Biosafety Regulation and Capacity Building Initiatives in Bhutan

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BAFRA, Ministry of Agriculture and Forests
Bhutan
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Background Info on Bhutan

- Total Area: 38,394 km²
- Forest land area: 70.46%
- Population (2017): 681,720
- Capital: Thimphu
- Government: Democratic Constitutional Monarchy
Major Concerns: Environmental Conservation

- Constitution of Bhutan mandates - at least 60% of area under forest cover at all times to come.
- Forest Coverage (including shrubs) : 80.89 %
- 51.44 % of the land area : Protected area
- One of the 10 global hotspots for biodiversity
The Agriculture Sector

- Population engaged in agriculture and forest: 62.2%
- Land under some form of agricultural cultivation: 2.93% of area (1,125 sq. km)
Biotechnology status in Bhutan

Conventional biotechnological applications used in research organizations are:

- Traditional methods of plant and animal breeding, Tissue culture applications, Studies on conservation of nature, soil, forests, genetic resources and wild life.

**Organizations involved in biotechnology applications**

1. National Seed Centre (NSC)
2. National Livestock Breeding Programme
3. National Centre for Animal Health
4. Research Centers under MoAF
Bhutan’s Approach

- Bhutan has opted for a GMO free strategy.
- Bhutan would allow the introduction or import of processed or semi-processed GM products, incapable of reproduction and whose safety assessment has been conducted, and would ban the introduction, release and research involving GMOs.
- Research involving development of GMOs has been banned by a Ministerial notification from the MoAF in April 2011.
MAJOR CONCERNS

Protection of pristine environment

Ensuring high level of human and animal health safety

Ensuring food security and meeting food self-sufficiency objectives

Socio-economic impacts
1995 - Bhutan became party to the International Convention on Biological Diversity (CBD)

2002 - Bhutan ratified the Cartegena Protocol on Biosafety (CPB)

2010 - 2014 NBF was implemented through the NBF Project, with financial support from UNEP/GEF
BIOSAFETY REGULATORY FRAMEWORKS

- Ministerial Decree 2000 as per Cabinet Order
- Biodiversity Act 2003
- Food Act of Bhutan 2005
- Seed Rules and Regulations of Bhutan 2006
- National Biosafety Framework 2006
- National Environment Protection Act 2007
- Constitution of the Kingdom of Bhutan 2008
- The Biosecurity Policy of the Kingdom of Bhutan 2010
- Economic Development Policy of Bhutan 2010
- Ministerial Notification 2011
Biosafety legislations of Bhutan 2015

- Act was passed on: 5 July 2015
- Commencement Date: 20 July 2015
- Biosafety Rules and Regulations: Endorsed in 8th March 2018
SCOPE OF THE BIOSAFETY ACT

- All genetically modified organisms;
- Products derived from GMOs;
- All stages of import, export, and direct use of products that have GM content
EXEMPTIONS

- Traditional and domestic methods of animal and plant breeding;
- Traditional and domestic exchange and sale of local seeds, plants, and livestock;
- Gene sequencing, tissue culture, and other similar methods, which do not involve the use of modern biotechnology; and
- Products derived from GMOs for pharmaceuticals for human and veterinary use.
The Prohibitions as per the Act

Import, Transit, Intentional introduction, contained use, Research and development of any GMOs and any other genetically modified biological material capable of reproducing.
Organization of Biosafety Administration

Organizational Structure

National Biosafety Board

Bhutan Agriculture and Food Regulatory Authority
BAFRA – NCA

Technical Working Group
1. National Biosafety Board (NBB)

The highest decision making body on all biosafety related issues.

Chairperson – Minister, MoAF

BAFRA  DoL  DoFPs  NBC  DoA

MoEA  MoF  MoHCA  NEC  BCCCI  MoH
2. Bhutan Agriculture and Food Regulatory Authority

- National Competent Authority for implementing the Biosafety Act of Bhutan 2015 and its Rules and Regulations 2018

- BAFRA also function as the:
  - National Food Safety Control Agency
  - Implementer of related legal instruments of the MoAF
  - National Competent Authority for implementing Biosecurity measures
3. Biosafety Technical Working Group

Composition
Technical experts from relevant agencies—exploring to include other experts like nutritionist, toxicologist, immunologist

Task
To advise the National Biosafety Board through BAFRA on technical and scientific issues related to genetically modified organisms
Some of the documents developed so far....

1. Guidelines for handling applications for GMO/LMO and their products
2. Guidelines for inspection and monitoring of GMO/LMO
3. Guidelines on Environmental Risk Assessment of GM plants
4. Risk assessment of food and feed products derived from GM plants
5. GMO detection method and protocols
6. Laboratory manual for the detection of GMO
7. Manual for training workshop on GMO/LMO-handling application and inspections
Some of the recent initiatives

1. Capacity development in GM laboratory
2. Conducted 4 day training on GM Food Safety Assessment and Risk Communication through financial and technical support from FAO
3. Conducted GMO surveillance in food and feed samples by using rapid test kit and qPCR
Thank you very much