

# The Biosafety Regulatory Regime in Bangladesh

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# **Biosafety Regulatory Focal Point**

**Ministry of Environment and Forests (MOEF) acts as a focal authority to enforce Biosafety in the country and develop sound administrative and legislative system.**

- Bangladesh is a party to the Cartagena Protocol on Biosafety (CPB)
- Bangladesh signed the Protocol on 24 May 2000 and ratified it on 5 February 2004.
- As party to the protocol Bangladesh has developed Biosafety Regulatory System in order to safe use of modern biotechnology

# Chronological Advancement of Biosafety Regime in Bangladesh:

- 1999 : Biosafety Guidelines developed by MoST
- 2000 : Signing the Cartagena Protocol on Biosafety (CPB )
- 2004 : Ratification of the CPB
- 2006 : Updated Biosafety Guidelines by MoEF
- 2006 : Development of NBF
- 2007 : Updated Guidelines gazetted by MOEF
- 2008 : NBF published
- 2008 : BCH developed
- 2012 : Bangladesh Biosafety Rules Gazetted
- 2012 : Prepared NBF Implementation Project
- 2014 : INBF Implementation started

# Biosafety Guidelines of Bangladesh

## Development Process of Biosafety Guidelines

- ❑ Biosafety Guidelines of Bangladesh was earlier formulated by the Ministry of Science and Technology in 1999 and published in 2000
- ❑ The Guidelines have been updated by the Ministry of Environment and Forests in the line with the Cartagena Protocol during 2004-2006
- ❑ Updating of the Guidelines took into account of the National Policy on Biotechnology into consideration and
- ❑ Recasted various aspects of Risk Assessment and Risk Management in the light of Cartagena Protocol.

# Scope and Objective of Biosafety Guidelines

- 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 organizations located in Bangladesh, private companies or non-governmental organizations.
- It applies to lab experiment and field trial, trans-boundary 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.

# Chapters included in Guidelines

Chapter-I : Scopes and Objectives of Biosafety Guidelines

Chapter-II : Institutional Arrangements

Chapter-III: General Provisions on Biosafety  
(risk assessment and risk management)

Chapter-IV: Physico-chemical and Biological  
Containments: Procedures and Facilities



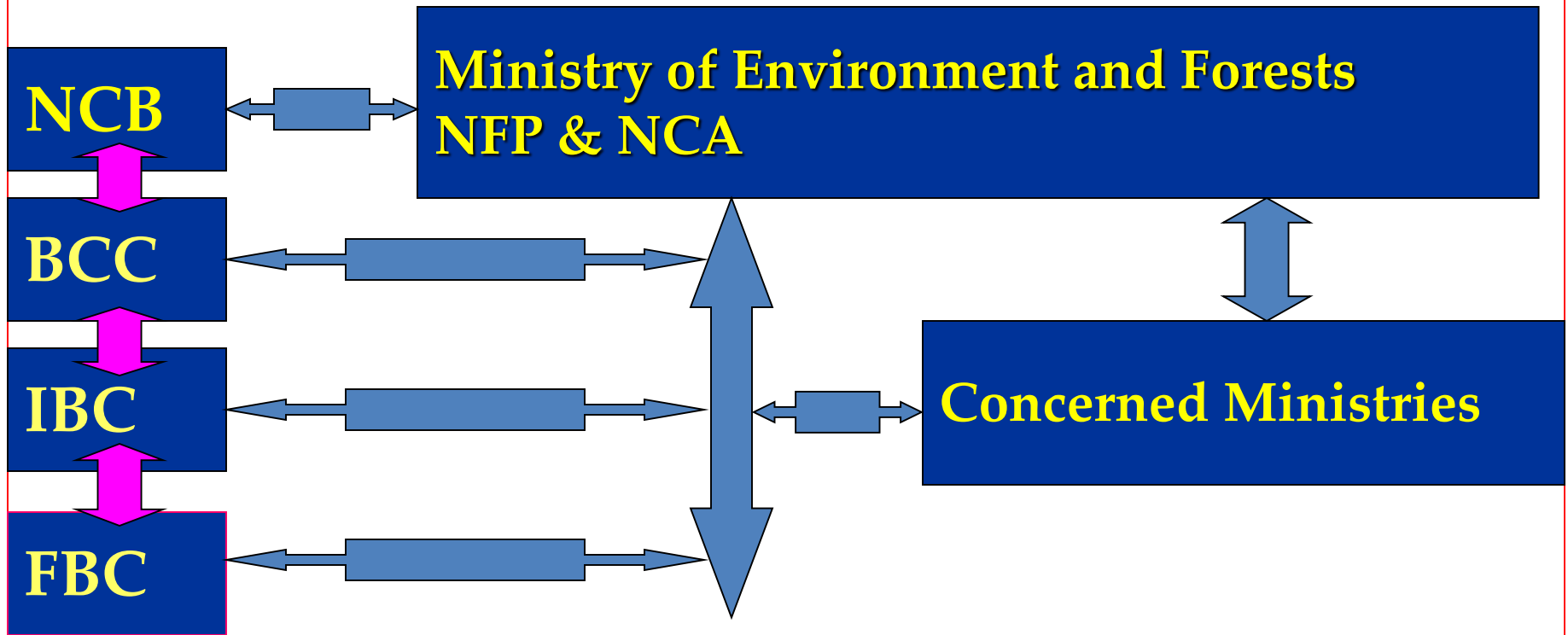
## Annexure included in Guidelines

- ✓ Guidelines for Classification of Microorganisms according to their Risk Potential
- ✓ Good Laboratory Practice
- ✓ Good Industrial Large-Scale Practice: The GILSP concept
- ✓ List of Organisms according to Different Risk Groups
- ✓ Framework for Risk Assessment
- ✓ Information needed in Trans-boundary Movement of GMOs
- ✓ Information required Concerning GMOs Intended for Direct Use as Food or Feed, or for Processing under Article 11 of Cartagena Protocol on Biosafety
- ✓ Biohazard Communication
- ✓ Glossary of the Terms used in Biosafety Guidelines

# Regulatory Committees under the Biosafety Guidelines of Bangladesh

- National committee on Biosafety (NCB) headed by the Secretary, MOEF
- Biosafety Core Committee (BCC) Headed by DG, DOE.
- Institutional Biosafety Committee (IBC)
- Field level Biosafety Committee (FBC)

# Biosafety Administrative Structure



# Application Procedure of GM Products

**Applicant/Researcher**



**Application processed by the  
Institutional Biosafety Committee (IBC)**



**Submission of application to the  
respective National Technical Committee  
(NTC) of concerned Ministry**



**Reviewed by the Core  
Committee NTC  
(BARC)**



**Submission of application to the  
National Committee on Biosafety (NCB)  
headed by the Secretary, MOEF through  
the respective NTC**



**Reviewed by the  
Biosafety Core  
Committee (BCC)**



**Approval/Rejection by the NCB**

# **Biosafety Rules of Bangladesh, 2012**

# Bangladesh Biosafety Rules, 2012

## Main Features of Biosafety Rules:

- 13 number of Rules
- Restriction on import, export or any other kind of uses of GMOs
- Notification for transboundary movement or any other uses through the respective ministries
- Biosafety Guidelines of Bangladesh has been appended as part of the Rules
- Oversight on Risk Assessment and Management is assigned to various committees already formed
- Overall coordination in implementation of the Rules is assigned to DOE
- Crucial Decision and Policy Making Job assigned to MOEF

# Documents Developed to Support Biosafety Regulations

- Biosafety Guidelines of Bangladesh 2006
- National Biosafety Framework 2007
- Bangladesh Biosafety Rules 2012
- SOPs for Confined Field Trial 2008
- Data Recording Formats for CFT 2008
- Guidelines for Foodsafety Assessment of GE Foods, 2012 (BSTI has taken the foodsafety assessment guidelines as standard)
- ERA Guidelines for GE Plants 2014
- Biosafety Policy of Bangladesh developed
- Monitoring and Enforcement Manual developed

## R&D endorsed by NCB, so far

- Limited Environmental Release of Bt Eggplant for Field Cultivation
- Confined Field Trial of Late Blight Resistant Potato at BARI research stations
- Confined Field Trial of Golden Rice by BRRI
- Contained Trial of Bt Cotton in the Greenhouse by Cotton Development Board (CDB)
- Contained Trial of Edible Vaccine Producing Transgenic Rice in the Biochemistry and Molecular Biology Department, DU
- Contained Trial of Transgenic Rice for Salinity and Drought Tolerance by BRRI



## Progress made under Implementation Project

- National Biosafety Policy developed
- Biosafety Guidelines Updated
- Updated Biosafety Rules
- Functioning of the regulatory committees strengthened
- GMO Detection Laboratory Established
- Monitoring and Enforcement Manual developed
- IT Based networking system for monitoring institutions and R&D projects
- Printed Outreach Materials Developed in Bangla
- Video Documentary and TV Spot is underway to be developed
- Regular Progress Reports are submitted to UNEP

# Ways Ahead of us

- To publish Updated Biosafety Policy, Biosafety Rules and Guidelines into the Gazette
- Operationalization of the GMO Detection laboratory
- Establishment of inter-institutional networking for wider range of safety analysis
- Training on and Strengthening of Monitoring and Enforcement of Biosafety Rules
- Provide training to relevant government agencies such as border control (customs), quarantine and inspection facilities
- Setting-up data collection, management and storage facilities
- Establishment of Inter-institutional networks for risk analysis, reporting, communication and management

*THANK YOU*

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