The Biosafety Regulatory Regime in Bangladesh

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Biosafety Regime in Bangladesh: Chronology of Advancement

- 1999- Biosafety Guidelines (MoSICT)
- 2000- Signing the CPB
- 2004- Ratification of the CPB
- 2004- DNBF project
- 2006- Updated Biosafety Guidelines (MoEF)
- 2006- NBF developed
- 2007- Updated Guidelines gazetted
- 2008- NBF published
- 2008- BCH developed and inter-connected with the BCH Central Portal
- 2010- Drafted Bangladesh Biosafety Rules
- 2012- Bangladesh Biosafety Rules Gazetted
- 2012- Prepared NBF Implementation Project
- 2014- INBF Implementation started
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/LMOs 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 GMO/LMO
✓ Information required Concerning GMOs/LMOs 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)
Institutional Arrangement Established

- Various Committees Established under Biosafety Guidelines of Bangladesh
  - NCB
  - BCC
  - IBC
  - BSO
  - FBC
Biosafety Administrative structure

Ministry of Environment and Forests
NFP & NCA

Concerned Ministries

NCB
BCC
IBC
FBC
BSO
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 is responsible to administer the foodsafety assessment guidelines as standard)
- ERA Guidelines for GE Plants 2014
- Biosafety Policy of Bangladesh
- Monitoring and Enforcement Manual
R&D endorsed by NCB, so far

- Limited Environmental Release of Bt Eggplant Field
- 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
- Contained Trial of Edible Vaccine Producing Transgenic Rice in the net house of Biochemistry and Molecular Biology Department, DU
- Contained Trial of Transgenic Rice for Salinity and Drought Tolerance
## Progress made under Implementation Project

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<tr>
<th>Project components</th>
<th>Outcomes So Far</th>
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<tr>
<td>Development of National Policy on Biosafety and Updating Guidelines on Biosafety</td>
<td>• National Biosafety Policy developed</td>
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<td>and Biosafety Framework (NBF)</td>
<td>• Updated Biosafety Guidelines</td>
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<td>Development and Promulgation of Regulatory Regime on Biosafety</td>
<td>• Updated Biosafety Rules</td>
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<td>Functional Administrative System for Handling and Notification on LMOs</td>
<td>• Functioning of the regulatory committees strengthened</td>
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<td>• GMO Detection Laboratory Established</td>
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<td>Monitoring and Enforcement</td>
<td>• Monitoring and Enforcement Manual developed</td>
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<td>• IT Based networking system for monitoring institutions and R&amp;D projects</td>
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<td>Public Awareness, Education and Enhancing public participation, regional networking and collaboration</td>
<td>• Printed Outreach Materials Developed in Bangla</td>
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<td>• Video Documentary and TV Spot is underway to be developed</td>
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<td>Project Monitoring and Evaluation and Audit</td>
<td>• Regular Progress Reports are submitted to UNEP</td>
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Ways Ahead of us

- To publish Biosafety Policy, Updated 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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