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

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FOREWORD

Biotechnology is of tremendous importance to agriculture and human health. Biotechnology offers promise that could make a significant contribution to sustainable development and has the potential to mitigate the impacts of climate change. Biotechnology has the potential to enhance food security, improve food quality, deliver major health-care benefits, improve supplies of potable water and deliver cleaner technologies. Just as the technology is indispensable, so is the diversity of life on which it depends. Biodiversity, the very gene pool from which the technology derives its raw material, must be protected.

Preserving biodiversity is an asset to biotechnology's future business opportunities. This asset will not be protected without access to and the fair and equitable sharing of benefits arising from the use of genetic resources. However the potential of biotechnology must be fully exploited while taking into account the possible impact on human health and the environment. It is for this reason the Cartagena Protocol on Biosafety, was adopted in January 2000 has to date been ratified by 142 Parties including Bangladesh.

Being a party to the protocol, Bangladesh is internationally committed to develop and implement the Biosafety regulatory regimes. To this end, National Biosafety Framework (NBF) is a way forwarding us towards institutionalization of Biosafety regulations and strengthening infrastructural facilities for risk assessment and management of GMOs be imported and introduced through transboundary movement.

I congratulate the Department of Environment for successful completion of the development project with the outcome of the National Biosafety Framework. My heartfelt appreciation goes to UNEP-GEF for the assistance towards developing NBF and promoting Biosafety regulatory regimes to be opertionalized in the country. I hope that NBF would contribute a lot in going ahead with formulation of effective rules and regulations on Biosafety. At the institutional or organizational level, NBF would be used as one of the many tools to protect human heath and conserve the Biodiversity.

National Biosafety Framework will go long way. I wish every success of it.

Raja Devasish Roy

Special Assistant to Hon'ble Chief Adviser,
Ministry of Environment and Forest,
Government of the People's Republic of Bangladesh

FOREWORD

Modern biotechnology has tremendous potential for the well being of the world particularly in meeting the impending needs of improved and value added agricultural crops, food products, medicine, industry and environment. While there is an enormous prospect of modern biotechnology, there also exists apprehension as it may pose some certain or uncertain risks to biological world including the human being.

Government of Bangladesh has put the emphasis on positive development of biotechnology in the policy regime. Harvesting the beneficial aspects of modern biotechnology is very crucial for the overall development of a country like Bangladesh. The essence of the precautionary approach to mitigate, avoid or prevent the potential adverse or harmful effects of Genetically Modified Organisms (GMOs) to the bio-diversity, environment and human health must be taken into account while working with modern biotechnology.

Bangladesh ratified the CPB on 5 February 2004, which came into force in 5 May 2004. Being a party to the CPB**,** it is an obligation for each party to develop the National Biosafety Framework (NBF). The prime objective of this effort is to provide the basis of establishing regulatory regime to ensure safe transfer, handling, transit, transboundary movement, development, field trial and commercial release of Genetically Modified Organisms (GMOs).

Developing National Biosafety Framework, from part of the government is a step towards ensuring safe transfer, handling, transbounadry movement, import, transit and introduction of GMOs into the environment. NBF is a complimentary to our national commitments towards implementation of multilateral environmental agreement like the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity.

I express my sincere gratitude to UNEF-GEF for the technical support extended towards development of NBF for Bangladesh.

I appreciate the project director for his strenuous effort to present a very useful document to the government and international community. Thanks are also due, for various committee members, authors, experts, reviewers and editors for their arduous endeavour toward making the document comprehensive, consistent and coherent.

I hope the NBF will definitely serve its purpose and it will go a long way with regard to very safe and successful development of modern biotechnology and its appropriate use in Bangladesh.

AHM Rezaul Kabir ndc
Secretary,

FOREWORD

This is indeed a matter of great pleasure for us that we have National Biosafety Framework in hand which is not merely a regulatory document but fulfilling our commitments of implementing international environmental agreements like Cartagena Protocol on Biosafety. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and specially focusing on transboundary movements".

The Cartagena Protocol on Biosafety ensures basic guarantees for all stakeholders. Socio-economic issues arising from the impact of Genetically modified organisms (GMOs) on the conservation and sustainable use of biological diversity are taken into account within the protocol, especially with regard to the value of biological diversity to indigenous and local communities. The protocol promotes and facilitates public awareness, education and participation concerning the safe transfer, handling and use of GMOs as parties are obligated to consult the public in their decision-making processes. Department of Environment has developed the National Biosafety Framework taken into account of the obligations and mandates under the said protocol. It is clear that the technical and socio-economic issues including public participation has well taken care of into the document.

We are really grateful to UNEF-GEF for the financial and technical support extended towards development of NBF for Bangladesh. I fervently acknowledge the project director, for his persistent effort to make the development project a success with the outcome, the National Biosafety Framework. I appreciate the experts who participated from various universities, research institutes, government and non-government organizations and contributed a lot with their valuable comments and suggestions in developing NBF. Thanks are also due, for National Coordinating Committee members who provided fruitful guidance in coming up with NBF.

It is noteworthy that NBF is always living document that might undergo further updating and up-gradation or even modification in terms of the development of information, science and technology and above all, the societal needs.

I hope that NBF will certainly be a useful document for safe transfer and handling of genetically modified organisms and their beneficial use in Bangladesh.

Khandaker Rashedul Haque, Ph.D
Director General,
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Development of the National Biosafety Framework would never have been possible without active participation of nationally and internationally renowned individuals, dignitaries and experts. On behalf Department of Environment, Ministry of Environment and Forests Government of the People's Republic of Bangladesh we would like to thank the distinguished individuals, researchers, authors, experts, representatives of various relevant ministries, departments, agencies, research organisations and universities as well as the representatives of the NGOs and the private sectors who have actively participated in the process of developing the National Biosafety Framework. Without their valuable contribution in the preparation of the National Biosafety Framework of Bangladesh it would have never taken a shape.

Thanks are also due to UNEP-GEP Regional Coordinator, Dr. Nizar Mohamed and also his successor, Dr. Fee Chon Low for their all-out support in the development and finalization of the Framework. Special thanks are due to Dr. A Moeed who participated in development process as an expatriate consultant all the way from New Zealand.

Special thanks go to the Ministry of Planning for augmenting the project in revision and smooth implementation. Planning section of the Ministry of Environment and Forest always expedited the implementation activities of NBF. We are expressing our gratitude to the personnel in the Ministry of Environment and Forests and in the Department of Environment who all the time supported the events and the procedures of the project.

In this opportunity, we would like to acknowledge the contribution of the Director General of the Department of Environment, Dr. Khandaker Rashedul Haque. His able and dynamic leadership and his straightforwardness in decision making made it possible to develop NBF with a successful completion of the development project. Professor Dr. Ainun Nishat of World Conservation Union (IUCN, Dhaka), Professor Dr. Naiyuum Choudhury of Bangladesh Academy of Sciences, Professor Dr. Imdadul Haque of the University of Dhaka, Dr. Abdur Razzaque of BARC, Mr. Farhad Mazhar of UBINIG, Ms. Rizwana Hasan of Bangladesh Environment Lawyers Association (BELA), all them are a few names among many more distinguished experts who supported the process of developing NBF with their valuable time and effort. We are really, really thankful to all of them.

We wish everybody's participation in our future endeavours to implement NBF.

Mohammed Solaiman Haider
Project Director
Development of the National Biosafety Framework
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EXECUTIVE SUMMARY

The 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. NBF is an outcome of Development of the National Biosafety Framework (DNBF) project of the Department of Environment (DoE) implemented under the Ministry of Environment and Forests (MoEF) of the Government of the People's Republic of Bangladesh.

NBF has been developed through a multi-stakeholder consultative process. For information and data acquisition, surveys were conducted on the current use of modern biotechnology, existing relevant polices, laws and regulations, capacity building activities and requirements and expertise of biotechnology and biosafety within the country. **The Framework provides the basis for developing a regulatory regime on biosafety for effective and safer management of GMOs in Bangladesh.**

NBF has been structured in accordance with the UNEP/GEF proposed format into six main chapters. Chapter 1 includes introductory issues, such as, project background, process of developing the NBF and relationship of the NBF with the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD).

Chapter 2 reviews the existing national policies relevant to biotechnology and biosafety and proposes an outline of a new national policy on biosafety for addressing biosafety concerns arising from the application of modern biotechnology and use of GMOs in the country.

Chapter 3 includes a review of present laws and regulations with potential relevance to biosafety and also argues for adoption of a new regulatory regime for biosafety. An outline of a new regulatory framework for biosafety with elements such as institutional set-up, prohibition and authorisation requirements, licence with condition and revocation of licence, system for handling request for licence/permit to deal with GMOs, contained use including research and field test, commercial release, export, import, transit, a deliberate or unintentional release into the environment, packaging, labelling and transport, offences and penalties and any other dealings with GMOs has also been proposed in this chapter.

It has been proposed in the outline of regulatory framework that the Biosafety Rules under the existing environment conservation act (ECA, 1995) could be formulated taking the necessary elements and issues of Biosafety into consideration. Whether to formulate Biosafety Rules under ECA, 1995 or a Separate Biosafety Act, shall be finalized following appropriate mechanisms of the government and in due process of public consultation. In this regard, Ministry of Environment and Forest shall formulate the detailed of the draft regulation and that could be sent to the Ministry of Law and Parliamentary Affairs for finalization.

Chapter 4 proposes structure of the administrative system for biosafety related activities in the country. The chapter includes proposed procedures for handling applications for use of GMOs (research and development) in containment, laboratories or greenhouses; permit to field test/trial; permit to import for direct use as food or feed or for processing; permit to import into containment for research and development and permit to release into the environment. The chapter also includes risk assessment, risk management, risk communication and decision making in this regard. In the administrative framework, it has been proposed that for obtaining permit/authorisation in order to carry out any GMOs related

activity, the applicant or the proponent must need to apply to the NCB/MoEF for final decision regarding approval or denial of a specific application.

Chapter 5 of the NBF highlights the proposed monitoring and enforcement system and suggests potential regulatory basis in this regard. Functions of different administrative units and follow-up actions regarding monitoring and enforcement are also highlighted in this chapter. The NCB/MOEF will be broadly responsible for Monitoring and Enforcement of Biosafety activities. The BCC, IBC, FBC and BSO will be involved in strengthening monitoring and enforcement activities at the field level.

Chapter 6 describes the tools and mechanisms for public information, education and awareness building on biosafety issues and public participation in the decision-making process on any GMO related issues. This chapter contains details of public participation in decision making with potential stakeholders who will be participated in the process of consultation and hence, decision making. The chapter identifies also the potential stakeholders for facilitating and promotion of public education and awareness building on biosafety.

In the annexure of NBF, details of survey results on biosafety and biotechnology status in the country, existing regulations with potential relevance to biosafety, information requirements for export and import of GMOs, risk assessment and management procedures, public information and consultation keys and information regarding the steps involved in the development of NBF are given for making NBF a comprehensive document.

This is very important to be noted that NBF is a living document. It may be updated and upgraded anytime as and when government seems it to be done. It is expected that upon the development of the NBF, Bangladesh shall make her endeavour to finalize the associated regulations for ensuring safe and sound development of modern biotechnology in Bangladesh. NBF provide enough elements those could easily lead the government to formulate Biosafety Rules and Regulations.

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 Repo. 0rts
DNBF	Development of the National Biosafety Framework
DLS	Department of Livestock Services
DoA	Department of Agriculture
DoE	Department of Environment
DoF	Department of Fisheries
DoH	Department of Health
EC	Expert Committee
ECA	Environment Conservation Act
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
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
NFP	National Focal Point
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 Equivalence
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 Convention on Biological Diversity (CBD), 1992: 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'. In the Article 19(4) of the CBD, describes dealing 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

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 NBF

The National Biosafety Framework (NBF) provides a basis for administrative system and regulatory regime to be developed for adequate level of protection in the environment and human health against uses of GMOs resulting from modern biotechnology.
The purposes of development of the NBF are:

- To give an outline of the administrative system to deal with GMOs for adequate level of protection in the filed of the safe transfer, handling and use of GMOs resulting from modern biotechnology.

- To give an overview of existing legislations relevant to biosafety and to give an outline of a proposed regulatory regime to be developed.

- To indicate what is the status of biotechnology and biosafety in the country and what should be done in order to strengthen biotechnological research and development capacity and to ensure biosafety aspects arising from modern biotechnology.

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. Process of developing the NBF

Development of the NBF was an outcome, which came across the process of multi-stakeholder participation. Collaboration and consultation with potential stakeholders was an important part in developing the NBF, by which they made their contribution not only through participation in arrangements on preparation of document, but also by useful written and oral comments. Comments received were thoroughly studied by the NBF team before completion of the final document.

The process of the NBF development was consisted into following phases: First phase dealt with inception of the project with its expected objectives and scopes, developing work plan with respective time frame; review of the national policies; review of the protocol and international biosafety frameworks and regulations; visiting and introduction with the relevant institutes/agencies; contacts with representatives of parties/stakeholders concerned for collaborative interaction on the NBF preparation; development of structured questionnaires for gathering information through surveys of biosafety and biotechnology capacity in the country.

During the second phase of NBF development, surveys were conducted on existing Acts/Regulations with potential relevance to biosafety, current status of biotechnology and biosafety and their requirements for capacity building. Workshops and meeting were conducted throughout this phase on a regular basis to get inputs on the elements of the NBF. The outcomes of the workshops, working meetings, individual consultations, surveys reports and analysis were studied thoroughly and documented as accordingly. Development of regulatory framework, administrative systems, decision making procedures and public participation in decision making were considered key issues for using modern biotechnology in a safe manner. Special attention has been paid to international obligations of the country and existing regional mechanisms of cooperation in the region.

Third and final phase of developing the NBF involved compiling and editing process. During this process a series of working meeting, NCC meeting, expert/group discussions, workshops and individual consultations on chapters of the draft NBF were conducted. A national workshop on the NBF was conducted on 16 November 2006 in Dhaka with greater participation of the relevant government and non-government agencies. The input received in the national workshop helped to come up with a harmonized document that would serve the national purpose and international obligations as well. Comments received in the workshop, written reports from the participants and panel discussants and comments received through e-mail were thoroughly reviewed and necessary inclusions were made in the final version of the NBF.

1.6. **Organizational systems of biosafety in Bangladesh**

Biosafety systems in Bangladesh would be administered through involvement of various ministries and the associated departments working under those ministries. Various committees like NCB, BCC, IBC, and FBC etc. entities are mainly responsible for ensuring Biosafety at respective organizational levels. Ministry of Environment and Forest being the NFP and NCA to the Cartagena Protocol will be the focal ministry to enforce biosafety regulatory systems and making oversight on GMO related overall biosafety activities. The proposed Biosafety Act/Rule, which shall be formulated to enforce regulatory regime on Biosafety in Bangladesh, may include specific roles and responsibilities and interactions of each entities with other. A schematic diagram of the involvement of various ministries and committees in biosafety related activities has been shown below:

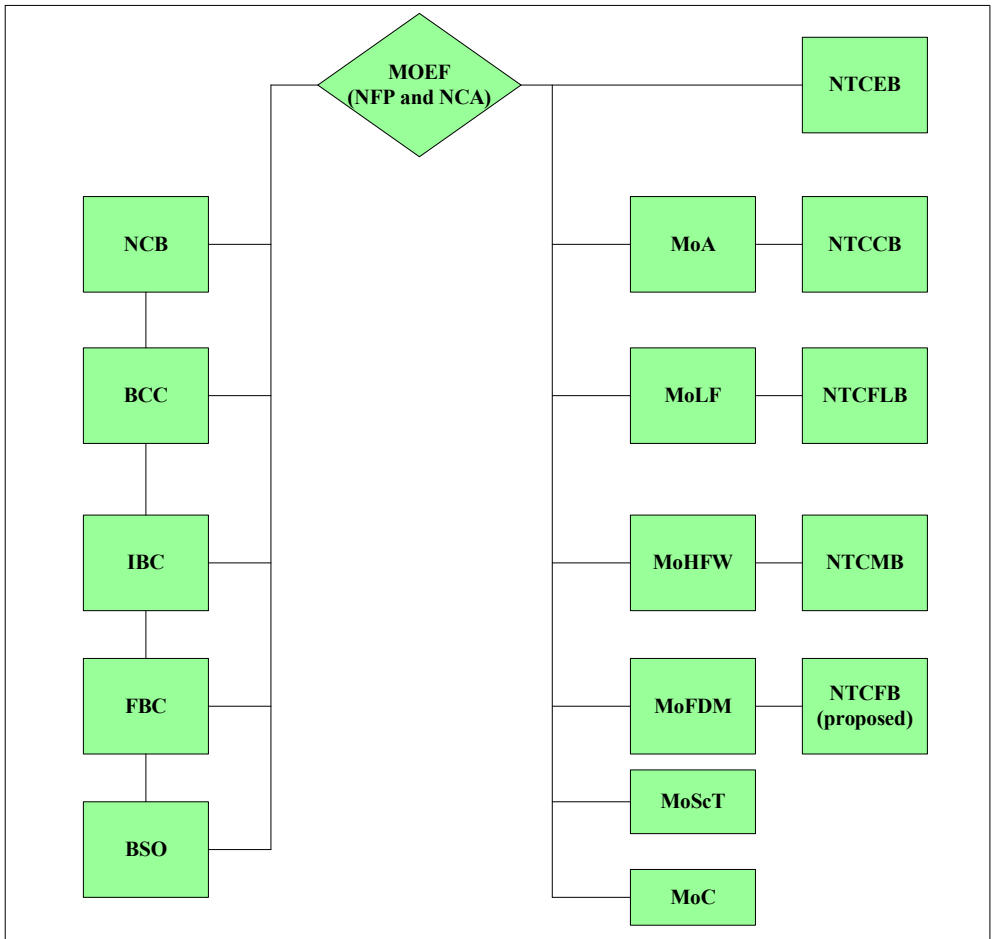

Figure 1. Organizational systems of biosafety in Bangladesh

CHAPTER 2

2. NATIONAL POLICY AND GUIDELINES 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 Guidelines for Fish and Animal Biotechnology, 2006 (vi) 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 and 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 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.

The Ministry of Science and Technology formulated the Biosafety Guidelines in 1999 before the adoption of the CPB 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. In order to oversee the biosafety aspects of biotechnology related activities it is important to have a full-time member secretary of the NCB and that has been recognized in the guidelines. 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.

It appears that there should have been the provisions 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.

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 MoEF formulates guidelines for field-testing of GMOs. The guidelines will need to include detailed mechanism for crop-wise monitoring.

2.2.5. National Guidelines for 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.

2.2.6. 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. The elements and issues those may come under the purview of national policy on biosafety have been proposed in the following sections.

2.4. National policy on biosafety:

As there is no stand-alone policy as such to cover Biosafety issues, Government of Bangladesh may formulate a policy in this regard taking the following issues into consideration.

2.4.1. Preambles or policy statements

(i) Recalling that Bangladesh is committed to the obligations of the Cartagena 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 proposed 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.

2.5 Priority areas of capacity building for biosafety in Bangladesh

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 the survey are presented in Annex 1. 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.

CHAPTER 3

3. REGULATORY REGIME ON BIOSAFETY

3.1. Introduction

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-1, 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 address biosafety issues in Bangladesh.

3.2. Laws and regulations relevant to biosafety

The existing laws relevant to biosafety, their scope, and responsible agencies are summarised in the table-1 below and details are provided in Annex 2. In respect of biosafety related to 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 system outlined in this document.

Table-1 : Summary of existing laws and regulations with potential relevance to biosafety

Laws & Regulations	**Scope**	**Responsible agency**	**Year of adoption**
Constitution of Bangladesh	Regulates powers and functions of the Government	The Supreme Court of Bangladesh	1972
The Destructive Insects and Pests Act	Regulates quarantine measures of plant and plant products	Plant Protection Wing	1914
The Seeds Ordinance	Regulates seeds quality	Seeds Wing	1977
The Seeds Rules	Regulates seeds quality	Seeds Wing	1988
The Agricultural Produce (Grading and Marking) Act	Regulates regarding and marking of agricultural produce	Department of Agriculture	1937
Bangladesh Agricultural Research Institute Ordinance	Regulate agricultural research activity	Ministry of Agriculture	1976
Bangladesh Rice Research Institute Act	Establishes the BRRI	Department of Agriculture	1973
Laws & Regulations	**Scope**	**Responsible agency**	**Year of adoption**
The Fish and Fish Products (Inspection	Regulates inspection and quality control of fish and	Department of Fisheries	1983

and Quality Control) Ordinance	fish products for export		
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	1997
The Protection and Conservation of Fish Act	Regulates fish protection and conservation of pubic fisheries	Department of Fisheries	1950
The Protection and Conservation of Fish Rules	Regulates protection and conservation of public fisheries	Department of Fisheries	1985
The Marine Fisheries Ordinance	Regulates conservation and development of marine fisheries	Department of Fisheries	1983
The Marine Fisheries Rules	Regulates conservation and development of marine fisheries	Department of Fisheries	1983
The Private Fisheries Protection Act	Regulates private fishery rights	Department of Fisheries	1889
The Fisheries Research Institute Ordinance	Regulates fish related research activities	Ministry of Fisheries and Livestock	1984
The Forest Act	Regulates conservation activities in public forest	Department of Forest	1927
The Private Forest Ordinance	Regulates conservation activities in private forest	Department of Forest	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	2005
The Bangladesh Wildlife (Preservation) Order	Regulates wildlife conservation activities	Department of Forest	1973
The Livestock Research Institute Ordinance	Regulates livestock research activities	Department of Livestock	1984
The Pure Food Ordinance	Regulates manufacture and sale of foods for public consumption	Department of Food	1959
The Pure Food Rules	Regulates the manufacture and sale of foods for public consumption	Department of Food	1967
The Bangladesh Standards and Testing Institution Ordinance	Regulates standards, testing, metrology, quality control, grading and marking of goods	Ministry of Industries	1985
The Merchandise Marks Act	Regulates marks on merchandise	Ministry of Industries	1889
Laws & Regulations	**Scope**	**Responsible agency**	**Year of adoption**
The Drugs Act	Regulates import, export, manufacture, distribution and sale of drugs	Ministry of Health and Family Welfare	1940

The Drugs Rules	Regulates import, export, manufacture and sale of drugs	Ministry of Health and Family Welfare	1946
The Patents and Designs Act	Regulates registration and protection of inventions and designs	Ministry of Industries	1911
The Patents and Designs Rules	Regulates registration and protection of inventions and designs	Ministry of Industries	1933
The Bangladesh Environment Conservation Act	Establishes the Department of Environment	Department of Environment	1995
The Environment Conservation Rules	Regulates the EIA procedure	Department of Environment	1997
The Environment Court Act	Regulates the powers and functions of the Court	Department of Environment	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

A review of the existing laws (see annex-2) reveals the followings facts: Firstly, there is no separate law to deal comprehensively with the adverse impacts that might arise from 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 procedure 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 human food then other institutions, for example, Department of Food and Bangladesh Standard Testing Institution (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 thirty existing 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 covering the biosafety concerns arising from all sources of GMOs (GM plants, animals, insects, microbes, fishes and their products such as GM food, feed and medicine etc.) should be put in place in order to implement the obligations of the Protocol.

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 the National Competent Authority on biosafety may issue a permit for the importation of GMOs.

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: "Notwithstanding any provisions contained in any other laws and regulations, the provisions of this (new) law shall apply in all matter relating to GMOs". However, such a law should be fairly comprehensive.

3.4. Separate biosafety regulatory regime

An act or rules, 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), an act or rules 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 Environment Conservation Act (ECA, 1995) are wide enough to authorise rule-making on biosafety. The purposes of the ECA 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 also wide enough and provides that'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, protection of human health 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

The regulatory regime will regulate and manage production, development, use, handling, transfer, sale, contained use, field test/trial, general/commercial release, export, import, transit, research and any other dealings with 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 against potential risks arising from any dealings with GMOs resulting from modern biotechnology.

(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 "Bangladesh Biosafety Rules, 2007" or "Bangladesh Biosafety Act, 2007".

Extent: The Rules/Act shall extend to the whole of Bangladesh.

Coming into force:

The Rules/Act 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 the Rules/Act unless there is anything repugnant in the subject or context: -

a. 'Act' means the Environment Conservation Act (ECA), 1995 (in case of framing rules under the ECA, 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 Forests 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 and the administrative mechanism developed under the NBF may be followed in preparing the Rules/Act. 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 programmes, 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 Ministry of Environment and Forests (MoEF)/ NCB.
b. Applications seeking license for any dealing with GMOs shall be submitted in conformity with the requirements of the Biosafety Guidelines/ Bangladesh Biosafety Rules, 2007” or “Bangladesh Biosafety Act, 2007”to be developed.
c. A licensee shall notify the NCB/MoEF for any change in and/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 NCB/MoEF.
b. The NCB 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) non compliance of any condition stipulated by the NCB/MoEF has taken place.

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

Ministry of Environment and Forests has been designated as the competent authority to handle the application and awarding permits for various kinds of dealings with GMOs. The system for handling request for license/permit to deal with GMOs has been detailed with flowcharts in Chapter 4. Application requirements should vary depending on the type of dealing asked for: contained use, field test, and 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 perform or conduct any field test, use in containment, release a GMO to the environment without obtaining the written permission of the NCB/MoEF.
b. A person wishing to release a GMO directly into the environment shall submit an application to the NCB/MoEF, 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/MoEF 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. Deliberate and Unintentional release into the environment

Deliberate or unintentional release of GMOs, whatever it may be, should be controlled by the regulation. The NCB/MoEF may consider a 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 shall be informed to the persons/authorities designated by the Rules/Acts for immediate remedial actions.

Unintended GMO release situation may require emergency action and it is essential that the Rules/Acts will have provision for rapid action or response mechanism for management of 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 Rules/Acts allows for rapid response mechanisms 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/Acts.

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 ECA 1995, the offences should be punishable under the Act itself.

3.5.8. Jurisdiction of environmental courts

In the case of establishing regulations under the ECA, 1995; 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 the Rules/Acts to be framed.

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 and deliberate release of GMOs into the environment, commercial release and placing of GMOs and GMO products into the market. Such systems also include designated administrative functions, risk assessment, decision making for approval or denial of GMOs related activities, ensure public participation in decision making and monitoring and enforcement activities.

4.1. A system to handle notifications or requests for authorisations

4.1.1. Introduction

The Ministry of Environment and Forests of the Government of Bangladesh (MoEF) is the designated National Focal Point according to the Protocol. The Protocol also requires the designated of National Competent Authority or 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 and positive development of modern biotechnology, a transparent procedure is required for receiving applications, evaluation, decision making on applications of GMOs. 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 updated in the light of the CPB. These guidelines have formed various committees to implement the biosafety activities in Bangladesh. Biosafety guidelines could be a basis for establishing an administrative system of the NBF.

4.1.2. Structure of the administrative system

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. With pursuant to biosafety guidelines MoEF establishes the NCB to manage overall GMOs related activities. It is proposed in the NBF that the NCB under the MoEF shall ensure the overall biosafety issues and NCB shall recommend to the government for making administrative decisions on any GMOs related applications. 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. There is also provision of field level biosafety committee (FBC) to be involved to ensure biosafety in case of field release of GMOs. The composition, functions and responsibilities of these committees are given in the biosafety guidelines.

It is noteworthy to mention here that Government of Bangladesh has constituted a National Task Force headed by the hon'ble Prime Minister to ensure sustainable development of biotechnology in Bangladesh. Under this national task force a National Executive Committee, headed by the principal secretary to the Prime Minister is in place. Five National Technical Committees headed by respective

secretaries of the concerned ministries have been formed to augment biotechnological research and development in the country. The technical committees already formed are: National Technical Committee on Crop Biotechnology (NTCCB) in the Ministry of Agriculture; National Technical Committee on Medical Biotechnology (NTCMB) in the Ministry of Health and Family Welfare; National Technical Committee on Fisheries and Livestock Biotechnology (NTCFLB) in the Ministry of Fisheries and Livestock; National Technical Committee on Biosafety (NTCB) and National Technical Committee on Biodiversity (NTCBD) in the Ministry of Environment and Forests. National Technical Committee on Biosafety (NTCB) has been renamed in the updated Biosafety Guidelines as National Committee on Biosafety (NCB).

It is expected that biotechnological development shall touch the sector like food and environment. To address biotechnological development in food sector, a technical committee could be formed as National Technical Committee on Food Biotechnology (NTCFB) in the Ministry of Food and Disaster Management. For environment sector, a National Technical Committee to deal with Environmental Biotechnology (NTCEB) could be formed in the Ministry of Environment and Forests.

The following sections outline the proposed systems for handling applications for the development of GMOs in contained facilities, field test, and general release and for processing. It is anticipated that powers for the oversight of these activities will be provided in the Biosafety Rules/Act and the NCB will practice effective administrative procedures to handle GMO issues.

4.1.3. Existing operational system for containment use

Presently, there is limited operational practice to handle GMO applications. But, in one or two cases the process followed for obtaining permissions to work with GMOs is shown in Figure 2. Recently, NCB/MoEF has given permissions for conducting research under containment condition in case of fugal resistant GM potato. In this case, the NTCCB at the Ministry of Agriculture received the application from Bangladesh Agricultural Research Institute (BARI). After preliminary screening done by BARI, the application was transferred to the Technical Core Committee of NTCCB for their review. The application was forwarded to MoEF with recommendations of NTCCB for final approval.

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

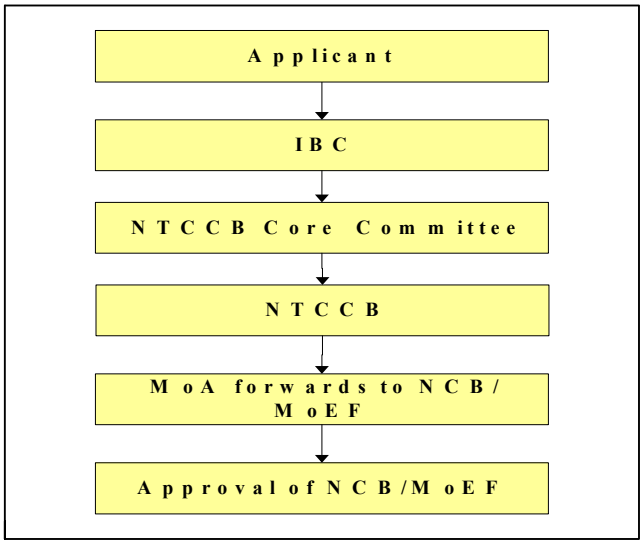

Figure 2. Existing system of handling applications and issuing permissions under containment

4.1.4. Proposed procedures for handling applications for permit

Effective system for handling applications or requests for authorization has to be in place for regulation of GMO activities under containment, laboratories or greenhouses, field test, processing, export, import and/or general release. Under the proposed structure of the administrative system, designated authorities/committees shall be liable for assigned jobs to handle applications. For making application on import or any other cases of GMOs, 4 copies of application along with the relevant information will be required to submit to NCB/MoEF or any other point of entry. Various categories of permits will be given depending on the type of application only after receiving satisfactory information on risk assessment. These are as follows:

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

A person who is issued a permit should comply with conditions specified in the permit. 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 or a minimum period specified in the biosafety regulation. In case of denial of an application, the applicant may appeal in writing to the NCB/MoEF within a given time mentioned in the denial letter or specified time that would be fixed in the biosafety regulation. The appeal should clearly state all the facts and reasons to justify it and shall be referred back with application documents to the NCB for final decision.

4.1.4.1. Proposed procedure for permit to work under containment laboratories or greenhouses

For use or import of gene constructs, GMOs under containment requires application (in prescribed form) along with required information/documents to be submitted to the respective IBC. The IBC will issue a receipt and register the time/date it receives the application. The IBC with its evaluation report will send the application to the NTC of the respective ministries. The NTC will consult its Expert Committee and forward it to the NCB/MoEF for approval or denial. After having technical review report of BCC, the case will be presented to the NCB meeting. MoEF will inform the decision of the NCB in writing to the applicant/party, and the copy will be forwarded to all concerned committees, institutes and ministries. The whole procedure will be completed within the given time to be framed in the proposed 'Bangladesh Biosafety Rules' or 'Bangladesh Biosafety Act'.

A flow chart for permit to work under containment laboratories or greenhouses is presented in Figure 3.

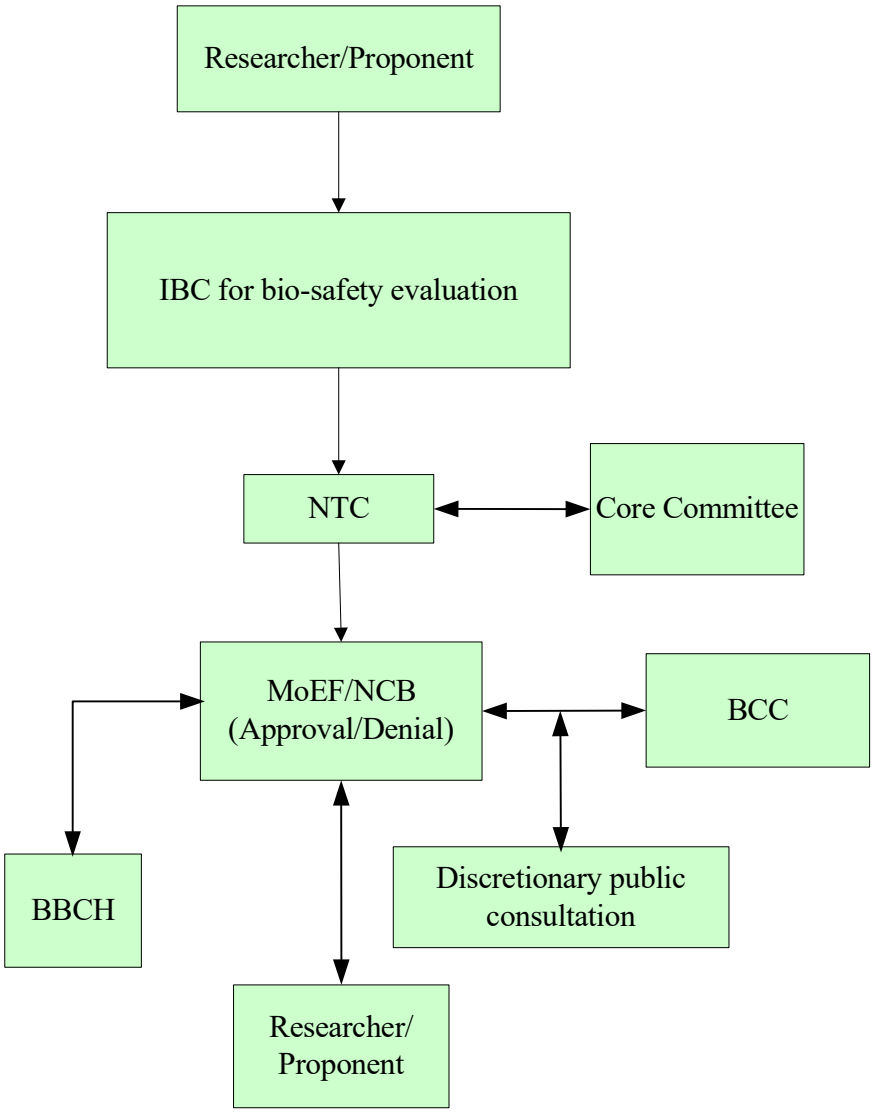

Figure 3. Flow chart of procedures for evaluation of applications for work under containment (laboratory and greenhouse)

4.1.4.2. Proposed procedure for permit to field test and/or general release into the environment

Field trial/test of GMOs is the next step after trial in containment. Field-testing of GMOs is very important with regard to data acquisition, analysis for risk characterisation, assessment and management. To obtain a permit for field-testing, the applicant needs to apply (in prescribed form) along with all necessary documents, to the NCB/MoEF. The secretariat of the NCB will issue a receipt and register the time/date of application. The application will then be forwarded to the NTC of respective ministries. The NTC may consult with the respective Core Committee and Field Level Biosafety Committee simultaneously. After having input from these committees, the incumbent ministry shall forward the application to the NCB/MoEF with detailed comments and evaluations. The NCB once receives the application with comments shall seek input from BCC for finalisation of the decisions to be made in NCB meeting. In order to get input from the BCC, the application with all relevant information will be sent from MoEF to BCC immediately. BCC will review the application, analysis and evaluate relevant information including the data generated during contained use. If necessary, BCC may consult FBC to finalize their comments. After having technical review report of BCC, the case will be presented to the NCB meeting. The MoEF will inform the decision of the NCB, in writing to the applicant/party and a copy will be forwarded to all concerned committees, institutes and ministries. The whole procedure will be completed within the given time to be framed and finalized in the proposed 'Bangladesh Biosafety Rules' or 'Bangladesh Biosafety Act'. But a proposed time frame is given in accordance with the Cartagena Protocol on Biosafety in Table-2.

A flow chart for receiving approval for field-testing or general release into the environment is presented in Figure 4.

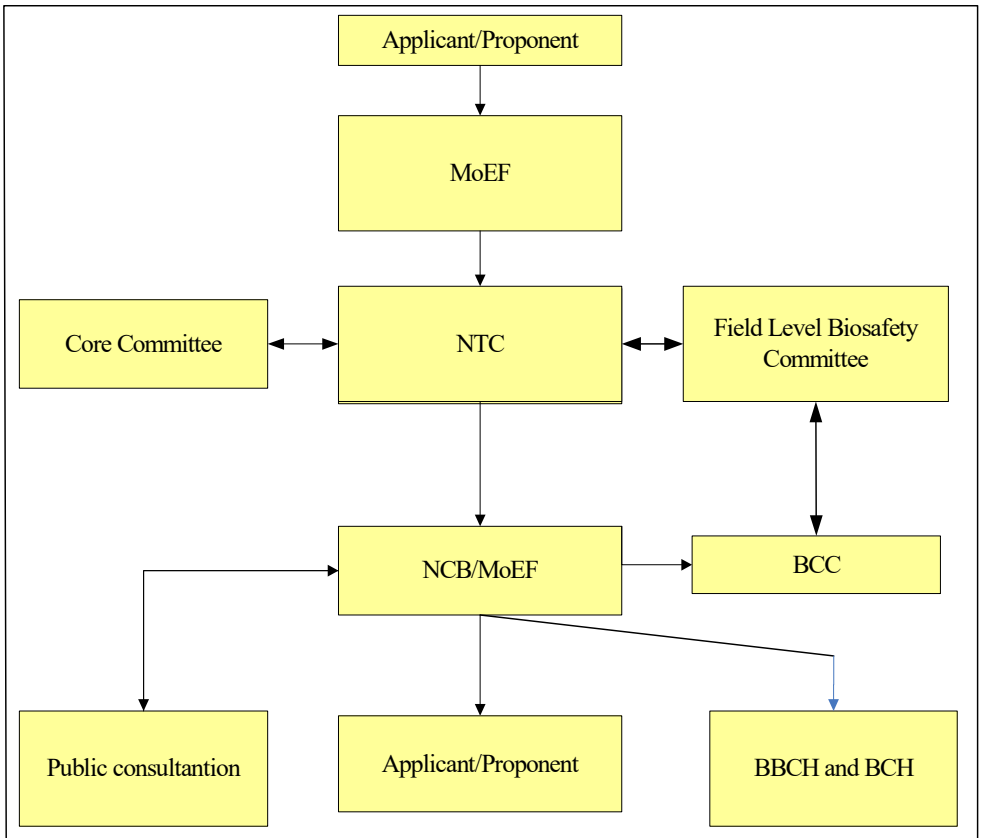

Figure 4. Evaluation procedure of proposals for field testing or general release into the environment.

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

In accordance with the CPB, a party may take decision on using GMOs as food or feed or processing under its domestic regulatory framework. In Bangladesh, guidelines/manual on safety of GM food is yet to be formulated. In case of import of GMOs for food or feed or processing and import into containment for research and development, relevant institutions, organisations and stakeholders will be consulted. Public notifications and consultations for some proven or tested cases of non-harmful GMOs may be discretionary to the NCB/MoEF.

The NCB/MoEF shall make public notification and will invite comments (within the given time mentioned in the Rules/Acts to be developed) in case of import of GMOs-FFP and import into containment (for research and development) and those would be considered to have significant public interest. Applications that will not warrant public notification by the NCB/MoEF will be handled having without public notification and consultation.

Import, transboundary movement and development of GMOs for processing, required clear declaration of type of processing, name of resulting food/feed/ingredient from processing and their potential use. There shall have no provision for any other use of those GMOs imported/developed only for processing and under no circumstances, those GMOs will be placed in the market for direct/household public consumption.

Those GMOs that are to be consumed directly as human food (e.g. GM papaya, soybean oil etc.), food ingredients derived from GMOs, animal feed should require a general release approval under the Biosafety Rules/Acts to be developed. For import/development of those GMOs and their placing on the market, the NCB/MoEF will give decisions taking into account of food analysis report, allergenicity and toxicity reports, provisions for standard labelling and placing in the market etc. issues those will be detailed in the Biosafety Rules/Acts to be framed. A schematic diagram for handling of application for direct use as GMOs-FFP is shown in Figure.5

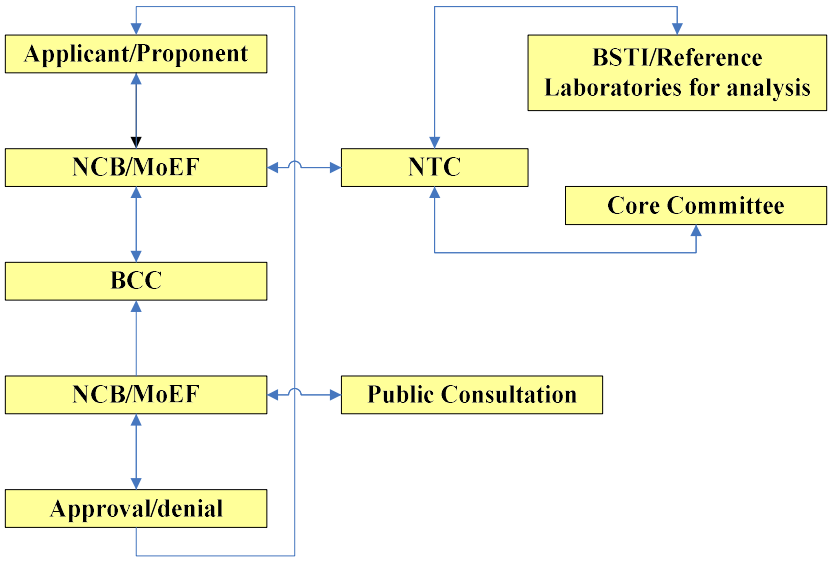

Figure 5. Processing of application for import of GMOs-FFP for direct use

4.1.4.4. Information requirement

The Biosafety Guidelines of Bangladesh provides information that would be required at a minimum for import and export of GMOs as per Annex I and II of the CPB and these are annexed in Annex 3 of the NBF.

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 2 below and such instances would be identified in the regulatory regime to be established in future.

Table 2: Timeframe for decision making

	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 set-up 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 of risks. 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 (WHO,1995; 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 adheres importance on abiding 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 traceability.

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.

- 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 and management 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 the inspectors appointed by the NCB/MoEF. BCC/DoE could play a vital role for monitoring Biosafety aspects of all GMO related activities

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 NCB/MoEF. 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 human and animal health. The areas those may come under the purview of monitoring are following.

- Field trials of GMOs if they are allowed for environmental release
- Contained use and reporting of risk to NCB/MoEF
- Deliberate release of GMOs to the environment
- 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.

In-house monitoring format to be used for various activities with GMOs and enforcement manual for various application of GMOs are very important guiding reference to be developed in furthering biosafety systems in Bangladesh.

5.4. Administrative system for monitoring and enforcement

The NCB/MoEF will be directly responsible for the execution of the regulatory regime and it is the mandate of the NCB/MoEF 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.

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

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

- 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.

- 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.

- 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.

- 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 biosafety procedures and regulations 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/MoEF on any significant unforeseen occurrence regarding the work.

5.7. Monitoring and enforcement by the NCB/MoEF

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.

- Review all existing projects and research.
- Review, monitor and recommend measures to minimise potential risks that may result from, development, import, contained use, field trial and release of GMOs.
- Instruct the respective authority to ensure implementation of biosafety measures related to all activities involving GMOs.
- Prepare various record keeping, application and reporting formats 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.
- 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.
- Cooperate with other national authorities dealing with import of GMOs 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 can help in improvement of compliance activities on Biosafety. If there be any change in the international sector on surveillance techniques that should be made available to the stakeholder or user of GMOs through education, training and awareness raising activities. NCB/MoEF should take the prime responsibility to update the manuals, guidelines for monitoring and enforcement. The follow up actions for monitoring and enforcement may be considered as follows.

a. The institutional infrastructure including the logistic support 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 up
c. The technical methods of monitoring and enforcement shall be developed to equip the ME personnel
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/MoEF or BCC and there-under 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. Available documents and records show that the awareness and extent of knowledge on genetic engineering, biotechnology, and GMOs among people are inadequate. 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 in this NBF are expected to be effective to fulfil the obligation under the Protocol.

6.2. Necessities and benefits

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

- People will be more conscious, careful, and may accept or reject GMOs that pass through the regulatory system of Bangladesh
- There will be understanding about risk assessment, management and risk communication
- Reduce misunderstanding and miscommunication on the issue
- Will make transparency about decision making
- Reduce potential risks of GMOs to environment and human health
- Enable the public in taking right decisions whether to accept or reject GMOs and/or their products

6.3. Mechanism of public information disclosure

Providing adequate information to stakeholders and public notification in a transparent manner is necessary for public awareness, education and participation. Effective way of public information disclosure to the people might involve various agencies engaged in GMOs related activities or for regulating the same. The NCB/MoEF shall engage BCC/DoE, IBCs and FBC for public awareness and education at various levels. According to the category or the nature of the message to be reached to public, NCB/MoEF may utilise the practiced system and logistics of other relevant organization for public education, awareness and participation about biosafety of GMOs and their products. Such departments are: Public Information Department (PID), Directorate of Health (DoH), Agriculture

Information Service (AIS), DAE (Department of Agricultural Extension), Department of Livestock (DLS) Services and Department of Fisheries (DoF). The PID, DoE, DoH, AIS, DAE, DLS and DoF have information disclosure activities through distributing printed materials (such as poster, bulletins, booklets, leaflets/folders, weekly and monthly magazines, and demonstrations on various issues at community level.

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 extension workers/personnel about the technological trials and developments. Similarly, some agricultural universities have outreach programmes to contact public and deliver information and messages to them and these are particularly related to agricultural extensions and technology disseminations. The DoE has publicity section to raise awareness and education on overall environment and biodiversity conservation issues. Information disclosure mechanism of the DoE includes, poster and banner display, distribution of booklet and leaflet, preparation of TV spots, World Environment Day programs like mass rallies and environment fair, workshops and seminars etc. Besides these, DoH and NGOs working in the health sector have awareness building activities extended up to the grass root level through their community level health workers. These existing modes of public awareness are important in promoting education on GMOs and the related biosafety 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.

- Using the media and the press - radio, television, newspapers, magazines, booklets, leaflets, and folders to provide information on GMOs.
- 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.
- Publication of articles – articles on biosafety regarding the use of GMOs can be published in newspapers, magazines and periodicals occasionally in order to enrich public knowledge about biosafety.
- Film shows – arrangements may be made for film shows and documentary films to rural areas for mass awareness.
- 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.
- 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.
- Group discussions – small group discussion (based on homogenous categories) can be used to provide information to various sections and categories of people.
- 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.
- Personal localite (friends, relatives, neighbours and near peers) sources of information - people believe most on their closed friends and relatives. 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.

- 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 decision making process with GMO issues

A coherent and holistic approach is very important to ensure biodiversity and also protecting human health from any harmful and uncertain effect of GMOs. In this regard it is very logical that the stakeholders related to all sort of use/handling of GMOs should be identified so that they can take part in the decision making. It is proposed that the DoE should form a core group of scientists and the group to be led by the DG, 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 come up to participate in generating, assembling, disseminating information and decision making on GMOs.

It is important that stakeholders are involved in decision-making process in open and transparent process. The potential stakeholders on biosafety issues at the operational levels are as follows.

- Scientists/ researchers, environmental experts, legal experts on environment and IPR, physicians
- Teachers
- Students
- Government officials
- Extension agents/field workers
- Farmers/producers
- NGO personnel/activists on environment
- Consumers
- Traders/dealers
- Manufacturers
- Public representatives and the public generally

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 in decision making on GMOs will be made possible through disclosure of information and gaining the trust of the public Many types of participation need to be considered for different groups of people. 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 cell in the DoE and other relevant institutions/organisations to help achieving goals and to facilitate information exchange between decision makers, managers, experts and the public.

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 should be planned and executed at various levels and to be credible, the public must recognise competence, trustworthiness, fairness and lack of bias. 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 electronic media.
2. Consulting the community to gather ideas, suggestions and information needs on the issues to be consulted or decided on GMOs. 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. The potential stakeholders for promotion and facilitating public awareness, education on biosafety have been identified in section 6.3.2. It is also noted that in Bangladesh, various implementing agencies will be involved at different stages in the management of GMOs. Proposed regulatory regime of the NBF specifies the activities requiring mandatory or

discretionary public consultation. In this regard, a simplified overview of public involvement and participation for decision making has been shown in Figure 6 below:

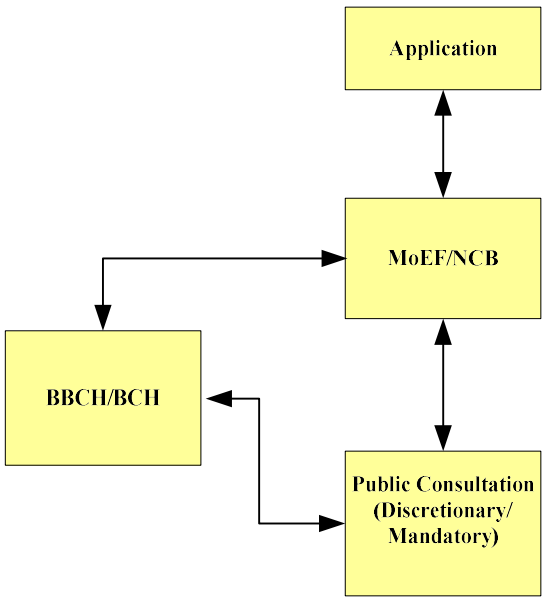

Figure 6. Simplified procedure for public involvement in different GMO activities

In each of the stages of decision-making there are scopes and opportunities for public consultation. For biosafety aspects arises from crop biotechnology, various agriculture related departments have their own ways of verifying and testing technologies at field level situation through setting demonstrations, and multi-location testing (MLT) technique. Through these programme farmers get an opportunity to be involved in the planning, designing, executing and evaluating the technologies. Agricultural research institutes in their regional stations and sub-stations conduct adaptive trials at farmers' field where farmers are directly involved with all stages of technological development and work in close contact with the scientists/technologists. Through the MLT and adaptive trials procedure, agricultural extension workers could teach biosafety aspects of GM crops to the farmers. NGOs have extended access to the grass root level people and thus could play role in public notification, participation and education of biosafety aspects to the very terminal group of peoples. A flow diagram indicating the public participation in decision-making, for different activities is presented in Figure 7.

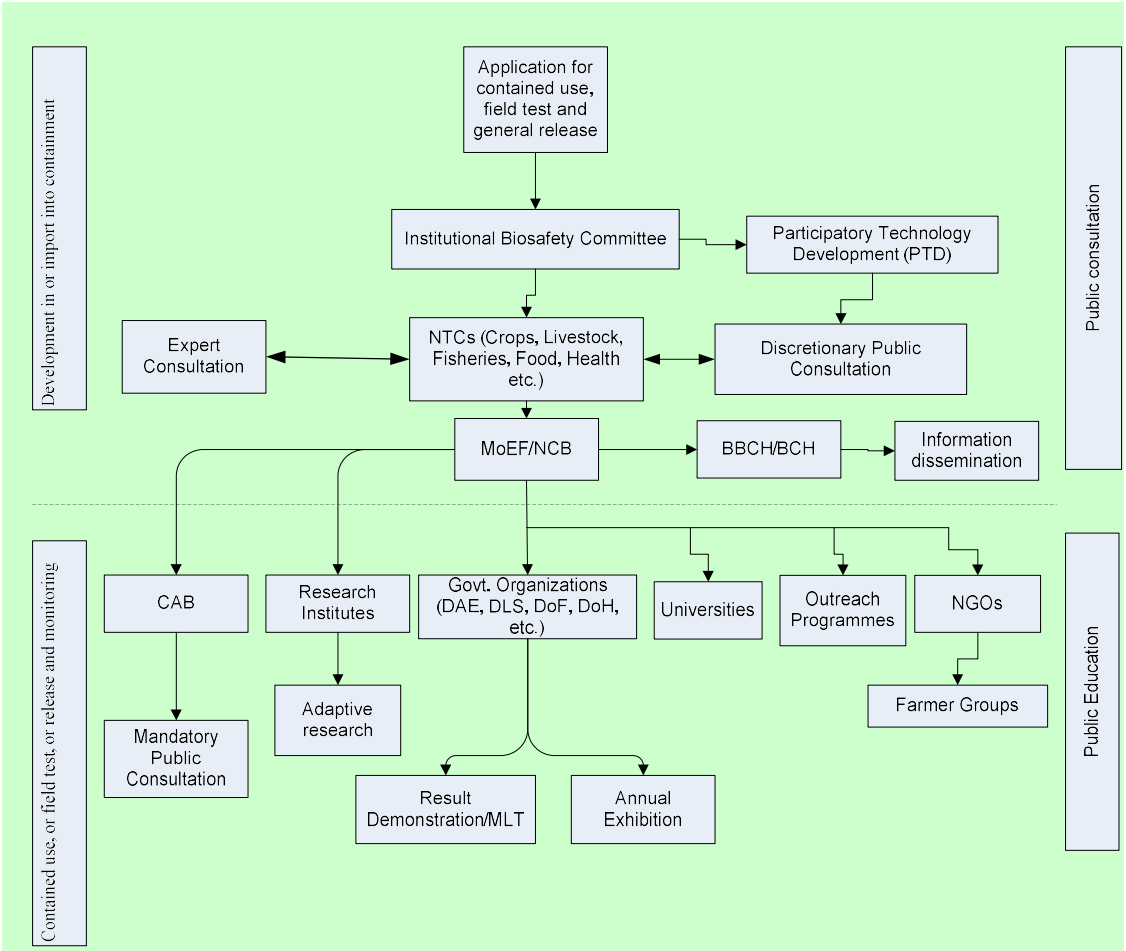

Figure 7. Mechanisms of public participation in decision making at stages of approval for contained use, field test, general release and monitoring

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 a core group at 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. 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.

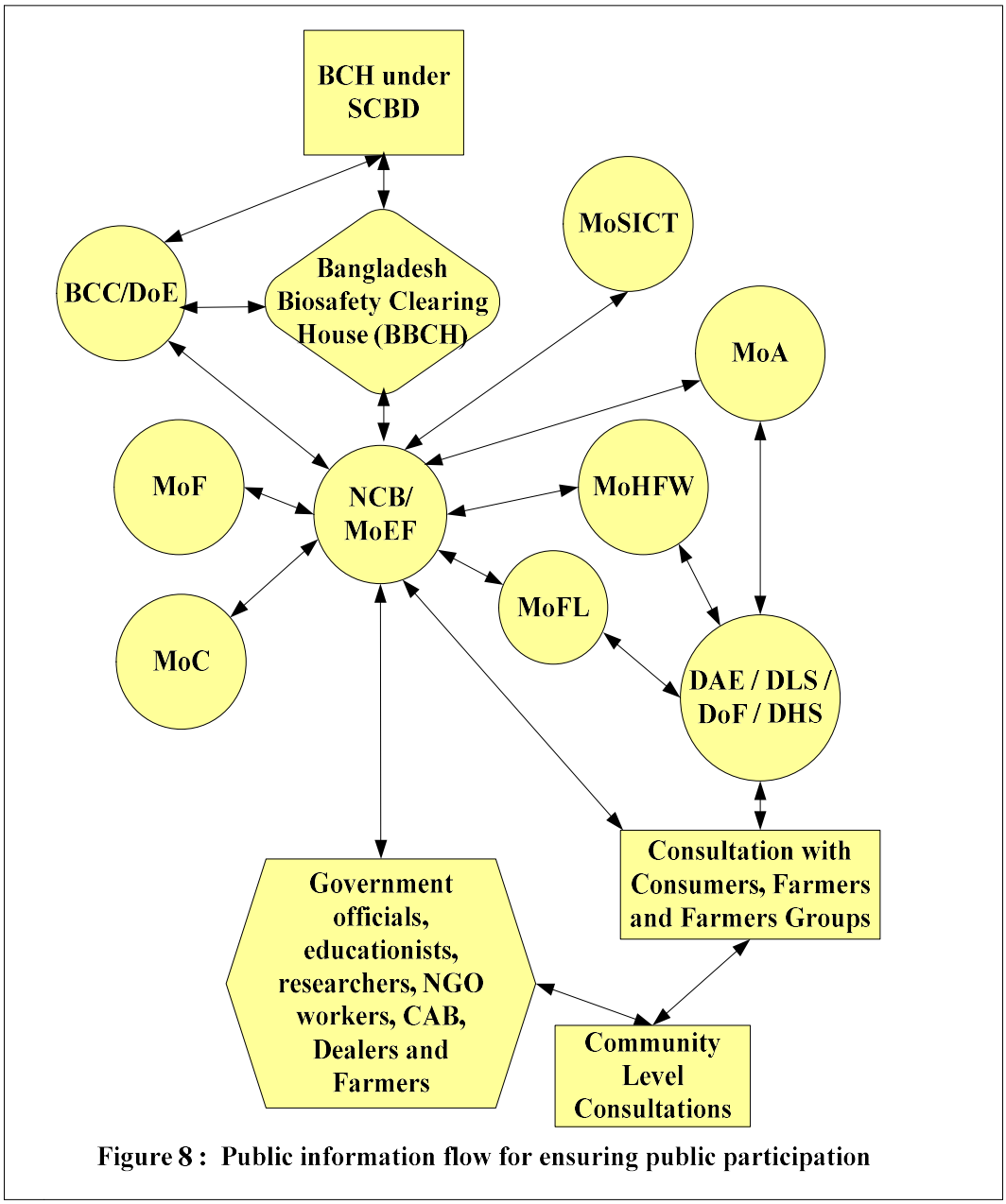

Figure 8 : Public information flow for ensuring public participation

The NCB/MoEF will collect relevant information regarding the import, contained use, development, field test, and general release of GMOs. Concerned ministries may contact and co-ordinate with the NCB/MoEF to collect/provide necessary information in this regard. The proposed BBCH is a web based storehouse of information and will be linked with BCH for exchange of biosafety information. A biosafety information cell to be established at DoE under MoEF/NCB and takes main responsibility to disseminate information and messages regarding biosafety. In addition, biosafety cell at DoE would maintain close co-operation and co-ordination with other national agencies for information exchange, that have direct/extended contact with the public and public have their 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
- **Biosafety Cell of DoE; such biosafety cell also be established in other concern ministries and organisations for dealing with GMOs**
- Official 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: Proposed Capacity Building Areas for Biosafety:

In order to assess national capacity on biotechnology, genetic engineering and LMOs a national level survey was conducted using a structured questionnaire. From the survey it has been revealed that public universities and research institutes and some NGOs have come forward to take up the research and development work in the field of biotechnology. The main constraints in this sector are the lack of infrastructures, availability of equipments and chemicals, trained manpower etc. Doing research in the field of Modern Biotechnology and Biosafety is obviously a costly venture.

It has been clear from the survey that lack of financial support is the main hindrance for development on Biotech and Biosafety activities in Bangladesh. For example, some public and private universities opened the new department on Biotechnology and Genetic Engineering, but none of them has proper facilities due to financial constraints. It was reported that research and development of GMOs in Bangladesh is not accelerated due to absence of appropriate Biosafety regulatory mechanism.

Bangladesh has to strengthen the capacity for biosafety through trained human resource both at technician and higher level, development of appropriate infrastructures suitable for development of modern biotechnologies. Further, development of rules-regulations and congenial policies with regard to Biosafety, establishment of administrative machinery for regulating GMOs and adequate funding for biosafety related development programmes are essential. Technical assistance from the development partners as well as active participation in the international and regional cooperation programme will be required for the capacity building activities. Prior to implement future development activities on Biosafety it is imperative that a plan of action is in place to move forward. Taking broader aspects of capacity building requirements at individual, institutional and systemic level into consideration a plan of work has been outlined in the table below:

A. **Capacity Development at Individual Level**				
	Proposed activity	**Outline of the activities**	**Time-frame**	**Probable source of funding**
1	Training/ Advocacy/ Mainstreaming program for policy-makers and regulators	• Enhancement of understanding on linkage among various international treaties with biosafety protocol; negotiation skill development on bilateral, regional and international agreements related to biosafety; • Harmonisation of biosafety related sectoral laws/policies; standardised formats and procedures for information exchange; • Review mechanisms of biosafety decisions, regulatory training (legal, policy, enforcement, inspection etc.); • Multidisciplinary strategic planning; analysis of risk assessment and management and integration of socio-economic considerations; • Enabling policies and mechanism for technology transfer and; • Funding and resource management: fund raising skills, including proposal writing, project implementation training;	Short Term (0-3 yrs.)	GoB and/or bilateral funding from UNEP-GEF or other development partners.

		• Analysis of Biosafety Guidelines, NBF and other relevant documents for effective coordination and implementation of biosafety activities.		
2	Training for scientists /researchers/ NCB members /technical members of other biosafety committees/ officers and staffs of implementing agency(s)	• Higher studies and research on biosafety and biosafety related courses (e.g. biosafety, food safety, food regulation, EIA, Risk assessment, Risk management, safe use of Genetic Engineering Techniques (gene isolation, gene-construct development, gene sequencing and insertion etc.); • Development of Scientific methods and protocols relevant to risk assessment and management (e.g. extent and effects of Gene Flow, Substantial Equivalence etc.); monitoring and enforcement; safety operation of laboratory equipments; Good Laboratory Practices; handling of GMOs and their safe disposal systems, standard documentation and auditing and accreditation procedures etc.; • Develop competence for detection, testing and quantitative analysis of GMOs, food safety analysis and levelling aspects.	Long Term (0-10 Short Term (0-3 yrs.) Medium Term (0-5 yrs.)	GoB and/or bilateral funding from UNEP-GEF or other development partners
B. **Capacity Development at Institutional Level**				
	Proposed activity	**Outline of the activities**	**Time-frame**	**Probable source of funding**
1	Strengthening Institutional entities for handling biosafety issues	• Establishment of a secretariat/cell for biosafety activities with, full functional NCB, BCC, IBCs and FBC. • Capacity building to implement/adopt the NBF, relevant guidelines and manuals etc at the institutional level. • Strengthening of existing Biotechnology and Genetic Engineering departments/ laboratories and Government Institutions (e.g. DoE, BSTI, IFST etc.) in terms of modern equipment set-up and infrastructure development with full facility for contained use of GMOs and for their safety assessments. • Strengthening relevant government agencies such as border control (customs), quarantine and inspection facilities, and set-up data collection, management and storage facilities. • Development of reference/accredited laboratories for wide range of safety analysis such as detection, testing and quantitative analysis of GMOs, analysis of food derived and/or processed from GMOs, Substantial Equivalence and Toxicological tests etc. and biosafety research. • Establishment of Inter-institutional networks for risk analysis, reporting, communication and	Mediu m Term (0-5 yrs.) Medium Term (0-5 yrs.) Medium Term (0-5 yrs.) Medium Term (0-5 yrs.) Medium Term (0-5 yrs.)	GoB and/or bilateral funding from UNEP-GEF or other development partners

		management. • Enhancement of regional and international cooperation activities.	Short Term (0-3 yrs.)	
C. **Capacity Development at Systemic Level**				
1	Development of decision making system and administrative and regulatory procedures	• Implementation of the NBF and Biosafety Guidelines. • Drafting, promulgation and enforcement of Biosafety Rules/Act. • Formulation of required/prescribed formats and manuals etc.	Short term (0-3 yrs.)	GoB and/or bilateral funding from UNEP-GEF or other development partners
2	Information management system	• Development of Bangladesh Biosafety Clearing House (BBCH), network development for information on international collaboration and funding for risk assessment, management and harmonisation etc.		
3	Public information and education system	• Publication of awareness and education materials (preferably in Bangla); capacity development for public notification and participation		

Annex 2: Statutes with potential relevance to biosafety

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

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 expenses 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 the regulation of 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 Agriculture.

(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 from use, handling, and 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 produces. 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 might 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 from 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, crossbreeding 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 forestland or wasteland 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 from 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

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: This law does not specifically deal with the adverse impacts of GM animals on environment and human health. Biosafety issues relating to transboundary movement of GM animals are adequately addressed in this 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 such a 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 Forests.

(vi) Gaps in the law: This law does not focus on the introduction, preservation, export, import, transit of GM exotic species of animals and the adverse impacts that it might have on the environment and human health.

(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 from 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

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

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

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

(iv) 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.

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

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

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

7. Public health related laws and regulations

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

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

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

(iv) 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.

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

(vi) 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.

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

8. Intellectual property related laws

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

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

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

(iv) 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.

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

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

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

9. Environmental laws

9. A. The Environment Conservation Act

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

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

(iii) 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.

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

(v) 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/Act is to promote conservation of biodiversity from the adverse impacts of GMOs.

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

9. B. The Bangladesh Environment Conservation Rules

(i) Title: The Bangladesh Environment Conservation Rules

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

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

(iv) 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).

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

(vi) 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.

(vii) 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.

Annexure 3: Information requirement for import and export of GMOs

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 corrects.

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: Information requirement for risk assessment of GMOs

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 Bio-safety along with country needs.

a. 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.

b. Detailed Characterization of insert(s) and its products

- Complete nucleic acid sequence of the transferred gene(s).
- Deduced amino acid sequence of expressed protein(s).
- Biochemical functions 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 fertilized ovum.
    - Injection of embryonic stem cells into embryos.
    - Use of Retroviruses as the biological vectors to insert rDNA fragments into embryos.
    - Any other methods.

c. 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 DNA into the recipient.
- Complete nucleic acid sequence of vector DNA.
- 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.

d. 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 performed in accordance with the recent guidelines of Codex Alimentarius Commission.

e. Detection and identification method of the GMO/LMO: Suggested detection and identification methods and their specificity, sensitivity and reliability.

f. Information relating to the intended use of the GMOs/LMOs.

g. Receiving environment: Information on the location, geographical, ecological, climatic and ecological characteristics, including information on biological diversity.

h. Information on the method of eradication in case of the unwanted deviation.

(I) 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.

i. 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.

ii. 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.

iii. Agronomic performance

At least one season of observations at multiple sites of agronomic performance (e.g., growth rate, maturity and yield) will be conducted.

iv. 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).

(II) 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.

i. 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 mobilize 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 Genetically Modified organisms 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).

ii. The donor organism

- Nature of pathogenicity and virulence, infectivity, toxicity and vectors or disease transmission.
- Nature of indigenous vectors:
  - Sequence.
  - Frequency of mobilization and specificity.
  - Presence of genes, which confer resistance to anti-microbial compounds including antibiotics.

- Host range.
- Other relevant physiological traits.

iii. 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).

iv. 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 Genetically Modified organisms frequency of mobilization of inserted vector and/or capability of transfer of genetic material.

v. Stability of inserted gene and gene efficacy.
vi. Kind of food, method of processing before consumption and the quality of the food after processing.
vii. Generally regarded as safe to be consumed.
viii. Suggested appropriate therapies and prophylactic measures.

(III) Additional Information required for the risk assessment of genetically modified microorganisms used for fertilizer, pesticide, and other production inputs

i. Information on targeted plants.
ii. Information on non-targeted plants.
iii. Mechanism of action on the target.

(IV) Additional Information required for the risk assessment of Genetically Modified microorganisms

i. Expected toxic or allergenic affects of the Genetically Modified O and/or its metabolic products.
ii. Comparison of the modified microorganism with the recipient or (where appropriate) parental organism regarding pathogenicity.
iii. Expected capacity for colonization.
iv. 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.

v. Expected survivability, multiplication and extent of dissemination of the modified microorganism in the identified ecosystems.
vi. Anticipated result of interaction between the modified microorganism and the organisms or microorganisms, which might be exposed in case of unintentional release into the environment.
vii. Known or predicted effects on plants and animals such as pathogenicity, toxicity, allergenicity, vector for pathogen, altered antibiotic-resistance patterns, altered tropism or host specificity, colonization.
viii. Known or predicted involvement in biogeochemical processes.
ix. Suggested appropriate therapies and prophylactic measures.

(V) 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.

3. Susceptibility to prion disease

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

4. Nutritional quality or value if it is used as food or feed
5. Generally regarded as safe to be consumed if it is used as food or feed

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

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

(VI) Socio-economic Factors in Risk Assessment and Management

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

1. Factors such as the potential impact on trade, labour, food security, gender, small business development, sustainable development and poverty alleviation would be taken into consideration in the evaluation process.
2. The impact on food security, impact on livelihood of communities, and ethical issues and the right to choice would identified as key socioeconomic factors that need to be considered.
3. Ethical issues and the right to choice - The right to choice could be addressed by having an effective labeling system.
4. 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. Detailed environmental impact analysis including socio-economic impact analysis will be the responsibility of the applicant/notifier/proponent and the competent authority concerned or NCB/MoEF would undertake a detailed review of this analysis with the technical support of BCC.

(VII) Area specific risk assessment criteria and guidelines to get permission to work with LMOs/GMOs are as stipulated in the Bio-safety Guidelines

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

A. Laboratory

i. Principles of good laboratory practice (GLP) should be adhered to. GLP (Biosafety guideline) is concerned with the organizational 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/LMO being used.

B. Use of GMOs/LMOs in the field

i. For field testing of GMOs/LMOs risks can be minimized 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 behavior 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.

C. Direct release of foreign GMOs/LMOs into the environment

i. GMOs/LMOs 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/**LMO** does not interfere with the protection of genetic resources and biological diversity.

D. Industrial use of GMOs/LMOs

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.

E. **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. The 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.

Annex 5: Information recommended to be made available within a public notification and participation process

A. The following information shall be actively notified to the public concerned in decision-making procedures

- The proposed activity and the application on which a decision will be taken and the commencement of the process
- The type of decision which is being taken (e.g. a decision on whether to grant a permit for the import of a GMO, a deliberate release, etc.) and authority responsible for making the decision
- The opportunities for the public to participate (these can vary depending on the case-to-case e.g. examination of the dossier and/or draft decision, possibility for written comments, and the time and venue of any planned public hearing)
- The NCB/MoEF or any other designated office from which relevant biosafety information can be obtained, and where the relevant information has been deposited for collection/examination by the public
- The NCB/MoEF or any other designated office to which comments or questions on biosafety can be submitted
- An indication of what environmental information relevant to the proposed activity with the GMOs is available, e.g. a notification, dossier, and any other information that the NCB/MoEF considers appropriate

B. Information recommended to be made available within a public participation process

In addition to the information items listed in preceding section-A, the following information should be made available to the public in the context of the decision-making procedures referred to chapter 4:

- A general description of the GMOs; including the common, scientific, and technical name, the unique identification code and transformation event
- The name and address of the notifier and/or applicant and the purpose of the proposed activity with the GMOs
- A description of experience obtained with deliberate releases into the environment of certain GMOs and in the case of a proposal for simplified procedures for deliberate releases of certain GMOs into the environment, experience obtained with deliberate releases into the environment of those GMOs
- The location of the site where the proposed deliberate release of the GMOs into the environment will take place (e.g. plot number, address as according to the land register or the local community); the intended uses of the GMOs; an environmental risk assessment including a description of the potential effects on the environment and/or human health; a description of the measures, if any, to limit potentially adverse effects on the environment and/or human health; a description of the plan for monitoring the effects on the environment and/or human health; a description of the measures, if any, to treat waste arising from the deliberate release of the GMOs; a description of any emergency response plan.
- The location of the facility where the contained use of GMOs will take place; and a description of the specific containment measures; a description of the expected waste of the GMOs and its treatment; a description of any emergency response plan and the possibility for its implementation
- A non-technical summary in Bangla of the above and the main reports and advice issued by the NCB/MoEF or technical committees to the NCB/MoEF (NTCs, BCC, FBC, IBCs etc.), in accordance with the Biosafety Rules/Act to be framed.

C. Possible ways to make information on GMOs available to the public

- Providing sufficient information to the public about the type and scope of information on activities with GMOs, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained. This can be done through internet sites (http://www.doe-bd.org), BCH or regular publications in printing media (mass/public notice) and electronic media like television channels;
- Establishing and maintaining practical arrangements, such as: (i) publicly accessible lists, registers or files free of charge; (ii) operate a fully-equipped biosafety cell with required manpower and logistics to support the public in seeking access to information; and (iii) the identification of points of contact. The National Executing Agency of the Development of NBF, the DoE might establish the biosafety cell. Also, the institutes working with GMOs may establish such cells in their premises.
- The lists, registers or files, bulletins with publicly accessible information on activities with GMOs may be circulated and make available at national, regional and/or local government or public premises, as appropriate, and progressively on their internet sites.

D. Possible contents of publicly accessible lists, registers or files on activities with GMOs

Following items of information could be applied in a flexible manner according to the specific activity with the GMOs. Any parts or all the following aspects are dealt with in an existing national or regional register/database/web site, no new mechanism needs to be established. Parts of this list are already mentioned in the preceding section-B and are not meant as duplication but have to be seen as complementary to each other. The NCB/MoEF should take measures within the Biosafety Rules/Act for the purpose of disseminating, storing and maintaining the information items listed below:

- Biosafety Rules/Acts and other policy documents (e.g. NBF, biosafety guidelines, etc.) on activities with GMOs prepared at various levels (local, national, regional and international). This may include a description and, where applicable, the actual texts of legal and policy frameworks related to GMOs and contact point(s) for further information
- International treaties, conventions and agreements relevant to activities with GMOs (the CBD, the CPB etc.); other significant international documents on regulatory approaches and the risk assessment of GMOs by international organizations, such as the Food and Agriculture Organization of the United Nations, the World Health Organization and their *Codex Alimentarius Commission*, the United Nations Industrial Development Organization, International Plant Protection Convention, and the Organization for Economic Co-operation and Development
- A non-technical explanation of the types of activities with GMOs regulated by national, regional and international legislation; a list of GMOs which have gained approval for placing on the market within the country including contact points and links to internet sites for further information on the risk assessments of these GMOs; this may include a list of GMOs which have been approved for food use, feed use or any other use within the country, and the requirements for product information
- Notifications of and/or applications for certain contained uses of GMOs, a summary of the risk assessment and any decisions on such applications made by the NCB/MoEF; notifications of and/or applications for deliberate releases of GMOs into the environment, non-technical summaries of applications for deliberate releases and summaries of the risk assessment and decisions made by the NCB/MoEF

- Experience obtained with deliberate releases into the environment of certain GMOs, in particular those for which simplified authorization procedures are proposed and information on methods of protection if any risk arises for the environment and/or human health
- New information relevant to the risk assessment that may become available whilst the notification of or application for a specific activity with GMOs is under consideration of the NCB/MoEF, the advice on a notification or application for a specific activity with GMOs of any expert committee or advisory body to the NCB/MoEF and/or the public/stakeholders comment on a notification or application for a specific activity with GMOs
- Decisions to grant or refuse consent or permit for a proposed specific activity with GMOs; any limitations and/or conditions attached to any consent or permit granted, including the reasons of the NCB/MoEF for attaching limitations and/or conditions
- Significant new information on a specific activity with GMOs for which a consent or permit has previously been granted and which may have an influence on the risk assessment; information on the effects of deliberate releases of GMOs into the environment, including information on the results of the monitoring of their effects on the environment and/or human health, and its implications for any further deliberate releases; information on the monitoring of products containing or consisting of GMOs which have been placed on the market
- Decisions taken by the NCB/MoEF to revoke or to differ from limitations and conditions attached to a consent or permit granted; information on the advance informed agreements on Living Modified Organisms (LMOs) imported into the country as foreseen by the CPB (reference should be made to the BCH);
- Information shared by the National Biosafety Authority of different countries, if a deliberate release of GMOs into the environment will take place in more than one country; information on sites of deliberate releases of GMOs and, where appropriate, places where GMOs are grown commercially and contact points to obtain further information from the NCB/MoEF

Annex 6: Project Background Information

National Biosafety Framework (NBF) has been developed under UNEP-GEF Project Number GF/2716-4319 on the Development of the National Biosafety Framework (DNBF). The project started in July 2004 and ended in June 2007. The National Executing Agency (NEA) for the UNEP-GEF project was the Department of Environment (DoE) under the Ministry of Environment and Forests (MoEF).

The development of the National Biosafety Framework has been implemented under the overall coordination and guidance of a 30 member National Coordination Committee (NCC) headed by the Secretary of MoEF. NCC has been formed on 12 December 2005 to providing technical advice to the project.

Some relevant information about the project implementation, such as the executing agency, the project team, list of NCC members, list of workshops and consultative meetings for the process of developing NBF are illustrated below.

a) National Executing Agency

Department of Environment (DoE),
E-16, Agargoan, Sher-E-Bangla Nagar
Dhaka- Bangladesh
Fax: 880-2- 9118682
Website: http://www.doe-bd.org/

b) Project Director

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c) National Project Coordinator

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monzur_29@yahoo.com

d) The National Coordination Committee consists of 30 representatives of the concerned agencies:

01	Secretary, Ministry of Environment and Forests	Chairperson
02	Director General, Department of Environment and Forests	Member
03	Joint Secretary (Development/Administration), Department of Environment and Forests	Member
04	Director General, Directorate of Food	Member
05	Executive Chairman, Bangladesh Agricultural Research Council	Member
06	Director General, Bangladesh Standard Testing Institution	Member
07	Director General, Bangladesh Livestock Research Institute	Member
08	Director General, Bangladesh Rice Research Institute	Member
09	Director General, Bangladesh Agricultural Research Council	Member
10	Director General, Department of Fisheries	Member
11	Director General, Department of Agricultural Extension	Member
12	Commissioner, Customs Division	Member
13	Representative (not below the rank of Joint Secretary), Ministry of Agriculture	Member
14	Representative (not below Joint Secretary), Ministry of Science and Technology (MoSICT)	Member
15	Representative (not below Joint Secretary), Ministry of Health and Family welfares	Member
16	Representative (not below Joint Secretary), Law, Justice and Parliament Affairs Ministry	Member
17	Dr. Ashraful Haque, Director, Bangladesh Forest Research Institute	Member
18	Dean, Faculty of Biology, Dhaka University, Dhaka	Member
19	Dean, Faculty of Agriculture, Bangladesh Agriculture University, Mymenshing	Member
20	Dean, Faculty of Biology, Khulna University, Khulna	Member
21	Dean, Faculty of Biology, Chittagong University, Chittagong	Member
22	Director, National Institute of Biotechnology	Member
23	Deputy secretary/Deputy Chief, Ministry of Environment and Forests	Member
24	Project Director, NBF Project, Department Environment and Forests	Member
25	Country Representative, IUCN-Bangladesh	Member
26	Chairman, BRAC, Dhaka, Bangladesh	Member
27	Chairman, East-West Seed Ltd, Dhaka, Bangladesh	Member
28	Farmers Representative (1), Nominated by BARC, Dhaka	Member
29	Senior Assistant Chief-5, Ministry of Environment and Forests	Member
30	National Project Coordinator, NBF Project, Department Environment and Forests	Member Secretary

e) Lists of Workshops, Seminars and Consultation Meetings held during development of NBF

Sl. No.	Date & Venue	Title of Meeting/Workshop
1.	08.02.2006,MoEF, Dhaka	National Coordinating Committee (*First NCC*) meeting
2.	09.02.2005, BEMP-DoE, Dhaka	Experts meeting on development of National Biosafety Frameworks
3.	02.01.2006, BARC, Dhaka	Experts Meeting on Future Action Plan for developing the NBF
4.	23.04.2006, IDB Bhaban, Dhaka	Inception Workshop on development of the National Biosafety Framework
5.	26.06.2006, MoEF, Dhaka	National Coordinating Committee (*Second NCC*) meeting
6.	18-07-2006, DoE, Dhaka	Experts Meeting on progress of the development of the NBF
7.	20.07.2006, CWBMP-DoE, Dhaka	Meeting with Subcontracting Agencies on Capacity Survey and Database development
8.	17.08.2006, BESIP-DoE, Dhaka	Experts Workshop on progress of the development of the NBF
9.	18.10.2006, MoEF, Dhaka	National Coordinating Committee (*Third NCC*) meeting
10.	11-12.10.2006; BESIP-DoE, Dhaka	Experts Workshops on presentation of Chapters/Elements of the NBF (1st Draft)
11.	08.11.2006, AQMP-DoE, Dhaka	Experts Workshops on Deliverables of BAURES for the NBF
12.	16.11.2006, LGED, Dhaka	National Workshop on the drafted NBF for Bangladesh
13.	10.12.2006, MoEF, Dhaka	National Coordinating Committee (*Fourth NCC*) meeting
14.	23.05.2007, MoEF, Dhaka	National Coordinating Committee (*Fifth NCC*) meeting
15.	19.05.2007, Chittagong	Divisional Training Workshop on Biosafety
16.	14.06.2007, Rajshahi	Divisional Training Workshop on Biosafety
17.	23-24.6.2007, IDB Bhaban, Dhaka	National Training Workshop on Risk Assessment and Risk Management of GMOs
18.	24.06.2007, IDB Bhaban, Dhaka	National Coordinating Committee (*Sixth NCC*) meeting