Ministry of Forests and Soil Conservation
Kathmandu
Nepal

National Biosafety Framework

Nepal

2006

Acronyms

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CITES	Convention on the International Trade in Endangered species of Wild Fauna and Flora
CPB	Cartagena Protocol on Biosafety
DBCC	District Biodiversity Coordination Copmmittee
DDC	District Development Committee
DNA	Deoxyribonucleic Acid
EIA	Environment Impact Assessment
ELISA	Enzyme Linked Immuno Sorbent Assay
GEF	Global Environment Facility
GMO	Genetically Modified Organisms
HDI	Human Development Index
IEE	Initial Environment Examination
IPR	Intellectual Property Rights
IUCN	The World Conservation Union
MDGs	Millennium Development Goals
NARC	Nepal Agriculture Research Council
NAST	Nepal Academy of Science and Technology
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBS	Nepal Biodiversity Strategy
NBSIP	Nepal Biodiversity Strategy Implementation Plan
NCA	National Competent Authority
NGOs	Non-Governmental Organizations
OIE	Office International des Epizootics (World Organization of Animal Health)
PCR	Polymerase Chain Reaction
PPR	Pest de Petit Ruminants
R & D	Research & Development
RAPD	Random Amplified Polymorphic DNA
rDNA	recombinant Deoxyribonucleic Acid
RFLP	Restriction Fragment Length Polymorphism
RNA	Ribo Nucleic Acid
SCA	Sectoral Competent Authority
TADS	Transboundary Animal Diseases

TRIPS	Trade Related Intellectual Property Rights
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
VDC	Village Development Committee
WTO	World Trade Organization

Contents

Definition of Terms

“Advanced informed agreement” means the procedure applicable 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 measures to be taken to avoid or minimize of risk to human health and safety, and to the conservation of the environment likely to be caused from the research, transport, marketing and use of GMOs.

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

"Contained use" means any operation such as importation, development, fermentation or field test undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

"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.

“Genetically Modified Organism (GMO)”means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

“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.

"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 GMO to be imported;

“Intentional Introduction" means the deliberate release of GMOs resulting from modern biotechnology into the environment for the `purpose of field testing or commercialization, or the import of GMOs for the purpose of field testing or commercialization, this term does not refer to GMOs intended for contained uses that are subject to other measures, or for direct use as food or feed , or for processing.

"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 (rDNA) 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.

"**National Biosafety Framework or NBF"** is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

"**Proposal**" means a proposal prepared for import, intentional release into the environment, content use or marketing of GMOs.

"**Proponent**" means a person or an institution who applies for approval of a proposal and implement the approved proposal

"Release" means the use of GMO outside the constraints of physical confinement that are found in a laboratory, contained greenhouse,\or a fermenter or othert contained structure.

"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.

"Unintentional transboundary movement" means the movement of a GMO or GMO product into the country from outside its borders without going through the appropriate import procedures. This could occur either by introduction through accidental means, or by natural means such as movement of pollen or seeds.

Note: The word "Living Modified Organism - LMO" has been used in the Cartagena Protocol on Biosafety. Most of the countries advanced in the modern biotechnology have been using the word " Genetically Modified Organism - GMO" and is commonly used for the commercial purpose as well as by the larger mass of people. According to the definition of GMO, GMO includes LMO too. Hence in this NBF, the word LMO has been used in the relevant sentences in accordance with the Article of the Cartagena Protocol and in rest of the text the word GMO has been used.

CHAPTER 1: GENERAL INTRODUCTION

1.1 Country Background:

Nepal, situated to the south of the Himalayan Range, has an area of 1,47,181 square kilometres. The elevation of Nepal ranges from 60m to the highest peak in the world Sagarmatha (8848m) above mean sea level. The plain low land is situated in the southern part of the nation and the elevation rises gradually from the south to the north. The hills and the high mountain regions cover about 86% of the total area of the nation while the Terai plain land covers the remaining 14%.

Nepal's biological diversity is a reflection of the nation's peculiar geographical structure and climatic diversity. Because of the climatic diversity there is diversity in habitat, plants and animals. The seasonal variation in the climate such as the rains in the monsoon, snow fall in the winter and the increased temperature in the summer season has been reasons for the occurrence of diversity in the animal and plant species. The productive capacity of the land also differs according to the variation in soil structure of the different geological landscape.

The species diversity differs according to the elevation of the Nepal. The ecosystem in the Terai and Siwalik range, with altitude in between 60 to 1000m above the mean sea level, is important from the point of view of conservation of the world's endangered species. Accordingly, five protected areas have been established in this region, among them the Chitwan National Park is listed in the world heritage site too. The biological

diversity in the Terai is at high risk because of the increasing population in the region. The Middle hill region, with elevation ranging from 1000 to 3000 m above mean sea level, is recognized as the biodiversity rich area. About 32 per cent of the total forest area lies in this region. Protected areas in the high mountain region above 3000m cover about 78.52 percent of the region. There are 38 ecosystems in this region.

Figure No.1: A glimpse of Mid-hills to the high Himal landscape and biological diversity.

Nepal, though geographically small, is rich in biodiversity. Nepal represents 0.1 percent of the terrestrial area of the earth but it has 118 ecosystems and comparatively higher presence of different plants and animal species of the world. The data in the table 1 shows its richness in biological diversity.

Figure No.2: Biological Diversity of a Wetland of Inner Terai

Among these diversity, 15 species of vascular plants, 58 species of mammals, 40 species of birds, 13 species of reptiles, two species of insects and one species of amphibians belongs to the CITES list. In addition to it, among the recorded plants and animal species of Nepal, 342 species of plants and 160 species of animals are endemic to Nepal. Hence, this biological diversity is valuable renewable natural resources to Nepal. These resources can be of great value to bio prospecting.

The biodiversity is closely linked to the most of the Nepalese livelihoods and economic development. The biodiversity is closely interlinked to the agricultural productivity and the sustainable agricultural development, human health and proteins, traditional knowledge of the indigenous communities, gender equity, construction materials, water resource and societies' cultural values.

Table 1:Nepal' Richness in Organism as Compared to the World

Group of Organism	Nepal's Representation as compare to the number of species in the World (%)
Lichens	2.3
Fungi	2.4
Algae	2.6
Bryophytes	5.1
Pteridophytes	3.4
Gymnosperm	5.1
Angiosperm	2.7
Spider	0.2
Other insects	0.7
Butterflies and Moths	2.6
Birds	9.3
Reptiles	1.6
Amphibians	1.0
Fish	1.0
Mammals	4.5

Source: NBS, 2002

The natural resources of Nepal are of high economic values. Only 20 percent of the total land area of Nepal is suitable for agricultural cultivation; this is a factor for limiting important economic activities. The agricultural sector is the major income source and livelihood of over 50% of the total household families, and it provides employment to about 80 % of the total

population. Agricultural production represents one of the major raw materials for industrial production and export. In addition, it has contributed to food security at the household and national level.

In developing nations, the sustainability of agricultural ecosystem depends on many things including diversity of the local landraces too. In Nepal, agricultural occupation has been adopted as a life supporting system in tropical, temperate and sub-alpine zones. Knowingly or unknowingly, our farmers have been conserving agricultural biodiversity substantially contributing to the development and expansion of new agricultural biotechnology. In this regard, it is of prime concern to conserve, use and manage the existing biodiversity in this sector. For thousands of years, the agricultural producers have been developing and using new varieties of seed or seed varieties with new traits developed by using the traditional technology. This has contributed to the conservation of agricultural biodiversity of the nation. Recognizing the importance of old varieties of the crop, the local farmers have been using these varieties too.

The population of Nepal is about 29.4 millions. The population distribution in the Terai , hill and the Himalayan regions are respectively 48.5%, 44.2% and 7.3% of the total population. The population growth rate is 2.27 %. The urbanization rate is low as compared to the developed country and henceforth, yet about 85 % of the total population lives in the rural area, to the basic health services and education is poor. On average, the national literacy rate is only 39.6%.

The Human Development Index of Nepal is 0.527 in 2006, which is lower than the South Asian Human Development Index. The prime reason for this is the low opportunity for employment rather than the availability of opportunity to the education and health cure. Disaggregation of these statistics in terms of gender reveals that women are worse off than men.

The geo-political situation of Nepal has to be taken into account while regulating biosafety. To the north, Nepal has its boundary with Tibet, the autonomous region of China. To the east, south and west, Nepal has its boundary with different provinces of India. Nepal has close relations with India not only in terms of geography, politics and the economy, but also in terms of social and cultural at a people to people level. Consequently, the boundary between these two countries has remained open since history and there is no practice of recording the movement of the people of these two countries across their common border. In a scenario of the occurrence of the production and use of GMOs and products thereof in China and India, the task of controlling and regulating the transboundary movement of these materials in Nepal is challenging.

1.2 Biotechnology and Nepal

Recombinant Deoxyribonucleic Acid (rDNA) technology resulting from the modern science and technology has made it possible to apply traditional grafting technology in taxonomically distant species too. This technology has been proven as highly useful in transferring a specific trait of an organism to a different group of organism and developing the latter organism with new character. Insect resistance crops and disease

resistance or disease free animals and birds have been produced through this technology. It is believed that higher production at low input can be obtained in crop and livestock farming by using the seed and animal produced in this way.

In general biotechnology has been applied to transforming specific traits of an organism or living cells/ tissues into another organism for the benefit of human well-being. The biomass production has been improved through this technology. The modern biotechnology has been useful for improving the genetic character of plants and animals according to desire, orienting the micro organisms towards a specific task, modifying the genetic structure of the seed, plants and animals. Biological resource is central to the modern biotechnology. The use of biological resources, traditional knowledge as well as modern technology can contribute to well being of human. Nepal is quite behind in modern biotechnology and hence the days ahead are challenging.

1.3. The Principle of Biosafety

Nepal's biosafety policy is based on the precautionary principle. Transparency, advanced informed agreement and participatory approach will be followed and all groups of the people who may be affected will be involved in applying the principle. The main objective of the Nepal's biosafety policy is to contribute to the poverty alleviation though the development and application of biotechnology in sectors where comparative benefits can be achieved by proving the biotechnology as a strong means for the development of the nation, protection of environment

and advancement of human well-being. To ensure high level of biosafety in transboundary movement and use of GMOs, the Government of Nepal has aimed at developing a detailed national biosafety framework and implementing it effectively.

1.4 Nepal's International Obligation

As a party to the Convention on the Biological Diversity, Nepal has made its commitment to biosafety by signing the Cartagena Protocol on Biosafety on 2nd March, 2001. The main objective of the protocol is to pay special attention to the transboundary movement of GMOs, produced by using modern biotechnology, because of its trade between nations, and regulate the export and import of such goods only on the basis of the advanced informed agreement.

According to the provision of the Nepal Treaty Act, 1990, if there is an obligation to be fulfilled to an international agreement, in a given situation of by being a party to it but it has not been ratified or approved by its parliament, the government has to take actions as soon as possible to prepare for implementing such a treaty. According to the provision of this Act, it is an international obligation of Nepal to prepare policy and legislations on Biosafety.

To fulfil this international obligation of Nepal, it has to prepare the said policy and legislations as soon as possible. Accordingly, laws and policies related to the release, use and marketing of GMOs have to be formulated as per the provisions of the Cartagena Protocol.

1.5 Methodology of Biosafety Framework Preparation

In the process of developing this framework, existing policies and legislations that are directly or indirectly related to biosafety are reviewed and analyzed in view of their relevancy, usefulness and adequacy. Moreover, this framework has been prepared on the basis of the analysis of the survey reports of the biotechnology and biosafety related institutions and their activities. As part of the framework development process, central level consultations workshops at Kathmandu and regional level workshops at Biratnagar, Hetauda and Pokhra have been organized. Representative from the government and non-government organizations working for forestry, agriculture, health, education and media have participated in the workshops organized at Kathmandu. Similarly, representatives from the government and non-government organizations working for forestry, agriculture, health, education and media at the regional level and district level forestry and agriculture government offices in the region have participated in the workshops organized at regional level. Primary draft of the biosafety framework has been prepared by considering the recommendations of these workshops too. The primary draft of the framework has been shared with the participants from the concerned government and non-government stakeholders at the workshop organized at Kathmandu. This national Biosafety Framework has been prepared by considering the workshop comments.

To enhance and guide the process of the preparation of the National Biosafety Framework, a Committee comprising Secretary of the Ministry of Forests and Soil Conservation as the chairperson and Joint Secretary level representatives from Ministry of Agriculture and Cooperatives;

Ministry of Health and Population; Ministry of Environment, Science and Technology; Ministry of Law, Justice and Parliamentary Affairs; Ministry of Industry, Commerce and Supply; and Director Generals of the Department of Plant Resources and the Department of Food Technology and Quality Control, and the Executive Director of the South Asia Watch on Trade, Environment and Economy as the members and Chief of the Environment Division, Ministry of Forests and Soil Conservation as the member secretary. The guidance and the suggestions of the committee are of great value in preparing this National Biosafety Framework.

CHAPTER 2: POLICY ASPECTS OF BIOSAFETY IN NEPAL

2.1 The Current Policy Regime:

2.1.1 Sustainable Development Agenda, 2003

Amongst other things, the Sustainable Development Agenda has incorporated conservation of forests, ecosystem and biodiversity too under its broader theme. It states that biodiversity of agricultural crop varieties will be ensured by using participatory agricultural plant reproduction, varieties selection, community seed banking and endemic species and through the local knowledge system as well as on the basis of traditional farming system. In addition to this, one of the objectives of the Sustainable Development Agenda, 2003 is to ensure easy access of each citizen to adequate nutritious food. This objective may not be achieved without use of biotechnology.

2.1.2 Millennium Development Goals (MDGs), 2000

The MDGs has aimed at reducing by half the number of people suffering from hunger during the period from the year 2000 to 2015. It is in this context that biotechnology along with biosafety has to be adopted and utilized, though nothing has been directly stated as to using biotechnology as such in its goals. The MDGs include decreasing environmental degradation and integrating sustainable development concept/ principle into policies and programs and so in this context adopting biotechnology along with biosafety is necessary. The MDGs, 2000 has the target of

minimizing poverty and hunger and ensuring environmental sustainability, which could be achieved by paying adequate attention to biosafety while using biotechnology to increase production and productivity.

2.1.3 The Tenth Plan (2002–2007)

Since 1950, Nepal has been adopting periodic planning system as the nation's development strategies. It has implemented nine periodic plans and the current year is the last year of the tenth plan. The tenth plan has stressed on the need of using biotechnology and bioengineering along with biosafety measures. Accordingly, the plan has accepted biosafety as one of the important aspects of development thrust. The plan has directed to formulate necessary policies, laws and safety measures in order to avoid or minimize adverse effects on human health, environment and biodiversity, which may occur during production, trade, transportation and import or export of GMOs or their products.

2.1.4 Nepal Biodiversity Strategy, 2002

The Nepal Biodiversity Strategy, 2002 has given priority to conserve and sustainable use of the biodiversity of the nation, which is rich in biodiversity, and equitable sharing of benefits arising from the use of the biological resources. Realizing the need of biosafety for the conservation of biodiversity it has made a provision of forming a biosafety sub-committee under the National Biodiversity Coordination Committee.

2.1.5 Nepal Biodiversity Strategy Implementation Plan (NBSIP)

The Nepal Biodiversity Strategy Implementation Plan, 2006–2010 is a plan to implement the Nepal Biodiversity Strategy and thereby achieve the goals of sustainable use of biological resources and of alleviating poverty for conservation of biodiversity. This plan has set priority of the activities to be carried out for implementing the strategy and has also accorded priority to implement the plan through direct participation of all concerned stakeholders and people.

2.1.6 National Wetland Policy, 2002

The National Wetland Policy has stressed on taking concrete steps in banning unwarranted entry of alien GMOs that may displace and destroy endemic species and destroy wetland biodiversity.

2.1.7 Science and Technology Policy, 2004

The Science and Technology Policy, 2004 has adopted policy of using science and technology to increase production and productivity, and strategies to carryout studies, research and development activities in the field of biotechnology.

2.1.8 Biotechnology Policy, 2006

The overall objective of the biotechnology policy is to contribute to poverty alleviation through the development, extension and application of biotechnology in comparatively beneficial sectors and thereby establishing

it as a strong means of the national development, environmental conservation and public well being.

2.1.9 Bio Safety Guidelines, 2005:

Giving due consideration to conservation of environment and biodiversity as well as to promoting public health, and with the aim of developing and extending scope of biotechnology, the Ministry of Forests and Soil Conservation has framed Biosafety Guidelines, 2005. While assessing any potential risks posed by GMOs or their products, and conducting regulatory procedures the guidelines points out to pay more attention to the GMO or GMO products than to molecular or multi-cellular methodology applied for producing these materials. It also points out that step by step GMOs or their product may be released one after another in the environment by taking due precaution, prior to releasing GMO or products thereof in the environment it is to be ensured that no adverse effect to the human health or environment is observed at each stage of the risk assessment. According to the guidelines, if any harm is not detected by the release of GMOs or their products in the environment the control on such GMOs or products thereof be relaxed as per the situation. It sets out the directives of disallowing the entry of such organism or material in the market unless the field test of these materials, developed as a result of research and development, ensures no adverse effect to the ecosystem and the human health.

2.1.10 Agricultural Policy: 2005

The Agricultural Policy, 2005 has a provision of regulating GMOs, promoting the production and use of productive hybrid species, developing standards for food, controlling its quality and certifying the food products.

It has also provisions of regulating agricultural products according to the international treaties and agreements as well as to the national need. The policy states to develop, extend and use suitable agricultural technologies by utilizing the local potentialities, comparative advantage and available special opportunities, which will boost agricultural production and productivity, and emphasizes on commercialization as well as diversification of agriculture to increase income generation and additional employment opportunities.

2.1.11 National Seed Policy: 1997

This policy has emphasized on conserving agro-biodiversity and establishing variety rights over seed as the local seed varieties are important for developing new seed varieties. It states to conduct study and research on GMO seed and plants and they will be released to public use only if the study, research and test conducted in presence of the concerned competent authority show that adverse effect on local living things and environment is not likely to occur.

2.2 Gaps and weakness

In totality, the existing policies, strategies and plans have stressed on minimizing poverty and hunger, regulating the use of biotechnology and GMOs for easy access of people to nutritious food and on taking concrete steps in prohibiting the unwarranted entry of GMOs that may have adverse effects on biodiversity. The Seed Policy states that GMO seed and plants shall be released to the public use if the result of test of GMO seed and

plants shows that adverse effect on local living things and the environment is not likely to occur.

The Cartagena Protocol on Biosafety stresses on adopting necessary measures in order to avoid or minimize the adverse effect on the human health, biodiversity and environment likely to be caused from the use of GMOs for agriculture purpose, animal husbandry, fishery, forestry purpose or processing. The existing Seed Policy is focussed on seed and plants including GMO seed and plants to be used for agriculture sector.

However, the reviewed policy documents lacks clear provisions on safeguarding human health, environment and biodiversity from negative impacts or minimizing the negative impacts that may occur during the trans-border movement, operation, storage and use of GMOs produced by using modern biotechnology or the materials containing GMOs, and on managing risks associated with such materials and acquiring public participation in the overall aspect of biosafety as required by the Cartagena Protocol on Biosafety.

2.3 National Biosafety Policy, 2007

2.3.1 Need for Biosafety Policy

Though Nepal is an agricultural prime country, there is scarcity of food in the Himalayan and the mountain regions, where the agricultural systems are based on the traditional approaches. On one hand, it is required to increase food production to the extent possible in the limited arable land in

the remote areas in order to solve the problem of food scarcity faced by people in these areas and on the other hand the threats of potential adverse effects on the Nepalese territories, agricultural system or environment from GMOs cannot be taken lightly when cultivation of GMO crops in both the neighbouring countries India and China are taking place. There is a high possibility that in the name of high yielding varieties, seeds with GMOs may be imported to Nepal from neighbouring countries. Moreover, there is threat of disappearance of local crop varieties in Nepal through cross pollination among GMO crops cultivated in bordering Indian territories and the local crop varieties in Nepal. Similarly, there is high probability that the imported processed food items may be modern biotechnology products and may contain GMOs. Therefore, it is realized that the Biosafety Policy has to be in place to protect health of Nepalese people and to prevent any adverse impacts on biodiversity and the environment of Nepal. Accordingly, the Government of Nepal has given high priority to preparing Biosafety Policy in its budget policies and programs statement for fiscal year 2006–007.

2.3.2 Scope of Biosafety Policy

The proposed biosafety Policy shall cover the following aspects of GMOs and use of modern biotechnology:

2.3.2.1 The existing or potential use of GMOs in laboratory or in an open space.

2.3.2.2 Human health, biodiversity, natural environment, agricultural product, foods and drinking products, animal feed and areas of sewerage management.

2.3.2.3 Regulation of experiment, flow of information, review, assessment of risks including socio economic and ethical effects.

2.3.2.4 Monitoring of import and export, laboratory and field test.

2.3.2.5 Research and development in academic and industrial sectors,

2.3.2.6 Safety of the place where functions relating to GMOs are carried out.

2.3.2.7 Public participation on the issues of modern biotechnology and bio-safety.

2.3.3 Objectives

The main objectives of the biosfety Policy is to protect the biodiversity, human health and the environment from adverse effects of research and development activities of modern biotechnology and its use and materials produced by using modern biotechnology.

In addition to the main objective, other objectives shall be as follows:-

2.3.3.1 To develop legal, technical, administrative aspects of biosafety and public participation mechanisms for biosafety.

2.3.3.2 To develop institutional, human resources and technical capabilities for functions relating to biosafety.

2.3.3.3 To adopt and accommodate regional and international standards on risk assessment and management, and experiences and research findings which are suitable to the national context.

2.3.3.4 To effectively regulate the trans-border movement of the materials produced using modern biotechnology on the basis of scientific facts, transparent system and advanced informed agreement and exchange of information.

2.3.3.5 To conduct or cause to be conducted extensive awareness raising campaigns in order to involve citizen in various aspects of modern biotechnology and biosafety for their participation in decision making process.

2.3.3.6 To establish mechanisms to respond to any emergency situations arising from modern biotechnology and materials produced using modern biotechnology.

2.3.4 Directive Principles:

The directive principles of the biosafety policies shall be as follows:–

2.3.4.1 Modern biotechnology or the GMOs produced using such technology and goods containing such GMOs shall be used on the basis precautionary principle.

2.3.4.2 Due attention shall be given that use of modern biotechnology or the GMOs produced using such technology and the materials containing such organism shall not affect human health, environment and biodiversity.

2.3.4.3 Modern biotechnology or the GMOs produced using such technology and their products shall be used for assisting in poverty alleviation and for promoting food security.

2.3.5 Biosafety Policy

The following policies shall be adopted in order to achieve the aforesaid objectives:-

2.3.5.1 Making legal provisions relating to biosafety

To frame a national biosafety Act, Rules and Guidelines in order to regulate the use, development, import, movement, storage, and release of GMOs.

2.3.5.2 Management of Administrative System for biosafety

2.3.5.2.1 To follow the principle of one door system while confirming the Ministry of Forests and Soil Conservation, the national focal point of the Cartagena Protocol on Biosafety, as the main administrative center for carrying out activities relating to biosafety and secretariat of the National Biosafety Committee.

2.3.5.2.2 To form the National Biosafety Committee (NBC) with representation from all relevant stakeholders for taking decisions on modern biotechnology, GMOs and their products so that the decisions are beneficial to all having regard to the overall interests of modern biotechnology, GMOs, and their products.

2.3.5.2.3 To establish creative inter-relationships amongst the main stakeholders of biosafety and national management of biodiversity to ensure their participation and coordination.

2.3.5.2.4 To designate sectoral competent authorities on the basis of working areas.

2.3.5.3 Risk Assessment and Management for bio-safety:

2.3.5.3.1 Prior to use of GMOs or the materials produced using modern biotechnology, any potential risks to human health, environment and biodiversity shall be assessed. While carrying out such assessments, cultural, spiritual and local values shall be taken into consideration.

2.3.5.3.2 It shall be made mandatory to label GMOs and materials produced using modern biotechnology.

2.3.5.3.3 Minimum base line of national biosafety shall be determined on the basis of regional and international standards of biosafety.

2.3.5.3.4 The quality standard of the goods produced from GMOs or using modern biotechnology in Nepal shall be determined and certified.

2.3.5.3.5 Risks shall be managed on the basis of assessed risk of GMOs and the materials produced using modern biotechnology to human health, environment and biodiversity.

2.3.5.3.6 Emergency response procedures shall be established in the relevant laboratory, test site, store and so on in order to take emergency action in case of accidents during production, use,

test, movement, disposal and so on of GMOs and the materials containing such organisms.

2.3.5.4 Public Participation for bio-safety

2.3.5.4.1 *Publicity/Flow of Information*

For the benefit of the people, information on events taking place at the international level relating to modern biotechnology, GMOs, and products thereof and their advantages and disadvantages shall be disseminated to public through various media. The Nepal biosafety clearing house shall be established for exchange of information and data on biosafety at national, regional and international levels.

2.3.5.4.2 *Awareness Raising*

Public awareness shall be raised in order to get their participation in biosafety issues which are directly related / concerned to human beings' basic needs - biodiversity, food, feed and human health.

2.3.5.4.3 *Public Hearing*

Provision of public hearing shall be made before allowing import, filed trial, farming and marketing for consumers' use of GMOs or goods containing GMOs.

2.3.5.4.4.*Public Participation on Decision and Implementation Process*

Provision for participation of various classes of society shall be made in decisions making and implementation process relating to biosafety.

2.3.5.5 Monitoring

Provision of regular monitoring of the impacts likely to be caused from the production, import, field trial, farming and use of GMOs or goods containing such organisms on biodiversity and human health, and ensuring the quality of GMOs or goods containing GMOs and effectiveness of the criteria and methods adopted for biosafety shall be made.

2.3.5.6 Miscellaneous

2.3.5.6.1 Research and Development

Conducting studies and research on impact arising from the use of GMOs or goods containing such organisms on human health, biodiversity and environment and its management shall be promoted

2.3.5.6.2 Provision of Accredited laboratory

The national laboratories that are capable to carry out experimentation, research and development of GMOs and goods containing such organisms shall be accredited.

2.3.5.6.3 Provision of fund

A Biosafety Fund shall be established for carrying out effective and regular monitoring, studies and research on the impact of GMOs and products of modern biotechnology on human health, environment and biodiversity, and for carrying out biosafety activities including emergency responses.

2.3.5.6.4 Bilateral and Regional Cooperation

Bilateral and regional cooperation shall be used and promoted in order to manage and control trans-border movement of GMOs and products thereof.

2.3.5.6.5 Compensation and Relief

Provision for compensation and relief shall be made for any adverse effects or damage caused by GMOs and goods containing such organisms. Such provision shall be inseparable part of the agreement relating to production and use of GMOs or goods containing such organisms.

2.3.5.6.6 Patnesrship with Civil Society

Developing partnership on biosafety related programmes with civil society, NGOs and consumers' society shall be adopted.

2.3.5.6.7 Compliance of the Biosafety Guidelines, 2005

The conditions and procedures of biosafety prescribed in the Biosafety Guidelines, 2005 for studies, research, production, experiment, import-export, movement and sale and distribution and use of GMOs, which are not contradictory to the National Biosafety Framework shall be adopted.

CHAPTER 3: LEGAL PROVISIONS RELATING TO BIO-SAFETY

3.1 Existing Legal Provisions

Though the review of the existing laws and rules in Nepal does not show separate and special laws in Nepal on production, import, export, release and use of GMOs and on safeguarding their impact on biodiversity, human health and environment, it seems that some legal provisions directly or indirectly related to biosafety can be found in a number of laws including the constitution. These legal provisions are found to have been in place long before the emergence of the concept of biosafety itself. Major legislations relevant to biosafety have been dealt with in this Chapter.

3.1.1 The Constitution

The directive principle in the Constitution of the Kingdom of Nepal, 1990 has given highest priority to the protection of people's lives, property and freedoms and maintaining the country's sovereignty, integrity and independence in order to promote national dignity. Moreover, the state has expressed its commitment to conserve forest, wildlife and environment. Since the constitution has guaranteed its citizens right to information on publicly important issues, information on biosafety related decision, policies and programs of the government shall be made accessible to all citizens.

3.1.2 Local Self Governance Act,1999

The Local Self Governance Act, 1999 has entrusted the local government organizations such as District Development Committee, Municipality and Village Development Committee with the responsibilities of protecting public health and conserving environment and biodiversity. These

organizations have authority to impose a ban on any activity that is likely to cause adverse impact on these sectors within their territory.

3.1.3 Consumer Protection Act, 1997

The Consumer Protection Act, 1997 aims at protecting consumer's health, facilities and financial benefits and at prohibiting the acts of diminishing or degrading the quality or utility of consumable goods or services. According to the provision of the Act, only those goods or services that meet the desired standard must be exported or imported and stored. In addition, the act of producing or selling or distributing substandard goods for consumption is taken as punishable offence. This Act has stressed on human health, services and quality control and has made provision of inspecting label on consumable goods.

3.1.4 The Export Import (Control) Act, 1956

This Act has empowered the Government of Nepal to issue orders by publishing a notice for banning or controlling the import or export of any material throughout the country or any part of it, which is effective from the specified date of notification. The Act has also made a provision of seizing the material imported or exported against such notification and punishing the importer and exporter with imprisonment or fine or both.

According to the provisions of the WTO, all the member countries need to follow the Sanitary and Phyto-Sanitary Agreement which aims at avoiding the adverse effects on human beings, animals and plants from the goods to be imported or exported.

3.1.5 Plant Protection Act,1972

The purpose of the Plants Protection Act, 1972 is to prohibit and control the entry of destructive infectious bacteria or diseases and their spread through the means of plant or plant product to be exported or imported. This Act has defined 'plant' as all types of plants or their parts including root, stem, cutting, branch, fruit, leaf, bark, be it living or dead; and plant product has been defined as plant material which has been crushed into usable pieces or powder.

According to the Act, the Government of Nepal can prohibit import and export of any plant or plant products with or without soil or any other material on which plant may grow and determine desired conditions of container or package for transporting or storage. Moreover, it can prescribe the type of treatment required such as fumigation, prior to importing and exporting plant and plant product or soil or other goods. According to the Act, the Government of Nepal can prohibit import of organisms, insect, spider and snail.

3.1.6 Seed Act, 1989

The Seeds Act, 1989 has aimed at producing high quality seeds, their processing and testing in order to make available the quality seeds to general public. This Act has defined crops as fruits, food grains, vegetables, cash crops and fodder crops; and farming has been defined as the acts of producing food grains, fruits, pulses, oil seeds, vegetables, cash crops and fodder. In this Act, provision has been made for forming a seed committee under the chairpersonship of the secretary of the Ministry of Agriculture and Cooperatives to formulate national policies on seeds, to make arrangements for producing and distributing seeds and to control quality of

seeds. The committee has power to approve new seed varieties and release them, and to grant development ownership of the new variety of seed after testing its speciality, uniformity and permanence to the developer, and approve the standard of seeds set by the national and international practitioner. The Act has also made a provision of establishing an agency for certification of seeds, which is responsible for certifying seeds with prescribed quality standard.

The Seed Rules, 1997 framed under the Seed Act has provision for forming sub-committees for approval, release and registration of crop species. The functions of the sub-committee are to prepare infrastructures required for approval, release and registration of newly developed plant and crop varieties, to get these approved from the seed committee and to make provisions for reproduction of the released seeds.

Looking at the above provisions, it seems that the pollution and quality degradation in agricultural sector and food grains through the seeds could be regulated. For necessary technical testing of the contamination in the seed and quality of the seed, provisions have been made to establish central and other laboratories with experts to conduct the test, and form various sub-committees at the centre.

3.1.7 Food Act, 1966

The Act has made various provisions for preventing unwarranted adulteration or diminishing natural quality or utility of food stuff so that appropriate quality of food stuff is maintained. Action may be taken to those who do not follow these provisions. The Department of Food Technology and Quality Control has been entrusted with the responsibility of implementing the provisions of this Act.

The Act has defined foodstuffs as the processed, unprocessed, semi-processed or manufactured stuffs to eat or drink and it includes the species, food additives, colour and flavour that are used in the foodstuffs or drinks. The Act has broadly defined the contaminated foodstuffs. It includes prepared or kept foodstuffs that are decomposed or turned into toxic which are harmful to human health. It also includes the foodstuffs that are not suitable for human consumption because they are partly or wholly prepared from diseased or disease infected animal or birds or harmful plant, and the content of food additive, inter-developed or externally mixed chemicals or insecticide in these food stuffs is higher than the permissible limit which are likely to cause adverse impact on health.

The Act has defined low quality foodstuffs as the foodstuff in which proportion of the main constituent of the foodstuff has been reduced or any other stuff has been mixed to decrease its natural quality. The Act has prohibited production, import or export and store for sale and distribution of contaminated or substandard foodstuff in Nepal. It has also prohibited sale and distribution of foodstuffs misrepresenting about its quality. If such foodstuffs are found in market, they may be withheld for sale or prohibited or confiscated.

The Food Rules, 1970 has provision of prohibiting the sale of food if there is the likelihood of transfer of infectious disease from it and prohibiting the export or import of food if its quality is suspected to be sub-standard, and such food item could be referred to the Department of Food Technology and Quality Control for testing. Similarly, according to the provision of the Act, the food inspector can prohibit the production and sale of food stuff by

employing persons suffering from transferable disease if the disease is likely to be transferred through such foodstuffs.

The review of the Foods Act and Foods Rules shows that the foods inspector has the greatest role in preventing or minimizing adverse effects of substandard or low quality foodstuffs on human health. The Chief District Officer, the Department of Food Technology and the Quality Control, Central Food Laboratory and Foods Quality Determination Committee do also have crucial roles in such activities.

3.1.8 Feed Act, 1966

The Feed Act has been enacted to prohibit adulteration on feed or diminishing the natural quality or utility of the feed. The Act has defined feed as solid or liquid materials used to feed birds, animals and fishes or the mixture of such solid materials or liquid materials or solid and liquid materials. Similarly, the Act has defined contaminated feed as the feed in which the proportional content of the main constituent has been decreased to make it substandard; or other materials has been mixed; or which has been decomposed, or waste or toxic materials has been mixed, which are harmful to birds, animals and fish has been mixed. The Act has made provisions for prohibiting the production, import and export, sale, distribution and storage of such contaminated feed.

According to the Act, one who wants to produce, sale and distribute feed must have license for such activity. It has a provision for determining the quality of feed, required minimum quantity of constituents and permissible limit of additives, and testing suspected feed. As the feed may affect human beings through the consumption of animal products, the above legal

provisions have to be applied to avoid or minimize the adverse effect on human health from the feed.

3.1.9 Animal Health and Livestock Services Act, 1998

This Act has made provisions for banning on import of animals suffering from infectious diseases and examining the animals or animal products to identify whether they are consumable or not prior to their production, import, export, sale and distribution.

3.1.10 Slaughter House and Meat Inspection Act, 1999

The Act has been formulated to prohibit the adulteration in meat and meat products and to maintain the quality standard of the meat by avoiding the degradation in its natural quality for the sake of common people's health. Persons willing to establish and run slaughter house and meat seller has to obtain permit for the action. The meat to be sold from meat shop should have to be certified and only consumable meat should be sold. The Act has provision of punishing the persons who implement activities against the Act with fine, imprison or both.

3.1.11 National Dairy Development Board Act, 1991

This Act has made provisions for establishing a National Dairy Development Board that will support in the formulation of policies relating to dairy business at national levels and to prepare development plans relating to it, and identify the measures for solving problems in the livestock development and animal health sector. The Act has entrusted the Board to assisting policies formulation on importing goods required for the production and promotion of milk and dairy products and exporting the produced milk, dairy products and feeds, and recommending to the government for its approval and implementing the approved policy, and to

providing technical support to establishment, reform, promotion and protection of dairy industries. The Act has also made the Board responsible to feed, pasture land and milk issues too.

3.1.12 Nepal Agricultural Research Council (NARC) Act, 1991

Under this Act, NARC has been established with the objective of conducting research and studies on the problems in the agricultural sector and to identify the measures for solving them. Since the Council has been working in the areas of new varieties of seeds, fertilizers and agricultural products and has facilities of agricultural firm and laboratories for such activities, these facilities may be used for studies and research including testing of GMOs for agriculture purpose. Available physical facilities and technical capacities in the NARC suggest that it could advise to the government on GMOs and their products.

3.1.13 Drug Act,1978

The main objectives of the Drugs Act, 1978 is to prohibit inappropriate use or misuse of medicines or its constituent compound and misleading publicity as to its utility; and to control the production, sale and distribution, export and import, storage or use of medicines that are not safe for public use or effective or of desired standard. The Act has defined 'medicine' as the substance or constituent added to the substance used for curing any disease occurred to human beings, animals, or birds or for preventing from diseases; or for destroying the bacteria and insects that transfer diseases to human being, animals or birds; or the substance used for causing effects on physical structure or process of human being or animals or birds.

This Act has made a provision for prohibiting the sale, distribution, storage or consumption of substandard medicines. If any substandard medicine

causes any harm or loss, the Act provides for recovering the cost of compensation paid to the concerned party from the distributor of the medicine. Similarly, the law has made a provision for inspection of the production, storage, sale or transportation of medicines; and forbidding such activities if suspicion arises on safety, effectiveness and quality of medicines and upon the testing of the medicine in case it is found that the medicine is unsafe for human, ineffective and of poor quality order may be given to prohibit such activities, seize or destroy such medicines and arrange for providing compensation to the seller from the producr, and production license may be revoked or suspended. For drugs administration, there are the following Rules in place:

a. The Drugs Advisory Council and Drugs Consultative Committee Formation Rules, 1980.
b. The Drugs Registration Rules, 1981.
c. The Drugs Quality Control Rules, 1986.
d. The Drugs Inspection and Inquiry Rules, 1993.

3.1.14 National Park and Wildlife Conservation Act, 1972

The objectives of the National Park and Wildlife Conservation Act, 1972 are to protect wildlife and its habitat, control poaching of wildlife, promote and develop appropriate management of wildlife and the places of natural beauty. Conservation of wildlife and plants within the national parks, wildlife reserves and hunting reserves and control of their poaching and to maintain natural ecology within those areas by controlling outside activities are the major objectives of this law.

3.1.15 Forests Act, 1999

The Forests Act, 1992 has been framed with the objectives of fulfilling basic needs of people, attaining socio-economic development, promoting healthy atmosphere and managing the national forests as government managed forests, protected forests, community forests, leasehold forests and religious forests in order to develop and protect the forests and utilize the forest products. This Act is an important tool for conserving and sustainable use of national forests, which is one of the precious natural resources of Nepal. This Act and the Forests Rules, 1993 have made significant contribution in biodiversity conservation as well.

3.1.16 Aquatic Animal Protection Act, 1960

The Aquatic Animals Protection Act, 1960 has prohibited the use of toxic materials to catch aquatic animals and activities that may threat to the existence of aquatic animals. However, it has not paid attention to release of new species of aquatic animals into nature and the impact of invasive aquatic animals on the natural aquatic animal species.

3.1.17 Environment Protection Act,1997

This Act has the objective of protecting environment through appropriate management and utilization of natural resources and minimizing the negative impacts on human beings, animal, plants, nature and physical materials by using environmental impacts assessment as a tool for it. Moreover, the Act has aimed at avoiding or minimizing the negative impacts of physical activities in forestry, agriculture and environment and development activities on human beings, animals, plants and infrastructure. Environmental impact studies have to be carried out for the activities which

has threshold limit as prescribed in the Environmental Protection Rule formulated under the Act .

3.1.18 The Patent, Design and Trademark Act, 1965

The Patent, Designs and Trademark Act, 1965 defines patent as the right over any useful new invention relating to composition or operation or device or method of producing any material or a group of materials or an invention based on a new theory or formula. In order to acquire patent rights, one has to register a patent in his/her name and the period of the validity of such registration is fourteen years.

3.2 Gaps and Weaknesses:

The existing laws and rules do have various provisions with regard to maintaining quality of food, feed, medicines and seeds. However, the Acts relating to Export Import, Plant Protection, Food, Feed, Drug, National Park and Wildlife Protection, and Aquatic Animal Protection have been formulated and enacted quite long ago before the emergence of the issues of the modern biotechnology. Hence it is inevitable that these Acts lack the explicit provisions relating to the modern biotechnology and GMOs.

Under the Environment Protection Act, Environmental Impact Studies have to be conducted for activities that meet the threshold of work or the investment as specified in the existing legislative framework of the Environmental Impact Assessment. Accordingly, it seems that environmental impact study is not required for the activities with less threshold level of work than the specified ones. But according to the provisions of the Cartagena Protocol on Biosafety, it is required to conduct risk assessment for the development, handling, transfer, transport, use and

release of GMOs, which does not specify any threshold level of the activity. Though the Environmental Protection Act is not applicable to the said activity of the modern biotechnology product it is required to conduct risk assessment for the above activities to meet the provision of the Protocol. Even the use or release of the smallest quantity of GMOs may be dangerous although it seems negligible in terms of threshold levels. Therefore, the criteria of threshold are irrelevant so far as regulation of biosafety is concerned.

3.3 The Proposed Legal Framework for Bio-safety

The development and spread of modern biotechnology has created new opportunities as well as challenges in the areas of food security, food safety, environment, biodiversity conservation and human health. To deal with the challenges and obtain benefits of the potential opportunities, a draft Biosafety Bill shall be prepared. The outline of the proposed Biosafety Bill is as follows:

3.3.1 Objective:

The objectives of the Biosafety Bill will be as follows.

3.3.1.1 To ensure, in accordance with the precautionary principle, an adequate level of protection in the field of production, development, use, handling, transfer, sale, contained use including field test, general release, export, import, transit, research and any other activities related to GMOs resulting from modern biotechnology that may have adverse effects on the environment, biodiversity, and human health.

3.3.1.2 To adopt a transparent decision making process relating to GMOs and related activities, including environmental risk assessment, social impact assessment, monitoring and enforcement, and provision for penalty and redress.

3.3.2 Scope

The Biosafety Bill shall apply to the development, production, contained use, field test, intentional introduction into the environment, and import and export of GMO that may have an adverse effect on the conservation and sustainable use of biological diversity, environment taking also into account the risks to human health.

3.3.3 Definitions

A number of key terms such as 'GMOs', ‘Biosafety’, 'Biosafety Guidelines’, 'Proposal', 'Proponent' and 'Risk management' etc. shall be defined for the purpose of clarity in the draft Bill.

3.3.4 Institutional set up

The institutional set up proposed in the Biosafety Bill will include:

3.3.4.1 The Ministry of Forests and Soil Conservation is the National Focal Point for the Convention on Biological Diversity and the Cartagena Protocol.

3.3.4.2 A National Biosafety Committee (NBC), with representation from different sectors, will be established under the chairpersonship of the secretary of the Ministry of Forests and Soil Conservation. The committee acts as a National Competent

Authority. The Environment Division in the MoFSC functions as a secretariat of the committee.

3.3.4.3 The functions of the NBC may include: (a) to draft policies, guidelines, legislations, and (b) to cooperate with national and international bodies on biosafety, (c) to establish standards and procedures for risk assessment and labelling of GMOs; (d) make decisions on all proposals on GMOs and products thereof.

3.3.4.4 The Biosafety Bill will establish a number of sectoral competent authorities and define their roles and responsibilities on the basis of the types of GMOs and their products.

3.3.5 Submission of Proposal along with Risk Assessment and Management Report

A proponent willing to conduct research, development, production, tests, import and utilization of any material produced by application of modern biotechnology shall submit a proposal along with its risk assessment and management report to the NBC on the proposed activity/ activities.

3.3.5.1 The proposal should contain the description on following subjects:

(a) General information about the proponent.

(b) Information about GMOs and products thereof.

(c) Information on conditions of import, intended introduction into the environment, contained use and marketing of the GMOs.

(d) Objectives and location of marketing of the GMOs.

(e) Information relating to monitoring, control, waste processing and emergency responses.

(f) Information on implementation of similar proposals by the proponent within Nepal or abroad, if any.

(g) Information on refusal of similar proposals of the proponent, if any.

(h) Information on interactions between the GMOs and local environment.

(i) Information relating to labelling and packaging of the GMOs.

3.3.5.2 Points that should not be missed while assessing the risks:

(a) Relevant scientific evidences and experiences.

(b) Characteristics associated with GMOs, identification and description of the biological resources and genetic materials used for producing the GMOs.

(c) Parental organisms and their habitat.

(d) Descriptions relating to use or consumption of the GMO and its products.

(e) Instant and long-term benefits and effects of the GMO.

(f) Direct and indirect impacts on the environment, biological diversity and human and animal health.

(g) Economic and social impacts.

(h) Impacts on ethical and cultural traditions and values and norms.

(i) Description relating to the risk assessments carried out in any other countries and certified copies of such reports, if any.

(j) Possible benefits to the nation and consumers while granting approval.

3.3.5.3 Points that need not be covered in risk management:

(a) Identification of Alternatives.

(b) Reformative Measures.

(c) Preventive Measures.

(d) Risk Minimization Measures.

(e) Cost of Risk Management and Responsible Institutions.

3.3.6 Environment Impact Assessment (EIA)

Upon evaluation of the risk assessment report relating to the proposal and prior to the approval of the proposal, the NCA shall ascertain whether or not IEE or EIA has to be conducted as per the prevailing Environmental Protection Act and in case of its requirement the process set out in the Environment Protection Act, 1997 has to be followed.

3.3.7 Public Hearing

The NCA shall publish notice for public notification seeking comments from the public on the impacts likely to be caused on human or animal health, biodiversity and environment from the implementation of the proposal and for the sake of impartiality the NCA shall arrange public hearing on the proposal through an independent body. The proponent bears cost incurred for notification and public hearing

3.3.8 Decision on Proposal and Risk Assessment and Management Report

NCA makes necessary decision on the proposal and the risk assessment and management report on the basis of the comments of the SCA and the public hearing.

3.3.9 Determination of Biosafety Standard

The NCA determines biosafety standard and execute it.

3.3.10 Packaging and Labelling

Specific requirements for packaging, labelling, and transport of GMOs will be set up.

3.3.11 Monitoring, Inspections and Emergency responses

The Biosafety Bill will contain provisions for monitoring any impacts on the environment or on human health from the implementation of the approved proposal of GMOs or GMO products and inspecting the implementation of the approved risk assessment and management report too. Emergency response will be carried out in case of accidental releases of GMOs or any negative impacts.

3.3.12 Protection of Confidential Information

If the proponent request for protecting the confidential commercial information submitted to the NCA, the NCA may maintain confidentiality of such information if it deems so.

3.3.13 Declaration of GMOs Free Zone

The Bill will contain a provision that the Government of Nepal may publish a notification on the Nepal Gazette to declare any important places from the point of view of natural resources, endangered flora or fauna, biodiversity or places of aesthetic importance as the GMOs Free Zone. In

such zones, the government may prohibit production, movement, contained use or release of GMOs in the environment.

3.3.14 Provision of Biosafety Officer

To ensure the effective implementation of the risk minimization measures the NBC may appoint biosafety officers who will inspect and monitor implementation of the approved proposal.

3.3.15 Offences and Penalties

Violation of any of the rules, or conditions attached in the approval, etc will constitute an offence under the Biosafety Bill and will be subject to a fine and/or imprisonment. In case of conviction of such offences, the court shall issue order to pay compensation for actual harm caused to the aggrieved party from the offender. The case under this law shall be filed in the concerned District Court and the cases shall state cause for which the government has to file the cases at the court.

3.3.16 Biosafety Fund

A Biosafety Fund shall be established to facilitate promotion of biosafety and launching of various programs for minimizing adverse impact of GMOs likely to be caused on human or animal health, biodiversity or the environment.

The proposed fund will be supported by:

(a) Amount received from Government of Nepal;

(b) Amount received from foreign or International Organization; and

(c) Amount received from other sources such as fees for processing applications.

3.4 Capacity Building

It is necessary to make aware, train and sensitize law enforcement officials, at the central to the district level, on national and international law, policies, practices related to biosafety and its sensitivity through trainings, seminars, workshops or similar programs. In addition to it, the law implementing officials of custom, revenue investigation, revenue tribunal and police needs to be trained and sensitized on biosafety.

CHAPTER 4: TECHNICAL ASPECTS OF BIO-SAFETY

4.1. Background

The Genetically Modified Organism (GMOs) are of different nature from the natural organisms and it has been accepted throughout the world that they may possess risks. There is a global recognition of the fact that GMOs are inherently different and associated with special kinds of risks and hazards. The risks to the biological diversity and human health either through the biological process such as cross pollination or sex among the GMOs and natural organisms or chemical reaction among the chemicals contained in the GMOs and the natural environment.

The technical framework of biosafety mainly covers the scientific research and testing of seed, plants, food, feed and animals with GMOs, which may be imported or produced within the country. The test aims to identification of the components of the GMOs, character and the analysis of the results of the testing would help in identifying whether the tested GMOs pose any adverse risks to biological diversity and human health. On these grounds, decision will be made whether to allow or restrict the import of the tested GMOs. It also covers the management of risks from the use of GMOs.

4.2. Potential risks

In general, risks of GMOs could be of - plant-based GMOs, microbes-based GMOs, animal-based GMOs and their products. The potential risks of GMOs and their products can be viewed from two angles *viz*. 1) risk to

environment from the use of GMOs and 2) risk from the consumption of food containing GMOs.

4.2.1. Potential Risks of Plant GMOs and their Products

In general, potential hazards associated with Genetically Modified plants and products may be: a) expression of toxic or allergenic compounds b) effects on biogeochemistry, c) transfer of various disease resistant, insect resistant, herbicide resistant genes to wild species, and cultivated or domesticated wild or semi wild species can create super weed with increased persistence in the environment and invasiveness, d) transfer of genetic material (bacterial, fungal and viral disease resistant genes etc.) i. e. gene flow via pollination to other wild relatives or and cultivated wild or semi and cultivated or domesticated wild or semi wild species creating unpredictable effects, e) instability of genetic modification, f) unintended effects (the insertions may influence the expression of adjacent genes leading to unintended genetic modifications that may cause some adverse effects, and g) Issue of impacts of acquired new characteristics on target and non-target organisms.

4.2.2. Potential Risks of Genetically Modified Micro-organisms

Following have been considered as possible adverse effects caused by Genetically Modified micro-organisms: a) diseases of human and animal including toxic or allergenic effects, b) plant disease and development of epidemics in agricultural and natural environments, c) adverse effects resulting from the inability to treat diseases or offer prophylaxis, d) adverse effects resulting from the natural bio-geo chemical cycles, e) adverse and complicated ecological effects resulting from establishment or dissemination of such GMOs having strong adaptability and

competitiveness in environment i.e. species replacement can also occur, and f) adverse effects resulting from natural transfer of inserted genetic materials to other organisms.

4.2.3. Potential Risks of Genetically Modified Animals and Products

Potential hazards associated with **Genetically Modified animals and products** may be: a) adventitious infectious agent transfer, b) endogenous retroviral activation (if the transformation is based on Retroviral mediated gene insertion), c) entopic expression of transgenes (the presence of transgenes or their products in non target tissues can have adverse effects on human and animals exposed to these products), d) excess production of transgene products or its metabolites, e) pleiotropic effects of transgene expression (transgene insertion and expression can have unpredicted effects on the expression of other genes), f) prion disease susceptibility hazard (production of transgenic animal could produce a hazard through the accidental inclusion of genetic material with the transgene or alteration of the functioning of genes related to prion susceptibility), and g) leakage of expressed products from target tissues etc.

Risk posed by GMOs and products thereof may be short or long term and direct or indirect. Risk may appear during the testing or use of GMOs or after long duration of its release in the environment. Hence, it is necessary to be alert on the potential adverse effects that may arise during the production, testing and use of the GMOs.

Because of the potentiality of the above risks of the GMOs, the Cartagena Protocol on Biosafety clearly points out the need for taking safety measures against such risks and is called the risk management. In order to manage

the risks it is required to identify the risks and understand their consequences. Identified risks determine the management measures.

The risks of GMOs and their products on biodiversity, environment and human health may be variable depending upon the type of GMOs (plant, animal, microrganism or products containing GMOs) in question and kind of genetic modification being carried out on them. Therefore, risk assessment and management also vary accordingly and cannot be generalized that a single system and process be applied for all types of GMOs.

4.3. Need of Technical Framework

The technical management is necessary to identify the risks to potential receiving environment, biological diversity and human health from the release of the GMOs, and determining whether the GMO is risk free or with low risks or with acceptable risks on the basis of evaluation of the associated risks. This helps in making decision whether or not to issue permit import and use of GMOs. A technical framework of biosafety is required to control any adverse effects from the use of permitted GMOs in the environment. For this, trained human resources, well-equipped laboratories and operational procedures are required. The risk examination of GMOs should be done on a scientific basis. At the same time, it is also necessary to pay attention during the assessment as to whether the GMO may have an adverse impact on the social and cultural values of the nation. The results of the risk examination is used for making decision whether to allow permit for the implementation of a proposal of GMOs or products thereof or reject it and managing the risks of the implemented proposals.

It is necessary to understand the susceptibility and resilience of biodiversity, human beings and environment to the risks posed by GMOs, where the GMOs are intended for release, in order to identify appropriate measures to avoid or reduce the risks, as well as to evaluate the effectiveness of such measures. On the basis of these considerations, appropriate risk management measures could be applied. In general, following points are to be considered in risk management:

a) Prior to permitting release of GMO, the GMO in question should subject to an adequate period of observation, at least to its lifecycle or generational time.

b) The package containing GMOs or its products need to have labelling with general information on GMOs or its products and potential allergy.

c) The application of the accepted risk management measures identified by performing risk examination of GMOs by the different countries depending upon the type of GMO and its risk level, such measures may be

   - physical - separation of the area, where GMO will be used, by dams, canal, barrier board, setting up nets, etc;
   - chemical - sterilization of the used instruments, facilities and media.
   - biological - establishment of biological buffer areas.

d) to band certain products (such as products marked with antibiotic resistance).

e) to prohibit certain activities or work in order to take risk avoidance or minimization measures.

f) application of emergency measures.

Ensure that these measures are implemented. It may be required to review the evaluation of risks and decisions on risk management on the basis of the findings of the monitoring report on the impact of the release of the GMOs and their products on the environment.

4.4. Desirable Technical Capacity

The minimum infrastructure required for the detection of GMOs/LMOs in trade is based on the kind of diagnostic protocol that will be employed for the purpose. A number of methods are available and in use for the detection of different GMOs. They range from simple bioassay to more complicated protein based techniques such as Lateral Flow Strip method, ELISA and Western Blot to most advanced DNA-RNA based PCR, PCR-RFLP and Southern and Northern Blot techniques. The commonly applied methods for testing GMOs and the equipments required for these methods are presented in table 2.

In addition to the above method of testing and identification of GMOs, it is also equally necessary to have facilities for contained use and trained human resources to identify and examine the potential risks of GMOs, particularly testing the GMOs in conditions with adjustable environment similar to the site where the GMOs is intended for release.

Scientific sound risk assessment of GMOs requires a wide range of expertise such as: Nucleic acid technology or Molecular biology, Molecular genetics, Population genetics, Taxonomy, Ecology,

Microbiology, Virology, Botany or Plant Science, Zoology, Entomology, Veterinary science, Agronomy, Forestry, Pathology, Epidemiology, Process technology, Biochemistry, Toxicology and so on.

- **Table 2: Commonly employed techniques for GMO testing and infrastructure needed for various techniques**

GMO detection technique	Advantages	Disadvantages	Desirable Minimum Infrastructure
DNA and RNA-based (PCR, Southern Hybridisation and PCR-RFLP)	-Confirmed proof of transformation -Presence in all plant tissue -Very sensitive -Small sample size -Can be tested at any time after transformation	Expensive instruments and extensive laboratory set up -Highly skilled manpower -Expensive -Farm testing not possible -Processed food testing difficult -Primarily a qualitative test -Quality of the sample very important -Error prone	PCR laboratory, Autoclave, PCR machine, RT-PCR facility, Oven, Gel electrophoresis and documentation unit, machine, Micro-centrifuges, ice machine, clean bench, trans-illuminator, Fridges, Deep fridge, Dot-Blotter, Spectrophotometer, Double distillation plant, Electrical Balance, X-ray cassettes, Hybridization ovens, Microwave, Uninterrupted power supply, Pipettes, nitrocellulose membrane, capillary transfer, DNA probes, electrophoresis transfer or vacuum transfer, consumables etc.
Protein-based or techniques (ELISA, Lateral Flow Strips, Western Blots)	-Confirmed proof of presence of gene product i.e. protein -Farm testing possible -Processed food testing easy -Quick and easy -Inexpensive -Quantitative testing possible -Quality of sample less critical compared to PCR	-Protein may be organ specific -Quantity may vary depending upon environmental condition -Plants may need to grow for few days before testing	Biotechnology laboratory, Grinding apparatus, ELISA kit, ELISA reader, antibodies, Strip test kits, SDS-PAGE unit, Polyprotein probes, nitrocellulose membrane, Fridge, Centrifuge, Balance, other consumables etc.

Source: Modified from and Bhanushali, 2006

For the monitoring and inspection of illegal introduction of various GMOs and their products from various sectors, supporting staff for inspection, monitoring and sampling for detection of GMOs are required at the initial stage. For the detection of GMOs and their products in the laboratory, graduate and postgraduate staffs with relevant training in DNA-based

techniques and microbiological procedures are required to perform PCR-based, Southern Hybridisation-based and Dot Blot Hybridisation-based techniques and similar graduate staffs trained in immunological techniques and microbiological procedures are required for ELISA and Western Blot techniques.

4.5 Existing Situation

4.5.1 Technology, Human Resources and Infrastructure

According to the survey report on biotechnology and biosafety carried out by the NBF project, biotech lab, tissue culture lab; and parasitological lab, microbiology lab and molecular biotech lab with PCR machine are available in Nepal. It also reveals that human resources are available in the fields of tissue culture, molecular biology in plant, animal, microbial, forensic sciences, and molecular ecology. These human resources are engaged in molecular Research & Development activities. In addition to these human resources, human resources are also available in the field of environment and social science.

Plant biotechnology in Nepal is largely limited to tissue culture activities and this technology has been applied for protocol development of and in-vitro propagation of disease free planting materials of economically important crop and horticulture species such as potato, banana, citrus, and flower. In addition to it, biotechnology activities related to disease diagnostic, genetic diversity study; production of bio-fertilizer, microbial bio-pesticides, livestock vaccine against endemic animal diseases using tissue culture and mushroom; embryo transfer in animal are being carried out. Some biotech laboratories in private sector such as Botanical Enterprises, Nepal Biotech Nursery, Research Lab for Agricultural

Biotechnology and Biochemistry, Green Research and Technologies, Himalayan Botanical Research Centre are equally competitive in mass propagation of plants and also involved in R&D of tissue culture technologies on agricultural and horticultural crops.

Though the available technical human resources in the field of modern biotechnology is inadequate, the existing situation in Nepal is not discouraging. A number of universities have initiated producing human resources in the field of biotechnology. Similarly, institutions working in this field have initiated developing their human resources through training. These human resources are engaged in molecular Research & Development activities.

Nepal Agricultural Research Centre (NARC) and Nepal Academy of Science and Technology (NAST) are the main national organizations where PCR based genetic diversity studies and plant disease diagnostic are performed. In Forensic Laboratory human identification using DNA fingerprinting techniques is performed. Enzyme-linked Immuno-sorbent Assay (ELISA) based diagnostic of plant virus diseases are being used few crops such as potato and citrus in NARC. Central Veterinary Laboratory has started producing vaccines for Pest de Petit Ruminants (PPR) and Rabies for animals.

4.5.2 Risk Assessment and Examination

Basic sanitary and phytosanitary, quality testing are used for testing agricultural, forestry products, food and feed and pharmaceuticals. The seeds to be used are tested for quality, variety identification, desirable germination capacity, and treatment with pesticides. The plant quarantine check posts use testing techniques for checking plant and plant products to

be used for agricultural or forestry purposes and provide certificate for export and import of these goods. As to safety measures in import of agricultural plants and products, simply visual observations and diagnostic tests are being carried out with limited laboratory facilities and they usually look for the organisms that have not been introduced in the country.

In case of export and import animals, animal products and feed, animal quarantine office and veterinary authority takes necessary testing in relation to transboundary diseases notified at national and international level in OIE list.

The current testing mechanism of food products is focussed on adulteration and radiation level in food and the quality of the food. Similarly, the testing of feed whether produced within the nation or imported is focussed on adulteration, contamination of feed with toxic materials and quality of the feed.

4.5.3 Risk Management

Safety measures that are practiced during testing of seed, plants, animals, food and feed, pharmaceuticals in the laboratory are common laboratory safety measures, burning, sterilization, incineration, autoclaving, dumping of diseased seed and animals. In this process, use of ultra violet light, disinfecting before entering lab, ammonia-clearing device are also used when necessary.

4.6 Gap

The current testing of animal, bird, seed, plant, plant product, food and feed are focused on their purity, quality and whether they are disease free or not rather than testing for GMOs or their potential impacts on animals, birds, seeds, plants, food and feed, as well as any impacts of GMOs on the

conservation and sustainable use of biological diversity, and on indigenous people and local communities. Though a quarantine certificate is required for export and import of food, feed, seed, plant, animal and animal products, it is the responsibility of the respective inspector to arranges testing of suspected animal, bird, seed, plant, plant product, food and feed at the market or in the factory rather than making the producer and the seller responsible for it.

As described in section 4.5, although a number of activities have been implemented in the field biotechnology, none of the institutions involved in this field have initiated research and development program on modern biotechnology, which involves recombinant DNA technology, in Nepal. Existing infrastructure is not adequate to test GMOs in different aspects of biosafety such as examining and assessing the risks. The technical capacity of Nepal is poor in risk examination, assessment and management. There is lack of human resources required for identifying GMOs, examining and assessing the associated risks to GMOs and managing the risks.

4.7 Proposed Technical Framework

4.7.1 Laboratory

Some of the existing microbiology laboratories will be developed as reference laboratories for checking and verifying proponent's information on the GMOs including information on parental organism, donor organism, process of modification, characteristics of modification; and assessed risks and suitability of the suggested risk management measures. Human resources and infrastructure required for such laboratories will be developed.

4.7.2 Risk Examination

Adverse effects of GMOs or products thereof may occur at any stage of GMO activities such as developing GMOs, testing, releasing, marketing and use. Hence, at each stage, measures for risk assessment and management will be needed. Accordingly, the second stage of action will be allowed to operate only if the observation in the first stage of action suggests that either there are no risks, or the risks observed are manageable. In other words, pilot testing, field trials, release in the market and use of GMOs will be allowed only after the research or testing of the GMOs in contained demonstrates that there is no risk, or the associated risks are manageable.

At the time of assessing the risks, it is required to look at the potential socio-economic impacts also. In addition to the consideration of the impact on traditional culture, values and norms of the nation in the risk assessment report it is equally necessary to address the potential adverse effects on the biological diversity, which in turn affects to local communities' income.

The risks of GMOs or products thereof will be classified into four levels which are as follows:

Level 1: No risk to human health, biological diversity and environment.

Level 2: Low risks to human health, biological diversity and environment.

Level 3: Medium risk to human health, biological diversity and environment.

Level 4: High risk to human health, biological diversity and environment;

The criteria of differentiating the level of the risks will be developed by considering the international, regional, sub-regional and neighbouring nations' practices too.

4.7.3 Risk Management

After evaluating the proposal and its risk assessment report including the suggested risk management measures submitted by the proponent, appropriate risk management measures according to the approved proposal will be enforced.

4.8 Capacity Building

For the successful implementation of the Cartagena Protocol on Biosafety in Nepal and to take maximum benefits from the modern biotechnology, adequate human resources and well equipped laboratories are necessary in order to develop and test GMOs; assess, examine and manage the risks and monitor these activities. Guidelines for risk examination and management are necessary. As Nepal is not in a position to afford substantial funds for research and development in modern biotechnology, it is required to get support from international, regional, sub-regional and developed nations in order to operate the following programs on bio-safety:

a) Capacity building of institution on modern biotechnology and biosafety related R & D.

b) Capacity building of central to district level institutions responsible for risk assessment and management.

c) Capacity building in GMO detection techniques in order to control the illegal transboundary movement of GMOs or products thereof (food, feed and processing).

d) Development of technical recombinant DNA safety guidelines.

e) Improving the infrastructure requirements of quarantine offices.

f) Development of technical guideline for risk assessment and management of GMOs and products (both for environmental safety as well as food and feed safety assessments).

g) Develop capacity in establishing IPR issues of Nepalese biodiversity in the context of modern biotechnology, TRIPS and CITES.

h) Capacity building on labelling GMOs.

i) Develop Biosafety Technology.

CHAPTER 5: ADMINISTRATIVE ASPECT FOR BIO-SAFETY

5.1. Introduction

The Cartagena Protocol on Biosafety, formulated and adopted to regulate and control the transboundary movement of Living Modified Organisms (LMOs) and products thereof and placing on the market, and releasing on the environment has been a global instrument for biosafety. The Protocol has placed responsibility on its parties to develop a national biosafety framework to avoid or minimize the risks to the environment, biological diversity and human health from LMOs and products thereof.

5.2. Administrative Provisions in the Cartagena Protocol

As an obligation to the Cartagena Protocol on Biosafety and its Article 2, each party has to adopt a necessary administrative system which ensures the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that avoids or minimizes the risks to the biological diversity and human health. In addition, according to the Article 19 of the Protocol, each party has to designate a national focal point to liaise with the secretariat of the Convention on Biological Diversity and the parties to the protocol. Similarly, the Protocol has made a provision that each nation has to designate one or more competent national authorities to perform specific tasks of the Protocol. According to the provisions of the Protocol, the major administrative tasks to be performed in relation to regulation, control and management of the development, production and commercialization of the GMOs and products thereof in the Nepalese context are:

a) Establishment of a body responsible for actions to be taken and decision to be made on proposals of research, test, development, import, use and marketing of the GMOs and products thereof.
b) Mechanism for monitoring the implemented approved proposals as per point (a).
c) Take actions against those who violate the terms and conditions set during the approval of the proposals.
d) Prohibit illegal transboundary movement and use of GMOs and products thereof and take action against those who performs illegal actions.
e) Designate institute for examining and testing GMOs and products thereof, whether included in the proposal, in a scientific manner to ensure that the implementation of the proposal will not affect the biological diversity and human health adversely.
f) Designate a body/ bodies responsible for minimizing and managing the risks from the implementation of proposal of GMOs and products thereof, and for taking emergency measures.
g) Designate an institute which is responsible for informing the international BCH about the decisions of proposals on GMOs and products thereof, summary of the risk assessment and environmental reviews, adverse effects observed from the implementation of the proposals, Acts, Rules, guidelines bilateral and multilateral agreements on bio-safety, incidence and actions taken against biosafety related illegal activities.
h) Submit periodical national reports to the secretariat of the Protocol.

i) Promote and facilitate public awareness, education and participation in biosafety.

5.3 Existing Status

The Ministry of Forests and Soil Conservation is the National Focal Point for the Convention on Biological Diversity and the Cartagena Protocol on Bio-safety. According to the provision of the Nepal Biodiversity Strategy (NBS) approved by the Government of Nepal, a National Biodiversity Coordination Committee has been formed. Its members are comprised of representatives from the institutions which are directly or indirectly involved in the field of biodiversity.

According to the NBS, there is provision of establishment of the District Biodiversity Coordination Committee, under the National Biodiversity Coordination Committee at district level. The District Biodiversity Committee is chaired by the chairperson of the District Development Committee. The DBCC will have three members from among the chiefs of the district level offices of the forestry sector, three members from among the chiefs of the district level offices of the agriculture sector, one member from among the head of district level office of the health sector, two representatives nominated by the DDC either from the Village Development Committee or from the Municipality members. These Biodiversity Coordination Committees at the central and district levels are responsible for coordinating the implementation of programs to achieve the goals of the Convention on Biological Diversity.

Table 3: Composition of National Biodiversity Coordination Committee

Designation	Institution	Position in the Committee
Minister or State Minister	Ministry of Forests and Soil Conservation	Chairperson
Joint Secretary	Ministry of Agriculture & Cooperatives	Member
Joint Secretary	Ministry of Finance	Member
Joint Secretary	Secretariat of the National Planning Commission	Member
Representative	UNDP	Member
Country Representative	IUCN	Member
Chairperson	Industry & Environment Committee, Nepal Federation of Industry and Commerce	Member
Five Chairpersons	Thematic Sub-Committees on Forests; Agricultural Biodiversity; Genetic Resources; Sustainable Use of Biological Diversity; Biosecurity	Members
Secretary	Ministry of Forests and Soil Conservation	Member-Secretary

The study and review of the administrative mechanism and organizational structure of the government institutions responsible for biodiversity, natural resource management and health sector reveals that sectoral ministries, departments and offices including offices at the district level are providing services in the respective sectors. Each of these sectors has institutions from central to the district level and has been working according to the

existing sectoral Acts and Rules. The Ministry of Forests and Soil Conservation and line agencies under it are working for the conservation of biological diversity, natural resource management, conservation and management of environment, testing of micro-organisms; research on tissue culture and application of tissue culture; identification of plants, plant diseases and insects, advisory role on CITES, forest research and survey. The offices under the Department of Forests and the Department of National Parks and Wildlife take legal actions too.

Similarly, the Ministry of Agriculture and Cooperatives and the line agencies under it are working for agriculture biodiversity, quality control of seed; production, processing, testing and distribution of seed, agricultural crop, horticulture, fish, fertilizer, pesticides, veterinary services, quality control of food and feed; quarantine testing of seed, plants and plant products, animals, and food and feed. Nepal Agriculture Research Center aims to uplift the economic conditions of the farmers through research on developing improved variety of seed, animals and the agricultural technology. The NARC and the Nepal Academy of Science and Technology are working in the field of biotechnology too.

The Ministry of Health and Population and the line agencies under it work for health plan, research on public health service and planning for better health, quality control of medicines, price control of medicines, regulating marketing of medicines; prohibiting the import, sale and use of medicines below the national standard or which are not safe.

5.4 Gaps

Existing legislation has not designated any responsible institutions for research, development, testing, import and release in the market of GMOs, and monitoring such activities. Nevertheless, the Ministry of Forests and Soil Conservation, as focal point for the Cartagena Protocol on Bio-safety, has been working for the biosafety related activities in coordination with other agencies.

An administrative mechanism has to be established in order to perform biosafety related activities such as receiving application with a proposal on research, development, import-export of GMOs and products thereof and placing them on the market; evaluation of the proposal; making decision on the proposal; monitoring the implementation of the proposal and informing stakeholders about these activities in a transparent way. In view of the nature of functions to be performed in relation to these activities, an administrative system has to be developed to administer biosafety related activities in close cooperation with the major relevant institutions responsible for biological diversity, natural resource management, agriculture, human health, biotechnology, environment, commerce and custom.

5.5 Proposed Administrative Mechanism

The Ministry of Forests and Soil Conservation is the National Focal Point for the Convention on Biological Diversity and the Cartagena Protocol on Bio-safety. It has also been acting as National Clearing House Mechanism for the Convention on Biological diversity as well as National Biosafety

Clearing House for the Biosafety Protocol. Hence, it is the responsibility of the ministry to keep the records of the all the activities, occurring in the nation, related to biosafety and to report to the Secretariat of the Convention on Biological Diversity as well as to inform the world community through the National Biosafety Clearing House. The draft bill on "Access to Genetic Resource and Benefit Sharing" has proposed the Ministry of Forests and Soil Conservation as the responsible agency for the registration of the biodiversity and its associated traditional knowledge in the country. Accordingly, it is the responsibility of the ministry to keep the records of the GMOs, either developed in Nepal or imported from other countries, used in the field of agriculture or forestry in the nation too. The national workshops and the regional workshops on Biosafety have also recommended to adopt one window policy for decision making on biosafety.

In this context, it is the need of the hour to develop an effective and authorized administrative system in order to regulate and control the activities such as transboundary movement, study, research and testing of the GMOs and the products thereof in the laboratory. While fulfilling the obligations of the international conventions, Nepal has to adopt a simple and cost effective administrative system. Moreover, the proposed administrative system should match the administrative functions to be performed as required by the provisions of the Convention on the Biological Diversity and the Cartagena Protocol on Biosafety. In addition to it, the proposed administrative systems need to ensure that the structure and functions of the different sectors match their potential roles and

functions in biosafety. A National Biosafety Committee, with representation from different sectors, will be established under the chairpersonship of the secretary of the Ministry of Forests and Soil Conservation, the focal point for the CBD and CPB. This committee will make decisions on all kinds of proposals on GMOs and products thereof. The committee will act as a National Competent Authority. The Environment Division in the MoFSC will function as the secretariat of the committee. The respective sectoral agencies are designated as the Sectoral Competent Authorities responsible for reviewing, evaluating proposal for GMOs and their products in their sector, including assessment of risks. In addition, these sectoral institutions are responsible for regular monitoring of the concerned implemented proposals and their effects on biological diversity, human health and socio-economic conditions.

The National Biosafety Coordination Committee plays an overall coordinating role for risk management and the District Biodiversity Coordination Committee, established according to the provision of the NBS, as described in the section 5.3, implements the primary risk management actions. The DBCC may use the local non-governmental organizations for primary risk management.

A Biosafety Clearing House has to be established at the secretariat of the National Biosafety Committee in order to ensure the public awareness and public participation in bio-safety activities. Non-governmental organization working in the field of biosafety will be involved as partners for public awareness and public participation.

Support from respective quarantine and custom offices will be necessary to control the illegal entry of the GMOs and products thereof.

5.6 Decision Making and Implementation Mechanism

A proponent willing to develop, produce, import, test and use GMOs or products containing GMOs, has to submit an application with the proposal and risk assessment report to the secretariat of the National Biosafety Committee. Depending upon the type of GMOs and the products thereof, the proposal and the risk assessment report will be reviewed, examined and evaluated by the concerned sectoral competent authority, which will submit its comments to the National Biosafety Committee. The later will decide whether or not to approve the proposal and what conditions will be placed on the approval. The secretariat notifies the decision to the sectoral competent authority, the proponent, the Department of Commerce, the Department of Custom and Quarantine Offices. The biosafety monitoring and emergency risk management is carried out as described in section 5.12 and 5.13 respectively. The interrelationship among the decision-making body and institutions involved in implementation of biosafety activities is presented in the diagram 3 and the flow chart of biosafety actions in diagram 4.

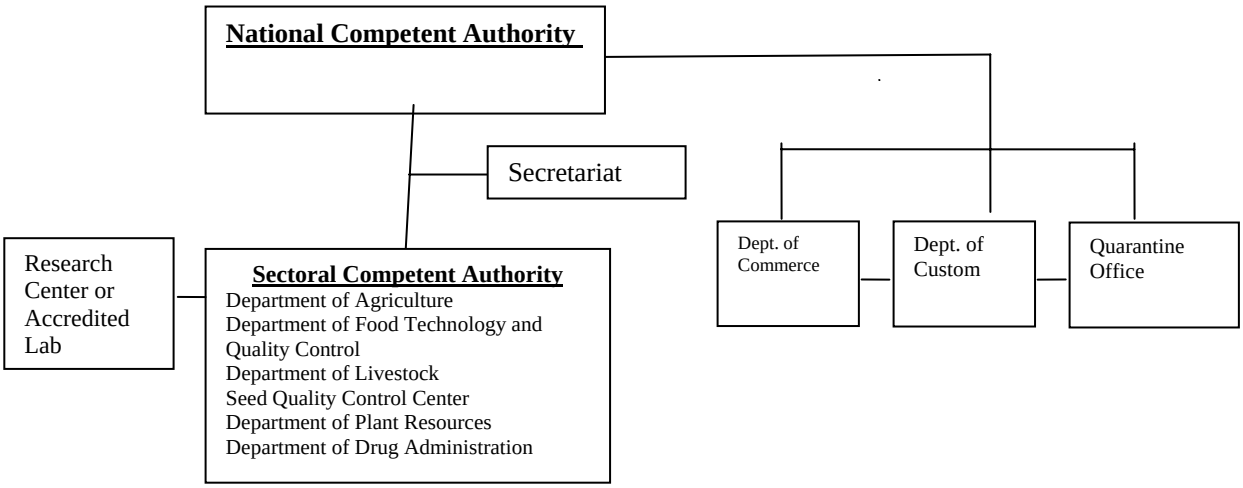

Diagram 3: Inter-linkage among the institutions involved in the decision making process and the implementation of biosafety

5.7 Public Hearing on the Proposal

It is essential to conduct public hearing and get their views on the use of the GMOs and products thereof as they may affect on the biodiversity, which is the basis of livelihood of the human beings and the social customs of the local communities. Accordingly, Article 23 of the Cartagena Protocol has provided for consulting the public in the decision-making process regarding GMOs. Therefore, depending upon the type of GMO and products thereof, the NCA publishes notice on the national newspaper asking people to submit written comments or views on the proposals of GMOs or products thereof. People have to submit their comments within a given time frame as published in the newspaper. The SCAs conducts public hearing during the process of the review, examination and evaluation of the proposals. Provision is made for representation in the decision making body, National Biosafety Committee, from the central consumers association.

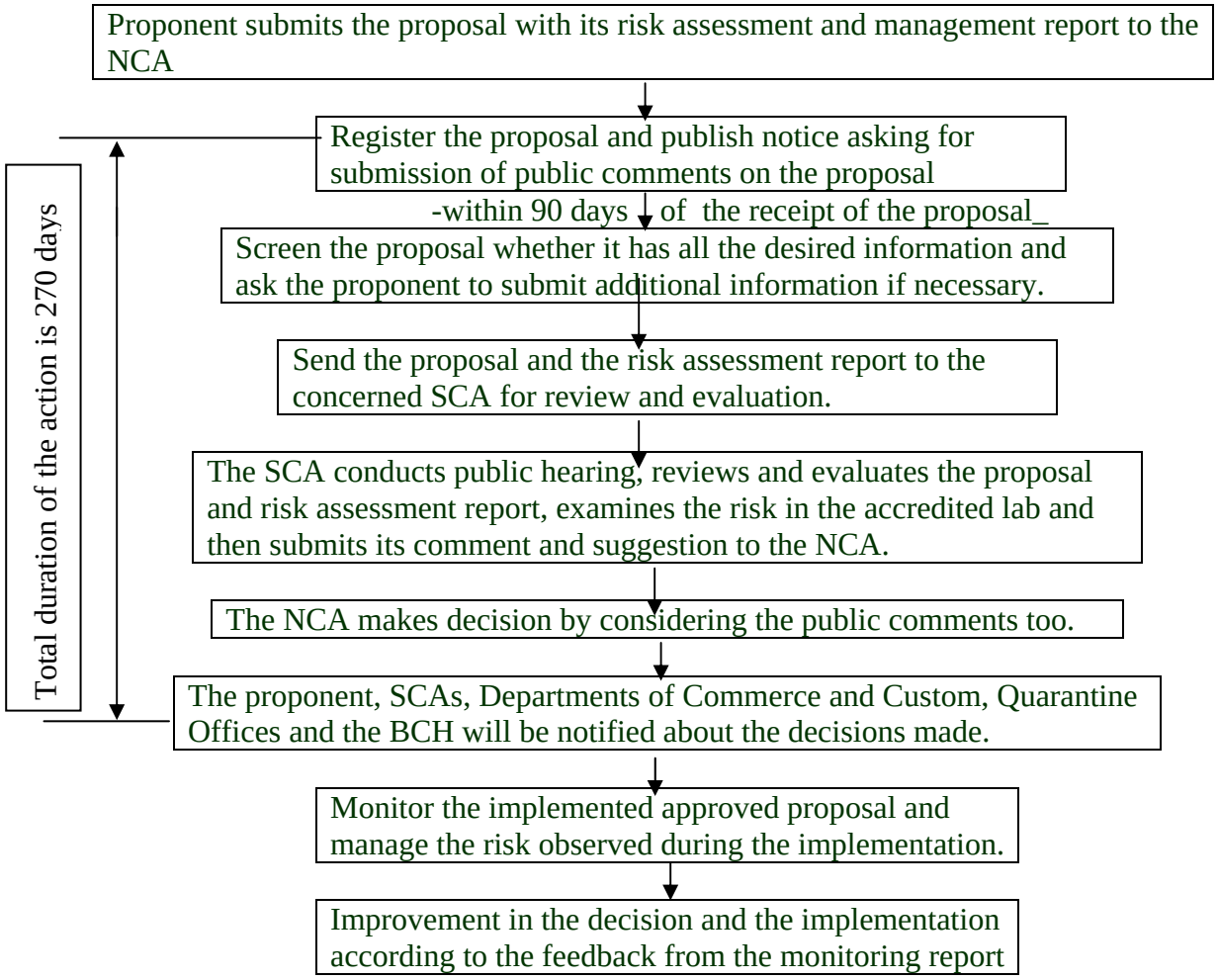

Diagram 4: Flow chart of the decision making and implementation of a proposal on GMOs or Products thereof

5.8 National Biosafety Committee/ National Competent Authority

Biosafety issues are of a multidisciplinary nature. A National Biosafety Committee with representation from the major biosafety stakeholders as mentioned in table 4 will be formed. It makes decision on biosafety proposals in a participatory and transparent way. The National Biosafety Committee acts as National Competent Authority. Proponents have to

submit their proposals to the NCA. The NCA makes decision after receiving comments from the SCA.

Table 4: Composition of the National Biosafety Committee

Status in the Committee	Designation	Institutions
Chairperson	Secretary,	Ministry of Forests and Soil Conservation
Member	Joint- Secretary	Ministry of Environment, Science and Technology
Member	Joint - Secretary	Ministry of Health and Population
Member	Joint - Secretary	Ministry of Agriculture and Cooperatives
Member	Biotechnologist	Nepal Agriculture Research Center
Member	Biochemist/Botanist	University
Member	Biodiversity Expert	Free Lancer
Member	Representative	Consumers' Society (preferably farmer)
Member	Representative	Private Institution (Industrialist or the Business Person)
Member	Social Scientist (female)	Free Lancer
Member-Secretary	Joint - Secretary	Environment Division, Ministry of Forests and Soil Conservation

5.9 Sectoral Competent Authority

GMOs may be seed, plants animals for the agriculture or forestry purpose, and products of GMOs or products containing GMOs such as food, feed or pharmaceuticals. Therefore, depending upon the types of the GMOs and

products thereof, respective sectoral line agencies as presented in table 5 will be designated as Sectoral Competent Authority responsible for the evaluation of the respective proposals and its risk assessment report, monitoring of the implemented proposals, ensure that the GMOs or its products permitted for testing, storage, use are properly labelled with the description of its composition, direction for use, potential risk, and management of the risks arising from implementation of the proposal.

The SCA evaluates a proposal on GMOs and products thereof, and the risk assessment report in consultation with experts of the concerned GMO, biodiversity, ecology, social science and representative of consumers or farmers association. Moreover, depending upon the type of GMO, the SCA consults with any or group of the experts in the field of nucleic acid technology or molecular biology, molecular genetics, population genetics, taxonomy, microbiology, virology, botany, zoology, entomology, veterinary science, agronomy, forestry, pathology, epidemiology, process technology, biochemistry and toxicology and so on as required. Any tests of the GMOs have to be carried out in accredited laboratory. The SCA submits its comments to the NCA on the basis of any laboratory tests and the evaluation conducted in consultation with the concerned experts of different fields.

Table 5: Sectoral Competent Authorities and Responsible GMOs

Name of Institution	GMOs and Products thereof
Department of Agriculture	Plants, Micro-organism and Fish for Agriculture Purpose,
Department of Food Technology and Quality Control	Food and Feed
Department of Livestock and Animal Health	Animal, Birds and Forage
Seed and Quality Control Centre	Seed for Agricultural Purpose
Department of Plant Resources	Seed and Plant for Forestry Purpose
Department of Drug Administration	Pharmaceuticals

5.10 Duration

Prior to the transboundary movement of GMO or products thereof, a proponent has to submit application to NCA seeking permit for such actions. According to the provision of the Protocol, acknowledge the receipt of application within 90 days of the receipt of the application and within 270 days communicate the decision to the proponent and the Biosafety Clearing House Table 6). In general, the time frame for making decisions on biosafety related activities is given in the table 6.

Table 6: Time from for decision-making

	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 the decision on an application	270 working days from date of acknowledgement
3	Inform the BCH of a decision on Proposal and Risk assessment and management Report of GMO	15 working days
4	Notify the applicant of a change in the decision regarding a transboundary movement	30 working days
5	Party of imports' response to changed decision on transboundary movement	90 working days
6	Notification of unintentional transboundary movement likely to have significant adverse effect	Immediately

5.11 Role of Other Institutions

5.11.1 Department of Commerce

On the recommendation of the NBC, the department issues permit to import GMOs or products thereof according to the prevailing legislation.

5.11.2 Custom Offices

The Custom Offices allows importing GMOs or products thereof according to the recommendation of the NBC and the import permit issued by the Department of Commerce and after receiving positive comments from the quarantine office. The Custom office provides information on the imported GMO and its quantity to the ministry.

5.11.3 Quarantine Offices

The Quarantine Offices examines the samples of the imported GMOs or products thereof in accordance with its rules and regulations and recommends accordingly to the custom offices.

5.11.4 Research Centre and Accredited Lab

5.11.4.1 For Importing GMOs

The Scientific Research Center verifies the scientific information and examines the potential risks to the local environment by testing the sample as necessary and furnishes the results of such examination and research to the relevant agencies.

5.11.4.2 In case of GMOs produced within the Country

Provide the scientific information of the GMOs or products thereof produced within the country to the concerned agencies. In case the scientific research center itself is a proponent of a proposal it has to be examined by another scientific research center or accredited laboratory.

5.12 Monitoring and inspections

Often, the adverse effects of GMOs on the biological diversity and human health do occur or can be seen only after a long time of their use or consumption. Hence, it is required to monitor continuously any GMOs released into the environment for field trials or commercial purposes in order to know the kinds of effects on human health, biological diversity and the environment. It is also required to inspect whether the proponent

has implemented the proposed risk management measure for avoiding or reducing the risks along with the implementation of the approved proposals.

The monitoring report contributes to risk management actions and decision making process of GMOs proposals. The SCAs mobilize their respective district level line agencies to regularly monitor and inspect GMOs or the products thereof released into the environment for which they are responsible. The SCAs submit the monitoring report to the NCA. In order to evaluate the activities happening or occurring in the nation, the NCA has to arrange for regular inspection, monitoring and evaluation of the activities of the GMO related firms in Nepal and monitoring of used GMOs for long term. It also arranges to prepare database on the above functions.

5.13 Emergency Measures

In order to avoid or minimize the risks from the use of the GMOs or products containing GMOs, the principle of adopting the precautionary approach has been put forward by the Cartagena Protocol on Bio-safety. Nevertheless, in case adverse effects occurred to the human health or the environment from the use of such products, remedial action has to be taken to control the accident. Proper administrative mechanism for biosafety plays a vital role to manage and control such events. Particularly, the NBC's role is vital. For this, it is essential for the NBC to coordinate with the main concerned line agencies in the district where the accident has occurred and to apply emergency response measures. In addition, it may need to send experts from the centre to the accident site. The NCA is also

required to inform neighbouring countries and the international community about the accident and to seek expert assistance as needed.

5.14 Financial liability

The proponent has to bear all the costs required for risk assessment and examining or verifying the assessed risks and implementation of the risk management measures specified during the approval of the proposal.

5.15 Capacity Building

Following are the areas requiring capacity buildings of the institutions and the human resources:

- Develop biosafety monitoring systems.
- Improve organizational structure of the institutions that have direct. responsibility in biosafety issues, and develop their human resources.
- capacity building in the management of bio-safety.
- Development of cooperation and coordination among institutions responsible for biosafety.
- Establish a National Biosafety Clearing House for Dissemination of Information through implementation of the UNEP-GEF BCH project.

CHAPTER 6: PUBLIC PARTICIPATION

6.1 Introduction

Public participation is necessary in the decision making process of production, import, handling and use of GMOs. As GMOs affect human health and the biological diversity, which is a basis of the livelihood of the human life on earth, people at all levels should be aware of both the positive and negative aspects of GMOs. As a part of the public awareness program, it is required to disseminate available information on GMOs and products thereof through appropriate media and publications. In addition to the dissemination of information, awareness-raising programs on the issues of GMOs are required to be conducted in order to sensitize the public. Only then, effective people's participation on decision-making process of the GMOs related issues can be expected. The knowledge of the representative of people on positive and negative aspects of the GMOs and the number of issues on biosafety helps him/ her in providing concrete comments in the meeting of the decision making body.

Considering information, education, consultation and participation as the main elements of public participation, Article 23 of the Cartagena Protocol on Biosafety places emphasis on promoting public awareness, education and participation in each country to ensure the safe transportation, handling and use of GMOs in the respective country. Moreover, the Article also endeavours to ensure that public awareness and education encompasses access to information on GMOs identified

in accordance with this Protocol that may be imported. The need to consult the public in the decision making process regarding GMOs and make the results of such decisions available to the public have also been mentioned in the Article.

6.2 Existing Situation

The government and the non-government organizations have provisions for disseminating information, conducting public awareness raising programs, asking for public comments and participation in the decision making process by the representative of civilians in their respective field of works.

6.2.1 Information Flow

In order to disseminate the information to the target group, measures such as publication and distribution of information note, leaflet, pamphlet, bulletin, newsletter, annual reports and so on; broadcasting or telecasting of the information and notice through medias such as radio and television; loading information on websites have to be taken. Important information are published on Gazette. Biosafety is a new topic to Nepal and the biosafety program has been disseminating the information on it. Articles on general issues of biosafety have been published in the national language and distributed. Similarly, the text of the Cartagena Protocol, translated into the Nepali language, has been published and distributed. The reports of Biosafety Workshops conducted as a part of the preparation the National Biosafety Framework has been published and distributed. On few occasions, news on biosafety has been disseminated through mass media. Interested

intellectual persons browse information on websites of a number of countries.

6.2.2 Consultation and Awareness Raising Program

Training, informal education, street drama, interaction program and consultation workshops are the major types of programs practiced for raising awareness of the people in Nepal. Accordingly, the national biosafety program conducted national consultation workshops at the central level and awareness workshops at the regional levels during the preparation of the national biosafety framework, consultations workshops with participation of the stakeholders have been conducted. Nepal Agriculture Council and the Gothenburg University, Sweden have jointly organized Rice Biotechnology Workshop, which is related to biosafety issues, at Kathmandu on 31 July to August 1, 2006. Representatives from agriculture, forestry, health, university, NGOs and media participated in these workshops.

In relation to the preparation of the national biosafety framework, a committee has been formed under the chairpersonship of the secretary of the Ministry of Forests and Soil Conservation. A joint secretary from each of the ministries of Agriculture and Cooperatives; Environment, Science and Technology; Industry, Commerce and Supply; Law, Justice and Parliamentary Affairs and Health and Population are members of this committee. Similarly, director generals of the Department of Food Technology and Quality Control and the Department of Plant Resources, and a representative from each of the South Asia Watch on Trade, Economy and Environment and Nepal Chambers of Commerce are also

members of this committee. In the meetings of this committee issues on biosafety and national biosafety framework draft have been discussed.

6.2.3 Public Hearing

It is a common practice to publish notice for submitting the public comments on the issues of the adverse impacts of proposed major construction projects and to hold public hearing at the project sites on these issues. Due attention has been paid to address the potentially affected people's concerns while approving the environmental impact assessment of the project and the projects are implemented accordingly.

6.2.4 Representation of civil society in the decision making body

In general committees formed by the different institutions do have provisions to have at least a representative from any one of civilians, farmers or consumers as member of the committee. Such committees make decisions by considering the views and comments of representative of civilians, farmers or consumers.

6.3 Gaps

Information on the benefits and risks of GMOs and products thereof as well as the measures to be taken to avoid or minimize the risks of such products have to reach the common people in remote mountains too, where the literacy rate is also low. It is hard to reach the limited publication materials on these issues in the hands of all the common people. Moreover, almost all publications are in the national language.

Nepal, different ethnical communities have their own dialects /language. They understand easily if new issues are communicated on their own

language. Therefore, information on GMOs issues has to be transmitted through regional radio programs according to the target group of the region, using the target group's dialects in the program

Organized number of workshops and the awareness programs on biosafety were low and have not been able to reach to the people at the grassroots level. Therefore, it is impractical to expect people's participation in biosafety without implementation of appropriate awareness programs on risks and benefits GMOs and products thereof and the biosafety measures to be adopted.

6.4 Public Participation as viewed by the National Biosafety Framework

6.4.1 Information Flow

The issue of GMOs and products thereof relates to people's direct concerns. Therefore, they are to be made aware of these issues through maximum information flow. In order to inform people and make them aware of biosafety issues, mass media will be used in the biosafety extension program. On behalf of the National Biosafety Committee, its secretariat will manage the overall information flow on bio-safety, working with other government and non-governmental agencies.

6.4.2 Awareness Raising Program

The sectoral competent authorities will implement suitable awareness and public participation programs according to their sectoral issues. The sectoral competent authorities may develop district level awareness programs such as training, awareness and informal education. The district level coordination body will coordinate the concerned line

agencies at the district level to run such program in an integrated approach.

6.4.3 Comments & Public Hearing

Opportunities will be given to public to comment on GMO related proposals by publishing notice on the national newspaper. Arrangements will be made for public hearing by the SCAs during the evaluation of risk assessment reports.

6.4.4 Representation of civil society in the decision making body

Provision has been made to include a representative of the central consumers' forum/ society as member in the decision making body of the GMO related proposal, the National Biosafety Committee. All the decisions on GMOs related proposals will be disseminated through national newspapers and National Biosafety Clearing House.

6.5 Conceptual Programs for Public Participation

For effective public participation on biosafety issues including production, import, transboundary movements and testing of GMOs and products thereof it is required to develop and implement programs such as:

- Work with NGOs and private institutions to develop and disseminate information on biosafety through central and regional radio programs.
- Work in close cooperation with NGOs and Private organizations to develop and implement awareness raising programs on biosafety at the grassroot level.

- Develop curriculum and education materials on biosafety for different grades.
- Develop human resources for producing literature and flow of information on biosafety in local communities' language.
- Establish a national biosafety clearing house for information flow at the national, regional and international level.