



National Biosafety Framework of the Kingdom of Bhutan, August 2006

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Introduction

- The Royal Government of Bhutan ratified the Convention on Biological Diversity on 25th August 1995
- The government acceded to the Cartagena Protocol on 26th August 2002



Current Situation

- There is no biotechnology activities in Bhutan
- Arrangement for safe use of biotechnology is also non-existent
- Surveys revealed that Bhutan imports 35 percent of its food from neighboring countries
- These imports could potentially contain GMO products
- Imports are both in bulk, maize and rice and as processed and packaged foods

Current Situation

- Agencies involved in import of foods are Food Corporation of Bhutan and some private import houses





Biosafety Policy

- Ministerial decree was issued by the Ministry of Agriculture in 2000 banning all imports of GMOs into the country
- Environmental policy
 - Is to avoid over exploitation of its forests, minerals and natural resources
 - Maintain 60 percent of forest cover at all times to come



Biosafety Policy

- Agriculture Policy

- Achieve food self-sufficiency through intensification, diversification and integrated nutrient and pest management
- Promotion of superior breeds of higher productivity and reduction of total livestock
- Develop and promote high value low volume cash crops
- To conserve the country's rich floral and faunal diversity



Biosafety Policy

- Health Policy

- Established drug regulatory authority
- Issued rules and regulations on imports of drugs and vaccines to safeguard the health of citizens

- Trade Policy

- Promote and expand trade within the region and other countries
- Creation of conducive policy and legal framework for promoting trade and industrial development



Regulatory Regime

- Existing Biosafety Related Legislation

- Food Act 2005

- Chapter VII, section 59 and 60 directly address issue of food safety resulting from genetically modified food

- Livestock Act 2000

- Ensure that only quality and appropriate breeds of livestock, poultry and fish are introduced and to ensure the units used for semen and embryo production and storage are free from diseases



Regulatory Regime

– Plant Quarantine Act 1993

- Safeguard agricultural and wild flora from pests, defined as “any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant product.” in particular, it ensures that all imported plants are quarantined and screened prior to entry into the country.

– Seed Act 2000

- Regulate import and export of agricultural seeds, to prevent introduction of plants and diseases and to promote seed industry in the country aimed at rural income and livelihood



Regulatory Regime

- Biodiversity Act 2003
 - Safeguard the genetic resources in terms of bio-prospecting and export
 - Ensure national sovereignty over genetic resources
- Environmental Assessment Act 2000
 - EIA
 - Risk assessment
 - Public consultation



System to Handle Application

- National Environment Commission is the Biosafety Focal Point
- Bhutan Agricultural and Food Authority is the National Competent Authority under the Ministry of Agriculture



System to Handle Application

- Pre-application consultation between the BAFRA and the applicant
- Applicant prepares an application
- Applicant will be responsible for carrying out risk assessment, Environmental Impact Assessment and Public Consultation
- Applications will be submitted to BAFRA



System to Handle Application

- BAFRA
 - NEC for policy advise
 - NCB for technical advise
 - BAFRA may seek clarification or additional information
 - BAFRA approves the application
 - BAFRA denies the application
 - If approved, applicant seeks trade license of permits
 - The applicant may appeal to the Ministry of Agriculture



Timeframe for Decision Making

	Activity	Timeframe
1	Acknowledgement of receipt of notification and how to proceed with an application for a permit for import of a GMO	90 working days
2	Communicate a decision on an application	270 working days from date of acknowledgement
3	Inform the BCH of a decision to approve a GMO for domestic use as food feed or processing including placing on the market	15 working days
4	Notify an applicant of a change in decision on transboundary movement	30 working days
5	Party of imports' response to changed decision on transboundary movement	90 working days
6	Notification of unintentional transboundary movement likely to have significant adverse effect	Immediate



Key Agencies

- National Environment Commission
 - Provide central direction, leadership and coordination, and formulate policies, programs and projects to support implementation of NBF
 - Ensure that best available science is applied in making biosafety decisions
 - Highest decision making body on environmental related issues
 - Focal point for MEAs
 - Make policy decision on GMO related activities/research etc.



Key Agencies

- Ministry of Agriculture

- BARFA

- Main responsible authority regarding monitoring, inspection and enforcement
 - Safety control of placing on the market of GMOs and their products, including control of food products
 - Border control and market surveillance of GM animals, plants, seeds, reproductive materials, GM containing products including those of animal origin, and industrial feedstuffs



Key Agencies

- Ministry of Health
 - Advise BAFRA on
 - Import of drugs, vaccines and pharmaceuticals
 - Research on GMO drugs and vaccines on human subjects
 - Genetic research of the Bhutanese genome
 - Effect of GMO foods on human health
 - Stop unauthorized research of GMOs on human subjects
 - Seize and destroy illegal drugs and vaccines
 - Regulate movement of human genetic resources out of the country and require all research results to be declared and require benefits accruing from the research to be the sovereign rights of the people of Bhutan



Key Agencies

- Ministry of Trade and Industry
 - Will be involved in the issuance of import licenses/permit to FFP importers
 - Coordinate with BAFRA to monitor and control the labeling and packaging of imported FFPs
- Department of Revenue and Customs
 - Inspection at the checkpoints

Conclusion

- Regulation on Biosafety

