National Biosafety Framework

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Content

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- Overview of Biosafety Regulatory Framework
- Biosafety Legislations of Bhutan
- Institutional Roles
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Background Info 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



Background Info 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)





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 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.



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
- The Biosafety Act of Bhutan 2015



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

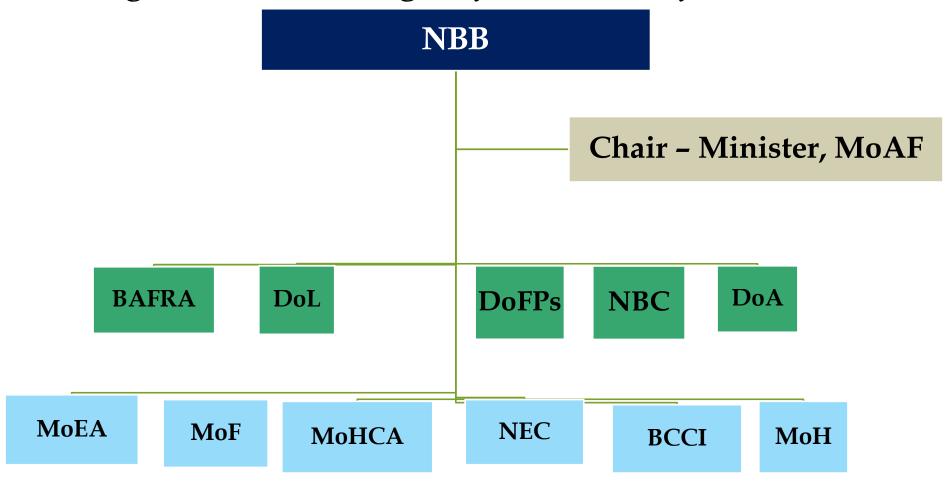
Bhutan Agriculture and Food Regulatory Authority BAFRA – NCA

Technical Working Group



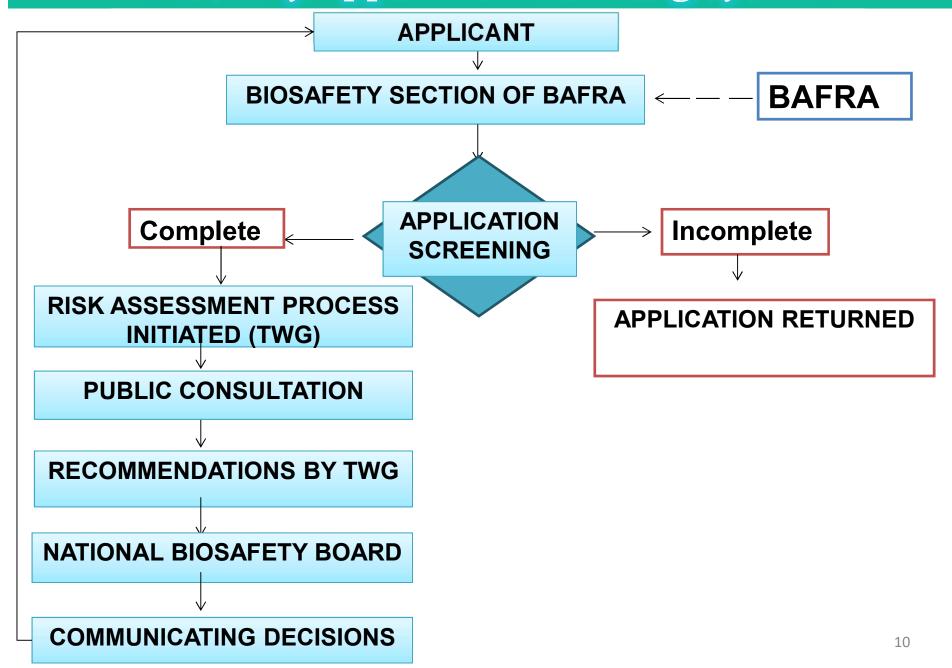
National Biosafety Board (NBB)

The highest decision making body on all biosafety related issues.





Biosafety Application Handling System



Testing facilities/Capacity

- Laboratory set up~NBFP
- Real time PCR (Biorad)
- Nanodrop 2000c
- Thermoshaker and centrifuges
- Biosafety cabinet
- Two personnel with back ground in LMO detection



Gaps and Constraints

- Financial (Budget Constraints Vs expensive molecular reagents)
- The difficulties to get the required molecular consumables (reagents/primer-probes/mastermix, extraction kit) on time
- Human resource (professional training in GMO detection and quantification)
 - >Biosafety quite a new activity in Bhutan

Required information

- Manufacturers of reliable CRMs and primers and probes
- Expert group on GMO/detection-discussion forum
- List of renowned GMO detection and identification training institutes
- List of GMO reference laboratories

Thank you for your kind attention

