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National Environment Commission

Royal Government of Bhutan

Draft National Biosafety Framework

of

the Kingdom of Bhutan

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Disclaimer

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Acronyms

AAS	Atomic Absorption Spectrophotometer
ACD	Analytical and Certification Division
AIA	Advanced Informed Agreement
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BBCH	Bhutan Biosafety Clearing House
BCH	Biosafety Clearing House
BIMSTEC	Bhutan, India, Myanmar, Sri Lanka, Thailand - Economic Cooperation
CA	Competent Authority
CBD	Convention on Biological Diversity
CoRRB	Council of RNR Research of Bhutan
CP	Cartagena Protocol
CPB	Cartagena Protocol on Biosafety
DDA	Dzongkha Development Authority
DoF	Department of Forest
DSC	Druk Seed Corporation
EIA	Environmental Impact Assessment
FCB	Food Corporation of Bhutan
FFP	Food, Feed and Processing
GC	Gas Chromatograph
GDP	Gross Domestic Product
GEF	Global Environment Facility
GMO	Genetically Modified Organism
GNH	Gross National Happiness
HMG	His Majesty's Government
HRD	Human Resource Division
HYVs	High Yield Verities

ICS	Information and Communication Services
IPPC	International Plant Protection Convention
IRRI	International Rice Research Institute
LMO	Living Modified Organism
MoA	Ministry of Agriculture
MoF	Ministry of Finance
MoH	Ministry of Health
MoHCA	Ministry of Home & Cultural Affairs
MTI	Ministry of Trade and Industry
NBC	National Biodiversity Center
NBF	National Biosafety Framework
NCA	National Competent Authority
NCB	National Biosafety Committee
NCD	Nature Conservation Division
NEC	National Environment Commission
NPPC	National Plant Protection Centre
NQCL	National Quality Control Laboratory
NRTI	Natural Resource Training Institute
NSB	National Statistical Bureau
OIE	World Organization for Animal Health
QCQD	Quality Control & Quarantine Division
RGoB	Royal Government of Bhutan
RNR	Renewable Natural Resources
SAARC	South Asian Association for Regional Cooperation
SAFTA	South Asian Free Trade Agreement
SRA	Scientific Risk Assessment
SRE	Scientific Risk Evaluation
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization

Definition of Terms

“Advanced informed agreement” means procedures which applies to the intentional transboundary movement of GMOs for intentional introduction into the environment of the Party of import.

"Biodiversity" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

“Biosafety” means the avoidance of risk to human health and safety, and to the conservation of the environment as a result of the use for research and commerce of infectious or genetically modified organisms.

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Conference of the Parties" means the Conference of the Parties to the Convention on Biological Diversity

"Contained use" means any operation such as importation, development, fermentation, or field test, undertaken within a facility, installation or other physical structure, which

involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

"Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.

"Export" means intentional transboundary movement from one Party to another Party;

"Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

“Food, Feed, and Processing” means GMOs intended for direct use as food or feed, or for processing that are agricultural commodities which are subject to a more simplified procedure than the AIA procedure. Under this procedure, A Party must inform other Parties through the Biosafety Clearing House, within 15 working days, of its decision regarding domestic use of GMOs that may be subject to transboundary movement.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

“GMO products” mean products containing dead or non-living modified organisms or components including certain vaccines; drugs; food additives; and many processed, canned, and preserved foods. They can also include corn and soybean derivatives used in many foods and nonfoods, cornstarch used for cardboard and adhesives, fuel ethanol for gasoline, vitamins, vaccines and pharmaceuticals, and yeast-based foods such as beer and bread

"Genetic resources" means genetic material of actual or potential value.

“Genetically Modified Organisms” has the same meaning as living modified organisms.

"Import" means intentional transboundary movement into one Party from another Party;

"Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

"Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Has the same meaning as GMO;

"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"Modern biotechnology" means the application of:
a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity and to ensure its potential to meet the needs and aspirations of present and future generations.

"Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

“Working days” means days other than national and public holidays and Saturdays and Sundays.

Bhutanese Terminology:

"Dzongkhag" Bhutanese terminology for district

"Geog" Bhutanese terminology for Administrative unit (block) under the district.

"Gross National Happiness (GNH)" The sustainable development philosophy of the Royal Government of Bhutan which equally prioritizes environmental conservation, economic development, cultural maintenance, and good governance.

1 Introduction

It is generally accepted that biotechnology both traditional and modern could contribute to sustainable development by improvements in the fields of agriculture, food and feed production and supply, industry, health care (human and animal) and environmental protection. Traditional biotechnology has been in use for centuries notably in the brewing and fermentation industries and in the production of animal vaccines. Modern biotechnology, however, includes, among other technologies, cell and tissue culture, monoclonal antibodies, and recombinant DNA (rDNA) or "genetic engineering" or "genetic modification" techniques. The increased precision and shorter time required in producing results with modern biotechnology make these new techniques particularly attractive.

The development of new techniques of genetic modification in the early 1970s introduced a new dimension to biotechnology. Scientists can now recombine DNA from different organisms, giving rise to genetically modified organisms (GMOs). Recombinant DNA organisms are derived by introducing a section of DNA from a "donor" organism to a "recipient" organism. The genome of the recipient organism is, therefore, modified. While recognizing the potential benefits of this new molecular-technique which allows a greater diversity of genes to be introduced into organisms, the relative lack of familiarity with such modified organisms and the gaps in knowledge as regards the effect of the interaction of these GMOs with the environment, make it necessary to institute measures to ensure that the technology is developed in a precautionary and judicious manner. The results of this modification need to be assessed for risks to human health, conservation of biodiversity and the environment before the intentional release of the modified organism.

In recognition of the tremendous benefits of modern biotechnology and the risks inherent thereto, the guidelines contained in this document seek to provide appropriate regulatory measures to assist all stakeholders in the establishment and maintenance of national and

institutional capacities to provide for safety in biotechnology, development of expert human resources and efficient exchange of information.

1.1 Current Situation of Biosafety and Biotechnology in Bhutan

Initial surveys conducted in Bhutan on the existing uses of biotechnology and the arrangements for safe use of biotechnology reveal that the domestic biotechnology sector is non-existent at the moment in Bhutan. Therefore, arrangements for the safe use of biotechnology are also entirely non-existent. The surveys however did reveal that Bhutan imports almost 35% of its food requirements (NSB, 2004)[1] from neighboring countries and as food aid through the World Food Program (WFP). These imports can potentially contain GMO products since the source countries are producers of GMOs including food aid donor countries to the WFP. The foods are largely imported in bulk unprocessed form such as maize and rice. A significant amount is also imported as processed and packaged foods. Live plants and animals are also imported informally across the open border with India and formally by the Ministry of Agriculture (MoA) from the United Kingdom, Switzerland, and the Philippines. Table 1 is a summary of the relevant data sources for the survey by agency and type of information.

The Ministry of Agriculture is the key line ministry that potentially can benefit from the use of GMOs. There are four Renewable National Resource (RNR) Research Centers of the MoA in Bhutan situated around the country to cater to the needs of the farmers in all the regions. The mandate of the research centers is to improve agriculture production, and raise the per capita income of the rural population through technologies and information that will help to maintain and improve existing genetic and biophysical resources of the country. From a biosafety perspective, the research centers therefore are the main entry points of potential GMO crops, seeds, and livestock. Extensive field trails of new crops and seeds imported from outside are conducted prior to release to farmers. For example since 1982 the introduction and evaluation of high yield varieties (HYVs) of rice has gained momentum in the pursuit for domestic food security. From 5,000 or more introduced lines, seven improved HYVs have been recommended since 1988 for general cultivation in the middle and low-altitude environments. A small-scale shuttle breeding

[1] National Statistical Bureau, 2004

programme has been implemented to develop varieties suited to the high altitude areas (>1,800 m). More than 100 crosses were made between local varieties and HYVs generating 100 bulk populations and over 2,500 pedigree lines. Initially the research centers relied more on introduction of HYVs for different agro-ecologies and adaptation to local conditions. However, the rice shuttle breeding at the International Rice Research Institute (IRRI) has gained momentum and introductions have reduced greatly. The emphasis now is on utilization of local germplasm in breeding programs and improving the productivity of local cultivars while retaining their good traits such as red color and grain quality. From this cross-breeding program, four improved varieties that contain Bhutanese genes have been released in 2000, and three more with blast and cold tolerance have been released in 2005. The research centers have embarked on a nationwide exploration and collection of traditional rice germplasm, and to date have collected 500 varieties, 400 of which have been sent to IRRI.

The Druk Seed Corporation (DSC) is another agency with a potential role in the future development of agricultural biotechnology. The main mandates of the Druk Seed Corporation are production and supply of seeds and seedlings, procurement and distribution of fertilizers and production and export of high value seeds. Import for seeds in demand are also made from India and other countries. Seeds of cereals, oil seeds, pulses, vegetables, temperate and sub-tropical fruit plants, and seed potatoes are either produced at DSC or imported and distributed by DSC.

The Food Corporation of Bhutan (FCB procures and distributes essential food items and maintains food security reserves. FCB is also the dealer and distributor for leading food manufacturers in India. Aside from essential items the FCB now market products of various multinational companies. Other focus pursued in the business is a prompt delivery system and improving coverage throughout the country with as many agents as possible. The distribution is done by a network of *fair price shop* agents throughout the country supported by strategically located wholesale depots and transport facilities. The other main functions are to market locally produced goods to improve the cash income of the farmers. It maintains national and SAARC food security reserves and looks after the food import logistics on behalf of the WFP.

Private import houses are the largest importers of processed and packaged foods for direct retail sales to Bhutanese customers. The number of import houses and the type of

foods imported has increased significantly over the last few years. Imports from Thailand have grown substantially (US $ 8,000,000 in 2004). India still accounts for about 55 percent of all imports, about US$ 222,000,000 of Bhutan's total imports. Main import items included mineral products like oils and fuel, machinery and mechanical appliances, food and beverages, and vehicles and its parts. India also continued to be Bhutan's largest export destination, making up for about 94 percent of total exports. Trade represents over 60 percent of Bhutan's GDP (MoF, 2005)[2].

The Bhutan Agriculture and Food Regulatory Authority is a key agency that can play a lead role in biosafety. The chief mandate is to promote the quality of goods and services related to the Ministry of Agriculture and its clients; and coordinate and liaise with other agencies that are related to regulations and quality of the products that are locally produced and also those imported. With its crosscutting mandates, BAFRA can serve as a key regulatory and monitoring agency with regards to import of GMO for food, feed and processing (FFP).

Table 1: Survey Data Sources

Sl. No.	*Activities*	*Relevant Data Source*
1	Survey of existing uses of biotechnology and the arrangements for safe use of biotechnology, including review and assessment of existing legislation that may impact on the use of modern biotechnology. (This may include phyto-sanitary, pesticide, herbicide, import and export legislation and guidelines)	Ministry of Agriculture - Druk Seed Corporation – Seed Production, Tissue Culture - RNR-RC – Introduce new, improved crops and livestock. - Vaccine Production Centre, Serbithang – vaccine production - Food Corporation of Bhutan – import of FFPs - Dept. of Forestry – protection of biodiversity - National Plant Protection Centre – import of pesticides and agro-chemicals - Bhutan Agriculture and Food Regulatory Authority- regulate food safety and plant and animal quarantine. Ministry of Trade and Industry - Dept. of Trade – Trade policy and business license Ministry of Finance - Dept. of Revenue and Customs - regulate import of FFPs

[2] Trade Statistics, 2005. Ministry of Finance

		Ministry of Health - Drugs, Vaccine & Equipt. Division – import of drugs and vaccines. - National Institute of Traditional Medicine production of pharmaceuticals. Dzongkha Development Authority (DDA) Leiden University - Bhutanese Genome Project (with DDA) Legislation - Forest and Nature Conservation Act - Environmental Assessment Act - Biodiversity Act -Food Act -Seeds Act - Livestock Act - Plant Quarantine Act
2	Survey on existing national, bilateral and multilateral co-operative programmes in capacity building, R & D and application of biotechnology;	Royal Civil Service Commission - HRD Masterplan Ministry of Agriculture - Capacity building programmes and plans
3	Survey on existing national biosafety frameworks in the countries of the sub-region;	Govt. of India (NBF existing): Ministry of Environment and Forests Ministry of Science and Technology Royal Thai Government (NBF existing): National Biosafety Committee Govt. of Malaysia (NBF existing) Attorney General's Office HMG Nepal (NBF under process): Ministry of Forest and Soil Conservation Government of Bangladesh (NBF under process) Ministry of Environment and Forests
4	Survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation;	UNEP-GEF Biosafety Unit
5	Survey on the extent and impact of release of GMOs and commercial products.	Ministry of Agriculture, Ministry of Trade and Industry, Ministry of Health, Bhutan Chamber of Commerce and Industry, Food Importers and Businesses.

1.2 Biodiversity of Bhutan

Bhutan has a rich and varied biological diversity that has regional and global importance. Very few countries in the world match Bhutan's biological diversity. Bhutan ranks in the top ten percent of countries with the highest species density (species richness per unit area) in the world (Reid 1996). Bhutan's richness in biological diversity is due to its location at the juncture of the Palearctic realm of the temperate Eurasia and the Indo-Malayan realm of the Indian sub-continent, and also due to the country's great geological relief and climatic heterogeneity.

Bhutan is extraordinarily rich in wild species biodiversity, including a large percentage of endemics. Moreover, the ecological and biodiversity integrity of the country is still largely intact. The natural forest cover over 64% percent of the country (Table 2), agriculture remains largely the traditional, highly integrated farming systems, and the country has a very comprehensive Protected Area System.

Map 1. Geographical location of Bhutan

The Himalayan ecosystem that includes Bhutan has diverse biodiversity values of national and global significance. With over 64 percent forest cover, Bhutan is known to harbor approximately 7,000 species of vascular plants, 770 species of birds, and 200 species of mammals. The natural forest and the traditional integrated farming systems remain largely intact. Bhutan not only has a wide diversity of plant and animal genetic resources but also has a large number of endemics – both cultivated and wild species. Thus Bhutan, least developed in economic terms, plays an important role in conserving the global biodiversity in general, and the biodiversity of the Eastern Himalayas in particular.

Table 2. Land Cover Areas and Percentages

Land Cover	Area (sq.km)	%
Forest	25,787	64.4
Scrub Forest	3,258	8.1
Pasture	1,564	3.9
Shifting Cultivation	883	2.2

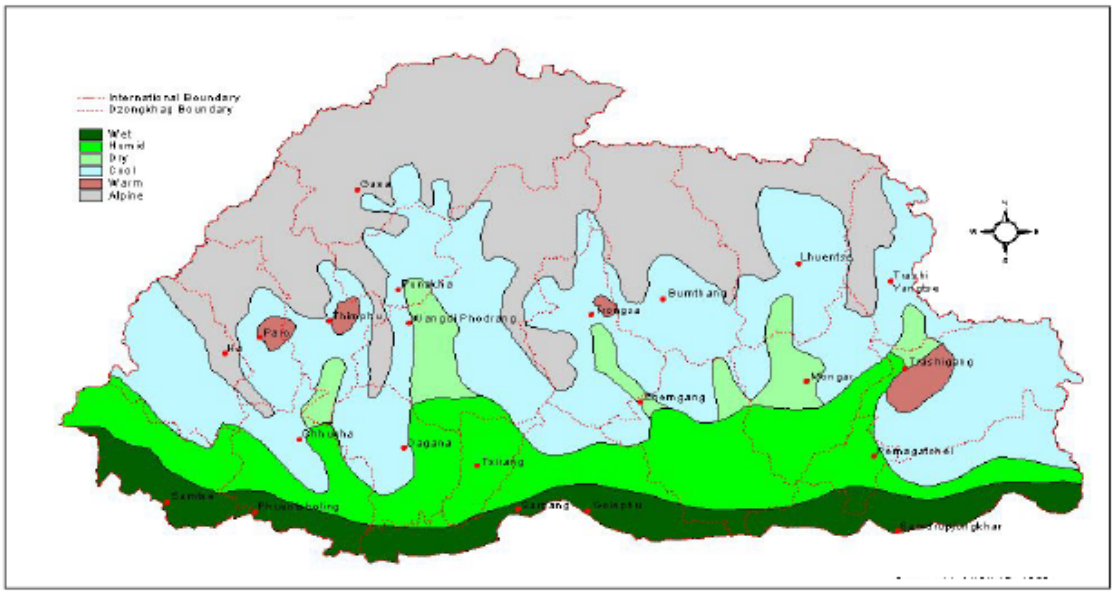
Agriculture	3,146	7.8
Snow and Glacier	2,989	7.5
Water Spread/ Marshy	339	0.9
Rock Outcrop	2,008	5.0
TOTAL	**40,076**	**100**

1.2.1 Agricultural Ecosystems

The country can be classified into agro-ecological zones based on the agro-climatic condition determined by altitude, rainfall and topography within three broad geographical zones: the Southern Foothills, the Inner Himalayas and the High Himalayas (Map 1).

Livestock and associated farming systems differ from one agro-ecological zone to the other based on altitude, temperature and rainfall distribution. Their combined effects greatly influence agricultural activities.

Alpine Temperate Zone – This zone covers cultivated areas in high altitude (2,500 – 4,000 m) with low rainfall, so dryland farming is common. Nomadic yak herders operate the livestock system. In this zone, livestock forms a predominant feature of the farming system.



Map 2. Agro-ecological zones of Bhutan.

Warm Temperate Zone – This zone falls between 1,800 – 2,500 meters above sea level. Within this zone rice is grown in summer followed by wheat, potatoes or other vegetables in late winter; rice verities are mostly traditional red types.

Dry Sub-tropical Zone – In this zone, the temperature is comparatively higher that the other two temperate zones. Rice is the main summer crop followed by wheat, mustard and vegetables. Improved crop varieties and use of fertilisers and herbicides are gaining popularity, however farmyard manure is still applied. High crop yields are obtained compared to other agricultural ecological zones.

Humid and Wet Tropical Zone – This zone fall within 150 – 1,200 meters above sea level and has excellent areas for crop cultivation. The main crop is rice followed by wheat or mustard as in the dry sub-tropical areas. However, due to higher rainfall and humidity there are more insect and disease problems in crops.

1.2.2 Domestic Biodiversity

1.2.2.1 Agriculture

The traditional, self-sustained farming system integrates crop production, livestock production and use of forest products. The wide range of climate and altitude has allowed Bhutanese inhabitants from different ethnic backgrounds to use a variety of crops and vegetables. This diversity in crop species surpasses normal expectations considering Bhutan's small size.

The dramatic elevation gradients account for the diverse flora and fauna, the species richness is further enhanced through Bhutan's relative isolation from other parts of the continent. Through a long process of natural and human selection, a wide array of crops and of varieties within crop species exists, sometimes hidden in remote areas. Many of the native crops, as well as those which have been introduced into Bhutan long ago, possess significant genetic diversity and are ecologically well adapted to the specific requirements of the local environment.

Today there is a global awareness concerning the urgency and importance of conserving biodiversity and the sustainable use of the biological resources in terms of their roles in

the survival of the human species. In Bhutan, farming has remained largely at the subsistence level. A special characteristic typical of Bhutan is its tremendous diversity in its landscape and ecosystems. The need to maintain a high level of self-reliance and the variation dictated by climate and other environmental factors has broadened the scope for biodiversity in the agricultural systems.

In addition to the major crop of rice, maize, millet, wheat, and buckwheat there are also minor crops such as finger millet, foxtail millet and amaranth. These play an important role in farmers' diet and cropping pattern.

1.2.2.2 Livestock

The main domestic livestock in different regions of Bhutan are cattle (12 breeds), yaks (10 breeds), poultry (4), pigs (3), equines (4), and sheep (3) and dogs. Goats and buffalo are other domestic livestock.

2 BIOSAFETY POLICY

2.1 Introduction

The United Nations Convention on Biological Diversity (CBD) defines biological diversity as "the variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and ecosystems."

The Royal Government of Bhutan singed the Convention on Biological Diversity on 11th June 1992 and ratified it on 25th August 1995 after the endorsement by the National Assembly. Bhutan acceded to the Cartagena Protocol on Biosafety on 26th August 2002 during the WSSD at Johannesburg, South Africa.

2.2 Existing Biosafety Policy: Current Situation and Gaps

Bhutan currently does not have a biosafety policy *per se* however a ministerial decree issued by the Ministry of Agriculture in 2000 bans all imports of GMOs into the country. Thus a precautionary approach is in application whereby any GMOs or potential GMOs are banned from entry into Bhutan. This attempts to ensure that Bhutan is free of GMOs since the domestic biotechnology sector is non-existent and the only source is from imports. This however is not adequate for the future especially since Bhutan imports more than 35% of its food needs from Asian countries which have active biotechnology industries and use GMOs in the production and processing of FFPs.

Also, the ban cannot be enforced at the moment due to lack of capacity and is meaningless.

A legal system for regulating the safe transfer, handling and use of GMOs resulting from modern biotechnology is in Annex I. Also, modern biotechnology is currently not practiced in Bhutan and there are no private industries or government agencies with modern biotechnology capability except for negligible tissue culture activities. Consequently, the only sources of GMOs are from outside the country and regulation of imports is of the utmost importance. However, other than a blanket decree from the Ministry of Agriculture banning import of GMOs, there is no biosafety policy or any enabling legislative framework, technical capacity and required infrastructure to implement the decree.

There is a pressing need for a policy statement on biosafety and biotechnology focusing on the safe transfer, handling and use of modern biotechnology products. Although there is an existing ministerial decree issued by the Ministry of Agriculture banning imports of all GMOs as stated above, the other line ministries, agencies, and most importantly food importers are not aware of this notice. Lack of technical capability and awareness also contributes to the non-effective implementation of this decree. However, this broad policy statement serves as an interim measure to counteract the emerging issue of modern biotechnology but is clearly not sufficient. Having a National Biosafety Framework in place and the subsequent implementation of the NBF should greatly enhance capacity and infrastructure needs of the Royal Government of Bhutan (RGoB).

Thus there is a need for a biosafety policy to address the issue comprehensively. This is all the more important due to the fact that the prevalent acts do not sufficiently cover biosafety issues and the results of modern biotechnology. Without a proper national legislation and a regulatory regime, it will be difficult to regulate the flow of GMOs regardless of its merits and demerits.

A key focus of the biosafety policy should be on a proper labelling mechanism for all the FFP products being imported into the country. The focus is made primarily on the food items that are being imported into the country that might contain genetically modified materials.

At the same time the biosafety policy should enable Bhutan to benefit from modern biotechnology and this can be done through the categorization of potential GMOs that may be imported. Certain products of biotechnology that have proved successful and

safe in other countries may be imported after providing proper certification and undertakings that no adverse effects are likely to occur in Bhutan. Clearly then Bhutan's priority is to safeguard the biodiversity of the country and the health of its citizens from the potential adverse effects of modern biotechnology and yet at the same time benefit from the safe and proven benefits of this technology. There is interest in the importation of transgenic plants for testing and possible release into the environment by the research centers of the Ministry of Agriculture. The intention of this research is to focus on subsistence crop plants and on problems that affect agricultural production for small farmers.

Currently there are a number of Acts that have provisions for dealing with Biosafety. However, these acts do not address Biosafety issues adequately. Therefore, draft rules and regulations for managing modern biotechnology in Bhutan have been drafted.

2.3 Existing Biosafety Related Policies

Currently, the Royal Government of Bhutan has in place several legislations on environment, agriculture, food, health, and trade policy to protect the country's rich biological diversity and the well-being of the people. These policies may have an indirect relation to biosafety issues and regulation of GMOs. Also, the foreword of the Biodiversity Action Plan for Bhutan 2002 clearly articulates the desire to pursue the use of GMOs to increase agricultural productivity:

> With the explosion in biotechnologies, the potential uses of biomaterials are far greater than what were possible in the past. Genetic materials are being incorporated into commercial products, and a considerable and increasing part of the global economy is based on biotechnological products. For our country, too, biotechnology holds bright prospect, and we must move in that direction as quickly as possible. The golden bridge linking development and conservation is biotechnology.

2.3.1 Environmental Policy

In spite of the many challenges that Bhutan faces, and the limited economic opportunities, the Royal Government of Bhutan has made it a policy to avoid over-exploitation of its forests, minerals, and natural resources. It has instead chosen to forego immediate economic gains and has placed a higher priority on the conservation of natural resources. The government has continued to take steps to strengthen its legislation and adopt policies that reflect the significance it places on long-term conservation of Bhutan's biodiversity.

2.3.2 Agriculture Policy

The main agricultural policy is to achieve food self sufficiency through intensification, diversification, and integrated nutrient and pest management. The promotion of superior breeds of higher productivity and reduction of the total population of livestock is another important objective. A third policy objective is to develop and promote high value low volume cash crops. On forest resources the policy is to place higher priority on conservation than on commercial exploitation and to maintain at least 60% of the country's area under forest cover. Another key policy objective is to conserve the country's rich floral and faunal diversity.

2.3.3 Health Policy

Health policy priorities reflect the national policies of equity, social justice, sustainability and efficiency, in the context of preservation of national culture. The health policy priorities are set within the long term objective of the Health Ministry. The long-term objective is: "to facilitate, through a dynamic professional health care, attainment of a standard of healthy living by the people of Bhutan to lead a socially, mentally and economically productive life, and within the broader framework of overall national development, enhance the quality of life of the people in the spirit of social justice and equity." The Ministry of Health has established the Drug Regulatory Authority which has issued Rules and Regulations on imports of drugs and vaccines to safeguard the health of citizens.

2.3.4 Trade Policy

Trade is seen as the key to growth, employment, poverty alleviation and development. The trade policy therefore seeks to promote trade and expand trade within the region as

well as with other countries. This is being done through the creation of a conducive policy and legal framework for promoting trade and industrial development.

2.4 Proposed National Biosafety Policy:

In implementing the National Biosafety Framework (NBF), the following policies mandated by the Draft Constitution of the Kingdom of Bhutan, 2005, (expected to be adopted in 2008) shall inform the formulation of the national Biosafety Policy of Bhutan which shall be directed by a set of Guiding Principles

The Constitution:

2.4.1 Trustees of the Environment

Every Bhutanese is a trustee of the Kingdom's natural resources and environment for the benefit of the present and future generations and it is the fundamental duty of every citizen to contribute to the protection of the natural environment, conservation of the rich biodiversity and prevention of all forms of ecological degradation including noise, visual, and physical pollution through the adoption of environment friendly practices and ethos (Article 5, Section 1 of the draft constitution).

2.4.2 Government's role

The Royal Government Shall:

1. Protect, conserve and improve the pristine environment and safeguard the biodiversity of the country;
2. Prevent pollution and ecological degradation;
3. Secure ecologically balanced sustainable development while promoting justifiable economic and social development; and
4. Ensure a safe and healthy environment. (Article 5, Sections 2a, 2b, 2c, and 2d).

2.4.3 Parliament's role

Parliament may, in order to ensure sustainable use of natural resources, enact environmental legislation and implement environmental standards and instruments based on the precautionary approach, polluter pay principle, maintenance of intergenerational

equity, and reaffirm the sovereign rights of the State over its own biological resources. (Article 5, Section 4).

2.4.4 Adequate livelihood and economic self-reliance

The State shall endeavour to promote those circumstances that would enable the citizens to secure an adequate livelihood. The State shall endeavour to achieve economic self-reliance within an open and progressive economy. (Article 9, Sections 11 and 9).

2.4.5 Right to Information and Participation

A Bhutanese citizen shall have the right to information. (Article 7, Section 4). The State shall encourage the free participation in the cultural life of the community to promote the arts and sciences and to foster technological innovation. (Article 9, Section 23).

2.5 National Policy on Biosafety

The objective of the NBF is to review existing national policy on modern biotechnology and biosafety and to develop a framework consistent with the provisions of the Cartagena Protocol on Biosafety. The legal basis of this framework is the existing and proposed policies, laws, regulations, and administrative measures. The aim is to consolidate the existing mechanisms in order to provide clarity and transparency in the future administration and decision making in respect of the management of GMOs in Bhutan.

The national Biosafety Policy of Bhutan is framed within the overall context of Bhutan's unique development philosophy of increasing Gross National Happiness. The Government shall safeguard the health of the citizens of Bhutan and protect the biodiversity and the natural environment of Bhutan from the adverse impacts of modern biotechnology. At the same time Bhutan should benefit from the safe use of modern biotechnology and the Government shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve food security, improve health services, and promote industrial development.

2.6 Guiding Principles

The following principles, based on national and international law, shall apply to the implementation of the NBF:

2.6.1 The Middle Path

A balanced approach shall guide the implementation of the NBF. This shall be based on recognition that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health. Such an approach recognizes both the potential benefits and risks of modern biotechnology to human health, agricultural productivity, food security, the livelihoods of the poor, biological diversity and the environment.

2.6.2 The Role of Science

The implementation of the NBF shall be based on the best available science. Such science must be of the best available quality, inter-disciplinary, peer-reviewed, and consistent with international standards such as Codex Alimentarius, World Organization for Animal Health (OIE), Cartagena Protocol on Biosafety, International Plant Protection Convention (IPPC) and World Health Organization (WHO).

2.6.3 Socio-economic and Ethical considerations

In implementing the NBF, the social, economic, ethical, cultural and religious impacts, including its use, benefits and risks, of research, development and release of genetically modified organisms in the country, and particularly farmers, women, small and medium enterprises and the fledging domestic scientific community, shall always be taken into account. Ethical considerations shall also be taken into account in biosafety decisions.

2.6.4 Precautionary Approach

This approach shall be implemented through the regulatory system proposed in the NBF, particularly through the procedure for scientific risk assessment to human health and the environment and evaluation of socio-economic risks.

2.6.5 Transparency and Public Participation

Decisions taken under the regulatory system proposed in the NBF shall be arrived at in a transparent and participatory manner. Biosafety issues are best handled with the participation of all concerned citizens and organizations. All concerned stakeholders shall have appropriate access to information and the opportunity to participate in biosafety decision-making processes. Dissemination of information on biosafety issues will be a priority of all the concerned agencies.

2.6.6 Consensus Building

In making biosafety decisions, all government departments and agencies shall seek consensus among all relevant stakeholders using well-accepted methods such as negotiation, mediation, and other appropriate dispute resolution processes.

2.6.7 Principle of Subsidiarity

Decisions should be made at the lowest level to involve all affected citizens regardless of their status, wealth, power, ethnicity, or gender. While it may not be reasonable to expect that local institutions such as *Geogs* have the technical capacity to evaluate scientifically the risks associated with the release of genetically modified organisms, they should have a substantial influence on the final decision after being presented with all the relevant information regarding the risks and benefits of GMOs potentially being released into their local environment because they have a better knowledge of the total picture locally, particularly the socio-economic, religious, and cultural implications of a biosafety decision.

2.6.8 Availability of Remedies

Effective access to judicial and administrative proceedings for redress and remedies is available in accordance with the laws of the land. National and international law on compensation and liability apply as appropriate.

2.6.9 International Obligations

In accordance with national law, the NBF will be implemented in a manner consistent with and mutually supportive of the international obligations of Bhutan, in particular its obligations under international trade and environmental law.

2.6.10 Efficient Administration

The biosafety decision-making process must be conducted in an efficient, coordinated, predictable, cost-effective and timely manner. Undue delay shall be avoided.

2.7 Capacity Building Needs

Capacity building at all levels of the implementation of the NBF in Bhutan is required. As will be discussed later, the Bhutan Agriculture and Food regulatory Authority (BAFRA) is the proposed national competent authority for the NBF. BAFRA has the legislative and administrative mandate as well as the basic institutional capability such as staff and laboratories, the technical capacity to implement the NBF is lacking. BAFRA scientists, technicians, and inspectors have not been trained on biosafety related sciences or issues. Also, labs lack the equipment and trained technicians to even conduct basic molecular work. Awareness among field inspectors on GMOs is limited or non-existent. The development and implementation of a national biosafety policy in Bhutan requires systematic capacity building at different levels.

1. The administrative systems with specific responsibilities for various government agencies proposed in the NBF need to be operationalized.
2. Coordination and cooperation between the involved ministries and other agencies is required.
3. Capacity for risk assessment and management and GMOs categorization criteria, analysis and listing through a central body that is qualified for this function as well as supporting infrastructure is required.
4. Capacity for monitoring and enforcement.
5. Implementation of the public participation approach needs to be done through clear public participation channels and mechanisms.

3 REGULATORY REGIME

3.1 Introduction: Current Situation

The main regulation in place at the moment for Bhutan concerning biosafety is a Ministerial Decree issued by the Ministry of Agriculture in 2000 which bans all imports of GMOs. This reflects the country's situation where the domestic biotechnology sector does not exist and the main concern is with the import of GMOs for agricultural and health care use. This becomes all the more pressing since we have an open border with India. The existing Rules of Procedure for Imports from other countries executed by the Ministry of Trade and Industry grants Bhutan and India the privilege of free trade, thus evading the import and export license requirements. In such a case where free trade agreement exists, regulation and monitoring becomes difficult thereby leading to relaxation of the objectives of the NBF. In the same manner free trade agreements are under review for Bangladesh and Nepal, and the whole South Asia region through SAFTA. Bhutan is also a member of BIMSTEC which allows for free trade with countries in South East Asia. By 2012 Bhutan will have become a full participating member of the World Trade Organisation (WTO). These free trade agreements present challenges for the regulation of biosafety in Bhutan. For instance, due to Bhutan's open borders with India and the huge volume of FFP imports from India, biotechnology developments in India and their biosafety policies have a direct bearing on Bhutan as highlighted in the survey results above.

The overriding concern then is with our open border and the rapid development of biotechnology in our neighbouring countries. These and the absence of biotechnology capacity in Bhutan informs the management of biosafety in Bhutan. Other than the Ministerial Decree which cannot be enforced due to capacity limitations at the moment, there are no other detailed regulatory measures in place to deal with biosafety issues on a case-by-case basis.

3.2 Existing Biosafety Related Legislation

The table below summarizes the existing and proposed biosafety related legislation.

Title of law/regulation	**Scope of law/regulation**	**Responsible agency**	**Status**
Food Act	Addresses the issue of food safety resulting from genetically modified food	BAFRA under the MoA	Adopted in 2005
Livestock Act	To 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	Ministry of Agriculture	Adopted in 2000
Plant Quarantine Act	To safeguards agricultural and wild flora from introduced 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.	BAFRA under the MoA	Adopted in 1993`
Draft Regulation on Biosafety	To provide for the assessment, management and control of potential risks associated with the genetically modified organisms (GMOs) and products thereof, and activities associated with them, in order to enable the country to benefit from modern biotechnology and at the same time to protect the biodiversity and people of Bhutan from their potential negative or adverse effects.	BAFRA under MoA	Draft form
Seeds Act	To regulate import and export of Agriculture seeds, to prevent introduction of plants and diseases and to promote seed industry in the country aimed at enhancing rural income and livelihood	MoA	Adopted in 2000
Biodiversity Act	to ensure national sovereignty of the RGOB over genetic resources in accordance with relevant National and International Law	NBC under MoA	Adopted in 2003

Environmental Assessment Act	This Act applies to strategic plans, policies, programs and projects which may have an impact on the environment	NEC	Adopted in 2000

3.2.1 Food Act of Bhutan, 2005

Chapter VII, Sections 59 and 60 of the Food Act of Bhutan, 2005 directly address the issue of food safety resulting from genetically modified food. The sections read:

"The Minister after consultation with the National Food Quality and Safety Commission shall regulate food business pertaining to genetically modified food. For the purpose of Section 59 the rules and regulations may define genetically modified organism and genetically modified food."

The Ministry of Agriculture implements the Food Act; in particular BAFRA is the lead agency.

3.2.2 Livestock Act, 2000

Two of the main objectives of the Livestock Act, 2000 which have a bearing on biosafety are Objectives 2.1 and 2.2:

"To ensure that only quality and appropriate breeds of livestock, poultry and fish are introduced;

To ensure the units used for semen and embryo production and storage are free from diseases"

The Ministry of Agriculture implements the Act and is authorized to quarantine all livestock including animal semen, embryos, fertilized fish eggs, fish larvae, honey bees, animal feed stuff, veterinary biologicals, and therapeutic substances imported into the country.

3.2.3 Plant Quarantine Act, 1993

The Plant Quarantine Act, 1993 safeguards agricultural and wild flora from introduced 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.

BAFRA of the Ministry of Agriculture is again the lead agency in the implementation of the Act.

3.2.4 Seeds Act, 2000

The Seed Act of Bhutan, 2000 is "An act to regulate import and export of Agriculture seeds, to prevent introduction of plants and diseases and to promote seed industry in the country aimed at enhancing rural income and livelihood."

In particular Chapter VII, Section 22 authorizes the Ministry of Agriculture to issue rules regulating the collection, import, export and exchange of genetic resources.

3.2.5 Biodiversity Act, 2003

The Biodiversity Act of Bhutan, 2003 safeguards the genetic resources of the country especially in terms of bio-prospecting and export of genetic resources. One of its main objectives is to "to ensure national sovereignty of the RGOB over genetic resources in accordance with relevant National and International Law." This has an indirect bearing on biosafety in so far as the development of biotechnology using indigenous genetic resources from Bhutan.

The National Biodiversity Centre of the Ministry of Agriculture is the lead implementing agency of the Act.

3.2.6 Environmental Assessment Act, 2000

The National Environment Commission (NEC) formulated the Environment Assessment Act, 2000, through a series of consultation with all affected stakeholders in the country. It was enacted in July 2000 with the primary objective of setting up procedures for the assessment of potential effects of strategic plans, policies, programmes and projects on the environment. This Act specifies the RGoB's policies on measures to avoid or mitigate potential adverse effects on the environment due to developmental activities.

3.3 Proposed Future Legislation

The national workshop held in April 2006 decided that instead of developing a new Biosafety Act, the legal instrument for biosafety should be prepared as a regulation under the Food Act 2005. Clause 60 of this Act provides for defining genetically modified organisms.

The proposed Draft Biosafety Rules and Regulations are attached as Annex 1.

3.4 Capacity building needs

BAFRA in its capacity as the NCA needs to draft the regulations as per recommendations above, seeking expert help where necessary, and enact the regulations. BAFRA also needs to develop capacity to draft specific regulations and the capacity to implement them.

BAFRA also needs to build capacities of its divisions for the implementation of the regulations. This is a priority issue that needs to be accorded attention by the Ministry of Agriculture and BAFRA during the implementation phase.

4 SYSTEM TO HANDLE APPLICATION

4.1 Existing Condition

At present, Bhutan does not have a system to handle notifications and requests related to GMOs. However, with the adoption of the Food Act and also in compliance with the provisions of the Cartagena Protocol, Bhutan is obliged to establish proper policies, regulations, and systems to handle requests and notifications.

The NEC is the focal agency for all environmental related issues at both national and international levels and is the focal point for the Protocol. It has so far served as the focal agency for the CPB also and has been taking the lead role in initiating biosafety measures in the country.

4.2 Proposed Strategy and Plans

The NEC Secretariat will be the Biosafety Focal Point. As the National Focal Point (NFP) the NEC is responsible for managing communication between the CBD Secretariat and Royal Government of Bhutan and the public of Bhutan.

The NEC as the designated NFP will be registered in the Biosafety Clearing House (BCH). With contact information, telephone numbers and email addresses.

The National Committee for Biosafety (NCB) shall be established by BAFRA in consultation with the NEC. This committee shall oversee the evaluation of biotechnology use and research, and advise BAFRA on GMOs.

BAFRA is a key agency that can play a lead role in biosafety. The chief mandate is to promote the quality of goods and services related to the Ministry of Agriculture and its clients; and coordinate and liaise with other agencies that are related to regulations and quality of the products that are locally produced and also those imported. With its crosscutting mandates, BAFRA can serve as a key regulatory and monitoring agency with regards to import of GMO food, feed, and processing (FFP) products.

BAFRA has two divisions- Quality Control and Quarantine Division (QCQD) and the Analytical and Certification Division (ACD). ACD issues certificates and permits for any import or export of agricultural goods. Likewise for the movement of products within the country is monitored by the Regulatory Inspectors posted at the various entry points, regions, Dzongkhags and major towns. Apart from the headquarters, BAFRA has offices at the entry points, regions, Dzongkhags and major towns of the country.

As such BAFRA will serve as a focal agency in regulating the import of GMOs through its Quality Control and Quarantine Division and also concurrently, protect the biodiversity of Bhutan by regulating removal of genetically valuable organisms and genes out of Bhutan through it ACD division.

4.2.1 National Competent Authority

BAFRA is the National Competent Authority (NCA) as required by the CPB. BAFRA under the Ministry of Agriculture has experience implementing legislation such as the Food Act, Seeds Act, the Plant Quarantine Act, and the Livestock Act. These Acts as described above have an indirect bearing on biosafety issues also. Although lacking autonomous decision-making power since it is under the MoA, BAFRA clearly has several advantages in addition to experience with biosafety related legislation. BAFRA also has the human resources which can be further developed to specifically meet biosafety needs and the infrastructure such as laboratories which can be upgraded.

Applications will be submitted to BAFRA. BAFRA will establish a technical advisory body to assist it in implementing the Biosafety Rules and Regulations. BAFRA may also seek technical advice from appropriate line ministries and agencies including the Department of Forests, RNR Research Centres, Ministry of Health, Ministry of Trade and Industry, and Department of Revenue and Customs and Ministry of Home and Cultural Affairs.

BAFRA's responsibilities as the NCA will include:

a. Establishment of process and procedures for handling applications, review of decisions, and developing forms, guidelines, codes of practice, standard for contained use
b. Establishing the procedure for assessing the risks presented to the environment, human and animal health by GMOs and their products, and the information required for risk assessment;
c. Categorizing GMOs and GMO products on the basis of the risk they represent and preparing an Annex to the Rules and Regulations that will be updated periodically;
d. Formulating guiding principles for the implementation of the administrative proces, including all the procedures on decision-making and consultations with the public;
e. Considering applications, reviewing the recommendations of the NCB before issuing final decisions, and preparing summaries of final decisions for the Bhutan Biosafety Clearing House (BBCH);
f. Ensuring that mechanisms are in place to communicate information and receive comments concerning applications, decisions, emergencies, and other matters related to GMOs and GMO products, including but not limited to through the BBCH;
g. Ensuring the protection of all information that BAFRA agrees to treat as confidential in the prior approval process;
h. Periodically reviewing its prior decisions on import and export of GMOs and GMO products and revising them at its discretion;
i. Establishing and maintaining a registry of GMOs and GMO products that have been approved for in-country operations;

j. Issuing guidelines on obligatory labeling requirements for GMOs and GMO products;
k. In coordination with other relevant national authorities, developing special safety and emergency measures to respond to and contain the effects of any risks and damages that might result from an unintentional transboundary movement or any activity that relates to GMOs;
l. Monitoring conditions and developments in the field of use of genetic technologies and GMO management;
m. Organizing public awareness initiatives on the national policy, guiding principles and other measures related to biosafety;
n. Adopting positions, providing opinions, advising the Government and informing the general public about initiatives, conditions and developments in the field of the use of modern biotechnology as well as the social, ethical, technical and technological, scientific and other aspects of GMO management;
o. Enforcing the Rules and Regulations and monitoring compliance with it.

4.2.2 National Committee for Biosafety (NCB)

BAFRA shall establish the National Committee for Biosafety (NCB). The NCB will be comprised of scientists, professionals, policy makers, business representatives, and members of civil society. This committee shall provide technical support and advice to BAFRA in implementing the Biosafety Rules and Regulations.

The NCB will assist and advise BAFRA with respect to:

a. Reviewing applications and the accompanying risk assessments for permission to import, develop, ferment, field test, release, export or use GMOs or GMO products and recommending to BAFRA whether additional risk assessment is required;
b. Categorizing GMOs and GMO products on the basis of the risk they represent and in updating the categorization, as required;
c. Preparing a scientifically-based template report for the results of risk assessments with recommendations for the action to be taken on the

application and, if the recommendation is to approve the application, for actions to be taken to minimize the risks of the GMOs or GMO products involved;

d. Containment measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures;
e. Developing guiding principles on risk assessment;
f. Developing action plans in accordance with the national priorities of the biosafety policy;
g. Mechanisms, procedures, and contingency plans to be put in place to prevent the intentional or unintentional release of GMOs into the environment, and the emergency measures that should be activated if and when such unintentional release occurs.

4.2.3 Mandates of Agencies

In addition to the mandates of the NCA and NCB described above, other agencies have the following mandates:

4.2.3.1 General Mandate

The National Environment Commission, The Ministry of Agriculture, The Ministry of Health, The Ministry of Trade and Industry, and The Ministry of Finance and other concerned agencies will, within the scope of the respective sectors, address current issues regarding the use of modern biotechnology. These ministries and agencies will conduct inter-ministerial consultations and, in consultation with BAFRA, formulate appropriate ministerial directives on issues related to biosafety in their respective sectors. In addition, they will coordinate activities and programs on biotechnology research and allocate appropriate resources for the upgrading of capacities and capabilities to effectively regulate and use modern biotechnology and its products, including but not limited to product testing and labelling of imported FFPs and GMOs.

4.2.3.2 Mandate of the National Environment Commission

The National Environment Commission shall provide central direction, leadership and coordination, and formulate policies, programs and projects to support implementation of the NBF. The NEC shall also take the lead in ensuring that the best available science is

utilized and applied in making biosafety decisions and shall exert all efforts to make sure that such decisions are made on the basis of scientific information that is of the best available quality, inter-disciplinary, peer-reviewed, and consistent with international standards. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, the NEC shall exercise such jurisdiction and other powers that have been conferred on it under existing laws.

4.2.3.3 Mandate of the Ministry of Agriculture

BAFRA, under the Ministry of Agriculture, is the NCA. The MoA and its other departments and agencies, having premier science and technology capacity in the country and being charged with the mandate of meeting food self sufficiency goals and promoting agricultural development, rural development and food security, will support BAFRA in addressing biosafety issues related to the impact of the research, development, handling, transport, use, transfer, transboundary movement, release and management of genetically modified organisms on the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, it shall exercise such jurisdiction and other powers that have been conferred on it under existing laws. The Department of Forests under the MoA as the primary government agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, shall take the lead in evaluating the environmental and biodiversity impacts of the research, development, handling, transport, use, transfer, release and management of genetically modified organisms. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, it shall exercise such jurisdiction and other powers that have been conferred on it under existing laws. In particular, as required by law, it shall conduct environmental impact assessment on all biotechnology activities conducted in protected areas and government reserved forests with oversight from the NEC.

4.2.3.4 Mandate of the Ministry of Health

The Ministry of Health, as the principal health agency in Bhutan, shall take the lead in assessing the health risks posed by the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, it shall exercise such jurisdiction and other powers that have been conferred on it under existing laws.

4.2.3.5 Mandate of the Ministry of Trade and Industry

The Ministry of Trade and Industry shall take the lead in the regulation of issuance of import licenses/permit to FFP importers. It will also coordinate with BAFRA to monitor and control the labeling and packaging of imported FFPs.

4.2.3.6 Mandate of the Department of Revenue and Customs

The Department of Revenue and Customs shall inspect and monitor the transboundary movement of genetically modified organisms at entry/exit points on the borders of Bhutan. They can greatly complement the work of BAFRA and close coordination will enhance monitoring and inspection

4.2.3.7 Mandate of the Ministry of Home and Cultural Affairs

The Ministry of Home and Cultural Affairs (MoHCA) shall take the lead in ensuring that the rights of local peoples and communities are recognized and protected in all biosafety decisions made which affect them. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, the MoHCA shall exercise such jurisdiction and other powers that have been conferred on it under existing laws. In particular, the MoHCA shall ensure that free and prior informed consent by local peoples and communities have been given to all biotechnology activities conducted within the ancestral lands and domains of local peoples and communities.

4.2.3.8 Mandate of Other Departments and Agencies

In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Chapter 6 of the NBF, all other departments and agencies shall exercise such jurisdiction and other powers that it have been conferred on them under existing laws. In particular, the following departments and agencies shall participate in biosafety decision-making where appropriate: the National Environment Commission in representing the country in international negotiations related to biosafety; the Ministry of Trade and Industry in relation to biosafety decisions related to trade; and the Department of Revenue and Customs in relation to the transboundary movement of genetically modified organisms.

4.2.3.9 The Role of Stakeholders and the Public

The role of relevant stakeholders and the public in biosafety decisions is provided for in Section 5 of the NBF.

4.2.3.10 Focal Point and Competent National Authorities

For purposes of Article 19 of the Cartagena Protocol on Biosafety, the National Focal Point to be responsible on its behalf for liaison with the Secretariat shall be the National Environment Commission. The National Competent Authority, responsible for performing the administrative functions required by the Protocol and set out in the Biosafety Rules and Regulations shall be BAFRA, assisted by the ministries and agencies described above.

4.3 Decision-making process (SRA, Risk Management)

4.3.1 Basis of Decisions

Biosafety decisions shall be made in accordance with the Biosafety Rules and Regulations. They shall be made on the basis of scientific risk assessment (SRA) complemented, where applicable, by a parallel and simultaneous process of informing and consulting at the national and local levels with individuals and communities likely to be affected by the decisions. Lack of scientific certainty or consensus due to insufficient relevant scientific information and knowledge regarding the extent of the potential

adverse effects of a genetically modified organism on the environment, human health, food security, cultural integrity and livelihoods of the country and its citizens shall not prevent concerned government departments and agencies from taking the appropriate decision to avoid such potential adverse effects. In such cases, concerned government department and agencies shall take the necessary action to protect public interest and welfare.

4.3.2 Principles of Scientific Risk Assessment

The following principles shall be followed when performing a SRA to determine whether a regulated article poses significant risks to human health and the environment:

The SRA shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of, and guidelines developed by relevant international organizations and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment.

Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk. The identified characteristics of a regulated article and its use which have the potential to pose significant risks to human health and the environment shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions.

The SRA shall be carried out on a case-by-case and on the basis of transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment.

If new information on a regulated GMO and its effects on human health and the environment becomes available, the risk assessment shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

4.3.3 Scientific Risk Assessment Guidelines

The conduct of SRA by concerned departments and agencies shall be in accordance with the policies and guidelines on risk assessment issued by the NCB. Annex III of the Cartagena Protocol shall also guide scientific risk assessment. As appropriate, such department and agencies may issue their own respective administrative issuances to regulate biotechnology activities under their particular jurisdictions.

4.3.4 Role of Environmental Impact Assessment

The National Environment Commission shall issue guidelines that apply specifically to biotechnology activities whenever such activities, as required by law, require environmental impact assessment (EIA), i.e. they are environmentally critical projects or are conducted in environmentally critical areas. Where required, the EIA process shall be integrated into and coordinated with the scientific risk assessment and the evaluation of socio-economic risks.

4.3.5 Socio-Economic Risk Evaluation (SRE)

In parallel to and simultaneous with the scientific risk assessment, an evaluation of the socio-economic risks shall be undertaken by concerned departments and agencies in accordance with the following principles and processes:

Biosafety decisions shall also take into account national priorities such as poverty alleviation, food security, rural development, and the development of science and technology.

The impact of the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms on the livelihoods, lands and natural resources of small farmers, local peoples, women, small and medium enterprises and other affected sectors shall be assessed.

Biosafety decisions shall take into account the impact of the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms on the cultural integrity of the country and its many

communities. Towards this end, ethical and religious considerations shall be considered in taking such decisions.

SRE shall be based on the best available social sciences which must be of the highest quality, inter-disciplinary, peer-reviewed, and consistent with international standards.

Where SRE is appropriate, no biosafety decisions shall be made without the submission of a report on the results of such an evaluation. All biosafety decisions by the concerned governments and agencies should include a section summarizing the results of the evaluation and its conclusions and how these were taken into account in making the final decision.

4.3.6 Biosafety Clearing House (BCH)

Concerned government departments and agencies shall utilize the BCH of the Cartagena Protocol on Biodiversity in developing guidelines for and implementing SRA and SRE.

4.4 System for Handling Notifications and Requests

4.4.1 Current Situation

Presently there is no system for handling applications and requests regarding GMOs. The blanket ban as per the Ministerial Decree requires that importers self declare the absence of GMOs from their imports. Monitoring of this is done by certification from the country of origin stating that the imports are GMO-free. However, in the absence of technical capacity, there is no means by which these claims can be verified.

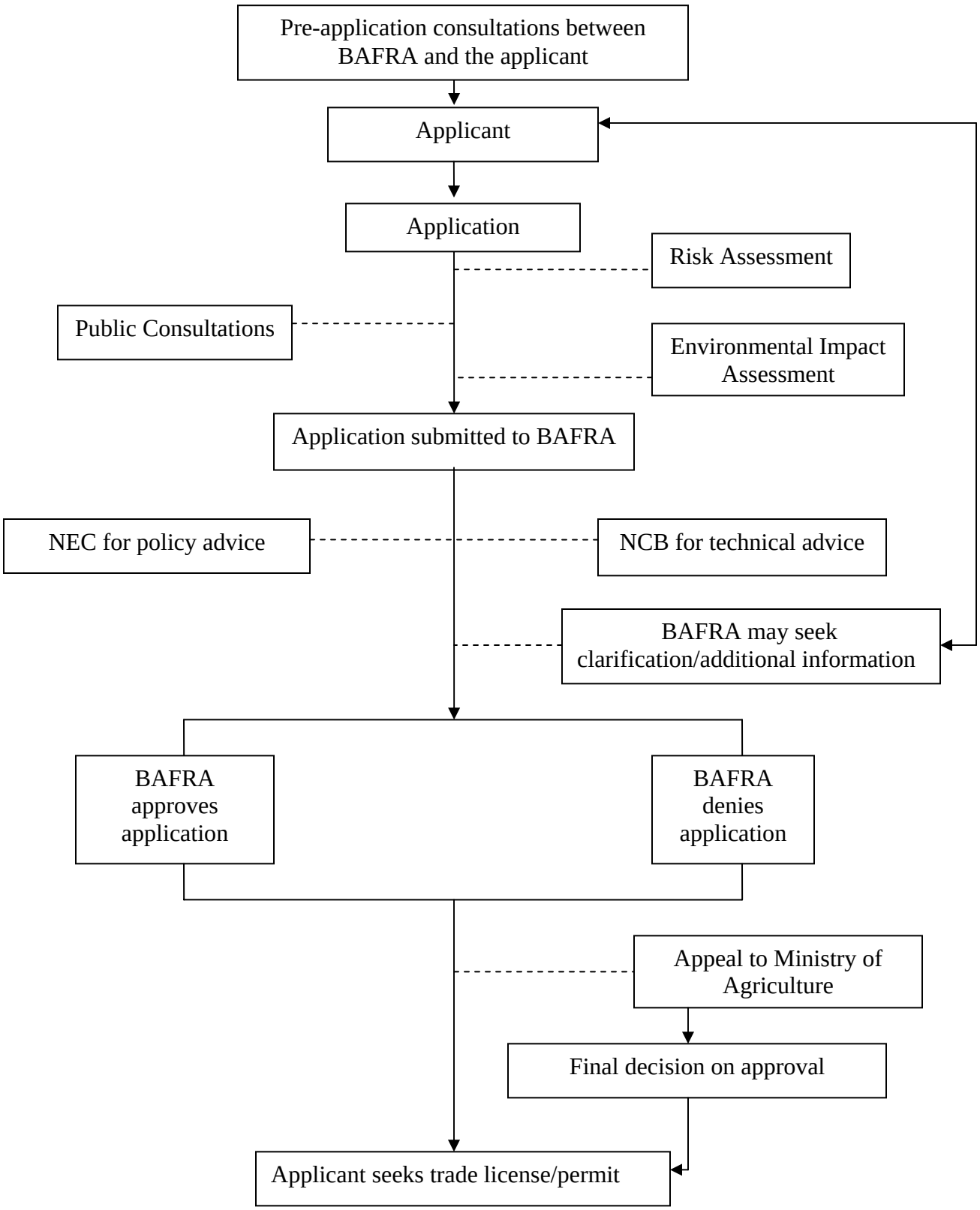
4.4.2 Proposed system for handling notifications and requests for permits:

Applicants should conduct preliminary consultations with BAFRA prior to preparing applications as per guidelines or norms issued by the NCA. This will streamline their efforts and they will get a general idea about the feasibility of their application prior to making any investments. Depending on the feedback from these institutions, applicants should prepare applications, *inter alia*, as per their recommendations. Once the

application is ready, public consultations should be sought by announcements through the media and clearly arranging meetings in effected areas with all stakeholders.

The application should then be submitted to BAFRA for review. BAFRA may refer applications to the NCB if technical backstopping is required. If an application presents issues that have potential long-term national implications, BAFRA may refer the application to the NEC for a policy decision. BAFRA may grant a permit with no conditions, grant a permit with conditions, or deny a permit.

The following flow chart shows the application process



4.5 Timeframe for decision making

The application for permits will be processed as per timeframe recommended by the CPB. It is noted that the timeframe under normal circumstances is expected to be the maximum unless a time extension became necessary. It is expected that for uncomplicated activities a lesser time than noted below is likely.

	Activity	Timeframe
1	Acknowledgment 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
5	Notify an applicant of a change in decision regarding a transboundary movement	30 working days
6	Party of imports' response to changed decision on transboundary movement	90 working days
7	Notification of unintentional transboundary movement likely to have significant adverse effect	Immediate

4.6 Access to information

4.6.1 Confidential Information

An important consideration of the assessment and evaluation of GMOs is that the general public and the scientific community have a right to be informed of and comment on applications and that information on the effects on the environment or people should be available for this purpose. Information submitted in support of an application is normally in the public domain and may therefore be requested by members of the public.

An importer or exporter of GMOs or their products may request that specified information be treated confidential. If the NCA accepts the request, it shall not be entitled

to use or permit the use of the information accepted as classified confidential without the written consent of the importer or exporter. However, if the NCA rejects the request, it must provide reasonable and sound reasons for such rejection, prior to disclosing that information. If disclosure of confidential information is the only course then importer or exporter will be given the choice to withdraw the application along with the confidential information.

5 MONITORING, INSPECTION AND ENFORCEMENT

5.1 Current Situation

The most relevant agency for monitoring, enforcement, and inspection of the regulatory system proposed in the NBF is BAFRA. BAFRA was created to promote the quality of goods and services related to the Ministry of Agriculture and its clients, and to coordinate and liaise with other agencies that are related to regulations and quality of the products that are locally produced and also those imported. Existing systems for monitoring food safety, import of seeds, plants, and animals that are administered by BAFRA are described below.

BAFRA regulates the quality of products that are both locally produced and imported for domestic market in accordance with set standards by Chapter VIII (Sections 61 to 64) of the Food Act.

BAFRA ensures that available food in the market is of good quality and safe for human consumption by checking against adulteration, contamination, pesticide residue levels, heavy metal contamination and general hygiene in collaboration with other relevant organizations including the Department of Health Services. Specifically, BAFRA's system for monitoring and enforcement is by applying Chapter VI (Sections 33 through 52) Chapter VII (Sections 53 to 60), and Chapter IX (Sections 68 to 71) of the Food Act.

The major responsibility of the food inspectorate under BAFRA is to ensure that all food sold to the people are clean to prevent diseases and of adequate quality to meet the necessary standards e.g. heavy metals, pesticide residues, microbial problems, etc. in accordance with the sections of the Food Act above. As of now:

1. The National Quality Control Laboratory (NQCL) of BAFRA consisting of the Food Laboratory, Seed Laboratory and the Veterinary Laboratory have been constructed.
2. Basic analyses are done at the NQCL. For more sophisticated analysis, samples are carried or sent outside the country to reference labs. BAFRA has plans to update the capacity to be able to analyze within country.

3. BAFRA has contact with Referral Laboratories outside the country to cross check analytical methods.
4. The Food Laboratory has two major sections viz. food chemistry and food microbiology
5. The Plant Laboratory has sections such as seed health testing, seed germination and viability testing
6. The Veterinary Laboratory has sections such as feed testing, serology, parasitology, bacteriology and virology
7. Apart from the NQCL, BAFRA has immediate future plans to establish satellite laboratories at the five entry points of imports into Bhutan.
8. Laboratory staff have been recruited i.e., Analysts, Technicians and Assistants. However none have any training related to biotechnology and biosafety.
9. Equipment such Gas Chromatograph (GC) (for pesticides), Atomic Absorption Spectrophotometer (AAS) (for heavy metals), basic glassware and expendables have been procured. However, specific equipment for molecular work to extract, identify, amplify, and sequence genetic material for biosafety analyses are not available.
10. BAFRA is in the process of framing the rules and regulations for implementation of the Food Act
11. BAFRA is the contact point for Codex Alimentarius Commission;
12. 29 food inspectors have been trained at NRTI and are posted in the field.

BAFRA also checks the flow of diseases and pests pertaining to food and agriculture crops and livestock to prevent introduction of pests and diseases that are not in the country or widespread in the country. BAFRA's system for enforcement and monitoring is by applying relevant chapters of the Plant Quarantine Act, Livestock Act, and Seeds Act.

1. Quarantine is enforced strictly for all livestock, vaccines, biologicals, plants, and seeds entering the country to prevent the entry of livestock diseases which may become detrimental if not checked;
2. Import permit must be obtained from BAFRA and all conditions specified in the import permit must be fulfilled including keeping the animals in quarantine to observe for diseases symptoms;
3. Plans are in place to construct and equip livestock quarantine stations at all the entry points simultaneously with training of quarantine personnel.

4. For all products imported, an import permit must be obtained;
5. When these products are brought into the country, they are inspected and certificates issued.

Therefore the main instrument used by BAFRA in the implementation of the Acts and monitoring is by issuing permits and certificates. For any import or export of agricultural goods, plant, animal, seeds, and foods, necessary permits have to be obtained from the BAFRA headquarters. Likewise for the movement of products within the country, movement permit is issued by the inspectors posted at the various entry points, regions, districts and major towns where relevant.

5.2 Gaps

The surveys executed during the first phase of the project showed that there is a general lack of capacity and trained experts in the field of biosafety and modern biotechnology and therefore the NBF aims to address that.

5.3 Proposed Monitoring Protocol

The proposed monitoring protocol for BAFRA and other relevant agencies is designed so as to ensure risks can be contained immediately in the case of unintended or accidental or deliberate release of GMOs. Monitoring needs to focus on:

1. Field trial of GMO crops by the agricultural research centers if they are permitted to do so;
2. Illegal transboundary movement of GMOs and their products and reporting of risks to appropriate agencies including the police and other appropriate ministries;
3. Contained use and reporting of risks to appropriate agencies for action;
4. Deliberate release of GMOs into the environment;
5. Commercial use and placement on the markets of GMO products by food importers;
6. Impact of GMOs on biological diversity.

5.3.1 Research Monitoring

Any future research proposals involving GMOs will also have to be monitored. Regulators will have to ensure that useful information is generated through any proposed research on GMOs. It will be the mandate of BAFRA to set plans and parameters for monitoring and to evaluate the data that is gathered. BAFRA and the researchers also need to identify clearly what needs to be monitored, how this should be done, and how the data will be used.

The monitoring plan will include the following main parts:

1. General strategy;
2. Program;
3. Data analysis, reporting, subsequent repeated examination;
4. Any remedial measures.

A general monitoring strategy is first prepared from data and research analyses done for similar cases and posted on the BCH, or from data gathered during the experimental phase of deliberate release into the environment, before placing on the market. Such a strategy needs to tackle all areas that may be at risk from a given GMO. For the implementation of the general monitoring strategy, a monitoring program is prepared on a case-by-case basis, meaning that different methods will be adopted for different GMOs.

The program will include the following information:

1. Identification of parameters and sites to be monitored, with adoption of approved sampling techniques and GMO detection methods;
2. Frequency of monitoring, number and time for inspections;
3. Methods for data gathering and analysis (use of statistical methods when needed);
4. Formats for data registration and aggregation (logbook for data collection);
5. Principal executives of the monitoring program, including the applicant, ministries and other governmental institutions;
6. Methods for public information dissemination of monitoring results (through the BCH);
7. Risk management plans in case of accidental releases.

5.4 Inspection

The main institution responsible for inspection will be BAFRA. Another lead agency will be the Department of Revenue and Customs given that they have checkposts and agents at all the main entry points for imported FFPs into Bhutan. Another important monitoring, inspection, and enforcement agency will be the Ministry of Health.

Field inspectors of these agencies need to have legal support and technical skills regarding biosafety. The day-to-day activities of an inspector could include inspection of facilities, imports, shipments, field trials, commercial field releases, as well as the follow up of reports of non-compliance.

Inspection should usually be followed by enforcement in the case of non-compliance.

5.5 Enforcement

The purpose of the enforcement mechanisms is to seek to establish that GMOs or their products which are being imported, developed, fermented, field tested, or released into the environment or placed on the market, comply with the mandatory biosafety requirements.

The responsibility for enforcement falls primarily on BAFRA and other concerned ministries. Inspectors need to provide evidence to support any legal action that is taken. If an inspector, during the performance of his or her work, or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment or human health are at risk because of possible adverse effects, the inspector may advise the following measures:

1. Prohibit contained use, release of a GMO into the environment, or placing a product on the market;
2. Order the temporary suspension of contained use, release of GMOs into the environment, or placing a product on the market;
3. Order the rectifying of established irregularities within a specific time limit;
4. Order remediation and other measures for rectifying or reducing the consequences of adverse effects that have occurred.

BAFRA will consider the advice, conduct necessary investigation, and communicate an informed decision to all concerned accordingly.

5.6 Responsible Agencies

5.6.1 Bhutan Agriculture and Food Regulatory Authority as the National Competent Authority

BAFRA is the main responsible authority regarding monitoring, inspection and enforcement. BAFRA is responsible for inspection of whether the foreseen monitoring plan or conditions for the granting of authorizations are being observed. It needs to inspect whether the actual GMO conforms to the risk class indicated, and depending on the nature of the GMO in question, whether other concerned ministries have been informed. BAFRA has to coordinate closely in this regard with other ministries and with customs authorities in particular.

BAFRA shall also carry out safety control of placing on the market of GMOs and their products, including the control of food products at the customs area, and border control and market surveillance of GM animals, plants, seeds, reproductive material, GMO-containing products including those of animal origin, and industrial feedstuffs.

5.6.2 The Ministry of Health

The Ministry of Health shall advise BAFRA on:

1. import of drugs, vaccines and pharmaceuticals into the country
2. research on GMOs drugs and vaccines on human subjects
3. genetic research of the Bhutanese genome
4. effect of GMO foods on human health

The Ministry of Health in addition shall have the following enforcement authority regarding biosafety issues:

1. Stop unauthorized research of GMOs on human subjects
2. Seize and destroy illegal drugs and vaccines
3. 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.

5.6.3 Ministry of Trade and Industry

The Ministry of Trade and Industry will be involved in the issuance of import licenses/permit to FFP importers. It will also coordinate with BAFRA to monitor and control the labeling and packaging of imported FFPs.

5.6.4 Ministry of Finance, Department of Revenue and Customs

The Department of Revenue and Customs has inspectors and checkposts at all entry points into Bhutan. They can greatly complement the work of BAFRA and close coordination will enhance monitoring and inspection.

5.7 Capacity building needs

BAFRA and other responsible agencies need to develop capacity for enforcement, inspection, and monitoring. These can range from awareness on biosafety by senior officials to practical training for inspectors. Specialized equipment and training on biosafety are urgently required.

6 PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

6.1 Current Situation and Gaps

As of now public awareness, education, and participation with biosafety-related issues is non-existent. However, public awareness programs in other sectors with regards to health and diseases awareness, agricultural extension, and so on do exist.

The Information and Communication Bureau, Ministry of Health is the leading institution in health education and communication and aims to achieve a significant reduction in morbidity and mortality through changing health behavior. This is done by developing and implementing communication initiatives such as through newspaper advertisements, TV commercials, and door to door campaigning.

The Information and Communication Services (ICS) of the Ministry of Agriculture is the communication arm of the Ministry of Agriculture. It consists of four functional sections, which are: Publication Section, Audio/Video Section, Information Technology Section and One Stop Information Shop Section. Its mandate is to design, develop, and produce information and communication materials in support of the Renewable Natural Resource (RNR) programs, serve as the portal of RNR information and activities and promote RNR programs and activities. It is in the same ministry as BAFRA and often employed by BAFRA for publicity campaigns.

6.2 Proposal for Public Awareness, Education and Participation in Decision-making Process

The draft Constitution of Bhutan guarantees the right to information for all citizens. The public can be meaningfully engaged in the decision-making process regarding biosafety in Bhutan through awareness and participation. Therefore raising the awareness of the public in general in the field of biosafety, and establishing a BBCH with all relevant

biosafety information in Bhutan are two key objectives to ensure effective public involvement and participation.

BAFRA and other agencies therefore need to develop and implement programs for public awareness, education and participation, including public access to information, concerning the safe transfer, handling and use of GMOs. In particular BAFRA can make effective use of the media to promote public awareness and education concerning the safe transfer, handling and use of GMOs. BAFRA should also submit to the BCH information regarding their capacity needs, gaps, programs and priorities with respect to public awareness, education and participation.

6.2.1 System for public participation

The creation of the BBCH will create an information field to be used by all stakeholders and the public. It is recommended that the website www.biosafety.gov.bt be reserved for the BBCH site.

Other means of information dissemination can be through provision of information on modern biotechnology by mass media, popular publications such as newspapers, radio, and television. The ICS of the MOA can be tapped by BAFRA to disseminate critical biosafety information.

Increasing public participation in decision-making processes can be facilitated through public hearings on proposed releases of GMOs by applicants, and proposed imports of GMOs by import houses. The outcomes of these public consultations must be legally recognized and the formulation of the Rules and Regulations of the Food Act must give due consideration for this requirement. Definite standards and procedures for public consultation must be specified in the Rules and Regulations.

Applicants and importers will have to submit information in local spoken language for the population through selected communication means such as the media and the BBCH.

Information has to be sent in a timely manner by official correspondence and also by mass media into Dzongkhags and Geogs where field tests or commercial release will be organized.

The process of public discussions regarding an application should not exceed 60 working days including submission of written comments via the proposed future BBCH. All received public comments and written recommendations have to be considered in the process of decision-making.

The right of the public and the relevant stakeholders to obtain information about applications for import,, development, fermentation, field test, handling, transboundary movement, transport, use, transfer, release and management of GMOs, as well as participation in the decision-making process shall be respected. BAFRA will, in collaboration with other concerned ministries, and subject to the reasonable provisions to protect confidential information, disclose all information on such applications, related studies, and final decisions, in a prompt and timely manner. For 60 [Please decide on this in view of earlier comments] days, the public will have the opportunity to respond in writing to the Applicant concerning the proposed application. In addition, opportunities for participation shall be made available through public hearings and announcements for public comments. For this purpose, during the 60-day period, discussions with stakeholders and the general public will be held by the Applicant, following consultation with BAFRA. Public response and feedback have to be taken into account by the Applicant in the application and by BAFRA in the decision-making process.

6.2.2 Mandate on Public Participation:

The concerned government departments and agencies, in making biosafety decisions, shall promote and facilitate public awareness, education, and participation concerning the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms. They shall incorporate into their respective administrative issuances and processes best practices and mechanisms, in Bhutan and internationally, on public participation.

6.2.3 Scope of Public Participation:

Public participation shall apply to all stages of the biosafety decision-making progress from the time the application is received. It shall apply, as appropriate, to scientific risk

assessment and socio-economic risks evaluation.

6.2.4 Minimum Requirements of Public Participation:

In conducting public participation processes, the following minimum requirements shall be followed:

a) Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective.
b) Adequate and reasonable time frames for public participation procedures.
c) Public consultations, as a way to secure wide input into the decisions that are to be made. These could include public hearings in certain cases, particularly where there is public concern about the proposed measures. These consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged.
d) Procedures for public participation should include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions.
e) Consideration of public concerns in the decision-making phase following consultation. Public opinion as gauged through the procedures for public participation must be taken into account in the decision. The public must be informed of the final decision promptly, have access to the decision, and must be provided with the reasons and considerations resulting in the decision.
f) Decisions are to be publicly notified with reasons.

6.2.5 Information on Applications

The right of the public and the relevant stakeholders to information about applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms shall be respected. Concerned

governments and agencies shall, subject to reasonable limitations to protect confidential information as provided below, shall disclose all information on such applications in a prompt and timely manner using the media.

6.2.6 Confidential Information:

Concerned departments and agencies shall ensure that it has procedures to protect confidential information. For applications to import genetically modified organisms into Bhutan, such departments and agencies shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms. The protection of confidential information is subject to the following requirements:

a. The declaration of confidentiality of commercial information is subject to proof that the information specified in the application is: a trade secret; or any other information that has a commercial or other value that could be destroyed or diminished if the information were disclosed; or other information that concerns the lawful financial and commercial affairs of a legal or physical person and that if it were disclosed it could reasonably affect that person.

b. The concerned governments and agencies may refuse declaring the confidentiality of such information if it is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

c. If an application is withdrawn, the concerned departments and agencies shall respect the confidentiality of commercial and industrial information, including research and development information.

d. In no case shall the following information be considered confidential:
    i. The name and address of the applicant;
    ii. A general description of the living modified organism or organisms;
    iii. A summary of the scientific risk assessment conducted by the applicant;
    iv. Where applicable, any methods and plans for emergency response.

6.2.7 Information on Biosafety Decisions:

The public and relevant stakeholders shall have access to all biosafety decisions approving or denying applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of genetically modified organisms. Such decisions must summarize the application, the results of the scientific risk assessment and the evaluation of socio-economic risks, the public participation process followed, and the basis for approval or denial of the application.

6.2.8 Raising Public Awareness

Currently there is no system for promoting public awareness and education on biosafety in Bhutan. The Information and Communication Bureau (ICB) of the Ministry of Health and the Information and Communication Services (ICS) of the Ministry of Agriculture are the communication arms of the relevant ministries. Under Access to Information of the NBF, the public and stakeholders shall have access to all biosafety decisions and the information on which they are based, subject to limitations set in Section 6.3 on confidential information. Existing capacity at ICB and ICS can be further developed and used to raise public awareness on biosafety

6.3 Capacity building needs

Technical capacity to develop the BBCH is crucial. In addition infrastructure such as powerful computers and servers to support the BBCH is needed. Also, relevant people need to be trained on biosafety issues and effective dissemination techniques.

The ICS and ICB capacity for raising public awareness on biosafety needs to be developed. Since infrastructure and trained staff already exists in these sections, value addition with specialized biosafety information can go a long way in facilitating public awareness and education on biosafety.

One particular target can be the retail food importers who import large quantaties of processed and packaged foods from India and other countries. Awareness on biosafety was non-existant among this gtoup as revelead during the surveys and as a group they form the single most important group which needs to be aware of biosafety concerns.

Special awareness workshops and training for this group is essential and capacity for conducting such awareness workshops needs to be developed. Consumers of these imported foods also need to be made aware of what they are eating and the use of popular media can reach this group effectively. Funds and capacity at the ICS and ICB are needed to produce TV commercials, brochures, and newspaper advertisements to reach this group. Capacity and funds to have all imported foods labeled are needed.

Another important group are farmers who are mostly illiterate. Audio-visuals and radio programs can reach this group more effectively and funds and capacity at ICS and ICB are needed to reach this group.

Agricultural experts working in the Ministry of Agriculture are another important group who can be harnessed to collect information on GMOs and inform colleagues, farmers, and consumers on biosafety. Raising awareness among this group on biosafety can lead to ethical work and research practices.

The NBF for Bhutan is timely and addresses the concerns of Bhutan as a landlocked country with an open and porous border. Bhutan's major concern is the safety of its citizens and its almost pristine environment. Yet at the same time increasing food security and food self sufficiency are critical objectives pursued by Bhutan as a sovereign kingdom. The use of biotechnology to achieve these objectives cannot be denied. Therefore the NBF is a balanced approach to safeguard Bhutan while meeting important food security objectives.

ANNEX 1

Draft
Biosafety Rules and Regulations of Bhutan, 2006

Preamble

Whereas the Food Act of Bhutan, 2005, under Sections 59 and 60 empowers the Ministry of Agriculture to adopt Biosafety Rules and Regulations to regulate genetically modified organisms as specified in the Act; and

Recognizing that the objective of the Ministry of Agriculture with respect to biosafety within the purview of the Food Act, 2005, is to regulate the use of genetically modified organisms in the Kingdom in order to enable the country to benefit from modern biotechnology and at the same time to assess and control potential risks associated with genetically modified organisms and products containing them, to protect the environment and the people of Bhutan from potential negative effects;

The Ministry of Agriculture hereby adopts this Biosafety Rules and Regulations.

TITLE, EXTENT, AND COMMENCEMENT

1. This Rules and Regulations shall be called the Biosafety Rules and Regulations of Bhutan, [2006].

2. It shall extend to the whole of the Kingdom of Bhutan.

3. It shall come into force from the date specified in the notification of enforcement issued by the Minister for Agriculture.

PURPOSE

4. The purpose of this Rules and Regulations is to provide for the assessment, management and control of potential risks associated with genetically modified organisms (GMOs) and GMO products, and activities associated with them, in order to

enable the country to benefit from modern biotechnology and at the same time to protect the biodiversity and people of Bhutan from their potential negative or adverse effects.

SCOPE

5. This Rules and Regulations applies to:

   a. All stages of import, development, fermentation, field testing, export, contained use, intentional introduction into the environment, direct use as food, feed or for processing, and any other type of use of GMOs for any purpose, including pharmaceuticals for human and veterinary use; and
   b. All persons within the jurisdiction of the Kingdom and all Applicants.

DEFINITION OF TERMS

7. For the purpose of this Rules and Regulations, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise:

   a. "Applicant" means a person, national or non-national, that notifies its intent and/or applies for prior approval to carry out any activity or operation including but not limited to import, export, contained use, and deliberate release of any genetically modified organism for any purpose in the Kingdom. "Applicant as used in this Rules and Regulations has the same meaning as "notifier" as that term is used in the Cartagena Protocol on Biosafety.

   b. "Application" means the documentation that must be submitted to request prior approval of any activity involving GMOs and GMO products. "Application" as used in this Rules and Regulations includes "notification" as that term is used in the Cartagena Protocol on Biosafety.

   c. **"**Biosafety**"** means the avoidance of risk to human health and safety, and to the conservation of the environment as a result of the use for research and commerce of infectious or genetically modified organisms.

   d. "Biosafety Clearing House" means the global and national mechanisms established to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms.

e. "Contained use" means any operation, including import into containment, development, fermentation, field testing, undertaken within a secure facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

f. “Emergency” means any significant unintended release into the environment of genetically modified organisms or products of genetically modified organisms which could present an immediate or delayed hazard to human health or the environment.

g. “Genetically modified organism (GMO)” means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology and which does not occur naturally by mating and/or natural recombination and includes both living and non-living modified organisms.

h. “GMO product” means any commodity, other than pharmaceuticals for humans, which consists of or contains a GMO or a combination of GMOs.

i. “In-country operations” means any undertaking, authorized or unauthorized, and including but not limited to national public and private sector research, projects, enterprises, and undertakings funded through overseas development assistance and foreign direct investment that involves the import, export, transit through, and/or any use of any genetically modified organism for any purpose in the Kingdom.

j. “Intentional introduction” means any release into the environment that is not contained use, including release for bioremediation, field release, planting and release into water and/or air, of genetically modified organisms subject to this Rules and Regulations with the exception of those imported for direct use as food or feed, or for processing.

k. “Kingdom” means the Kingdom of Bhutan.

l. “Living modified organism (LMO)” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

m. “Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

n. “Operator” means a legal or natural person, national or non-national, whether authorized or unauthorized, that undertakes any activity or operation including but not limited to import, development, fermentation, export, contained use, intentional release into the environment, and field testing of any GMO for any purpose in the Kingdom.

o. “Person” includes natural persons, which means an individual in his/her personal capacity, and legal persons, which means a company, un-incorporated association, Government agency, a natural person in his or her capacity as a legal representative, and any body of persons recognized as a separate legal entity.

p. “Risk assessment” means evaluating the potential risk to human health and the environment, including biological diversity, that is associated with a GMO or GMO product, estimating the likelihood that the risk will occur, and estimating how much damage would be caused if the risk does occur.

q. “Risk management” means adopting methods intended to reduce and/or mitigate the identified potential risk of a GMO or GMO product to an acceptable level and includes monitoring and subsequent modification, if necessary, of any methods used.

r. “Working days” means days other than national and public holidays and Saturdays and Sundays.

MANAGEMENT

8. The National Environment Commission (NEC) is the highest-level national body on issues related to biosafety and is designated as the national Focal Point responsible for

liaison with the Secretariat of the Cartagena Protocol to the Convention on Biological Diversity. The functions of the NEC with respect to the implementation of this Rules and Regulations shall be:

a. Make all policy-level decisions regarding the implementation of this Rules and Regulations;
b. Maintain communication with the global Biosafety Clearing-House (BCH);
c. Notify the BCH and relevant international organizations of any event in the Kingdom that may result in the unintentional transboundary movement of a LMO;
d. Establish and maintain the Bhutan Biosafety Clearing-House (BBCH);
e. Initiate analysis of the effectiveness of the National Biosafety Framework.

9. The Bhutan Agriculture and Food Regulatory Authority (BAFRA) is designated as the National Competent Authority for the purpose of administering this Rules and Regulations. BAFRA has the sole authority to grant or deny permission for import, export and use of GMOs and GMO products in the Kingdom. In implementing this Rules and Regulations, BAFRA shall perform the following functions:

a. Establish the procedure for assessing the risks presented to the environment, human and animal health by GMOs and their products, and the information required for risk assessment;
b. Develop forms, guidelines, codes of practice, containment standards, and other tools necessary;
c. Categorize GMOs and GMO products on the basis of the risk they represent and prepare an Annex to this Rules and Regulations that shall be updated periodically, as and when required;
d. Formulate guiding principles for the implementation of the administrative process which may include all the procedures on decision-making, including consultations with the public;
e. Set fees and charges;
f. Consider applications, review the recommendations of the NCB before issuing final decisions, prepare summaries of final decisions for the BBCH, and notify the public of its decisions and the justification for them;
g. Ensure that mechanisms are in place to communicate information and receive comments concerning applications, decisions, emergencies, and other matters

related to GMOs and GMO products, including but not limited to through the BBCH;

h. Ensure the protection of all information that BAFRA agrees to treat as confidential in the prior approval process;
i. Periodically review its prior decisions on import and export of GMOs and GMO products and revise them at its discretion;
j. Establish and maintain a registry of GMOs and GMO products that have been approved for in-country operations;
k. Issue guidelines on obligatory labeling requirements for GMOs and GMO products;
l. In coordination with other relevant national authorities, develop special safety and emergency measures to respond to and contain the effects of any risks and damages that might result from an unintentional transboundary movement or any activity that relates to GMOs;
m. Monitor conditions and developments in the field of use of genetic technologies and GMO management;
n. Organize public awareness initiatives on the national policy, guiding principles and other measures related to biosafety;
o. Adopt positions, provide opinions, advise the Government and inform the general public about initiatives, conditions and developments in the field of the use of modern biotechnology as well as the social, ethical, technical and technological, scientific and other aspects of GMO management;
p. Enforce this Rules and Regulations and monitor compliance with it; and
q. Any other function that may be assigned by the Ministry of Agriculture and/or the NEC.

10. BAFRA, in consultation with the NEC, shall constitute the National Committee on Biosafety (NCB) as a technical advisory body to provide scientific and other technical advice to BAFRA in reviewing notifications, applications, risk assessments and approvals, and in setting standards for in-country operations involving GMOs subject to this Rules and Regulations. The functions and responsibilities of the NCB shall include:

a. As requested by BAFRA, review applications and the accompanying risk assessments for permission to import, develop, ferment, field test, release, export or use GMOs or GMO products and recommend to BAFRA whether additional risk assessment is required;

b. Advise and assist BAFRA in categorizing GMOs and GMO products on the basis of the risk they represent and in updating the categorization, as required;
c. Prepare a scientifically-based template report for the results of risk assessments with recommendations for the action to be taken on the application and, if the recommendation is to approve the application, for actions to be taken to minimize the risks of the GMOs or GMO products involved;
d. Respecting all restrictions with respect to any confidential information that may be made available to it;
e. Recommend to BAFRA containment measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures;
f. Advise BAFRA on developing guiding principles on risk assessment;
g. Advise BAFRA on developing action plans in accordance with the national priorities of the biosafety policy;
h. Advise BAFRA on mechanisms and procedures to be put in place to prevent the intentional or unintentional release of GMOs into the environment, and the emergency measures that should be activated if and when such unintentional release occurs; and
i. Any other function that may be assigned by BAFRA and/or the NEC.

11. The NCB shall consist of members with relevant and necessary expertise. The members shall appoint a Chair and BAFRA shall be the Secretariat.

12. The Chair in consultation with the members may remove a representative where the NCB has determined and recommended to the Chair that representation by that organization or unit is no longer essential to the functioning of the NCB.

13. The Chair in consultation with the members may appoint any additional representative or representatives where the NCB has determined and recommended to the Chair that representation by such additional organization or unit is essential to the functioning of the NCB.

14. All members of the NCB shall hold office unless and until removed by the Chair.

15. A member of the NCB may resign in writing to the Chair; a replacement shall be appointed within 20 working days.

16. The NCB may make provision for the scheduling and conduct of its meetings and the procedures to be followed at its meetings. It shall meet as requested by BAFRA and no less than once a year.

17. The NCB may form such temporary committees or working groups, made up of NCB members, non-NCB members or both, as it deems fit, to analyse and report on such technical issues as it may assign to them.

18. Where the NCB so authorises, representatives of government organizations and agencies, as well as industry and consumer groups, may attend meetings of the NCB but may not vote.

RISK ASSESSMENT AND MANAGEMENT AND ENVIRONMENTAL CLEARANCE

19. Risk assessments and accompanying data and records must be submitted with all applications for prior approval for import of GMOs and GMO products and in-country operations involving GMOs and GMO products.

20. Risk assessments must be carried out on a case-by-case basis and must be based on actual biophysical and socio-economic conditions in the Kingdom at the time of assessment. At a minimum, the risk assessment must contain the information indicated in Annex 1, and must indicate specific risk management measures that may be applied.

21. Risk assessment is the responsibility of the Applicant or Operator, who bears all costs.

22. Environmental clearance may, under the terms of the Environmental Assessment Act, 2000, and its Regulation for the Environmental Clearance of Projects, as revised from time to time, be required for any application for prior approval for import of GMOs and GMO products and in-country operations involving GMOs and GMO products. Preparation of an environmental assessment is the responsibility of the Applicant or Operator, who bears all costs.

23. Risk management measures must be determined on a case-by-case basis, according to the characteristics of the GMO and/or GMO product and activities involved, and must be appropriate to the level of assessed risks.

24. Risk management is the responsibility of the Operator, who bears all costs.

PROCEDURES

25. The requirements specified in Sections 25-43 apply to all applications for prior approval for import and export and for in-country operations involving GMOs and GMO products in the Kingdom.

26. All documentation must be submitted in either English or Dzongkha to BAFRA.

27. All applications for prior approval must include a sworn declaration that the information contained in them is correct.

28. All procedures are subject to payment of non-refundable administrative fees. Fees shall be stipulated by BAFRA and shall be notified from time to time.

29. All in-country operations involving GMOs and GMO products are subject to payment of a security bond which amounts to 25% of the total value of the activity or operation must be deposited with BAFRA at the time of prior approval. The amount of the bond shall be returned to the Operator, without interest, on completion of the activity or operation for which prior approval or permission is granted. The security bond shall be used, if needed, to recover any unforeseen costs associated with issues of non-compliance and/or for risk management actions.

30. All Applicants must initiate preliminary consultations with BAFRA prior to preparing an application for prior approval of import, export and/or in-country operations involving GMOs and/or GMO products. Based on advice from BAFRA, an Applicant may proceed to prepare the application.

31. All Applicants for prior approval to import and/or use GMOs and/or GMO products shall, if so instructed by BAFRA, at their own expense conduct consultations to

inform the public, in layperson's terms, about the GMOs and/or GMO products involved in its application, specifically describing the potential risks and advantages of the GMOs and/or GMO products involved in the operations covered by its application, and to document public comments about the application.

32. At a minimum, these consultations shall include:

a. Initial publication, in at least three (3) newspapers of national circulation, of a description in layperson's terms of the purpose of the application and the GMOs and/or GMO products involved;
b. Supplementary written initial notice to be circulated through the chief Geog and/or Dzongkhag officials in the Geogs and/or Dzongkhags in which the proposed operations will be carried out;
c. Public hearings. Notice of public hearings shall be published in at least three (3) newspapers of national circulation at least one (1) week before the hearing. Supplementary written notice shall be given at the time of the newspaper publication to the chief Geog and/or Dzongkhag officials for circulation among local communities.

33. BAFRA may require the Applicant to submit a proposed plan for public consultation that includes public notice and review procedures beyond the minimum requirements described above. BAFRA may require changes to the proposed plan in order to ensure that concerned people and organizations are well-informed, that they are given adequate opportunity to express their views on the application, and that their views are adequately taken into account in the application. When BAFRA is satisfied that the Applicant's proposed plan for the public consultations will ensure that the views of concerned people and organizations are adequately taken into account, it shall approve the plan.

34. The Applicant shall immediately inform BAFRA of any proposed changes to the implementation of the plan. BAFRA shall review and evaluate implementation of the public consultation process and verify its findings.

35. Geog and/or Dzongkhag officials shall be responsible for helping concerned people express their views to the Applicant during the public hearing. Geog and/or Dzongkhag officials may represent the community and shall do their best to ensure that

local concerns are adequately and appropriately expressed to the Applicant. This includes, among other things, making copies of all environmental assessment documents and decisions available to the affected community and open for public inspection.

36. Comments from the general public and government agencies shall be submitted to the Applicant within 15 working days from the initial publication in national newspapers.

37. The Applicant shall document all comments received from all sources and shall take them into account in the application.

38. The Applicant may, on payment of administrative fees as provided in Section 27, submit the application to BAFRA, indicating how public comments have been integrated into the application and annexing documentation of the results of the public consultation process.

39. The Applicant may clearly indicate in its application all information that is to be considered confidential. Confidential information in the application must be submitted under separate cover clearly marked "confidential". If BAFRA determines that any of the indicated information does not qualify for consideration as confidential, BAFRA shall notify the Applicant and give the Applicant opportunity to provide additional justification for the request for confidentiality. If the Applicant accepts BAFRA's decision on confidentiality and proceeds with the application, BAFRA shall be responsible for ensuring the confidentiality of the information it has determined may be considered confidential. If the Applicant does not accept BAFRA's decision on confidentiality, it may withdraw the application.

40. BAFRA shall review each application as specified in Sections 44-46. BAFRA may forward any application to the NCB for its technical opinion and recommendations. BAFRA may forward to the NEC for its review and direction, any application which BAFRA believes presents one or more issues having long-term national implications.

41. In approving any application that does not require environmental clearance, BAFRA may impose specific risk management measures, labeling or marking requirements, and/or other conditions.

42. BAFRA shall announce its final decisions on applications accompanied by a non-technical summary of the decision and justification for it within fifteen (15) working days of the date on which the decision was taken. The announcement shall be made by publication in at least three (3) newspapers of national circulation at the cost of the Applicant.

43. For any import of GMOs or GMO products the importer must notify BAFRA in writing thirty (30) working days) prior to the scheduled arrival of the shipment.

44. BAFRA may at any time suspend or revoke approval to import a GMO or GMO product on the following grounds:

a. Evidence of incomplete or false information in the documentation for the original application for prior approval;
b. Non-compliance with or violation of any of the conditions of approval;
c. Refusal to allow inspection of the facility or facilities where the GMO or GMO product will be stored, used and/or disposed;
d. Suspension or revocation of the operating authorizations of the importer in the Kingdom or the exporter in the country of origin;
e. Availability of new technical information indicating that the GMO or GMO product, if allowed for its intended use, will result in significant risks to human health and the environment; and/or
f. Other grounds as may be announced by BAFRA.

Intentional introduction into the environment

45. Each GMO for intentional introduction into the Kingdom's environment is subject to risk assessment and prior approval by BAFRA**.**

a. The Applicant must notify BAFRA of the intent to import and apply for prior approval. The application for prior approval must include all requirements specified in Annex 2 of this Rules and Regulations.

b. Within ninety (90) working days of receipt of the application, BAFRA must acknowledge receipt:
   (i) Indicating the date of receipt of the application;

(ii) Stating whether the application for prior approval is complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and

(iii) Advising the Applicant whether it may proceed to the approval process.

c. Failure by BAFRA to acknowledge receipt of an application within ninety (90) working days does not constitute acknowledgement or approval of the application.

d. Within two hundred and seventy (270) working days of the date of receipt of the application for prior approval, BAFRA shall communicate in writing to the Applicant its decision, indicating either:

(i) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same GMO; or

(ii) Denying approval of the proposed import.

e. Failure by BAFRA to communicate its decision within two hundred and seventy (270) working days does not mean that the application for prior approval is approved.

f. Approval to import a GMO for intentional introduction is valid for a period of one (1) year from the date of approval, unless renewed or revoked for any reason specified in Section 43. The Applicant must include the original approval with the application for a trade license.

Direct use as food or feed or for processing

46. The first import of a GMO or GMO product for direct use as food or feed or for processing is subject to risk assessment and approval by BAFRA.

a. The Applicant must notify BAFRA of the intent to import and apply for prior approval. The application for prior approval to import GMOs or GMO products for direct use as food or feed or for processing must include all requirements specified in Annex 2 of this Rules and Regulations.

b. Within ninety (90) working days of receipt of the application, BAFRA must acknowledge receipt:
   (i) Indicating the date of receipt of the application;
   (ii) Stating whether the application for prior approval is complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and
   (iii) Advising the Applicant whether it may proceed to the approval process.

c. Failure by BAFRA to acknowledge receipt of an application within ninety (90) working days does not constitute acknowledgement or approval of the application.

d. Within two hundred and seventy (270) working days of the date of receipt of the application for prior approval, BAFRA shall communicate in writing to the Applicant its decision, indicating either:
   (i) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same GMO; or
   (ii) Denying approval of the proposed import.

e. Failure by BAFRA to communicate its decision within two hundred and seventy (270) working days does not mean that the application for prior approval is approved.

f. When BAFRA approves a GMO or GMO product for direct use as food or feed or for processing, it must notify the NEC as National Focal Point for the Cartagena Protocol who must notify the BCH within fifteen (15) working days of approval.

g. Approval to import a GMO or GMO product for direct use as food or feed or for processing is valid for a period of one (1) year from the date of approval, unless revoked on any of the grounds set out in Section 43. Approval may be renewed for successive one-year periods upon showing by the

Applicant/Operator that continued import of the GMO or GMO product as food, feed, or for processing, does not pose any significant risks to human health or biodiversity. The Applicant must include the original approval with the application for a trade license.

Contained use

47. The first import of a GMO or GMO product for contained use is subject to risk assessment and approval by BAFRA.

a. The Applicant must notify BAFRA of the intent to import and apply for prior approval. The application for prior approval to import GMOs or GMO products for contained use must include all requirements specified in Annex 2 of this Rules and Regulations.

b. Within ninety (90) working days of receipt of the application, BAFRA must acknowledge receipt:
   (i) Indicating the date of receipt of the application;
   (ii) Stating whether the application for prior approval is complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and
   (iii) Advising the Applicant whether it may proceed to the approval process.

c. Failure by BAFRA to acknowledge receipt of an application within ninety (90) working days does not constitute acknowledgement or approval of the application.

d. Within two hundred seventy (270) working days of the date of receipt of an application for prior approval, BAFRA shall communicate in writing to the Applicant its decision, indicating either:
   (i) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same GMO; or
   (ii) Denying approval of the proposed import.

e. Failure by BAFRA to communicate its decision within two hundred seventy (270) working days of the date of receipt does not mean that the application for prior approval is approved.

f. Approval to import a GMO or GMO product for contained use is valid for a period of one (1) year from the date of approval, unless renewed or revoked for any reason specified in Section 43. The Applicant must include the original approval with the application for a trade license.

In-country operations

48. In-country operations are subject to prior approval by BAFRA.

49. For GMOs in transit through the Kingdom, Operators shall apply to BAFRA ninety (90) working days in advance of the beginning of the transit period, providing the following information:

a. name, address, and telephone contact information of the Operator;
b. name, address, telephone contact information of the carrier, if different from the Operator;
c. origin and destination of the shipment;
d. the identity and relevant traits and/or characteristics of the GMOs in transit;
e. any requirements for their safe handling, storage, transport and use; and
f. any other information that BAFRA may require at the time of receiving the application.

50. Establishment of any enterprise in the Kingdom that will involve GMOs and/or GMO products shall require prior approval by BAFRA before a license may be issued.

51. BAFRA must establish and maintain a register of GMOs and GMO products that have been approved for in-country operations.

52. No GMO or GMO product may be considered for intentional introduction or placing on the market unless it has been field tested under contained conditions in the

Kingdom, and has shown no harmful effects to the environment, biological diversity and animal and human health. Field testing must have prior approval of BAFRA.

53. BAFRA may suspend or revoke permission for in-country operations on any of the following grounds:

a. Provision of false information in the application;
b. Violation of any conditions specified in the permit;
c. Failure to allow inspection of the field testing site;
d. Receipt by BAFRA of new information that the field testing of the GMO or GMO product being field tested poses significant risks to human health and the environment:
e. Such other grounds as BAFRA may deem reasonable to prevent significant risks to human health and the environment.

Export

54. Any Applicant or Operator who intends to export GMOs and/or GMO products from the Kingdom for any purpose must first apply to the Competent National Authority of the proposed importing country according to the laws and regulations of that country. With the permission from the Competent National Authority of the proposed importing country, the Applicant must then apply to BAFRA for prior approval for the export, prior to applying to the Ministry of Trade for a trade license.

Appeal

55. Any decision by BAFRA to grant, impose conditions on, deny, or revoke permission to import or export GMOs and GMO products or to conduct domestic operations may be appealed within thirty (30) working days to the Ministry of Agriculture.

LABELING

56. All GMOs and GMO products used in the Kingdom, and those exported from the Kingdom must be clearly labeled. The labeling shall specify any requirements for their safe handling, storage, transport and use, and the contact point for further information, including the name and address of the individual and/or institution to which the GMOs are consigned.

57. GMOs that are intended for intentional introduction into the environment shall be clearly labeled to identify them as GMOs. The labeling shall specify:

a. the identity and relevant traits and/or characteristics of the GMOs in the shipment; any requirements for their safe handling, storage, transport and use;
b. the contact point for further information, including the name, address and telephone number(s) of the importer and exporter; and
c. a declaration that the transboundary movement is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

58. BAFRA shall issue guidelines on additional labeling, packaging, handling, transport, and storage requirements for GMOs and GMO products.

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

59. BAFRA shall ensure the participation of the public in the process of making decisions concerning GMOs as provided in Sections 30-36, as well as public access to non-confidential information related to GMOs in general and in particular to their presence and use in the Kingdom.

60. BAFRA shall coordinate with the NEC to ensure that announcements of applications for prior approval, opportunities for public comment, joint guidelines for monitoring and emergency response, and any other information relevant to the regulation and use of GMOs and GMO products in the Kingdom are made available to the BBCH in a timely manner.

MONITORING, EMERGENCY RESPONSE, COMPLIANCE AND ENFORCEMENT

Monitoring

61. BAFRA shall, in cooperation with the relevant agencies monitor all in-country operations involving GMOs and GMO products. BAFRA, in consultation with the relevant agencies shall issue guidelines for this purpose.

62. The NEC, in consultation and coordination with the Ministry of Agriculture and other relevant agencies, shall coordinate to monitor the impact of GMOs and GMO

products on human health and on the environment generally and on biological resources and biodiversity in particular. The NEC shall issue guidelines for this purpose.

Emergency response

63. BAFRA shall, in coordination with the relevant agencies, form an emergency response team to deal with emergencies involving GMOs or for the use of GMOs in an emergency within the Kingdom. BAFRA shall issue guidelines for these purposes.

64. In the event of an emergency involving a GMO or GMO product, any person with knowledge of the emergency must immediately inform BAFRA or Geog and/or Dzongkhag authorities who must immediately notify BAFRA.

65. In the event that an emergency may lead to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on the environment, on the conservation and sustainable use of biological resources or on human health, BAFRA shall immediately notify the NEC, which shall immediately notify the BCH, the potentially affected States, and any relevant international organizations.

Inspection

66. A BAFRA authorized official may, at any time, enter and inspect the facilities where any activities or operations involving GMOs and/or GMO products are being, or have been, carried out.

67. An authorized inspector who enters premises under Section 70 of this Rules and Regulations shall, upon request, provide proof of identity/identification and justification of their action to any person on the site.

68. During an inspection, the owner or person in-charge of the premises or vehicle:

a. may accompany the inspector;
b. shall supply any information or documents requested by the inspector relevant to any inspection object;
c. shall permit the taking of samples and evidence such as photographs.

69. An authorized inspector may at any reasonable time enter any premises except a private home to:

a. inspect or search any part of such premises, and examine any GMO and/or GMO product and/or any appliance, material, object or substance which is being or is suspected of being used or destined for use in connection with the import, export, treatment, packing, labeling, storage, transport, or handling of a GMO or GMO product;
b. demand from the owner or person in charge of the premises any information regarding any GMO and/or GMO product, and/or any appliance, material, object or substance at such premises;
c. weigh, count, measure, mark, seal, open and remove samples of any GMO and/or GMO product, and/or any material, object or substance at the premises, and/or lock, secure, seal or close any door or opening giving access to them;
d. examine or make copies of, or take extracts from, any book, statement or other document found at such premises which refers to or is suspected to refer to any GMO and/or GMO product, and/or any appliance, material, object or substance referred to in sub-Section a., above;
e. demand from the owner or any person in charge an explanation of any entry in any book, statement or other document at that premises;
f. inspect and demand from the owner or person in charge information regarding any operation or process used in the premises;
g. read any values recorded by measuring instruments installed at the premises;
h. make controls with his or her own instruments;
i. take photographs; and
j. seize any GMO or GMO product, and/or any appliance, material, object, substance, book, statement or document which appears to provide proof of a contravention of any provision of this Rules and Regulations, providing a signed receipt which shall be countersigned immediately by the owner or person in charge of the premises or object.

70. An authorized inspector may stop and search any vehicle in which any GMO and/or GMO product is being or is suspected of being treated, packed, stored, transported, or handled or in which any other operation or activity in connection with GMOs and/or GMO products is being or is suspected of being carried out.

71. An authorized inspector may stop and search any person whom he or she suspects of committing an offence under this Rules and Regulations. Where a person refuses to be

searched, such person may be detained for the conduct of search. The person so detained shall be handed over to the Royal Bhutan Police with a statement in writing of the grounds for such detention.

72. Where there is a clear and present danger for human health or the environment, an authorized inspector may immediately destroy or order the destruction of GMOs and/or GMO products at the owner's cost.

73. Where GMOs and/or GMO products are destroyed or ordered to be destroyed under Section 71, the authorized inspector must submit a sample of the GMOs and/or GMO products to an authorised laboratory.

74. BAFRA shall coordinate with the Department of Revenue and Customs and with the Ministry of Health to issue joint guidelines on the biosafety aspects of inspections for customs inspectors and health inspectors.

75. Where BAFRA has reasonable grounds to believe that any condition of a permit issued under this Rules and Regulations has been breached, BAFRA may serve an order on the holder of the permit in question:

a. requiring that person to remedy the breach within a specified period at his/her own cost; or
b. suspending the permit with immediate effect if this is considered necessary to prevent or mitigate an immediate risk of significant adverse effects to the environment or to human health.

76. Where the order served under Section 76 is not complied with, BAFRA may:

a. take the necessary steps to remedy the breach and recover the cost from the permit holder;
b. alter the conditions of the permit;
c. revoke the permit; and/or
d. refer the matter to the appropriate law enforcement agency.

77. When necessary to achieve compliance with this Rules and Regulations, BAFRA may call upon the assistance of any agency or law enforcing body, which shall provide full cooperation to inspectors performing their duties as provided in Section 69.

Liability

78. No authorized official of the Royal Government shall be jointly or severally liable in respect of anything done in good faith in the exercise of a power or duty under this Rules and Regulations unless the act or omission contravenes any of the provisions of this Rules and Regulations or any direction or order made pursuant to it. The relevant agency shall be liable for paying the appropriate compensation.

79. Any person who intentionally or negligently commits any act or is responsible for an omission involving GMOs and/or GMO products which causes damage or threatens potential harm to human health and the environment shall be liable for the costs of restoration and remediation.

Legal action

80. Legal action may be initiated by any person affected by damage or threatened by potential harm to human health or the environment caused by violations of this Rules and Regulations, on that person's own behalf or on behalf of that person and other affected persons having similar or common interests in the proceedings.

Offences and penalties

81. Offences under this Rules and Regulations which are listed in the Penal Code shall be penalized as provided in the Penal Code.

82. The following offences not listed in the Penal Code shall be penalized as follows:

a. The penalty for any transboundary movement of GMOs and/or GMO products that is not accompanied by the permits specified in this Rules and Regulations shall be a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate. The person responsible for the unauthorized transboundary movement of any GMO shall, at the discretion of BAFRA, repatriate or destroy the GMO at his/her own expense;

b. The penalty for breaching the conditions of a permit or order issued under this Rules and Regulations shall be payment of a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) month and not longer than one (1) year, or both, as appropriate;

c. The penalty for failure to comply with an order issued under this Rules and Regulations shall be payment of a cash fine equivalent to the value of the damage caused, imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate;

d. The penalty for making a statement that is false or misleading for the purposes of obtaining an authorisation under this Rules and Regulations shall be payment of a cash fine of not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate;

e. The penalty for making a statement that is false or misleading for the purposes of obstructing an inspector in the exercise or performance of powers or duties under this Rules and Regulations shall be payment of a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) month and not longer than one (1) year, or both, as appropriate.

83. If any of the offences set out in Sections 81 are committed by a corporation, the corporation and every director or officer of the corporation shall be jointly and severally liable. The penalty shall be payment of a cash fine of not less than one (1) per cent of the total value of the operation and not greater than ten (10) per cent of the total value of the

operation, or imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate.

Amendment

84. The Minister of Agriculture may amend this Rules and Regulations as and when deemed necessary.

ANNEX Ia

Risk Assessment

The objective of risk assessment is to identify and evaluate the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into accounts risks to human health.

1. Risk assessment must be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organizations.

2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk.

3. Risk associated with GMOs and GMO products must be considered in the context of the risks posed by the non-modified recipients or parent organisms in the likely potential receiving environment.

4. Risk assessment must be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case depending on the GMO or GMO product concerned its intended use and the likely potential receiving environment.

5. Risk assessment entails, as appropriate, the following steps:
    a) An identification of any novel genotypic and phenotypic characteristics associated with the GMO or GMO product that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risk to human health;
    b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO or GMO product;
    c) An evaluation of the consequences should these adverse effects be realized;

d) An estimation of the overall risk posed by the GMO or GMO product based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
e) A recommendation as to whether or not the risks are acceptable or manageable; and
f) Recommendations for appropriate risk management strategies and for monitoring the genetically modified organism in the receiving environment.

6. Depending on the case, risk assessment must take into account the following:

(a) Recipient organism or parent organisms. The biological characteristics of the recipient organism or parent organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organism;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristic of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Genetically modified organism. Identity of the genetically modified organism, and the differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parent organisms

(f) Detection and identification of the genetically modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment, and information on potential adverse or beneficial effects on the environment of the Kingdom of Bhutan.

ANNEX Ib

Information Required in Applications for Prior Approval for Import of GMOs

1. Name, address and contact details of the exporter

2. Name, address and contact details of the importer

3. Name and identity of the GMO or GMO product, as well as the domestic classification, if any, of the biosafety level of the GMO or GMO product in the State of export.

4. Intended date or dates of the transboundary movement, if known.

5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parent organisms.

6. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parent organisms and a description of the habitats where the organisms may persist or proliferate.

7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms.

8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO or GMO product.

9. Intended use of the GMO or GMO product.

10. Quantity or volume of the GMO or GMO product to be transferred.

11. A risk assessment report consistent with Annex 1.

12. Regulatory status of the GMO or GMO product within the State of export (for example, whether it is prohibited in the State of export, whether there are other

restrictions or whether it has been approved for general release) and, if the GMO or GMO product is banned in the State of export, the reason or reasons for the ban.

13. Written certification issued by the National Competent Authority of the State of export that attests to the accuracy of the information provided concerning the GMO to be imported.

14. Documented information on previous approvals or rejections by any other country of the GMO or GMO product proposed for import, including the result and purpose of any application for prior approval by the exporter to other States regarding the GMO or GMO product to be transferred.

15. Documented information describing a previous or current release in the Kingdom or in any other country of the GMO or GMO product proposed for import.

16. A comprehensive description of the intended use of the GMO or GMO product proposed for import, including proposed monitoring and evaluation of that use, and the method of disposing of any waste.

17. The location and a comprehensive description of the facility or facilities where the GMO or GMO product proposed for import is to be stored and used.

18. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures.

19. A description of remedial measures to be undertaken in the event of any unintentional release into the environment caused by the activities to be undertaken.

20. Any additional information which the Applicant deems relevant to an assessment of the potential risk and/or benefit of the intended use of the GMO or GMO product.

21. Any other information as may be prescribed by the NBC.

22. A sworn declaration that all information contained in all documentation submitted is factually correct.