

Biosafety Regulation of GE/GM Plants in Bhutan

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BHUTAN



Druk-Yul : The Thunder Dragon Kingdom

- Capital - Thimphu
- National language - Dzongkha
- Total area - 38,394 km²
- Government - Democratic Constitutional Monarchy



BROAD OUTLINES

- Background information
- Major concerns
- Regulatory frameworks
- Current scenario
- Overview of Biosafety Bill
- Risk assessment
- Anticipated constraints



BACKGROUND INFORMATION

- 2002 - Bhutan Ratified the Cartagena Protocol on Biosafety
- 2006 - National Biosafety Framework (NBF) was developed
- 2010 - NBF was implemented through the NBF Project, with financial support from United Nation Environment Program (UNEP)/Global Environment Facility (GEF)



MAJOR CONCERNS

- Protection of pristine environment
- Ensure high level of human and animal health safety
- Ensuring food security and meeting food self-sufficiency objectives
- Socio-economic impacts



BIOSAFETY REGULATORY FRAMEWORKS

- Food Act of Bhutan – 2005
- Food Rules and Regulations of Bhutan – 2007
- Biosecurity Framework of Bhutan
- Biosafety Bill of Bhutan – ready for introduction at Parliament



DRAFT STAGE

- Biosafety Rules and Regulations of Bhutan
- Guidelines and Protocols



CURRENT SCENARIO

- No active research and development programs on GMOs
- GM Laboratory at National Food Testing Laboratory (NFTL) - established
- Regulatory Legislations – draft stage
- Capacity building of relevant stakeholders
- Public awareness and education



SCOPE OF THE BIOSAFETY BILL

- Genetically modified organisms;
- Genetically modified products;
- All stages of import, export, and direct use of products that have genetically modified content within the Kingdom.



The Bill – Establishes...

- BAFRA as the national competent authority
- National Biosafety Commission
- Technical Working Group on Biosafety
- Regulatory guidelines for reporting, monitoring and enforcement of the law
- Guidelines for risk assessment
- Database of GMO and its products



Bhutan Agriculture and Food Regulatory Authority (BAFRA)

BAFRA under MoAF functions as:

- The National Food Quality and Safety Control Agency
- Implementer of RNR related legal instruments
- National Competent Authority for implementing the NBF and biosafety related activities in the Kingdom



BAFRA, Ministry of Agriculture and Forests - Bhutan

EXEMPTIONS

- Traditional and domestic methods of animal and crop breeding;
- Traditional and domestic small-scale exchange and local sale of seeds, plants, and livestock;
- Gene sequencing, tissue culture, and other similar methods, which do not involve the use of modern biotechnology; and
- GM Products for pharmaceuticals - human and veterinary use



PROHIBITIONS OF GMO

- Environmental release (GMO and GM biological material capable of reproducing)
- Contained use
- Transit
- Research and development



REGULATION OF GMO

- Environmental Release - GE Plants and GM animals
- Safety – GMOs for food, feed and processing
- Labeling – Genetically modified products



Food/feed safety assessment

GM food and feed

- Genetically modified plants
- Genetically modified products
(food, feed, semi-processed
raw materials derived from GM Plants)



Environment Safety

- Low exposure scenario
 - Illegal intentional introduction of GMOs
 - Unintentional introduction of GMOs



Essence of the Regulation

The regulation shall address the transit, trans-boundary movement, safe handling and use of all **genetically modified organisms** that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the **risks to human health.**



Anticipated Constraints

- Consumer's acceptance of GM Foods
- Impacts of banning GM crops
- Labeling of GM foods
- Capacity enhancement of stakeholders
- Implementation challenges



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