Updates/status of the Bhutanese Biosafety Regulatory system

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BAFRA, Ministry of Agriculture and Forests
Bhutan
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Background Info

- Total Area: 38,394 km²
- Forest land area: 70.46%
- Population: 747,896 (NSB)
- Capital: Thimphu
- Government: Democratic Constitutional Monarchy
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)
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. Renewable Natural Resources Research Centers
Bhutan’s Approach on GMO

- 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 restrict 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
Background Information

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

2002 - Bhutan ratified the Cartagena 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 - banned research involving development of GMOs
- The Biosafety Act of Bhutan 2015
Biosafety legislations of Bhutan 2015


➢ Act was passed on: 5 July 2015

➢ Commencement Date: 20 July 2015

➢ Biosafety Rules and Regulations: Endorsed in August 2017 National Biosafety Board (awaiting enactment)
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 genetically modified content within the Kingdom.
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.
Organizational Structure

National Biosafety Board

Bhutan Agriculture and Food Regulatory Authority
BAFRA – NCA

Technical Working Group
The highest decision making body on all biosafety related issues.
2. Bhutan Agriculture and Food Regulatory Authority

- National Competent Authority for implementing the Biosafety Act of Bhutan 2015

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

Composition
Technical experts from relevant agencies

Task
To advise the National Biosafety Board through BAFRA on technical and scientific issues related to genetically modified organisms
GM Food/Feed Safety Assessment

- Genetically modified Foods
- Genetically modified Feed
- GMOs for Processing

- Guidelines for Risk Assessment of Food and Feed Products derived from GM Plants - 2014
Environment Safety Assessment

- Low exposure scenario
- Illegal or Unintentional release of GMOs

- Guideline on Environmental Risk Assessment of GM Plants - 2014
Labeling of GM Foods

Commercial products derived from GMOs placed in the market need to be labelled (threshold level - 5%)
Testing facilities/capacity

- Real time PCR-Biorad
- Surveillance on GM elements (35S promoter, Nos-terminator, pFMV, cp4-epsps, Cry1A(b), Cry1Ac, Cry3Bb1, Cry1F, rActin1, Pat, BAR, nptII, Barnase, Barstar, CaMV)
- EU-method (RIKILT)
- GM element surveillance-test kit—completed
- GM event detection-in future
Thank you for your kind attention