Biosafety Regulations and Capacity Building Initiatives in Sri Lanka

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Convention on Biological Diversity (CBD) & Cartagena Protocol on Biosafety (CPB)

- **Convention on Biological Diversity (CBD)**
  - Signed: June 1992
  - Ratified: May 1994

- **Cartagena Protocol on Biosafety**
  - Signed: 24.05.2000
  - Ratified: 28.04.2004

**National Focal Point** - Ministry of Mahaweli Development and Environment

**National Competent Authority** - Biodiversity Secretariat
Sectorial Competent Authorities

- Department of Agriculture
- Department of Animal Production
- Department of Health
- Dept. of Fisheries and Aquatic Resources
- Ministry of Industry and Commerce
- Dept. of Wildlife Conservation
Initiatives

- National Biosafety Framework – 2005
- The National Policy on Biosafety – 2005
- The National Coordinating Committee on Biosafety (NCCB) formed
- The Biosafety Act drafted
Implementation of the National Biosafety Framework in Accordance with the Cartagena Protocol on Biosafety - GEF/FAO Project

1. Strengthening policy, institutional and regulatory frameworks for biosafety

2. Enhancing the system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC)

3. Developing technical capacity for the detection and identification of LMOs and strengthening biosafety related infrastructure

4. Knowledge development, public awareness, education and participation
1. Strengthening policy, institutional and regulatory frameworks for biosafety

- address the gaps in existing regulatory and institutional frameworks to implement the NBF and to support the establishment of sound decision-making processes and law enforcement on biosafety.
  - Two National Consultants (Legal matters & Policy Development) & International Consultant
  - Working Group
  -- Technical Expert Group
  - Project Steering Committee

Progress

- Draft Biosafety Act revised
- Biosafety regulations drafted
- Biosafety Master Plan drafted
Draft Act

Objective

ensure that, production, at applications (uses, development, research, productions, marketing, & other commercial applications, handling, transport, import, export sale including contained use and re-export, transfer, disposal and release) of any LMOs undertaken in a manner that prevent / reduces risks to biological diversity and human health
Institutional Mechanism - Biosafety Act

Application Submission

Interested parties (e.g., importers and scientists) must obtain a permit by submitting an application to the NCA before GMOs are imported, commercially used or released to the environment.

GMO
(Genetically Modified Organisms)
APPLICATION PROCESS
of SRI LANKA

Risk Analysis of GMOs

The risk of GMOs on the environment and health is analyzed by the Relevant Sectoral Competent Authority (RSCA) and reports on Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC) are submitted to the NCA.

Application

Biodiversity Secretariat, Ministry of Mahaweli Development and Environment

Advisory Committee

Recommendations are made by the Advisory Committee considering the information in the application, Risk analysis reports and public comments.

The decision is made by the NCA considering the recommendations of the Advisory Committee whether to issue the permit or not. Rejected applicants are entitled to appeal.

Public Participation

The reports on RA, RM and RC are published by the NCA and the public is notified (through newspapers) to obtain public comments.

Process Outcome

A

B

You are entitled to Appeal

You are not entitled to Appeal

National Biosafety Project, Sri Lanka- 2018
4. Knowledge development, public awareness, education and participation

- Media Conference

- Biannual Biosafety Newsletter to increase public awareness of Biosafety and the guidelines and regulations important for the safe use of GMOs/LMOs

- Baseline data collection on the level of understanding of the stakeholders on biosafety in Sri Lanka in support of developing the public participation and outreach strategy
2. Enhancing the system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC)

- strengthening of technical capacity of the relevant national institutions in order to conduct Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC) systematically

3. Developing technical capacity for the detection and identification of LMOs and strengthening biosafety related infrastructure

- strengthen and make the key laboratories fully operational by upgrading necessary infrastructure for carrying out the required identification and detection of LMOs and thereby enable Sri Lanka to meet its obligations under the CPB.
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- Agreements with National Science Foundation and Agriculture Biotechnology Centre, University of Peradeniya for component 2,3

- Agreement with Biotech Consortium India
Institutions related to Biosafety

- Sri Lanka Customs
- Department of Agriculture
  - National Plant Quarantine Service
  - Registrar of Pesticide
- Ministry of Health Nutrition and Indigenous Medicine
  - Food control administration unit
  - National Medicinal Drug Regulatory Authority
  - Medicinal Research Institute
  - Commissioner of Ayurveda
- Department of Animal Production and Health
  - Registrar of Veterinary Drugs
  - Registrar of Animal Feed
Contd…

- Sri Lanka Standard Institute
- Central Environmental Authority
- Ministry of Commerce and Consumer Affairs.
- Consumer affairs Authority
- Ministry of primary Industries; Export Agriculture Department
- Universities
- Government and Private laboratories
- Ministry of Justice;
- Ministry of Trade;
- Ministry of Fisheries and Aquatic Resources;
- Ministry of Science Technology and Research;
- Ministry of development Strategies and International Trade
- Non-Governmental Organizations and Civil Societies
Thank you