF are expected to be effective to fulfil the obligation under the Protocol.

### 6.2. Necessities and benefits

It is necessary for the country to protect its biodiversity. Bangladesh is one of the world's richest storehouses of genetic diversity. Hence, biosafety issue regarding the use of GMOs is a great concern to environmentalists, consumers and the general public. People are concerned about the heath hazards originating from plants, animals and other biotechnological sources. Therefore, mechanisms for public awareness, education and public participation in decision making are recognised.

The potential benefits of public awareness and education regarding biosafety issues in the Bangladesh context are the following.

- People will be more conscious, careful, but may accept GMOs that pass through the regulatory system of Bangladesh.
- There will be understanding about risk assessment and management.
- Reduce misunderstanding and miscommunication on the issue.
- The regulatory system may be seen as transparent.
- People's acceptance may enhance biotechnological development in the country.

## 6.3. Mechanism of public information and disclosure

Providing adequate information to stakeholders in a transparent manner is necessary for public awareness, education and participation. Effective way of public information disclosure to public institutions might involve the following

- Institutional policy and systems for information disclosure through different channels.
- Strategies followed for information disclosure through outreach programmes.
- Policies of the government departments such as AIS (Agriculture Information Service), DAE (Department of Agricultural Extension), DLS (Department of Livestock Services) and DoF (Department of Fisheries) for information disclosure through different ways and channels.

Major agricultural research institutions, have their own mechanisms to contact public though their regional stations or sub-stations. People have regular contact and dialogue with the scientists about the technological trials and developments. People have easy access to discuss on any matter related to the development of GMOs. Similarly, Universities e.g. BAU (Bangladesh Agricultural University), SAU (Sher-e-Bangla Agricultural University), BSMRAU (Bangabandhu Sheikh Mujibur Rahman Agricultural University), and HSTU (Hajee Mohammad Danesh Science and Technology University) have mechanisms to contact public and deliver information and messages to them through outreach programmes. The AIS, DAE, DLS and DoF have information disclosure through distributing printed materials (such as poster, bulletins, booklets, leaflets/folders, weekly and monthly agricultural magazines, and demonstrations on various commodities at farmers' fields. These mechanisms are important in promoting awareness about GMOs and their related issues.

### 6.3.1. Public access to information on GMOs

Many tools can be applied to inform the public on modern biotechnology, its advantages and potential risks. The usual tools include the following.

1. Using the media and the press - radio, television, newspapers, magazines, booklets, leaflets, and folders to provide information on GMOs.
2. Interviews with experts – for most delicate and sensitive issues interviews may be held with the relevant experts in the field, information from a credible source is more likely to be accepted by the public.
3. Publication of articles – articles on of biosafety regarding the use of GMOs can be published in newspapers, magazines and periodicals occasionally in order to take correct decisions by the potential.
4. Film shows – arrangements may be made for film shows and documentary films to rural areas for mass awareness.
5. Meetings of all kinds – when the use of mass media (radio, TV and printed materials) do not properly serve the purpose, meetings with the key persons (opinion leaders) can be arranged for clarification and information exchange.

6. Demonstrations – result and method demonstrations can be conducted as and when necessary in order to build trust, confidence and determination of the safe use of GMOs.
7. Group discussions – small group discussion (based on homogenous categories) can be used to provide information to various sections and categories of people.
8. Discussion and dialogue with NGO workers – many NGOs have very active and viable farmers' groups (both male and female). Information can be delivered to these group members for its wide spread and transmission.
9. Personal localite (friends, relatives, neighbours and near peers) sources of information - people believe most on their closed friends and relatives. If possible some selected innovative and progressive farmers may be given training on the use of GMOs so that all other farmers in the community can get information from these persons.
10. Personal cosmopolite (government and non-government field workers) sources of information – farmers have easy access to many field level workers of different government officials and NGOs. If these workers are trained desirably, consequently the benefits would be disseminated to the public.

### 6.3.2. Identification of different stakeholders and their participation in GMO issues

It is logical that it would not be possible for a single department or organisation to run all the activities related to the conservation of biodiversity and maintaining biosafety in Bangladesh and therefore a coherent and holistic approach is required. It is proposed that the DoE should form a core group of scientists and the group to be led by the Secretary, DoE. The Department of Agricultural Extension (DAE), however, has personnel down to the block or village level and there is systematic way of sending messages to the farmers through a number of tiers. The DLS and DoF have also personnel up to Upazila (sub-district) level. The Ministry of Commerce (MoC), Ministry of Law (MoL), Ministry of Food (MoF), Ministry of Health and Family Welfare (MoHFW) should also participate in generating, assembling, and disseminating information on GMOs.

It is important that stakeholders are identified and their involvement ensured. The potential stakeholders on biosafety issues at the operational levels are as follows.

1. Scientists/ researchers.
2. Teachers.
3. Students.
4. Government officials.
5. Extension agents/field workers.
6. Farmers/producers.
7. NGO personnel.
8. Consumers.
9. Traders/dealers.
10. Manufacturers.
11. Public representatives and the public generally.

In order to have greater participation by different stakeholders the following arrangements would be useful.

- Empowering the civil society and NGOs in order to reinforce the foundations of hierarchical participation.
- Elaborating the participation of religious representatives.
- Holding opinion poll conventions and workshops.
- Creating suitable methods for public opinion polls (e.g. preparing questionnaires for different groups of people).
- Creating independent consultative committees.
- Creating and expanding a biosafety information centre to help achieving goals and to facilitate information exchange between decision makers, managers, experts and the public.

### 6.3.3. Public involvement in decision making on GMOs

Public participation in self-determination is one of the requisites of the constitution of the Government of Bangladesh, and the government has an obligation to encourage and make its realisation possible through relevant organizations. Participation will be made possible after informing, training and gaining the trust of the public, and it should be planned and executed at different levels. Different types of participation can be considered for different groups of people. Consistent messages received from multiple sources lend credibility to the risk message. To be credible the public must recognise competence, trustworthiness, fairness and lack of bias.

Decision has to be made by concerned authorities at different stages of GMO development, contained use including field test, general release, and monitoring. Public participation has to be ensured at the following points of decision making.

a) **Technology development:** Participatory approaches should be followed for the identification of researchable problems/topics for the development of GMOs in research institutes and universities.
b) **Importation, contained use or release of GMOs:** After receiving an application for importation, contained use or release of GMOs, the risk assessment data should be made public through mass media for comments. In addition, the relevant experts should be consulted through focus group discussion, seminar, symposium, workshop etc.
c) **Monitoring:** Public should be consulted during the stage of post release/marketing to make decision on continued use or discontinuing the use of GMOs. Field demonstration, attitude measurement, adoption studies, opinion surveys through questionnaires can be the effective tools in this regard.

### 6.3.4. Mechanism of public participation

To involve community, there are three different levels of participation that can be used and these are the following.

1. The best techniques used to involve and inform the public include printed materials (brochures, booklets, leaflets/folders newsletters, posters, flip charts), information centres, press information, radio, site visits or field trips, exhibitions or open houses and information hotline or key contact person and media.

2. Consulting the community to gather ideas, suggestions and information needs on the issue. Techniques used are public meetings, workshops, and presentation to community organisations, individual interviews or surveys, focus groups or groups interview, and technical assistance to public.
3. Shared decision or responsibilities through involving communities while their input is sought in decision making. The best techniques used are forming advisory groups and monitoring committees.

There are multiple players in the communication process, including regulatory officials, industry, consumers and the media. Each has a specific role to play and by sharing this responsibility, each can do their part to assure effective communication. It is anticipated that the proposed regulatory regime will specify the activities requiring mandatory or discretionary public consultation.

A flow diagram indicating the public participation in decision making, for different activities is presented in Figure 5.

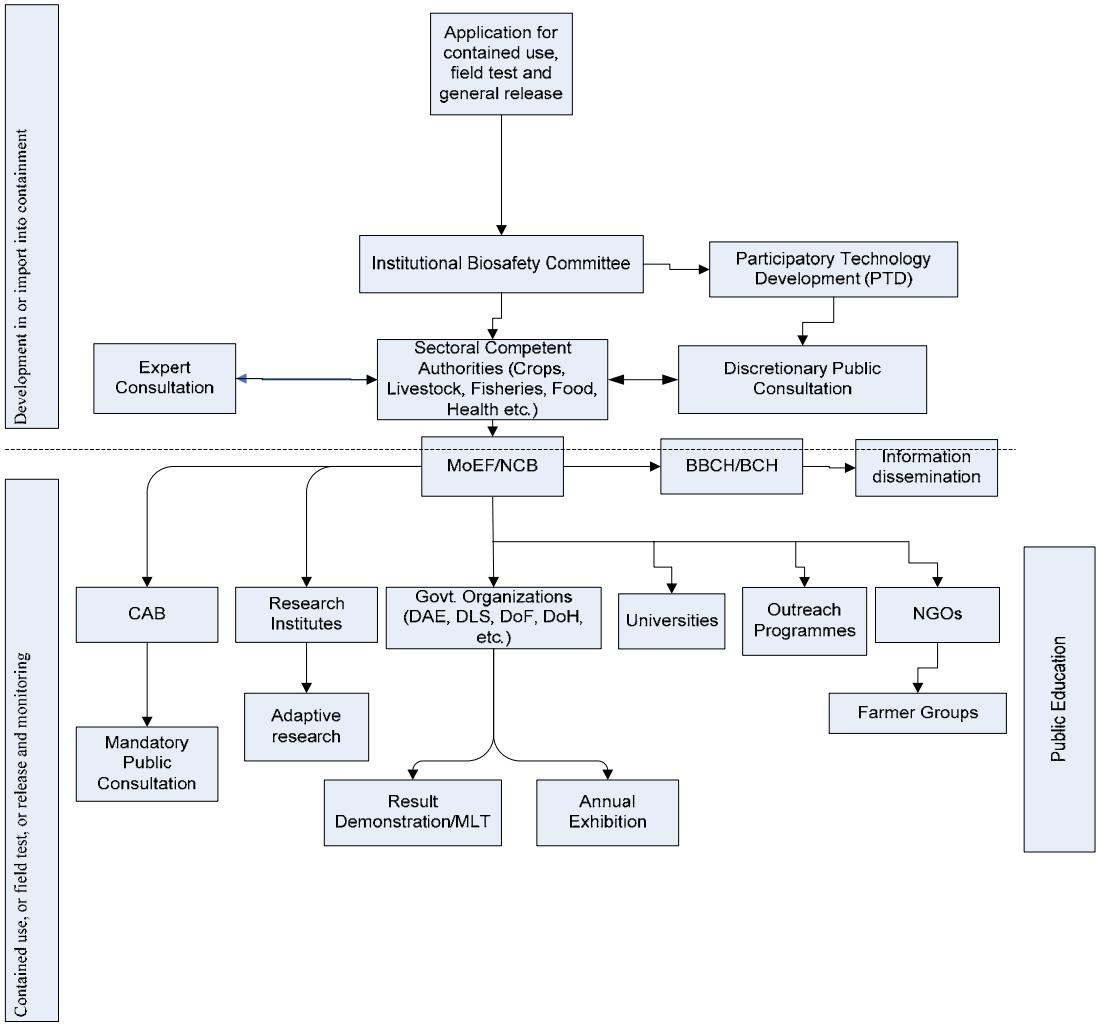



Figure 5. Mechanisms of public participation in decision making at stages of approval for contained use, field test, general release and monitoring

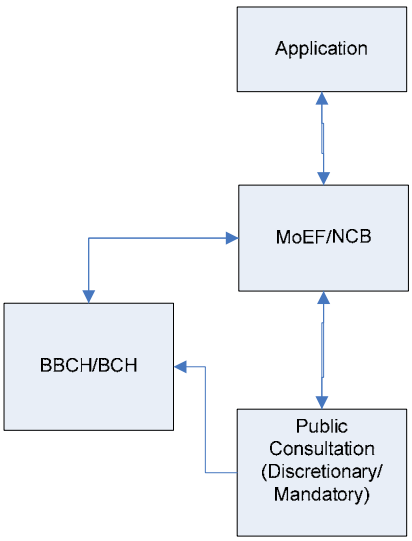
In each of the stages of decision making there is scope and opportunities for public consultation. The government departments have their own ways of verifying and testing technologies at farmers' field situation through setting demonstrations, and MLT (multi-location testing). Through this programme farmers get an opportunity to be involved in the planning, designing, executing, and evaluating the technologies. The research institutes in their regional stations and sub-stations conduct adaptive trials at farmers' field where farmers are directly involved in all stages of technological development and work in close contact with the scientists. Through this mechanism farmers give their views and opinion, assess and evaluate the technologies and finally decide whether to accept or reject the technologies. Some universities have their own outreach programmes where teachers and researchers of the universities get with farmers directly. The farmers also get direct access to the university teachers and researchers and often consult with them regarding the technological development. NGOs have close contact with the farmers through different client oriented groups where the public have direct access to give their opinion

to the NGOs. Similarly CAB has scope to conduct opinion survey through questionnaire for public consultation.

### 6.3.5. Information management strategy

The Department of Environment (DoE) should take the prime responsibility in managing information related to biosafety. There should be core group in the DoE who should accumulate information on biosafety, synthesise the information and mange to co-ordinate and send the messages to the relevant persons with the help of other concerned stakeholders as appropriate. The DAE has unique access to the farmers. At present the DAE has about 2000 cadre officers, about 12,000 Sub-Assistant Agricultural Officers, 6000 supporting staff, about 30 well equipped training centres and 84 Horticulture Centres for producing vegetable seedlings/saplings. There is a good scope for the DoE to utilise the resources of the DAE, DHS, DLS and DoF for public education, awareness and participation about modern biotechnology and the GMOs.

The potential stakeholders for promotion and facilitating public awareness, education and participation on biosafety have been shown in Figure 5. It is noted that in Bangladesh multiple agencies will be involved at different stages in the management of GMOs and therefore the structure for public involvement presented in Figure 7 is detailed and therefore a simplified overview is presented in Figure 6 below.




igure 6. Simplified procedure for public involvement in different GMO activities

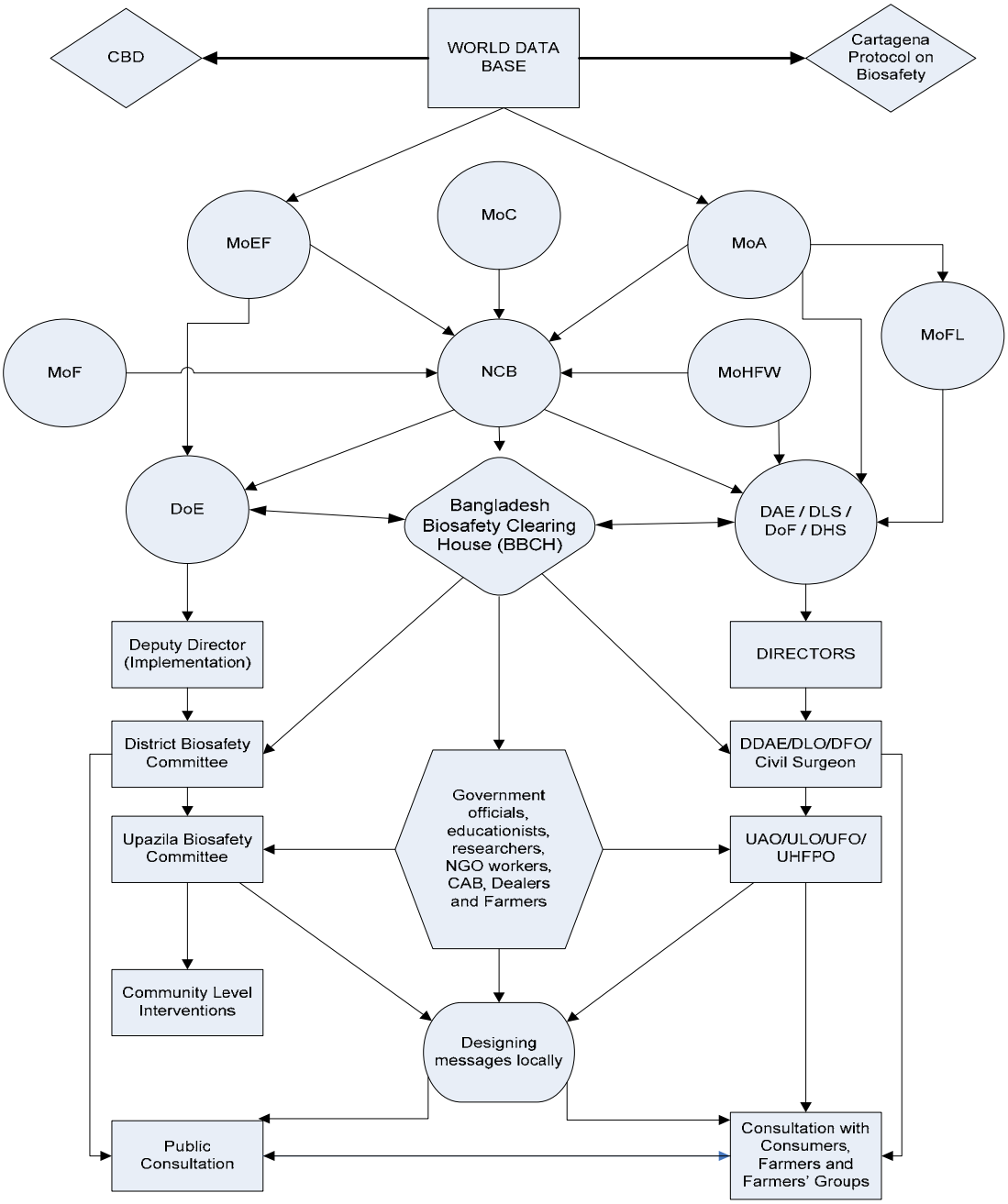



Figure 7. Public information management strategy on biosafety

The NCB would collect the all relevant information regarding the import, contained use, development, field test, and general release of GMOs. The concerned Ministries would main contact and co-ordinate with the NCB in respect of biosafety on the use of GMOs. On behalf of the NCB, the BBCH would take responsibility to disseminate information and messages regarding biosafety. In addition to maintaining contact with the BCH, BBCH would maintain close co-operation and co-ordination with other national agencies that have direct contact with the

public (e.g. DAE, DLS, DoF, and DHS), and the public on the other hand have direct access to the field workers of these agencies.

### 6.3.6. Awareness, education and communication

For creating awareness among people, giving them information on biosafety and for mass communication, the following activities will be undertaken.

**1. Building public awareness**

- Specific media programs/publications (leaflets, and posters).
- Public education/guidance offices in government departments.
- NGOs.
- Publications of professional and civil society organisations.
- Labelling, where feasible and practical.

**2. Using various methods for public education**

- Publications viz. Monthly magazines, booklets, and bulletins.
- TV and radio.
- Seminars.
- Workshops.
- School curricula.
- Exhibitions.
- Links on ministry website to approve education sites.

**3. General communication**

Using the existing channels that are available in the country can provide information on biosafety. The following channels are useful.

- The national information centre.
- Cell on biosafety under the Ministry of Information and Communication Technologies (ICT).
- Official monthly gazette.
- Media announcement (TV, radio, print).
- Providing a response button on a website.

**4. Risk communication**

Communication of acceptable risk to public during development, contained use, field test, general release, or marketing is necessary in the following areas.

- Labelling of GMOs and their products.
- Potential risks and hazards should be identified and communicated to the public as a part of good practice.

- Access to information on laboratory safety protocol to the scientists and laboratory workers involved.
- Risks associated with contained field trials should be identified and communicated to the concerned persons.

## Annex 1: Capacity survey of biotechnology and biosafety status

Though Bangladesh is small country, she has diverse terrestrial and aquatic flora and fauna. Biodiversity in Bangladesh is threatened by population pressure followed by over exploitation of natural resources. Natural calamities like cyclones, floods and use of land for cultivation of crops are also threatening the biodiversity. Being a member of CBD, Bangladesh has developed a few programme related to biodiversity. At present the government puts priority for advancing biotechnological research and development. Recently a national policy on biotechnology has been approved by the parliament. At present the government is putting more emphasis for advancing biotechnological research and development in order to feed the millions of people. More recently, National Policy on Biotechnology has been approved. However, due to lack of National Biosafety Framework, biotechnology based biodiversity exploitation is being hindered. While developing NBF, an assessment of the existing capacity to undertake research related to Biotechnology, Genetic Engineering and GMOs etc, it is essential to undertake a thorough national survey. The survey must bring into light the details as to the existing infrastructure (laboratories), human capacity, on-going projects, pipeline projects, field of science and industry, techniques and protocols being used, and status of institution wise biosafety committee etc. With this rationale in mind a national survey became imperative to undertake.

In order to assess national capacity on biotechnology, genetic engineering and GMOs, a national survey was conducted using a structured questionnaire. The questionnaire contained all elements necessary to reveal the truth in this area of research and development. Information of the questionnaire was collected through direct interviewing but for institutional capacity assessment a copy of questionnaire was left with the head of the institute/organisation for completion and to send to us. Once the survey was over the furnished information in the questionnaire were checked for unwanted errors and then entered into a database developed following the structure of the questionnaire. Both numerical and string variables were used to put information in the database. Simple frequency count, averaging and percentage calculations were used demonstrate some of the results of the survey.

The research and development of biotechnology is limited to standardisation of plant tissue culture protocols, artificial insemination and genetic improvement of cattle, micropropagation of different commercially important plants, molecular characterisation of crop, livestock and fish breeds/varieties etc. A few scientists have training on doing hardcore biotechnology like gene isolation, cloning, expression characterisation and development of DNA-recombinant vaccines. But the infrastructure and other facilities are very inadequate. Research and development of biotechnology in fisheries and livestock sectors is even less significant.

### Infrastructures

At present many public universities and research institutes and some have come forward to take up the research and development of work in the field of biotechnology genetic engineering and GMOs. Also several private sector organisations like BRAC, Proshika, Square Biotech, Biotech Bangladesh Ltd etc. showed interest to commercialise biotechnology products. The present capacity in terms of infrastructure such as building, equipments, lab facilities for doing research, human resources and areas of research and development has been presented in Table 1. The main constraints in this sector are the lack of infrastructures, availability of equipments and chemicals, trained manpower etc. By now due to government initiative, Biosafety committee has been

formed in every institute look after the Biosafety aspects involved in doing research in the field of biotechnology, genetic engineering and GMOs. Doing research in the field of Biotechnology, Genetic engineering and GMOs is obviously a costly venture and needs hand some amount of financial support compared to other field of research and development. However, lack of financial support slowed down the research and development works in this field in Bangladesh. For example, many public universities and institutes opened the new department in the name of Biotechnology and Genetic Engineering. But none of them has proper facilities due to financial constraints. Lack of proper biosafety related regulatory mechanism is also slowing down the use of GMOs in the field level.

**Table 1: Institutional capabilities of various organisations involved in research and development in the field of biotechnology, biodiversity, and biosafety**

***a) Public Research Institute/Organisation/Department***

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| **Institute/ Organisation** | **Biotech Experts PhD. + M.S.** | **No. Biotech R&D projects Ended + Running** | **Any plan for Biotech research** | **Biosafety measures documented-authority** | **Future capacity building area** |
| BARI | 5+5 | | | yes - IBC | GMO, Trial |
| BCSIR | 3+7 | | | yes - IBC | GMO, Microbial |
| BFRI | 1+0 | 1+1 | | yes - IBC | DF |
| BINA | 6+0 | 1+3 | | yes - IBC | GMO |
| BJRI | 2+1 | | | yes - IBC | GMO |
| BLRI | 1+4 | | | yes - IBC | |
| BRRI | 5+1 | | | yes - IBC | GMO, Trial |
| BSRI | 1+1 | 2+1 | | yes - IBC | GMO |
| BTRI | 0+1 | | | | TC |
| DAE | 0+1 | | yes | | TC, Mushroom |
| DLS | 1+1 | | yes | | |
| DoE | | | | | Biosafety |
| FRI | 1+0 | | yes | yes - IBC | TC |
| NH | | | | | TC, DF |
| NIB | 1+7 | | yes | yes - IBC | All Biotech sectors |
| WRC | 1+0 | | yes | yes - IBC | TC, GMO |
| NICVD | 1+0 | | yes | | Medical Biotech |

***b) Public/Private Educational Institute***

| | | | | | |
|---|---|---|---|---|---|
| BAU | 42+6 | 9+13 | | yes - IBC | GMO, DF, Biosafety |
| BSMRAU | 4+1 | | | yes - IBC | GMO, DF |
| CUVAS | 1+3 | | yes | | DF |
| CU | 5+5 | | | yes - IBC | GMO, DF |
| DU | 16+10 | | | yes - IBC | GMO, DF, biosafety |
| JU | 4+1 | | | | GMO, DF |

| | | | | | |
|---|---|---|---|---|---|
| KU | 2+5 | | | yes - IBC | GMO, DF |
| RU | 12+4 | | | yes - IBC | GMO, DF, biosafety |
| SAU | 2+3 | | yes | | GMO, DF |
| SUST | 1+5 | | yes | | GMO |
| SVC | 1+4 | | yes | | TC |
| BBMU | 0+1 | | yes | | MB, bosafety |
| GB | 1+3 | | yes | | GMO |
| BRACU | | | yes | | GMO |
| UODA | 1+4 | | yes | | GMO |

***c) Private sector, NGO, International Initiative***

| | | | | | |
|---|---|---|---|---|---|
| BRAC | 1+6 | | | | TC |
| BBL | 1+2 | 0+0 | | | TC |
| Biotech Intl | 0+1 | | | | TC |
| Biotech Seeds | 1+2 | | | | TC |
| DEBTEC | 1+1 | | | | TC |
| Freelance | 1+1 | | | | |
| Proshika | 1+3 | | | | TC |
| Square Biotech | 0+2 | | | | TC |
| ICDDR'B | 1+0 | | | | MB, microbial |
| IUCN | | | | | |
| BELA | | | | | |
| Bangladesh Medical | 0+1 | | | | MB |

***Abbreviations used in this Annex***

| | |
|---|---|
| BAU | Bangladesh Agricultural University |
| BBL | Biotech Bangladesh Limited (Alpha Agro Ltd.) |
| BELA | Bangladesh Environmental Lawyers Association |
| BFRI | Bangladesh Fisheries Research Institute |
| BINA | Bangladesh Institute of Nuclear Agriculture |
| BJRI | Bangladesh Jute Research Institute |
| BLRI | Bangladesh Livestock Research Institute |
| BMU | Bangabandhu Medical University |
| BRACU | BRAC University |
| BRRI | Bangladesh Rice Research Institute |
| BSMRAU | Bangabandhu Sheikh Mujibur Rahman Agricultural University |
| BSRI | Bangladesh Sugarcane Research Institute |
| BTRI | Bangladesh Tea Research Institute |
| CU | Chittagong University |
| CUVAS | Chittagong University of Veterinary and Animal Science |
| DAE | Directorate of Agriculture Extension |
| DF | DNA fingerprinting |
| DLS | Directorate of Livestock Services |

| | |
|---|---|
| DOE | Department of Environment |
| DU | Dhaka University |
| FRI | Forest Research Institute, Chittagong University |
| GB | Gono Bishyavidyalaya |
| GMO | Genetically modified organism |
| ICDDR,B | International Centre for Diarrheal Disease Research |
| IUCN | International Union for the Conservation of Nature |
| JU | Jahangirnagar University |
| KU | Khulna University |
| MB | Medical biotechnology |
| NH | National Herbarium |
| NIB | National Institute of Biotechnology |
| NICVD | National Institute of Cardio Vascular Diseases |
| RU | Rajshahi University |
| SAU | Sher-E-Bangla Agricultural University |
| SUST | Shahajalal University of Science and Technology |
| SVC | Sylhet Veterinary College |
| TC | Tissue culture |
| UODA | University of Development Alternative |
| WRC | Wheat Research Centre |

Survey results revealed than Bangladesh ahs started soft core biotech Bangladesh like Tissue Culture since eighties. At present, most of the public universities and research institutes have functioning biotech Departments/Divisions significant number of NGOs and private companies also have their facilities for Tissue Culture works. Dhaka University (DU), Bangladesh Agricultural University (BAU), Rajshahi University (RU), Bangladesh Agricultural Research Institute (BARI), Bangladesh Rice Research Institute (BRRI), Bangladesh Sugarcane Research Institute (BSRI), Bangladesh Institute of Nuclear Agriculture (BINA) have started genetic fingerprinting and genetic engineering works. Although the facilities are limited, the gene constructs are borrowed and shared with other labs from developed countries as a part of their collaborating partnership research activities. *Agrobacterium* mediated indirect genetic transformation method is followed and all GMO producing laboratories in Bangladesh. BRRI is doing the second round trial of Golden Rice in its contained facilities. BARI has received Fruit and Shoot Borer resistant *Bt* brinjal and Late Blight Resistant Potato for contained trial in its glasshouse. Applications for *Bt* brinjal by East-West Seeds Ltd and PRSV resistant papaya by BARI are in process for import and testing.

BAU has the highest number of experts on soft-core and hard-core biotechnology, biosafety and biodiversity followed by Dhaka University (26) and RU (16, CU (10) and BARI (10). In general universities have greater number of biotech and related experts followed by research institutes, whereas least number at private sector, NGO and International Initiatives (Table 1). Institutes do not have the facilities also have expressed their intension as start the biotech activities in near future. All the GMO producing Universities and research institutes are following the biosafety measures as mentioned in the Cartagena Protocol of biosafety through their institutional biosafety committee (IBC). Universities leading the GMO research have shown their interest for its improvement and DNA Fingerprinting (DF) research; research institutes also have shown interest in enforcement on GMO work and its trial, whereas NGO, Private and International initiatives are concentrating on tissue culture propagation of elite genetic materials. The GMO producing institutes are additionally interested for their capacity building on biosafety measures.

It is evident from the survey results that sectorwise human capacity in biotechnology, biosafety and biodiversity varied significantly among the disciplines. Plant sector has the extremely highest number of experts (61.54%) whereas animal, fish (21.37%) and microbial (17.09%) sector have shorter number of experts (Table 2). Medical and food sector have insignificant number of experts. Biosafety and biodiversity experts are increasing in slow pace with the development of biotech capacity in the country. Most of the respondents under survey have heard about GM foods/crops (96.35%) and think that it can benefit then (95.08%) as a result they are in favour of introducing GM food (86.17%) in Bangladesh (Fig. 1 & Q 3, 5, 13).

Majority of the respondents have trust on GM providers that safety tests are followed before marketing (84.70%) by international organisation like codex alimentarious commission, Organisation of Economic Cooperations & Development (OECD) etc (93.38%). However, majority also responded saying it needs further environmental safety data to be generated even it has gone through the same procedure abroad similar agro-ecosystem (80.70%), even to go through human testing (86.27%) (Fig. 1 & Q. 14, 19, 25, 28). Around one-forth of the biotech institutes are conducting GMO research where 59.00% have the GMO facilities and 61.59% institutes are planning for it. Softcore biotech products are developed in 22.93% institutes as 52.60% institutes are doing biotech other than genetic engineering.

Now-a-days, foreign and local collaboration is evident (45.73%) among the researchers with the difficulties of chemicals/consumables availability (79.07%). Most of the respondents are aware of Biosafety (90.45%), Biosafety Guidelines (76.28%), National Biosafety Framework (73.13%) but less on cartagena protocol (35.24%). GMO researches are carried out maintaining contained conditions at all stages (58.65%) following precautionary measures (73.74%).
The existing staff number has insufficient training on biotechnology, biosafety (16.75%), biodiversity (18.97%). Conservation of biodiversity (35.29%), and germplasm characterisation (41.18%) which needs to be invigorated (98.08%). Institutes has limited facilities for toxicological research and labeling (23.08%) and germplasm/characterisation facilities (37.04%), however, they are maintaining and using related crops (48.15%) and wild/native germplasm (50%) for crop improvement. Germplasm are maintained through germplasm/gene bank (42.86%) followed by in situ (35.71%) and *in vitro* methods (21.43%).

**Biosafety and Regulatory Framework**

Bangladesh is a party to CBD, CPB, ITPGR and TRIPS. From the Table-1, it can observed that biotechnology related activities in Bangladesh are largely confined to areas like tissue culture, genetic transformation in limited scale, microbial biotechnology and fermentation biotechnology. But at present different projects like Agricultural Biotechnology Support Service Project-II (ABSP-II), SABP, ISAAA etc are working with the objectives to popularise GMOs in Bangladesh. Golden rice is in its second year confined trial in glasshouse at BRRI. Already permission has been granted to conduct contained trial of Bt brinjal and late blight resistant potato. Therefore, the country needs Biosafety clearance. Bangladesh has developed Biosafety Guidelines and recently a National Technical Committee on Biosafety has also been formed. Organisational structure as well as the composition of various committees needs 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 a 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 has prepared Plant Variety and Farmers' Rights Protection Act that should be approved by the parliament as soon as possible. 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 do also not exist. The country does not have any regulation regarding the use of GMOs as food.

**Requirements for capacity building in biosafety: Priority areas**

Bangladesh has to build up capacity for biosafety through trained human resource both at technician and higher level, development of appropriate infrastructures suitable for developing GMOs and also for risk assessment and risk management, 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 international and regional cooperation programme will be useful for quick capacity building.

**Capacity Building in Human Resource Development**

Human resource development is a very important aspect to for doing research and development work in the field of biotechnology as well as to launch public awareness programme for increasing knowledge in risk assessment and benefit of biotechnology. In Bangladesh a number of scientist are involved in doing research and development works in different public and autonomous institutes/universities. A list of different categories of researchers involved in doing research and development in the field of biotechnology is given in Table 2. We categorised the scientists/researchers/development workers in different categories depending upon their present activities. The broad categories are: i) Biotechnologists; ii) Biodiversity Experts and iii) Biosafety experts including Toxicologist and contained and field experimentation specialist of biotechnological products.

**Table 2: Sectorwise human capacity in biotechnology, biodiversity and biosafety in various organisations of Bangladesh**

***a) Public Research Institute/Organisation/Department***

| **NUMBER OF BIOTECHNOLOGY** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Institute/ Organisation** | **Plant** | **Animal/ Livestock** | **Fish** | **Microbial** | **Medical** | **Food** | **Others** | **Total** | **Hardcore** |
| BARI | **9** | | | | | | **1+0** | **10** | **5** |
| BCSIR | **4** | | | **6** | | | | **10** | **4** |
| BFRI | | **1** | | | | | | **1** | **1** |
| BINA | **6** | | | | | | | **6** | **2** |
| BJRI | **6** | | | | | | **1+0** | **7** | **1** |
| BLRI | | **2** | | | | | | **2** | **1** |
| BRRI | **9** | | | | | | | **9** | **5** |
| BSRI | **2** | | | | | | | **2** | **1** |
| BTRI | **1** | | | | | | | **1** | **0** |
| DAE | | | | **1** | | | | **1** | **0** |
| DLS | | **2** | | | | | | **2** | **1** |
| DoE | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| FRI | | **1** | | | | | | **1** | **1** |
| NH | | | | | | | | **0** | **0** |
| NIB | **8** | | | | | | | **8** | **1** |
| WRC | | | | | | | **1+0** | **1** | **0** |
| NICVD | | | | | **1** | | | **1** | **0** |

***b) Public/Private Educational Institute***

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| BAU | **20** | **17** | | **7** | | | **2+2** | **48** | **24** |
| BSMRAU | **5** | | | | | | | **5** | **2** |
| CUVAS | | **3** | | **1** | | | | **4** | |
| CU | **3** | **1** | | **6** | | | | **10** | **5** |
| DU | **14** | **2** | | **10** | | | | **26** | **6** |
| JU | **3** | | | **2** | | | | **5** | |
| KU | **6** | **1** | | | | | | **7** | **2** |
| RU | **7** | **4** | | **5** | | | | **16** | **1** |
| SAU | **4** | | | **1** | | | | **5** | **3** |
| SUST | **4** | **2** | | **0** | | | | **6** | |
| SVC | | **3** | | **2** | | | | **5** | |
| BBMU | | | | | **1** | | | **1** | |
| GB | | | | | | | | | |
| BRACU | | | | | | | | | |
| UODA | | | | | | | | | |

***c) Private sector, NGO, International Initiative***

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| BRAC | **7** | | | | | | | **7** | |
| BBL | **3** | | | | | | | **3** | |
| Biotech Intl | **1** | | | | | | | **1** | |
| Biotech Seeds | **3** | | | | | | | **3** | |
| DEBTEC | **2** | | | | | | | **2** | **1** |
| Freelance | **2** | | | | | | | **2** | **1** |
| Proshika | **4** | | | | | | | **4** | |
| Square Biotech | **2** | | | | | | | **2** | |
| ICDDR'B | | | | **1** | | | | **1** | **1** |
| IUCN | | | | | | | | | |
| BELA | | | | | | | | | |
| Bangladesh Medical | | | | | | | | | |

It is observed that the main constraints in this sector are the lack of infrastructures, availability of equipments and chemicals, trained man power etc. By now due to government initiative, Biosafety Committee has been formed in every institute to look after the Biosafety aspects involved in doing research and development activity in the field of Biotechnology, Genetic Engineering and GMOs is obviously a costly venture and needs handsome amount and regular flow financial support compared to other fields of research and development. However, lack of financial support has slowed down the research and development works in this field in Bangladesh. For example, many public universities and institutes opened the new department in

the name of Biotechnology and Genetic Engineering, but almost none of them has proper facilities due to financial constraints. Lack of proper Biosafety related regulatory mechanism is also slowing down the use of GMOs in the field level.

It has been observed that the research and development of biotechnology are limited to standardisation of plant tissue culture protocols, artificial insemination in cattle, micro propagation of different commercially important plants, molecular characterisation of crop, livestock and fish breeds/varieties etc. It is worthy to note that a very scientist have training on doing hardcore biotechnology like gene isolation, cloning, expression, characterisation and development of DNA-recombinant vaccines. But the infrastructure and other facilities are very inadequate. Research and development of biotechnology in fisheries and livestock sectors is even less significant.

The Biotechnologists are categorised into three main categories depending on their dealing materials. These are: i) Animal Biotechnologist involved in research and development of animals and iii) Microbial Biotechnologist involved in research and development of microbes and iii) Plant Biotechnologist dealing with research and development of plants.

Again depending upon the nature of their work, the biotechnologists reported in this report have been grouped into two group's viz. hardcore biotechnologists and soft-core biotechnologists. Those who are involved in recombinant technology, genetic transformation and related activities are grouped in hardcore biotechnologists. On the other hand those who are involved in normal tissue culture, fermentation of different products and others are grouped in soft-core biotechnologists. We conducted survey in different public and private institutes/universities and the results of the survey indicate that there are in total 74 hardcore Biotechnologists in the country. Of them, 14 are hardcore Animal Biotechnologists, 10 hardcore Microbial Biotechnologists and 50 hardcore Plant Biotechnologists. Compared to hardcore Biotechnologists, the number of soft-core Biotechnologists in the country is comparatively higher. Results of our survey indicate that there are negligible number of Experts involved in research and development in the field of Biodiversity and Biosafety. Including toxicologist and contained field experimentation specialist of biotechnological products which is very alarming for future development of this sector in the country.

Because we need a good number of people for doing research in the aspect of biosafety and biodiversity for commercial use of GMOs or products derived from GMOs and conservation of our natural biodiversity. For strengthening the development and commercialisation of biotechnological products and to conserve the natural biodiversity, immediate action should be taken to develop and train man power at all levels in these two vital area.

## Annex 2: Statutes with potential relevance to biosafety

The following statutes are summarised in Table 3.1 in Chapter 3 of the NBF document.

### 1. Constitution of Bangladesh

(i) **Title:** The Constitution of the People's Republic of Bangladesh

(ii) **Status:** adopted, year of adoption: 1972

(iii) **What does it regulate**: It regulates the powers, functions of the organs of the Government, fundamental principles of state policy, fundamental human rights etc.

(iv) **Brief summary of the procedures and contents**: Part II of the Constitution of the People's Republic of Bangladesh, 1972 contains fundamental principles of state policy. As provided in Article 8(2) of the Constitution, these principles are 'fundamental to the governance of Bangladesh' and 'shall be applied by the State in the making of laws' and 'shall form the basis of the work of the State and of its citizens'. Fundamental principles are also considered as goals that the State should strive to achieve. Thus, under Article 15 it is a fundamental responsibility of the State to attain, through planned economic development, a steady ***improvement in the material*** and cultural ***standard of living of the people*** with a view to ***securing to its citizens the provision of the basics necessities of life, including food,*** clothing, shelter, education and ***medical care***. Article 16 provides that the State shall adopt effective measures to bring about a radical transformation in the rural areas through the ***promotion of an agricultural revolution***. Article 18 provides that the ***raising of the level of nutrition and the improvement of public health*** are among its primary duties. Articles 15 and 20 provide for ***right to work*** (Emphasis added). Biotechnological applications in crop, fishery, livestock, and medical sectors can help achieve the objectives of food security, improved health care, more employment opportunities, and poverty eradication in Bangladesh.

On the other hand, Part III of the Constitution guarantees fundamental rights. For example, Article 32 of the Constitution guarantees 'right to life'. In a remarkable decision of the High Court Division of the Supreme Court (Dr. Mohiuddin Farooque V. Bangladesh, 48 DLR, 1996, 442), 'the right to life' has been interpreted to include 'the right to protection of health'. Article 102 of the Constitution allows an aggrieved person to file a writ petition if such rights are violated. In another remarkable decision (Dr. Mohiuddin Farooque V. Bangladesh, 17 BLD, AD, 1997, 1), the Appellate Division of the Supreme Court recognised public interest litigation (PIL) by widely interpreting the terms 'any person aggrieved', referred to in Article 102 of the Constitution, to include organisations that have interest in public interest matters. In effect, now, if no other equally efficacious remedy is provided by law, threats or damage to environment, biodiversity or human heath arising from GMOs could be remedied by public interest litigation in Bangladesh.

(v) **Responsible institutions for implementing the law:** The Supreme Court of Bangladesh; Ministry of Law, Justice and Parliamentary Affairs.

(vi) **Gaps in the law:** As a supreme law of the land, constitutional provisions enshrined in Part II of the Constitution; provide the legal basis for further actions. They do not themselves establish the regulatory regime on biosafety. PIL is only a part of the regulatory regime.

(vii) **Bibliographic reference:** BG dated 14 December, 1972

## 2. Agricultural laws and regulations

### 2.1. Plant and plant product related laws and regulations

(i) Title: The Destructive Insects and Pests Act (Act No. II of 1914) and the Destructive Insects and Pests Rules (Plant Quarantine).

(ii) Status: adopted, year of adoption: The Act was adopted in 1914 and the Rules, made under section 5 of the Act, were adopted in 1966.

(iii) What do they regulate: They regulate the quarantine measures of exported and imported plants and plant product.

(iv) Brief summary of the procedures and content: (a) Firstly, the 1966 Rules regulate the quarantine measures of exported and imported plant and plant products; (b) Secondly, the import of plant and plant products is restricted. Rule 3 requires import permit. Under Rule 4, the permit may be granted under certain conditions. Imposition of specific conditions on the import may help reduce the adverse impacts of GMOs on biodiversity, environment and human health; (c) thirdly, under Rule 8(1), phytosanitary certificate from the country of origin is required for all plants and plant products. Adequate level of protection may be taken by requiring additional information on the adverse impacts of GMOs on the environment, biodiversity and human health; and (d) lastly, unauthorised plant or plant products may be returned, or confiscated and destroyed. Under Rule 8(6), plants and plant products imported under a valid import permit but without phytosanitary certificate shall either be released after necessary fumigation or treatment, or returned to the Shipper or confiscated and destroyed at the expanses of the consignee. These provisions may be used to prohibit unauthorised transboundary movements of GM plants or plant products.

The above quarantine measures have been designed to reduce the threats that might arise from the introduction of foreign pests with the imported plant and plant products. However, these quarantine measures may be used to reduce the threats that might arise from the import of GM plant and plant products.

(v) Responsible institution for implementing the law: Plant Protection Wing, Department of Agricultural Extension

(vi) Gaps in the law: There are following gaps in the plant quarantine law; Firstly, they regulate plant and plant products only and do not have special provisions for GM plant and plant products; secondly, the grounds for the regulation of plant or plant products are also limited: 'a source of infection or infestation by diseases' and 'plant pests destructive to agriculture' or 'medium for the introduction of noxious weeds' (Rule 3); thirdly, the rules are not comprehensive and do not clearly cover use, transfer, handling, contained use, direct release to the environment etc of GMOs; lastly, the rules also do not contain adequate mechanisms for public participation, transparency and awareness building.

(vii) Bibliographic reference: For the 1914 Act: BC, Vol. IX, pp. 1-2
For the 1966 Rules: PG, dated 27 January, 1967

**2.2. Seeds laws and regulations**

(i) Title: The Seeds Ordinance, 1977 (Ordinance No. XXXIII of 1977); the Seeds (Amendment) Act, 1997 (Act No. 13 of 1997) and the Seeds Rules, 1988.

(ii) Status: adopted, year of adoption: The Ordinance was adopted in 1977 and the Rules were made under section 23 of the Ordinance in 1988.

(iii) What do they regulate?

They regulate the quality of certain seeds to be made available for sale in Bangladesh.

(iv) Brief summary of the procedures and content: The definition of 'seeds' given under section 2(j), as amended by the 1997 (Amendment) Act, is wide enough to include GM seeds. Section 3 of the Ordinance establishes the National Seed Board. The major functions of the Board, described in Rule 3, are: to advise the government to notify any kind or variety of seeds for regulation, to advise the government to withdraw or denotify outdated varieties of seeds, to advise the government on a seed security system etc. Section 8 of the Ordinance also establishes a Seed Certification Agency. The major functions of the Agency, described in Rule 6, are: to certify seed of any notified kinds or varieties, certify seed of other registered varieties, inspect fields to ensure that the minimum standards for isolation, rouging etc are maintained as well as ensure that seed borne diseases are not present in the field beyond the prescribed limit etc.

Section 7 of the Ordinance prohibits the sale of notified seeds unless (a) such kind or variety of seed and the Seed Dealer is registered with the Board (b) such seed is identifiable as its kind or variety (c) such seed conforms to the standards of seed quality and the container of such seed bears, in the prescribed manner, the mark or label containing the correct particulars thereof. These laws may be used to set up standards for GM seeds and to regulate their sale through notification in Bangladesh.

(v) Responsible institution for implementing the law: Seeds Wing, Ministry of Agricultural.

(vi) Gaps in the law: These laws do not make any distinction between GM seeds and non-GM seeds. Therefore, these laws apply equally to GM seeds of notified variety in Bangladesh. Furthermore, there is no provision that requires special measures to reduce the threats arising form use, handling, transfer of GM seeds.

(vii) Bibliographic reference: Seeds Ordinance: BG dated 19 July, 1977; 29 DLR 1977, pp. 218-22, Seeds Rules: BG dated 26 February 1980.

### 2.3. Agriculture produce grading and marking laws

(i) Title: The Agricultural Produce (Grading and Marking) Act (Act No. I of 1937)

(ii) Status: adopted, year of adoption: 1937

(iii) What does it regulate? It regulates the grading and marking of agricultural and other produce.

(iv) Brief summary of the procedures and content: According to section 2(a) of the Act, 'agricultural produce' includes all produce of agriculture or horticulture and all articles of food or drink wholly or partly manufactured from any such produce, and fleeces and the skins of animals'.

Section 3 of the Act empowers the Government to make Rules fixing grade designations to indicate the quality of any scheduled article; defining the quality indicated by every grade designation; specifying grade designation marks to represent particular grade designations; section 6 of the Act empowers the Government to declare that the provisions of this Act shall apply to an article of agricultural produce not included in the Schedule or to an article other than an article of agricultural produce. This law may be used to specify grade designation to indicate the quality of GM agricultural produce.

(v) Responsible institution for implementing the law: Department of Agriculture

(vi) Gaps in the law: This law does not require any grading or marking for GM agricultural produce. Additional rules may be made under section 3 of the Act requiring special grading and marking for GM agricultural produce.

(vii) Bibliographic reference: Agricultural Produce Act: BC, Vol. XI, pp. 371-373; PC, Vol. 9, pp. 387-390

### 2.4. Agricultural research related laws

### 2.4. A. The Bangladesh Agricultural Research Council Act

(i) Title: The Bangladesh Agricultural Research Council Act (Act 7 of 1996).

(ii) Status: adopted, year of adoption: Agricultural Research Council Act: 1996.

(iii) What does it regulate: It regulates agricultural research activities in Bangladesh

(iv) Brief summary of the procedures and content: Section 3 of the Act establishes the 'Bangladesh Agricultural Research Council'. The major functions of the Council, under section 8 of the Act, are: (i) to determine the subject matters and the priority areas for research on the basis of national polices on agriculture (ii) to supervise the quality and progress of the activities of the scheduled institutions such as, Bangladesh Rice Research Institute (BRRI), Bangladesh Jute Research Institute (BJRI), Bangladesh Agricultural Research Institute (BARI), Bangladesh Institute of Nuclear Agriculture (BINA), Livestock Research Institute (LRI), Fisheries Research Institute (FRI) etc. (iii) to establish new research centre, research library, herbarium, germplasm, plant introduction centre etc. (iv) to supervise technology transfer process in agriculture, and to publicise the research results of the institutes and related organisations and to take necessary steps to remove the problems associated with the field level application and use of these results and if necessary advise the relevant authorities etc.

This law establishes the institutional framework that regulates the agricultural research activities of private and public organisations in Bangladesh. It facilitates public awareness building activities among the target groups, training of farmers and officials, dissemination of research information etc in Bangladesh. Thus, GM related research activities may be initiated, conducted and monitored under these laws.

(v) Responsible institution for implementing the law: Ministry of Agriculture

(vi) Gaps in the law: It does not pay special attention to biotechnology related research works and hence with contained use of GMOs in laboratories. It does not address the biosafety related issues as raised in the Protocol.

(vii) Bibliographic reference: Agricultural Research Council Act: BG dated 17 August 1996; 48 DLR, pp. 31-37

### 2.4.B. The Bangladesh Rice Research Institute Act

(i) Title: The Bangladesh Rice Research Institute Act (Act X of 1973).

(ii) Status: Adopted, year of adoption: 1973.

(iii) What does it regulate: It regulates the rice research related activities.

(iv) Brief Summary of the procedures and content: The major functions of the Institute under section 4 of the Bangladesh Rice Research Institute Act, 1973 are (i) to carry out research on various aspects of rice improvement and production (ii) to establish project areas for demonstration of new varieties of rice developed by the Institute and training of farmers for the cultivation of these varieties of rice.

(v) Responsible institution for implementing the law: Ministry of Agriculture

(vi) Gaps in the law: The precautionary approach is absent in this law. This law does not call for the formulation of special laws and regulations to prevent the threat that might arise from the development, use, transfer, handling etc. of GMOs.

(vii) Bibliographic reference: BG dated 30 June, 1973; DLR 1974, pp. 40-42.

**3. Fisheries related laws and regulations**

**3.1. Fish and fish products quality control laws for export purpose**

(i) Title: The Fish and Fish Products (Inspection and Quality Control) Ordinance (Ordinance No. XX of 1983) and the Fish and Fish Products (Inspection and Quality Control) Rules.

(ii) Status: adopted, year of adoption: the Ordinance was adopted in 1983 and the Rules were made under section 3 read with section 15 of the Ordinance in 1997.

(iii) What do they regulate: These laws deal with inspection and quality control of fish and fish products intended for exports from Bangladesh.

(iv) Brief summary of the procedures and content: Under section 5 of the Ordinance no person is allowed to export, sell for export or have in his possession for export, or deal in any fish or fish products intended for human consumption which is decomposed, unwholesome or contaminated with pathogenic organisms. This provision may be used to prohibit dealings with GM fish or fish products that might pose threat to environment or human health.

The 1997 Rules regulate the major activities from the production to the marketing of fish and fish products with a view to maintaining their export quality. Under Rule 14 a license is needed for processing, exporting, and servicing factories. Under Rule 5, a license will not be issued for supply to internal market or sell, or processing for the purpose of export to international market unless the quality assurance programme (QAP) stated in Schedule 9 to the Rules is followed. These provisions may be used to reduce the threats that might arise form the use, handling and transfer of GM fish and fish products.

(v) Responsible institution for implementing the law: Department of Fisheries

(vi) Gaps in the law: At present there is no quarantine law for fish and fish products imported into Bangladesh. As a result, GM fish and fish products having adverse impacts on environment or other fish species or human health might enter into Bangladesh without any restriction. Furthermore, there is no law to regulate the breeding, cross-breeding activities in local firms. As a result GM fish with adverse impacts might be developed locally for commercial purpose without any restriction. These laws do not regulate research, production, and contained use, direct release of GM fish or fish products that might pose threat to environment, biodiversity and human health.

(vii) Bibliographic reference: Fish Inspection Ordinance: BG dated 17 May 1983; 35 DLR 1983, pp. 161-163. Fish Inspection Rules: BG dated 10 December 1997.

**3.2. Fish conservation laws**

(i) Title: The Protection and Conservation of Fish Act (EBA No. XVIII of 1950)
The Protection and Conservation of Fish Rules
The Marine Fisheries Ordinance (Ordinance XXXV of 1983)
The Marine Fisheries Rules
The Private Fisheries Protection Act (Bengal Act II of 1889)

(ii) Status: adopted, year of adoption: the Protection and Conservation of Fish Act: 1950; the Protection and Conservation of Fish Rules were made under section 3 of the 1950 Act in 1985; the Marine Fisheries Ordinance: 1983, the Marine Fisheries Rules were made under section 55 of the 1983 Ordinance, the Private Fisheries Act: 1889.

(iii) What do they regulate? These laws regulate protection and conservation activities of fishes in public and private fisheries.

(iv) Brief summary of the procedures and content: According to section 2(1) of the 1950 Act, 'fish' includes all cartilaginous, bony fishes prawn, shrimp amphibians, tortoises, turtles, crustacean animals, molluscs, echinoderms and frogs at all stages in their life history. Thus, the definition is wide enough to include GM fish. The 1985 Rules impose certain restrictions on fishing activities to encourage protection and conservation of fishes. Thus, Rules 5 and 6 prohibit destruction of fish by explosives, gun etc. Rule 8 prohibits catching certain fishes in certain public fisheries at certain times mentioned in the Schedule. However, this prohibition does not apply to the catching, carrying, sale, transport or possession of any fish for pisciculture.

The Marine Fisheries Ordinance, 1983 deals with the management, conservation and development of marine fisheries in the Bangladesh fisheries waters. Under sections 8 and 16 of the Ordinance, a license is required for marine fishing activities which may be subject to certain conditions. Under section 28 of the Ordinance, the Government may establish 'marine reserve' to allow for natural regeneration of aquatic life in areas where such life has been depleted and to promote scientific study and research in respect of such areas.

The Private Fisheries Protection Act, 1889 provides for the protection of private fishery rights. Section 3 penalises a person who (a) fishes in any private waters, not having the right to fish therein (b) puts therein any matter for the purpose of catching or destroying fish without the permission shall be guilty of an offence.

These laws may be used to prevent the threats that might arise form the introduction of GM fish species and promote conservation and sustainable use of fish diversity in public and private fisheries.

(v) Responsible institution for implementing the law: Department of Fisheries.

(vi) Gaps in the law: These laws do not require any precautionary measures for conducting research with GM fish. Although hybrid fishes are being produced in local private fisheries, the existing laws do not put in place any monitoring mechanism on such activities.

(vii) Bibliographic reference:

Fish Act: EPC, Vol. VII, pp. 119-122
Fish Rules: BG dated 16 October, 1985
Marine Ordinance: BG dated 19 July, 1983; 35 DLR, 1983, pp. 190-199
Marine Rules: BG dated 12 September, 1983
Private Fisheries Act: BC, Vol. III, pp. 275-276

### 3.3. Fisheries research related law

(i) Title: The Fisheries Research Institute Ordinance (Ordinance No. XLV of 1984).

(ii) Status: Adopted, year of adoption: 1984

(iii) What does it regulate? It provides for the establishment of a Fisheries Research Institute.

(iv) Brief summary of the procedures and content: Section 3 of the Ordinance establishes the Fisheries Research Institute for carrying out the purposes of the Ordinance. Section 6 describes the functions of the Institute as follows: (a) to carry out and co-ordinate fisheries research in Bangladesh; (b) to assist in development of more efficient and economic methods for fish production, management, processing and marketing; and (c) to do such other acts or things as may be considered necessary for carrying out the purposes of the Ordinance.

(v) Responsible institution for implementing the law: Ministry of Fisheries and Livestock

(vi) Gaps in the law: This law regulates fish related research activities in Bangladesh. However, it does not have special focus on GM fish research and the mechanisms to monitor such activities.

(vii) Bibliographic reference: BG dated 14 July 1984; 36 DLR 1984, p.224.

**4. Forestry related laws**

(i) Title: The Forest Act (Act No. XVI of 1927); the Bangladesh Private Forest Ordinance (EPO No. XXXIV of 1959).

(ii) Status: adopted, year of adoption: Forest Act: 1927; Forest Ordinance: 1959.

(iii) What do they regulate: They deal with conservation of forests, transit of forest-produce and duty to be levied on timber and other forest produce.

(iv) Brief summary of the procedures and content: Under section 3 of the Act, the Government may constitute any forest-land or waste-land or any land suitable for afforestation, which is a property of the Government, a 'reserve forest'. Under section 26, the Government may prohibit certain activities in it, such as, kindling, trespassing, causing any damage etc. Under section 29 the Government may declare any forest land or waste land which is not included in a reserved forest, but which is the property of the Government a 'protected forest' and under section 30 restrict certain activities in it, such as, declare any trees or class of trees as reserved, close any portion of it, suspend private rights etc. Under the Bangladesh Private Forest Ordinance, 1959 the Government, in order to encourage conservation of biodiversity, is empowered to establish 'controlled forest' and 'vested forest'.

These laws encourage forest conservation activities. They were not originally enacted to ensure biosafety from the introduction of GMOs in forest. The fact that introduction of GM plants, trees, or timbers might pose threat to forest environment, biodiversity or human health is a modern idea. However, powers given under sections 26 and 29 of the 1927 Act may be used to regulate such threats. Furthermore, under section 32 of the same Act, the Government may make rules to reduce the adverse impacts arising form introduction of GM plant species in forest. The power of the 1959 Ordinance may be used to regulate the similar activities in private forest.

(v) Responsible institution for implementing the law: Department of Forest

(vi) Gaps in the law: These laws regulate the forest conservation activities and as such apply to conservation of GM plants, trees, and timbers. However, they do not require any special precautionary measures for the conservation of GM plants, trees and timbers.

(vii) Bibliographic reference: Forest Act: BC, Vol. XI, pp. 24-57; PC, Vol. 8, pp. 383-418; Private Forest Ordinance: EPC, Vol. VII, pp. 911-946; 11 DLR 1959, pp. 126-148

## 5. Animal and wildlife related laws

### 1.1. Animal and animal product related laws and regulations

(i) Title: The Bangladesh Animal and Animal Product Quarantine Act (Act VI of 2005).

(ii) Status: adopted, year of adoption: 2005

(iii) What does it regulate?

It regulates the import and export of animal and animal products with a view to controlling the spread of animal diseases and protecting the public health.

(iv) Brief summary of the procedures and content:

Under section 3 of the Act, animal or animal products that might be the cause of animal or human disease, could be subjected to quarantine or their import or export could be prohibited or restricted or otherwise regulated by imposing conditions in the Import or Export Policy Order, passed from time to time by the Government, under the Imports and Exports (Control) Act, 1950.

Section 12 regulates the export of animal and animal products and section 13 regulates the import of animal and animal products. A license is required for the import of animal and animal products. Health certificate is needed from the country of import. Under section 10, if animal and animal products are found to be infected with diseases, may be forfeited.

This law could be used to prohibit or restrict the import or export of GM animal species or products that have adverse impacts on environment, biodiversity or human health.

(v) Responsible institution for implementing the law: Department of Livestock

(vi) Gaps in the law: Necessary rules may be made under section 24 of the Act to regulate the import and export of GM animal species.

(vii) Bibliographic reference: Quarantine Act: BG adopted 28 February, 2005

### 5.2 Wildlife related laws

(i) Title: The Bangladesh Wildlife (Preservation) Order (P.O. No. 23 of 1973)

(ii) Status: adopted, year of adoption: 1973

(iii) What does it regulate: It regulates preservation, export, import, transit of wild animals.

(iv) Brief summary of the procedures and content: Sections 23 and 24 empower the Government to establish 'private game reserve', 'national park', and 'wildlife sanctuary'. While in a game reserve important animal species are protected, in a wildlife sanctuary wildlife including all natural resources, such as vegetation, soil and water, are protected. Sections 12 and 13 regulate export, import and transit of wild animals. Under section 23 of the Order, the Government by notification in the official Gazette can prohibit certain activities in a wildlife sanctuary including introduction of any exotic species of animal in any wildlife sanctuary.

This law may be used to prohibit the introduction or direct release of GM animal species in restricted areas.

(v) Responsible institution for implementing the law: Department of Forestry and Wildlife

(vi) Gaps in the law: Although this law focuses on preservation, export, import and transit of wild animals, necessary rules may be made under section 47 of the Order, to put in place quarantine mechanism for imported and exported animals, especially for GM animal species.

(vii) Bibliographic reference: Order: BG dated 28 March 1973; 25 DLR 1973, pp. 174-194

**6. Livestock research related law**

(i) Title: The Livestock Research Institute Ordinance (Ordinance No. XXVIII of 1984).

(ii) Status: adopted, year of adoption: 1984.

(iii) What does it regulate?

It provides for the establishment of a Livestock Research Institute.

(iv) Brief summary of the procedures and content: Section 3 of the Ordinance establishes the Livestock Research Institute for carrying out the purposes of the Ordinance.

Section 6 of the Ordinance describes the functions of the Institute which include: to identify and solve the basic livestock problems of the country; to develop suitable method for quick diagnosis and treatment of various livestock diseases, to develop suitable breed of livestock for increasing production of milk, meat and drought powers and poultry for eggs and meat, to identify poisonous plants and their effects

on animal health and their remedy, to improve livestock production technology, to disseminate information regarding research of livestock to the framers etc.

(v) Responsible institution for implementing the law:

Department of Livestock

(vi) Gaps in the law: This law has no special provisions on GM livestock research activities and the mechanism to monitor such activities.

(vii) Bibliographic reference: BG dated 23 April 1984; 36 DLR 1984, pp. 203-206.

## 6. Foods/goods/merchandise laws/regulations

### 6.1. Food safety law

(i) Title: The Pure Food Ordinance (E.P. Ordinance No. LXVIII of 1959); the Pure Food Rules

(ii) Status: adopted, year of adoption: Ordinance: 1959; Rules were made under section 49 of the Ordinance in 1967

(iii) What do they regulate?

They provide for better control of manufacture and sale of food for human consumption.

(iv) Brief summary of the procedures and content: According to Section 3(5) of the Food Ordinance, 'food' means 'any kind of edible oil, fish, fruit, meat, or vegetable or any other article used as food…. and those articles which will be notified by the Government form time to time,…'. Thus, the definition is wide enough to include GM foods.

Section 4A establishes a National Food Safety Advisory Council which shall advise the Government on matters related to the safety of food, standard and quality control (National and Codex Standard) for food with a view to ensuring the purity, safety and proper nutritional value, polices and strategies related to food safety and quality control. This power can be used to ensure the safety of GM foods and to set up standards and quality control measures for GM foods.

Section 18 prohibits the use of false labels. It says, 'no person shall…give to the purchaser a label, whether attached to or printed on the container…which falsely describes that article or is otherwise calculated to mislead as to its nature, substance or quality'. Section 19 prohibits the false advertisements of food articles. It says, 'no person shall publish...an advertisement which falsely describes any article of food or

is otherwise calculated to mislead the public as to its nature, substance or quality'. This provision may be used to require special labelling for GM food or food products.

(v) Responsible institution for implementing the law: Department of Food

(vi) Gaps in the law: These laws do not make any distinction between GM food and non-GM food. These laws do not require special measures for GM food and food products in order to protect public health.

(vii) Bibliographic reference: Food Ordinance: EPC, Vol. VII, pp. 525-527;
Food Rules: 20 DLR 1968

**6.2. Law on standards and testing of goods**

(i) Title: The Bangladesh Standards and Testing Institution Ordinance (Ordinance No. XXXVII of 1985)

(ii) Status: adopted, year of adoption: 1985

(iii) What does it regulate?

It provides for the establishment of an institution for standardisation, testing, metrology, quality control, grading and marking of goods.

(iv) Brief summary of the procedures and content: Section 3 of the Ordinance empowers the Government to establish the Bangladesh Standards and Testing Institution. The major functions of the Institute, described in section 5, include, to set up Bangladesh Standards of quality and dimensions; relating to materials, commodities, structures, practices and operations; to secure compliance with the Bangladesh Standards; to implement Bangladesh Standards through the administration of a national certification mark scheme or inspection of goods or both; to grant, renew, reject, suspend, or cancel a license for the use of Standard Mark etc.

Under section 23 of the Ordinance, the Government may, subject to certain conditions, prohibit, restrict, or control the taking out of Bangladesh of articles of any specified description which do not bear the Standard Mark or regulate generally all practices including trade practices and procedures connected with the export of such articles. Under section 24 the Government may, by notification in the official Gazette, prohibit the sale and distribution of any article specified therein which does not conform to the relevant Bangladesh Standard, established by the Institution.

These powers may be used to set up Bangladesh standards for GM goods and to control their export, sale and distribution if do not conform to such standards.

(v) Responsible Institution for implementing the law: Ministry of Industries

(vi) Gaps in the law: This law does not focus on GM goods. There is no standard for GM Products. Similarly there is no standard mark for GM goods.

(vii) Bibliographic reference: Ordinance : BG dated 25 July, 1985

**6.3. Law on merchandise marks**

(ii) Title: The Merchandise Marks Act (Act No. IV of 1889)

(iii) Status: adopted, year of adoption: 1889

(iv) What does it regulate? It deals with fraudulent marks on merchandise.

(v) Brief statements of the procedures and content: Under section 2 (2) of the Act, 'trade description' means any description, statement or other indication, as to the number, quantity or weight of any goods; or, as to the place or country in which any goods were made or produced; or, as to the mode of manufacturing or producing any goods etc. Under section 7, selling, exposing or possessing for sale or any purpose of trade or manufacture, any goods or things, to which a false trade description is applied, is a punishable offence. This law may be used to require correct trade description of GM goods.

(vi) Responsible Institution for implementing the law: Ministry of Industries

(vii) Gaps in the law: It does not contain any special provisions on GM merchandise.

(viii) Bibliographic reference: Act : BC, Vol. III, PP. 277-286; PC, Vol. 3, pp. 277-288

**7. Public health related laws and regulations**

(ii) Title: The Drugs Act (Act No. XXIII of 1940); the Drugs Rules

(iii) Status: adopted, year of adoption: Act: 1940; Drugs Rules were made under section 33 of the Drugs Act in 1946.

(iv) What do they regulate? They regulate the import, export, manufacture, distribution and sale of drugs.

(v) Brief summary of the procedures and content: According to Section 3(b) of the Act 'drug' includes all medicine for internal and external use of human beings or animals; diagnostic, abortive and contraceptive substances; such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals; any other substances which the Government may declare to be a drug for the

purpose of this Act. Thus, the definition is wide enough to include GM drugs such as, insulin for diabetics, vaccines and diagnostic reagents.

Chapter III of the Act regulates the imports of drugs and Chapter IIIA regulates the export of drugs. License is required for the import and export of drugs. The Schedule to the Act sets out the standards to which the drugs shall comply. Under section 8(2), the Government is empowered to add to or otherwise amend the Schedule. The Drugs Rules, 1946, made under section 33 of the 1940 Act gives procedural details on above matters.

This power may be used to regulate the export and import of GM drugs and to prevent their adverse impacts on human health.

(vi) Responsible institution for implementing the law: Ministry of Health & Family Welfare

(vii) Gaps in the law: These laws do not require precautionary measures for GM drugs. Schedule to the Act may be amended to include GM drugs and to set up standards for GM drugs.

(viii) Bibliographic reference: Drugs Act: PC, Vol. 10, pp. 121-124; Drugs Rules.

**8. Intellectual property related laws**

(ii) Title: The Patents and Designs Act (Act No. II of 1911); the Patents and Designs Rules

(iii) Status: adopted, year of adoption: Act: 1911; the Rules were made under section 77 of the Act in 1933.

(iv) What do they regulate? They deal with the protection of inventions and designs.

(v) Brief summary of the procedures and content: Under section 2(8) 'invention' means any manner of new manufacture and includes an improvement and an alleged invention. Under section 3 an application for a patent may be made by any person, whether he is a citizen of Bangladesh or not. Under section 3(2) the application must contain a declaration to the effect that the applicant is in possession of an invention, whereof he, or in the case of a joint application one at least of the applicants, claims to be the true and first inventor or the legal representative or assign of such inventor and for which he desires to obtain a patent, and must be accompanied by either a provisional or complete specification and by the prescribed fee.

Thus, biotechnological inventions may be registered under the 1911 Act. Moreover, any one can apply to obtain a patent. It, thus, encourages foreign companies to make investments in biotechnological research activities in Bangladesh and get their inventions patented under the Act.

Under section 29 a patentee may institute a suit in a District Court against any person who, during the continuance of a patent acquired by him under this Act in respect of an invention, makes, sells or uses the invention without his license, or counterfeits it, or imitates it. Temporary injunction may be granted by the Court in order to stop the infringement of patents rights.

Under section 69, the Registrar may refuse to grant a patent for an invention of which the use would, in his opinion, be contrary to law and morality. This provision may be used to refuse a patent for genetically modified invention on ethical, moral or religious issues in Bangladesh.

(vi) Responsible Institution for implementing the law: Ministry of Industries

(vii) Gaps in the law: Special provisions should be made in order to grant patent rights to biotechnological inventions with special precautionary conditions where necessary.

(viii) Bibliographic reference Act: BC, Vol. VII, pp. 321-370; PC, Vol. 6, pp. 1-55

**9. Environmental laws**

**9. A. The Environment Conservation Act**

(ii) Title: The Environment Conservation Act (Act No. 1 of 1995).

(iii) Status: adopted, year of adoption: 1995

(iv) What does it regulate? It provides for the conservation, improvement of environmental standard and control and mitigation of the pollution of the environment.

Brief summary of the procedures and content: Section 3 of the Act establishes the Department of Environment with Director General (DG) as the Chief. Section 10 allows any person empowered by the DG to enter any building or place for the purpose of performing his duties under this Act or Rule. Section 11 allows such person to take samples of air, water, soil or other substances for any factory, premises or place for analysis.

(v) Responsible institution for implementing the law: Department of Environment

(vi) Gaps in the law: This is a general framework law on the environment in Bangladesh. It does not specifically deal with the biosafety issues raised in the Protocol 2000. However, section 20 of the Act empowers the Government to make rules for carrying out the purposes of the Act. The purposes of the Act as given in the preamble are as follows: ‘to provide for the conservation, improvement of environmental standard

and control and mitigate the pollution of the environment'. The purpose of making biosafety rules is to promote conservation of biodiversity from GMOs.

(vii) Bibliographic reference: BG dated 16 February 1997; 47 DLR 1995, pp. 45-48.

**9.B. The Bangladesh Environment Conservation Rules**

(ii) Title: The Bangladesh Environment Conservation Rules

(iii) Status: adopted, year of adoption: Rules were made under section 20 of the 1995 Bangladesh Environment Conservation Act, in 1997.

(iv) What does it regulate?
It provides rules for the environmental impact assessment (EIA) for various categories of industries.

(v) Brief summary of the procedures and content: For the purpose of issuing environmental clearance certificate, Rule 7 categorises industries into four groups depending on their impact on environment and location. These groups are: green, orange-A, orange-B and red. Of these four categories, red category industries require environmental impact assessment (EIA).

(vi) Responsible institution for implementing the law: Department of Environment

(vii) Gaps in the law: It regulates the EIA procedures for industries that might have adverse impacts on the environment or human health. It does not deal with the use, handling, transfer, and transboundary movements of GMOs that might have adverse impacts on the environment, biodiversity and human health.

(viii) Bibliographic reference: BG dated 28 August 1997

**9.C. The Environment Court Act**

(i) Title: The Environment Court Act (Act No. 11 of 2000)

(ii) Status: adopted, year of adoption: 2000

(iii) What does it regulate? It provides for the establishment of environmental courts in Bangladesh.

(iv) Brief summary of the procedures and content: Section 4 of the Act empowers the Government to establish one or more environmental court (s) in each division in order to fulfil the purposes of this Act. Section 5 deals with the jurisdiction of environmental courts. Under section 8(1), environmental courts will be treated as criminal courts while trying offences committed under the 1995 Act and in such cases courts will follow the procedures prescribed for session courts in the Criminal

Procedure Code, 1898. Under section 8(6), environmental courts will be treated as civil courts while trying suits for damages and in such cases the Code of Civil Procedure, 1908 will apply. Under section 11, an aggrieved person may prefer an appeal to a higher court within 30 days from the date of decrees or orders passed by environmental courts.

(v) Responsible institutions for implementing the law: Department of Environment; High Court Division of the Supreme Court; Ministry of Law, Justice and Parliamentary Affairs.

(vi) Gaps in the law: There is no clear provision in the Act to deal with GMOs related disputes or disputes that might arise from the adverse impacts of GMOs on the environment, biodiversity or human health. Rules may be made under section 20 of the 1995 Act to empower the environment courts to try matters relating to GMOs.

Bibliographic reference: BG dated 10 April 2000; 52 DLR 2000, pp. 45-48.

## Annex 3: Information requirement

It is proposed that at a minimum the following information will be required for import and export of GMOs as per Annex I and II of the Cartagena Protocol on Biosafety

a. Name, address and contact details of the exporter.
b. Name, address and contact details of the importer.
c. Name and identity of the genetically modified organism, as well as the domestic classification, if any, of the Biosafety level of the genetically modified organism in the State of export.
d. Intended date or dates of the trans-boundary movement, if known.
e. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
f. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
g. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
h. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism.
i. Intended use of the genetically modified organism or products thereof, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
j. Quantity or volume of the genetically modified organism to be transferred.
k. A previous and existing risk assessment report consistent with Annex III.
l. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
m. Regulatory status of the genetically modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the genetically modified organism is banned in the State of export, the reason or reasons for the ban.
n. Result and purpose of any notification by the exporter to other States regarding the genetically modified organism to be transferred.
o. A declaration that the above-mentioned information is factually correct.

The following additional information will be required for GMOs intended for direct use as food or feed, or for processing.

a. The name and contact details of the applicant for a decision for domestic use.
b. The name and contact details of the authority responsible for the decision.
c. Name and identity of the genetically modified organism.
d. Description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism.
e. Any unique identification of the genetically modified organism.
f. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

g. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
h. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
i. Approved uses of the genetically modified organism.
j. A risk assessment report consistent with annexure III of the Cartagena Protocol.
k. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

## Annex 4: Risk assessment

### General information required for risk assessment

Risk assessment is a scientific process that makes use of the best up-to-date scientific knowledge and experience. Although details of risk assessment may vary from case to case, there are some common essential information to be considered during the risk assessment process which are indicated below as Article 15 of the Cartagena Protocol on Biosafety along with country needs.

### 1. Biology of the donor and recipient organisms

- Thorough knowledge, based on published literature, of the biology of the gene donor organism, especially taxonomic status, common name, origin, reproduction, habit, and its general uses, particularly for the presence of any toxins, allergens or anti-nutritional substances.

- Thorough knowledge, based on published literature, of the biology of the recipient organism, especially taxonomic status, common name, origin, habit, reproductive biology and potential ability to out-cross and form fertile offspring with wild relatives, the presence of and nature of any toxic, allergenic or anti-nutritional substances.

- History of safe use of them and their products as food, feed and health care products.

### 2. Detailed Characterisation of insert(s) and its products

- Complete nucleic acid sequence of the transferred gene(s).
- Deduced amino acid sequence of expressed protein(s),
- Biochemical function of expressed protein(s),
- Any anticipated changes (e.g., change of substrate or altered end products) in the functioning of the biochemical pathway(s) in which the protein(s) function.
- Description of "Gene Cassettes" used for transformation.
    - Genetic elements of the Gene Cassette(s) including control elements, structural genes, selectable marker genes,
    - Origin of control elements,
    - Function of control elements (e.g., tissue specific promoters, transcription enhancers and transcription terminators),
    - Complete nucleic acid sequence of all promoters, terminators, or other control elements (e.g., enhancers) and selectable marker genes,
    - Deduced amino acid sequence of protein(s) encoded by marker genes and their biochemical functions.

- Method(s) used for transformation: information regarding any of the transformation methods:
    - Biological vectors (Agrobacterium tumifaciens, bacterial plasmids, viruses),
    - Physical methods (particle gun),
    - Chemical methods (using $CaCl_2$ or polyethylene glycol),
    - Electroporation
    - Microinjection of cloned gene(s) into the pronucleus of a fertilised ovum
    - Injection of embryonic stem cells into embryos.
    - Use of Retroviruses as the biological vectors to insert recombinant nucleic acid fragments into embryos.
    - Any other methods.

### 3. Vector

- Complete description of the gene vector system including its source or origin, identity (if any), its host range and the potential, if any, for incorporation of unwanted vector nucleic acid into the recipient.
- Complete nucleic acid sequence of vector nucleic acid.
- Vector map showing location of key restriction enzyme sites, all genes, control elements and other open reading frames together with table showing details of all genetic elements.

### 4. Toxicity and allergenicity

- Detailed review of any safety data concerning transgene(s), including screening for similarity at the protein sequence (amino acid) level against databases of sequences of toxins, food allergens.
- Information of *in vitro* digestibility assay tests (digestible proteins have less potential to be food allergens),
- Information of heat stability assay test (heat labile proteins have less potential to be food allergens in heat processed foods),
- Information of acute oral toxicity testing in laboratory animals with maximum hazard dose.
- Food safety assessment should be perofrmed in accordance with the recent guidelines of Codex Alimentarius Commission.

5. Detection and identification method of the GMO: Suggested detection and identification methods and their specificity, sensitivity and reliability.
6. Information relating to the intended use of the GMOs.
7. Receiving environment: Information on the location, geographical, ecological, climatic and ecological characteristics, including information on biological diversity.
8. Information on the method of eradication in case of the unwanted deviation.

(A) Additional information required for the risk assessment for Genetically Modified Plants & its products

Specific information required for the risk assessment of genetically modified plants and products in addition to the general information listed general consideration.

- **Herbicide metabolites and residues**
  For genetically enhanced plants that are known as tolerant to specific herbicides, metabolism and residue data must usually be generated with the tolerant crop in order to obtain a new label for use of the herbicide on that crop.
- **Plant growth**
  Observations based on multiple plantings over at least 2 growing seasons of the genetically enhanced plant growing in different environments confirming that new trait(s) are stable, express the expected phenotype, and have no detrimental effects on plant development (e.g., growth habit, fertility, disease susceptibility, predation by herbivores or tendency to increased weediness) that could be indicative of unexpected effects of the genetic modification.
- **Agronomic performance**
  At least one season of observations at multiple sites of agronomic performance (e.g., growth rate, maturity and yield) will be conducted.
- **Environmental risk**
  Depending on the nature of the modification, some or all of the following hazard and risk considerations should be considered,
    - Weediness of the genetically modified plant
    - Mode of distribution, seeds or vegetative propagules
    - Trans-gene product released from any plant parts
    - Possible ways of horizontal gene transfer
    - Consequences of gene transfer
    - Any adverse effects caused by the accumulation of trans-gene products in food web in the natural environment.
    - Any adverse effects on ecosystem of soil, water, and biological resources.

  Tests for impacts on non-target organisms are designed based on this assessment. If the genetically enhanced plant can out-cross with wild or weedy species in the areas where it will be planted, additional field studies will be required to confirm that the fitness of the resulting crosses has not been significantly changed, which could potentially result in new weeds or invasion of natural habitats or species loss. These studies could involve screening collections of wild relatives to show that a trait (e.g., disease resistance) is already present in wild populations or the gene may have to be bred into wild relatives which can then be tested to see if they exhibit altered fitness (e.g., increased seed production on insect resistant plants due to reduced herbivore activity).

## (B) Additional information required for the risk assessment of Genetically Modified Microorganism used for food and feeds

The risk assessment process requires the identification of any potentially harmful properties of the genetically modified microorganisms as a result of the genetic modification or any

alteration of the recipient organisms' existing properties. Potentially harmful properties associated with the genetically modified microorganisms must be determined. This should be done by consideration of the recipient organism, the donor organism, the characteristics and location of the inserted genetic material and any vector.

**1. The recipient organism**

- Nature of pathogenicity and virulence, infectivity, allergenicity, toxicity and vectors of disease transmission;
- Nature of indigenous vectors and adventitious agents, where they could mobilise the inserted genetic material, and the frequency of mobilisation;
- Nature and stability of disabling mutations, if any;
- any prior genetic modifications;
- Host range (if relevant);
- Any significant physiological traits which may be altered in the final GMOs and if relevant their stability;
- Natural habitat and geographic distribution;
- significant involvement in environmental processes (such as nitrogen fixation or pH regulation);
- Interaction with, and effects on, other organisms in the environment (including likely competitive pathogenic or symbiotic properties);
- Ability to form survival structures (such as spores or sclerotia).

**2. The donor organism**

- Nature of pathogenicity and virulence, infectivity, toxicity and vectors or disease transmission;
- Nature of indigenous vectors:
    - Sequence;
    - Frequency of mobilisation and specificity;
    - Presence of genes, which confer resistance to anti-microbial compounds including antibiotics.
- Host range;
- Other relevant physiological traits.

**3. The insert**

- Specific identify and function of the insert (genes);
- Level of expression of inserted genetic material;
- Source of the genetic material, identity of the donor organism(s) and characteristics where appropriate;
- History of prior genetic modifications if appropriate;
- Location of inserted genetic material (possibility of insertional activation/deactivation of host genes).

**4. The Vector**

- Nature and source of the vector;

- Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified microorganism;
- If present in the final GMOs frequency of mobilisation of inserted vector and/or capability of transfer of genetic material.

**5.** Stability of insert gene and gene efficacy
**6**. Kind of food, method of processing before consumption and the quality of the food after processing.
7. Generally regarded as safe to be consumed
8. Suggested appropriate therapies and prophylactic measures.

**(C) Additional information required for the risk assessment of genetically modified microorganisms used for fertilizer, pesticide, or other production inputs**

- Information on targeted plants
- Information on non-targeted plants
- Mechanism of action on the target

(D) Additional Information required for the risk assessment of genetically modified microorganisms

- Expected toxic or allergenic affects of the GMO and/or its metabolic products;
- Comparison of the modified microorganism with the recipient or (where appropriate) parental organism regarding pathogenicity;
- Expected capacity for colonisation;
- If the microorganism is pathogenic to humans who are immunocompetent:
    - Diseases caused and mechanism of transmission including invasiveness and virulence;
    - Infective dose;
    - Possible alteration of route of infection or tissue specificity;
    - Possibility of survival outside of human host;
    - Biological stability;
    - Antibiotic-resistance patterns;
    - Allergenicity;
    - Toxigenicity;
    - Availability of appropriate therapies and prophylactic measures.

- Expected survivability, multiplication and extent of dissemination of the modified microorganism in the identified ecosystems;
- Anticipated result of interaction between the modified micro-organism and the organisms or microorganisms which might be exposed in case of unintentional release into the environment;
- Known or predicted effects on plants and animals such as pathogenicity, toxicity, allergenicity, vector for a pathogen, altered antibiotic-resistance patterns, altered tropism or host specificity, colonisation;

- Known or predicted involvement in biogeochemical processes.
- Suggested appropriate therapies and prophylactic measures.

## (E) Additional Information required for the risk assessment for genetically modified animals and its products

1. Prior to the production of transgenic animals, the pathogen status of the components (reagents, animals, semen, embryos, etc.) used in production should be evaluated. The information should be obtained as follows.

- Epidemiologic status of the country/ geographic region of origin
- Evaluation of the protocols of the production facility with respect to hygiene and animal health
- Health status evaluation of donor and recipient animals
- Evaluation of the sterility of reagents used in production
- Evaluation of the techniques for production of the biotechnology-derived animal

2. Endogenous Retroviral Activation

Endogenous retroviruses have been found in all vertebrate genomes investigated to date. Theoretically, the use of replication-incompetent retroviruses as transgene vectors could lead to the activation of endogenous retroviral sequences through a process of recombination. The activation of these replication-competent, recombined viruses could pose a hazard to both the host animal and others, including humans, if the retrovirus is transmissible. Another potential hazard posed by retroviral vectors is the possibility of recombination between transgenic retroviral sequences and wild-type retroviruses to which the animal may be subsequently exposed. The information is required therefore on the detection of the shedding of intact retro virions from genetically modified animals.

3. The presence of transgene products in non-target tissues and leakage of expressed transgene products from target tissues into serum

- The information on the mRNA based detection and protein based detection techniques are required to determine the presence of these transgene products in non-target tissues.

4. Susceptibility to prion disease

Occurrence of prion diseases in sheep and cattle has posing serious threat for the commercialisation of livestock and its products in the global market. Therefore, susceptibility of the GMOs to prion disease should be informed accordingly. Increased susceptibility to prion disease can be assessed by characterisation of the transgene and trans gene product in the transgenic animal, and comparison with known nucleic acid and protein sequences related to prion disease susceptibility.

5. Nutritional quality or value if it is used as food or feed

6. Generally regarded as safe to be consumed if it is used as food or feed.

**(F) Additional information required for the risk assessment risk assessment of genetically modified Fish and Fish Products**

- The genetic modification attempts carried out will not cause a change in fish behavior
- Information concerning the reproduction performance of transgenic fish (fertile or infertile) need to be elucidated. In case of the transgenic fish is fertile, the presence of similar fish, especially those having close relationships capable of cross breeding (including parents) with transgenic fish must be explained.
- Information on the method of eradication in case of the unwanted deviation.
- Nutritional quality or value.
- Natural or modified toxic compound, anti-nutrient or allergen (if any) and their mitigation.
- Generally regarded as safe to be consumed.
- Possible change on eco-system of soil, water and biological resources that might take place.

## (G) Socio-economic Factors in Risk Assessment and Management

*The Cartagena Protocol recognises the importance of socio-economic factors in risk assessment when considering import of GMOs, although it is not explicitly included in the risk assessment procedure. Article 26 specifies socioeconomic cosiderations arising from the impact of GMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities.*

Factors such as the potential impact on trade, labour, food security, gender, small business development, sustainable development and poverty alleviation may be taken into consideration in the evaluation process. The impact on food security, impact on livelihood of communities, and ethical issues & the right to choice have been identified as key socioeconomic factors that need to be considered[7].

(a) Impact on food security – Any appreciable use of GM crops in a country like Sri Lanka where there are no locally produced GMOs could mean dependence for food production upon multinational companies, and consequent undermining of food security.

(b) Impact on livelihood of communities – The introduction of GMOs or their products can pose a threat to livelihoods of communities. For instance, GM technologies are being used to produce substitutes for substances derived from plants such as vanilla, chocolate and sugar. It is cautioned that the livelihood of sugar farmers in the South are threatened by genetically engineered sugars and sweeteners being grown and processed in the North.

The price of inputs required for GM crops could be beyond the means of small and medium farmers and lead them into bigger debt situations.

(c) Ethical issues and the right to choice - The right to choice could be addressed by having an effective labelling system. However where genes of certain animals or human genes have been inserted to produce GM crops, livestock or food, serious ethical issues arise. This aspect must be given due consideration.

It is necessary to identify and incorporate the relevant socio economic factors in the protocol for risk assessment. Socio-economic impact analysis will then become the responsibility of the applicant/notifier and the competent authority concerned.

## (H) Area specific risk assessment criteria and guidelines to get permission to work with GMOs as stipulated in the biosafety guidelines

The assessment of the risk associated with modern biotechnological work can be subdivided into 5 areas depending on how and where GMOs or their products will be used. The specific criteria for each of these areas are given below:

### 1. Laboratory

i. Principles of good laboratory practice (GLP) should be adhered to. GLP (Biosafety guideline) is concerned with the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported.

ii. Ensure that qualified personnel, appropriate facilities, equipment and materials are available.

iii. Maintenance of records of the qualifications, training, experience and job description for each professional and technical individual.

iv. Ensure that health and safety precautions are applied according to national and/ or international regulations.

v. Risk assessment should be dependent on and be according to the risk group for the GMO being used.

### 2. Use of GMOs in the field

i. For field testing of GMOs risks can be minimised or eliminated by confining the introduced organisms to the target environment.

ii. In all cases involving microorganisms, plants and animals the following should be taken into consideration:

(a) Vector host specificity and stability.
(b) Potential for vector “leakage” into unintended hosts in the environment.
(c) Nature and case of possible recombination and spread of such vectors.

iii. Such consideration to be given to the receiving environment e.g. the characteristics of the areas and other organisms that might be affected.

iv. Sound scientific principles should be applied to adequately measure the effects of the introduced organisms on human and the environment.

v. Anticipation that in most cases there will be low environmental risk after modification of an organism by altering, deleting or adding a few genes and its re-introduction into its natural habitat.

vi. Plants with unfamiliar phenotypes should be subject to oversight until their behaviour is predictable and shown to be non-detrimental to the environment.

vii. Ecological uncertainties regarding microorganisms can be addressed scientifically regarding their genetic and phenotypic characteristics.

**3. Direct release of foreign GMOs into the environment**

i. GMOs that are considered harmless in one region might be potentially harmful in another region with different environmental conditions. Particular stress has to be given to the fact that extreme climatic conditions are prevalent in our country. Therefore adequate field-testing under criteria given above is essential.

ii. Consideration needs to be given to ensure that the introduction of GMO does not interfere with the protection of genetic resources and biological diversity.

**4. Industrial use of GMOs**

i. Should consider safe operational procedure such as good occupational hygiene and good microbiological techniques.

ii. Consideration of primary containment procedures in design. For example operation and equipment has to be designed to protect the personnel and the immediate processing facility from exposure to microorganisms.

iii. Consideration of secondary containment procedures such as facilities available to protect the external laboratory or factory environment from exposure to microorganisms.

**5. Products intended for release into the market.**

i. There should be awareness of the potential allergenicity of any genetically engineered plants or microorganisms and their products. Therefore risk assessment should include scope for evaluation of that potential.

ii. Awareness of the fact that in a global context strategies for assessing the food safety and wholesomeness of these novel foods are still in a phase of exploration. Therefore risk assessment criteria may be subject to frequent change.