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The National Biosafety Framework for Tanzania

VICE PRESIDENT'S OFFICE

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PREFACE

During the last century, conventional breeding produced a vast number of varieties and hybrids that have contributed to higher grain yield, stability of harvests and farm income in developed countries. Of recent, modern biotechnology has been a powerful tool that offers several opportunities to humankind. These opportunities exist in medicine, industry, the environment and agriculture. Genetically Modified Organisms (GMOs) are becoming part of an increasing number of products, including food and food additives, beverages, drugs, adhesives and fuels. Agricultural and pharmaceutical GMOs have rapidly become a multi-billion-dollar global industry.

Despite these advances, biotechnology has raised concerns about potential side-effects to human and animal health and the environment, including risks to biological diversity and socio-economic, cultural and ethical issues. The concerns on GMOs to biological diversity and human and animal health are now widely acknowledged. These concerns and opportunities surrounding modern biotechnology dictate the need to develop policy and legal interventions to guide the safe use of biotechnology to prevent or effectively reduce its risks to human and animal health and the environment to acceptable levels.

There is therefore an urgent need to institute elaborate legal, administrative and policy instruments to minimize risks of modern biotechnology to human and animal health and the environment. Tanzania has taken this step to develop its own National Biosafety Framework (NBF) to facilitate the regulation of modern biotechnology in the country. The framework covers key elements that include national policies related to biosafety, regulatory regime, administrative and decision-making mechanisms, monitoring mechanisms and mechanisms for public awareness and participation. In addition, this framework entails building capacity in risk assessment, risk management, detection of GMOs, and participation in decision-making process. I feel privileged to be part of this historic stride. The framework is a product of 18-months project funded by Global Environment Facility (GEF) through United Nations Environment Programme (UNEP). I am therefore indebted to thank them for their financial and technical support.

Building functional infrastructure to support national biosafety activities is undoubtedly a demanding task. Nevertheless, one would agree with me, that it is still necessary to undertake such tasks to cope with the rapid changes we see in modern biotechnology development as they necessitate our prompt response.

It is crucial the National Biosafety Framework be a living document to embrace scientific development of biotechnology to ensure effective and efficient implementation. All of us are responsible for contributing ideas to improve this framework. I therefore welcome your further cooperation.

Dr. Ali Mohamed Shein
Vice President
The United Republic of Tanzania

ACKNOWLEDGEMENT

The successful preparation of the National Biosafety Framework (NBF) is a result of the commitment and hard work of many individuals and institutions that deserve a vote of appreciation. Due to space limitation we cannot refer to all of them, but we assure them of our heartfelt appreciation and we value their cooperation and support.

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Hon. Arcado D. Ntagazwa (MP)
Minister of State - Environment
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ABBREVIATIONS AND ACRONYMS

AIA	Advance Informed Agreement
BL	Biosafety Level
CBD	Convention on Biological Diversity
CBI	Commercial Business Information
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
GEF	Global Environment Facility
GMO	Genetically Modified Organism
HEPA	High Efficiency Particulate Air
HV	Host-Vector
IBC	Institutional Biosafety Committee
LMO	Living Modified Organism
MARI	Mikocheni Agricultural Research Institute
NBAC	National Biotechnology Advisory Committee
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBFP	National Biosafety Focal Point
rDNA	Recombinant Deoxyribonucleic acid
SRI	Sugarcane Research Institute
SUA	Sokoine University of Agriculture
TFDA	Tanzania Food and Drug Authority
UDSM	University of Dar Es Salaam
UNEP	United Nations Environment Programme
VPO	Vice President's Office

DEFINITION OF TERMS

Advance Informed Agreement (AIA)	means consent obtained based upon full disclosure of all relevant information and the taking of full responsibility by the supplier of the information for its accuracy and completeness before any activity is undertaken
Biosafety	means avoidance of risk to the environment and to human and animal health, as a result of the use for research and commerce of genetically modified organisms (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.
Deliberate release or release	means any intentional introduction into the environment of a GMO or a product thereof; this includes releases for commercial purposes, aid food, remediation, research purposes in field experiments, use of GMOs in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use, as part of an approved laboratory or other installations, disposal of waste containing GMOs, import, export or transport of GMOs or products thereof.
Genetically Modified Organism (GMO)	means any biological entity capable of replication or transfer of genetic information, and includes plant, animals, bacteria and all other kinds of micro-organisms, cell cultures, viruses, plasmids and other kinds of vectors, created and propagated; by means of cell or gene technology; in which the genetic material has been altered in a way that does not occur naturally.
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
National Biosafety Framework (NBF)	means a combination of policy, legal, administrative and technical instruments that is set in place to address safety for the environment and human and animal health in the context of modern biotechnology.
Notification	means providing information to, and where appropriate, the lodging of samples, with the NBFP or Competent Authority, at the same time as taking responsibility for the accuracy and completeness of the information.

Placing on the market	means supplying or making available to third parties a GMO or a product thereof, whether there has been monetary exchange or not, and includes the giving as aid food
Product thereof / product of GMO	means any material derived by processing, or howsoever otherwise, from any GMO or from a product of a GMO
Public Awareness	means aa process of imparting relevant information to stakeholders about specific issues
Public Participation	means a process of encouraging all interested and affected parties to contribute to solving social problems and taking on responsibilities for action. It is both a *tool for development* as a way of reaching development aims, and a *development goal* in its own right. Public participation in the context of the NBF, aims to encourage the public and interested stakeholders to be aware of, and contribute to, the research, development, implementation and monitoring of the policy framework.

CHAPTER ONE

INTRODUCTION

1.1 Background and Context of National Biosafety Framework (NBF)

Modern biotechnology is an emerging novel tool with potentials in improving human and animal health, agriculture, industrial and agricultural production as well as environmental protection. However, the development and applications of modern biotechnology have been associated with both opportunities and concerns over the risks of GMOs to human and animal health, biodiversity and the environment. Concerns raised against modern biotechnology may be grouped into environmental; human health; biodiversity; and socio-economic and ethical concerns.

"Biotechnology could contribute significantly to the achievement of the objectives of the Convention on Biological Diversity and attainment of the Millennium Development Goals. However, it must be developed judiciously, and used with adequate and transparent safety measures".

United Nations Secretary-General Kofi Annan, Statement following entry into force of the Cartagena Protocol on Biosafety, September 11, 2003

a) *Environmental concerns* include increase in weediness; toxicity to non-target organism; superpests and superdiseases; negative impacts on biodiversity; and effect on the purity of other crops.

b) *Human and animal health (food and feeds)* concerns cover the potential for gene transfer from GM plant to gut microflora and mammalian cells; safety of antibiotic resistance marker gene used for the selection of GM plants; potential of transgenes contaminating the food chain and potential allergenicity and toxicity in GM foods.

c) *Socio-economic and ethical concerns* arise due to companies control of their processes, genes and chemicals. Socio ethical concerns revolve around ethical or dietary implications of vegetarians or certain religious groups and choice of consumers.

These and other concerns have raised the necessity of putting in place National Biosafety Frameworks. The necessity emerged as one of the priorities following adoption of the Cartagena Protocol on Biosafety in 2000. Tanzania acceded to this Protocol on 16 March 2003.

This draft NBF is an output of the "National Biosafety Framework Project", an 18-month project which commenced in September 2002. This project was funded by the UNEP-GEF and implemented by the Vice President's Office. The project involved the following activities:

a) Organizing National Coordinating Committee (NCC) meetings;
b) Organizing a National Biosafety Framework Stakeholders' Analysis Workshop, 13-14 June 2003;
c) A survey to establish the existing institutional, human resource base and legal capacities and uses of biotechnology. This survey took place between September – December 2003. The survey culminated into a draft Country Study on Biotechnology and Biosafety, draft Biosafety Guidelines and draft Biosafety Regulations;

d) Organizing a National Workshop to Review Biosafety Guidelines and Regulations, 29-30 January 2004;
e) Drafting of the NBF, May–July 2004;
f) Organizing National Workshop to Review the draft NBF, August, 2004.

It is worth mentioning that some of the activities will extend to the implementation phase. These include wider consultation with stakeholders and public awareness raising workshops.

1.2 Guiding Principles

The following principles, based on national and international regulatory regime, shall guide the implementation of the NBF:

a) *Precautionary Principle:* This shall be implemented through the decision-making system of the NBF, particularly in accordance with the procedure for risk assessment, risk management and evaluation of socio-economic risks.

b) *Preventive principle:* prevention of adverse effects of GMOs on environment and human and animal health

c) *A balanced approach:* A balanced approach shall guide the implementation of the NBF. Such approach recognizes both the potential benefits and risks of modern biotechnology to human and animal health, agriculture, biological diversity and the environment.

d) *Prior informed consent:* The exporting Party shall notify the NBFP prior to the first intentional transboundary movement of GMOs. A failure to acknowledge receipt of a notification should not imply consent to importation of GMOs.

e) *Strict liability*: A person who imports, arranges transit, makes contained use of, releases or places on the market a GMO or product of a GMO shall be strictly liable for any harm caused by such a GMO or product of a GMO. The harm shall be fully compensated.

f) *Socio-economic and ethical considerations:* In implementing the NBF, the social, economic and ethical considerations shall be taken into account in Biosafety decisions.

g) *Transparency and Public Participation:* decision taken under the NBF shall be arrived at in a transparent and participatory manner. All relevant stakeholders shall have appropriate access to information and opportunity to participate in Biosafety decision-making process.

h) *Duty to protect the environment:* Every person living in Tanzania shall have a stake and a duty to safeguard and enhance the environment and to inform the relevant authority of any activity and phenomenon that may affect the environment significantly.

1.3 Objectives

The NBF has the following objectives:

a) Establish science-based, holistic and integrated, efficient, transparent and participatory administrative and decision making system so that Tanzania can benefit from modern biotechnology while avoiding or minimizing the inherent environmental, health and socio-economic risks; and

b) Ensure that the research, development, handling, transboundary movement, transit, use, release and management of GMOs are undertaken in a manner that prevents or reduces risks to human and animal health, biological diversity and the environment.

1.4 Scope

NBF applies to the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof that may have adverse environmental, human and animal health and socio-economic as well as ethical and cultural effects on the inhabitants of Tanzania.

1.5 Key Elements

A National Biosafety Framework is a system of legal, technical and administrative instruments set in place to address safety for the environment and shall include the safety of humans and animals in the field of modern biotechnology.

The National Biosafety Framework (NBF) consists of the following key elements:

a) National policies related to biosafety;
b) Regulatory regime;
c) Administrative and decision mechanisms;
d) Monitoring mechanisms; and
e) Mechanisms for public awareness, Education and participation.

The NBF serves as a basic guide to the implementation of the biosafety system in Tanzania. The NBF shall apply in tandem with two important documents, the National Biosafety Guidelines and the Biosafety Regulations.

CHAPTER TWO

NATIONAL POLICIES RELATED TO BIOSAFETY

2.1 The Constitution of the United Republic of Tanzania

The Constitution of the United Republic of Tanzania recognizes the right of inhabitants of Tanzania to enjoy and protection of their lives, which by implication includes right to clean environment. Article 14 of the Constitution states, "Every person has the right to live and to the protection of his life by the society in accordance with the law".

The right to information is an important aspect of biosafety policy. Article 18 Section 2 of the Constitution provides that "every citizen has the right to be informed at all times of various events in the country and the world at large, which are important to the lives and activities of the people and also of issues of importance to the society."

On freedom to participate in public debate, the constitution states, "Without prejudice to expression of the laws of the land, every person has the right to freedom of expression, and to seek, receive and impart or disseminate ideas through any media regardless of national frontiers."

The Constitution therefore provides the fundamental rights for the people of Tanzania to have the right to information; to participate in public debate; and to protect their environment, which are important elements for the formulation of this national biosafety framework.

2.2 The National Environmental Policy

The National Environmental Policy (1997) recognizes the importance of conservation and sustainable utilization of the national biological resources. Paragraph 32 stipulates the need for undertaking programmes and actions for the conservation and sustainable utilization of biological resources to prevent and control the causes of significant reduction or loss of biological diversity. It further states, "Strategic measures shall be put in place for the ***development of biotechnology***, especially to ensure fair and equitable sharing of the results and benefits arising out of utilization by foreign recipients, of genetic resources originating from Tanzania, and ***biosafety***".

The Policy also puts emphasis on environmental impact assessment (Paragraphs 63-67) as an important policy instrument that would facilitate the integration of environmental concerns in the decision-making process. It further states that "one of the cornerstones of the environmental impact assessment process will be the institution of public consultations and public hearings in the EIA procedures". It further acknowledges the need to have an environmental management legislation to implement it (Paragraphs 68-72). This implies the need for regulations covering environmental impact assessment as well as biosafety issues.

2.3 Sectoral Policies

In addition to the National Environmental Policy, there are sectoral policies relevant to biosafety. For example the National Science and Technology Policy for Tanzania (1996) acknowledges the existing weakness in emphasis on basic and applied research. The Policy focuses on, *inter alia*, biotechnology, genetics and genetic engineering, and exploitation of medicinal, agrochemicals and industrial chemicals.

A number of other sectoral policies have been reviewed recently. The National Forest Policy of 1998 provides for the forest biological conservation and advocates for the environmental impact assessment. However, due to the recent nature of modern biotechnology, the Policy is not explicit on biosafety matters. Many other policies that are supposedly meant to deal with biosafety and biotechnology issues provide statements that do not explicitly address biosafety concerns. This national biosafety framework, as well as the forthcoming environmental management Act, will provide a basis for further revision of related policies and sectoral laws so as to take on board biosafety concerns.

CHAPTER THREE

BIOSAFETY REGULATORY REGIME

3.1 Existing Legislation Related to Biosafety and Biotechnology

A review of existing pieces of legislation has shown that there is yet no single legislative instrument that addresses biosafety concerns in the country. Rather there are various pieces of sectoral legislation covering plant protection, animal and human health, which would implicitly address issues of biosafety in their respective mandates. They address the issues of plant protection substances including pesticides and herbicides; animal health; food quality; health control; environmental protection and natural resources management. The following are some of the legislation and other legal instruments that have been assessed in order to establish the extent to which they regulate the application of biotechnology in the country.

a) The Plant Protection Act No. 3 of 1997

The main thrust of this Act is prevention and control of attacks by, or spread of harmful organisms or diseases in Tanzania. The Act includes:

(i) Right of entry and destruction of infectious articles (Section 5);
(ii) Contingency measures for containment of outbreaks of pests (Section 6);
(iii) Power granted to the Minister to make special regulations (Section 7);
(iv) National quarantine measures and plant import and export control (Section 8);
(v) Importation for research (Section 9);
(vi) Conveyance and goods in transit (Sections 10 and 12); and
(vii) Regulations on plant protection substances and plant resistance improvers for the protection of human and animal health or averting dangers, particularly to the natural environment (Section 16).

The law was enacted basically to regulate the introduction of exotic plants. The law, however, does not cater for biosafety with regard to plant GMOs, particularly with regard to risk assessment and management, breaches, liability and compensation, issues of environmental impact assessment, transboundary movement of GMOs, access to resources and benefit-sharing, and the protection of local/national plant varieties for biodiversity conservation.

Nevertheless, the legislation, if amended and modified, could be one of the major national legislation on biosafety.

b) The Tropical Pesticides Research Institute Act No. 18 of 1979

As regards to pesticides, the Tropical Pesticides Research Institute (TPRI) Act No. 18 of 1979 stipulates that TPRI shall provide the following technical services:-

(i) Pesticides registration and control;
(ii) National plant quarantine services;
(iii) National herbarium; and
(iv) Serves as the National Centre for Plant Genetic Resources.

TPRI has also been mandated by the Ministry of Agriculture and Food Security to undertake all phytosanitary activities under the Plant Protection Act, 1997. The mandates of TPRI make it one of the key institutions under the Ministry of Agriculture and Food Security that has a potential role in the future implementation of the NBF.

c) The Veterinary Act No. 16 of 2003

The Veterinary Act, 2003 provides for the registration of veterinarians, enrolment or enlistment of paraprofessionals and their assistants, and for the establishment of the Veterinary Council. The Act, despite being a recently enacted piece of legislation, has no provisions on biosafety. Despite this gap, the powers vested on the veterinarians, could play a very important role in the future implementation of the NBF.

d) The Animal Diseases Act No. 17 of 2003

The Animal Diseases Act provides for the control and prevention of animal diseases, for monitoring of production of animal products, for disposal of animal carcasses and for other related matters. The Act has a provision on GMOs barring their importation to Tanzania without permission of the Director responsible for animal diseases.

e) Fertilisers and Animal Feedstuffs Ordinance Cap. 467

The Fertilizers and Animal Feedstuffs Ordinance Cap. 467, regulates the importation, manufacture and sale of agricultural fertilisers and animal feedstuffs to Tanzania Mainland. The legislation includes the following substantive issues:-

(i) Obligations to furnish written statements on relevant substances/articles such as maize, bone meal, dried blood, fishmeal, barley, cassava and coffee husks (Section 3);
(ii) Deleterious ingredients prohibited in animal feedstuffs (Section 5);
(iii) Offences in respect of unsterilised bones, etc. (Section 6);
(iv) Restrictions on importation of bones, etc. (Section 7); and
(v) Appointment of analysts and inspectors (Section 12).

Like many other sectoral laws, this legislation is aimed at taking care of the sanitary aspects of feeds for animals, and not so much on the biosafety and human and animal health concerns animal health. In order for this law to take on board biosafety concerns, major amendments are needed.

f) The Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003

This Act repealed the Food (Control of Quality) Act of 1978. The current piece of legislation establishes the Tanzania Food and Drugs Authority (TFDA). Notably, TFDA is established to control the quality, safety and effectiveness of food, drugs, cosmetics and medical devices. The legislation sets out the procedure for controlling importation, manufacture, labelling, marking or identification, storage, selling and distribution of these products or any material or substances used in their manufacture.

The Act also deals with registration of herbal drug provided it is in the public interest to have it and proves to be safe, efficacious and of acceptable quality.

Despite the fact that this Act is very recent, it lacks mention of biosafety issues. Furthermore, regulations for the implementation of the law have not yet been developed. The Authority, however, has inspectors who could be used to enforce biosafety requirements under its mandate.

g) The Merchant Shipping Act No of 2003

This Act empowers the Director responsible for marine transport, among others, to:

(i) protect marine environment against pollution emanating from merchant ships and other sea-transport vessels;
(ii) make regulations providing that any goods, articles or materials carried by a ship to be dangerous and thus prescribe the mode of packaging and identification of such goods; and
(iii) inspect any ship to ensure that it complies with the laid down regulations.

The relevance of this Act lies in the opportunity to meet the requirements of the Cartagena Protocol on handling, transport, packaging and identification (Section 18); notification and advance informed agreement procedure (Sections 7 and 8).

The major weakness of the Act is the fact that is limited to the conventional industrial products without consideration of bio-products.

h) The Tanzania Civil Aviation Authority Act No. 10 of 2003

The Tanzania Civil Aviation Act of 2003 establishes the Tanzania Civil Aviation Authority (TCAA). Section 5 of the Act states that "it is the duty of the Authority, in carrying out its functions, to strive to enhance the welfare of Tanzania society by protecting the interest of consumers; enhancing public knowledge, awareness and understanding of the regulated sectors and (taking into account the need to protect and preserve the environment)".

The major strength of the Act is its focus and emphasis on environmental protection and the protection of consumer interest. These strengths could enhances the implementation of the National Biosafety Framework.

i) The Fisheries Act No 22 of 2003

This Act repealed the Fisheries Act No. 6 of 1970. The current legislation, among others, gives he Director of Fisheries powers to regulate the fishing industry through licensing. It also mandates the Minister responsible for fisheries to make regulations which in his opinion are necessary and expedite for the purpose of protecting, conserving, developing, regulating or controlling the capture, collection, gathering, manufacture, storage or marketing of fish, fish products, aquatic flora or products of aquatic flora.

The new law, however, is silent on biosafety issues. However the Minister has yet to make regulations that are of much importance for the implementation of the law. It is envisaged that the new regulations would have provisions which cater for biosafety concerns.

j) Forest Act No. 14 of 2002

This Act repealed the Forest Ordinance Cap. 389 which had been enacted in 1959. The current legislation empowers the Director of Forestry to regulate the harvesting of forest resources through licensing. It also mandates the Minister responsible for forestry to make regulations which in his opinion are necessary and expedite for the purpose of protecting, conserving, developing, regulating or controlling forest resources including conservation of flora and fauna in both terrestrial and marine.

The new law, however, is silent on biosafety or biotechnology concerns despite the available forest-research capacities with regard to forest seed research and other related activities needed during implementation of the biosafety requirements.

k) Beekeeping Act No. 14 of 2002

The Beekeeping Act is a new piece of legislation that was enacted at the same time with the Forest Act, 2002. The Act provides for orderly conduct of beekeeping, improvement of the products of beekeeping and for the prevention and eradication of diseases and pests among bees. This piece of legislation does not have provisions on biosafety or biotechnology.

l) Wildlife Conservation Act No. 12 of 1974

The legislation, among others, mandates the Director of Wildlife to control and regulate the hunting of wildlife resources through licensing. It is not surprising that the Act is silent on biodiversity and LMO concerns due to the fact that it was enacted when such concerns were not priorities in the country. The legislation is currently under review.

m) The Tanzania Commission for Science and Technology Act No. 7 of 1986

This Act establishes the Tanzania Commission for Science and Technology (COSTECH). Section 5 (1) of the Act stipulates the functions of the Commission as the "principal advisory organ of Government on all matters related to scientific research and development". Specifically, COSTECH shall:-

(i) Acquire, store and disseminate scientific and technology information; and
(ii) Mobilise funds for scientific research and technology.

Moreover, Section 15(1) and (2) establishes the National Centre for the Development and Transfer of Technology.

As an advisory organ, it has no regulatory machinery to enforce the law. However due to its role on scientific and technology information and mobilisation of funds for R&D, it is capable of promoting capacity building and public awareness on biosafety concerns.

n) The Tanzania Bureau of Standards Act No. 33 of 1975

This Act established the Tanzania Bureau of Standards (TBS), which is mandated to:

(i) recommend rules/regulations related to safety, trade descriptions, sampling and testing methods;
(ii) assist industries in setting up and enforcing quality control procedures;
(iii) provide for cooperation with the Government or the representative of industry or with any statutory body, or person, with the view to securing the adoption and practical application of standards; and
(iv) to specify and enforce environmental standards.

The major weakness of the Act is the fact that it is limited to the conventional industrial products without consideration of the GMOs.

TBS's major strength is the availability of its inspectorate services that could be a major source of skilled and experienced human resource to recon with in the enforcement of relevant biosafety requirements.

o) The Industrial and Consumer Chemicals (Management and Control) Act No 3 of 2003

The Act provides for the management and control of production, importation, transportation, exportation, storage, dealing and disposal of chemicals. This Act, as much as it does not express provision on biosafety, has useful provisions on risk assessment and risk management. The Act defines risk assessment to mean an act of assessing the risk of exposure and adverse effect to human and animal health and environment. It further defines risk management as a process and procedure of reducing or possibly eliminating risks associated with exposure to chemicals.

p) The National Environment Management Act No. 19 of 1983

This Act established the National Environment Management Council (NEMC), which is mandated to advise the Government on environmental matters. The major weakness of this legislation is that NEMC has no direct enforcement powers to inspect and prosecute environmental offenders. Further, the role of enforcing pollution control is also a mandate of some sectoral ministries such as those responsible for water and fisheries.

As a result of the current work on the formulation of the draft Environmental Management Bill, The Act will be reviewed accordingly. Further, the Government has made a decision on the institutional framework for environmental management in the country. The decision, *inter alia*, underlines the Council's roles, that are stipulated in the National Environmental Policy (1997), as an advisor to the government; the technical arbitrator in the undertaking of Environmental Impact Assessment; and an enforcer with regard to pollution control.

3.2 Future Plan

It has been established in the preceding part that reviews of sectoral pieces of legislation that are relevant to biosafety lack specific provisions on the subject. Despite that glaring gap some of these pieces may as an interim measure provide an avenue for biosafety regulatory framework.

In the long term there is need to enact a specific piece of legislation on the basis of the proposed regulatory measures summarized below.

3.3 Regulatory Mechanisms

3.3.1 General Principles

The main principles that are embodied in the regulation of development and use of GMOs are the precautionary principle, prevention principle and principle of strict liability (refer to Section 1.2).

3.3.2 Institutional Arrangement

The draft Biosafety Regulations proposes the following four institutions for the regulation of GMOs:

- National Biosafety Focal Point (NBFP)
- Competent Authorities
  Ministries responsible for Environment; Agriculture; Livestock; Health; Wildlife; Fisheries; Forestry, Transport and Communication, Industry and Trade, Science and Technology;
- National Biosafety Committee (NBC); and
- Institutional Biosafety Committees (IBCs).

3.3.3 Tools of Management

The draft Biosafety Regulations amply provide for tools to facilitate decision making in terms of risk assessment and risk management. It also provides for liability and redress and places strict liability on the one who carries out activity in relation to GMOs. It gives a wide *locus standi* which proposes that:

> (1) Any person or group of persons may be entitled to bring a claim and seek relief in respect of the breach or threatened breach of any provision of the proposed Biosafety Regulations, including any provision relating to damage to the environment and biological diversity:
>
> (a) in that person's or group of person's interest;
> (b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
> (c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;
> (d) in the public interest; and
> (e) in the interest of protecting environment or biological diversity.
>
> (2) No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

The draft Environmental Management Bill provides for the regulation of development, handling and use of GMOs and products thereof. It proposes to empower the Minister responsible for Environment in consultation with sector Ministries to make regulations, issue guidelines and prescribe measures for the regulation of the development, handling, and use as well as the importation and exportation of GMOs and their products. The regulations and guidelines will among other things specify the following:

- measures to protect environment and human and animal health including socio-economic, cultural and ethical concern;
- measures necessary to regulate the handling, transport, packaging and identification of GMOs and products thereof ;
- measure to regulate, manage and control risks associated with import or export of GMOs and products thereof; and
- measures to promote and facilitate public awareness, education and participation concerning the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof.

The draft Bill has penalties for a number of offences. It states that any person who contravenes any provision commits an offence and is liable on conviction to a fine or compensation. The fine of not less than two million shillings but not exceeding ten million shillings, or to an imprisonment of not less than two years but not exceeding seven years or both.

It is on the basis of the draft Bill, the proposed draft *Environmental Management (Biosafety) Regulations* will be established by the Minister once the Act has been enacted by the Parliament and made operational by the Minister.

3.3.4 Draft Biosafety Regulations

The draft *Environmental Management (Biosafety) Regulations* are arranged in ten parts as follows:

a) Part one deals with interpretation of various terms used in the regulations. Biosafety being a new area necessitates definition of some of the terms.
b) Part two dwells on general principles which give a general direction in implementation. Such principles include precautionary principle, the principle of prevention and strict liability.
c) Part three on institutional arrangement provides for the establishment of the National Biosafety Focal Point. It also proposes the establishment of the NBC and IBC.
d) Part four is on approval of an activity. This part prohibits any dealings in GMOs and their products without the prior written approval of the NBFP. It provides for an elaborate procedure of notification and approval, which includes public participation and a duty to disclose certain information to the public.
e) Part five is on risk assessment and decision making. It is this part which elaborates on the powers of the national focal point in decision making.
f) Part six deals with risk management and this includes measures that may be imposed by the NBFP that are necessary to prevent effects of GMOs or their products on human and animal health, biological diversity or the environment.
g) Part seven covers aspects of liability and redress. This part puts in operation the principle of strict liability. Strict liability is imposed on the person carrying out activity in

relation to GMOs or their products when they directly or indirectly cause harm, injury or loss.

h) Part eight is on offences and penalties. It lists a number of things if committed or omitted constitute offences under the regulations. It also provides for sanctions.
i) Part nine is on schedules. The schedules and any regulations made under or pursuant to this legislation is proposed to be an integral part of this legislation.
j) Part ten is on entry into force. The proposed regulations shall enter into force on the date of its publication in the official gazette.

3.3.5 Inspection and Enforcement

In accordance to section of the draft Environmental Management Act and Biosafety Regulations, inspection and supervision shall be performed by the Inspectorate of Competent Authorities. Authorised party shall pay inspection fees that will be established by the competent authorities. Inspectors have the authority to inspect sites containing GMOs like field trial sites etc for compliance with terms and conditions of authorization. Inspectors also have the authority to inspect contained facilities that may be used for research or storage of GMOs. Competences for the inspection supervision will be specified in permits or approvals.

The proposed system has flexibility to appoint different competent inspectorates on the case by case basis. On the other hand, the competent bodies already have other mandates, therefore, separation of the competences will have to be formalized for GMO regulation.

If an inspector during the performance of work or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment, human and animal health or socio-economic and ethical issues are at risk shall order the following measures:

(a) prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market,
(b) order the temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market,
(c) order the rectifying of established irregularities within a time limit that the inspector specifies, and
(d) order remediation and other measures for rectifying or reducing the consequences of adverse effect that have occurred because of GMO management.

In order for the inspectors to discharge their duties effectively, it is necessary to:-

(a) Carry out a capacity needs assessment;
(b) Develop and implement capacity building programme including training, infrastructure, equipment and tools.

CHAPTER FOUR

ADMINISTRATIVE AND DECISION MAKING MECHANISMS

4.1 Institutional Structure and Administrative Mechanisms

The NBFP, Competent Authorities and other concerned agencies should address issues regarding the use of modern biotechnology particularly on biosafety issues, such as health, environmental and socio-cultural and ethical impacts. These Authorities and agencies should make consultations, formulate departmental directives and regulations on the access and use of the products of modern biotechnology, coordinate activities and programs on research and development and their applications, and allocate appropriate resources for the upgrading of capacities and capabilities to effectively regulate the GM technology and its products.

The proposed biosafety institutional structure is summarized in **Figure 1.** On the onset, it is important to note that the proposed structure recognize mandates of Competent Authorities in their respective disciplines.

4.1.1 National Biosafety Focal Point (NBFP)

The NBFP should be the Ministry responsible for environment. Its roles and responsibilities include the following:

i) To review and approve biosafety applications for research, confined release, pre-commercial release or placing on the market;
ii) To oversee the implementation of biosafety issues;
iii) To receive and forward applications to the Competent Authorities;
iv) To collect and disseminate biosafety information to the public;
v) To establish contacts and linkages with national, regional and international agencies/institutions;
vi) To establish a database for the purpose of facilitating collection, storage, retrieval and dissemination of information relevant to biosafety;
vii) To establish and update a register of experts in biotechnology and biosafety;
viii) To decide whether to accept or reject an application based on the advice by the Competent Authority and NBC;
ix) To notify the Applicant about the results of the review;
x) To initiate actions as may be necessary for appropriate compensation to Tanzania inhabitants or organizations who may suffer damage as a consequence of the exposure to imported biotechnology products; and
xi) To liaise with the Secretariat of Cartagena Protocol on Biosafety and the Biosafety Clearing-House and for facilitating exchange of information among the relevant bodies and authorities.
xii) To declare through the Biosafety Clearing-House that a GMO or product thereof intended as food or feed or for processing (FFP) may be subjected to a full risk assessment;
xiii) To maintain and make available to the public on request, a database on GMO or product thereof intended for direct use as food or feed, or for processing;

xiv) To designate inspectors and undertake inspection as well as other control measures to ensure compliance with the Biosafety Regulations; and

xv) To establish a list of GMOs and products thereof to be regulated inTanzania. The list will be reviewed periodically.

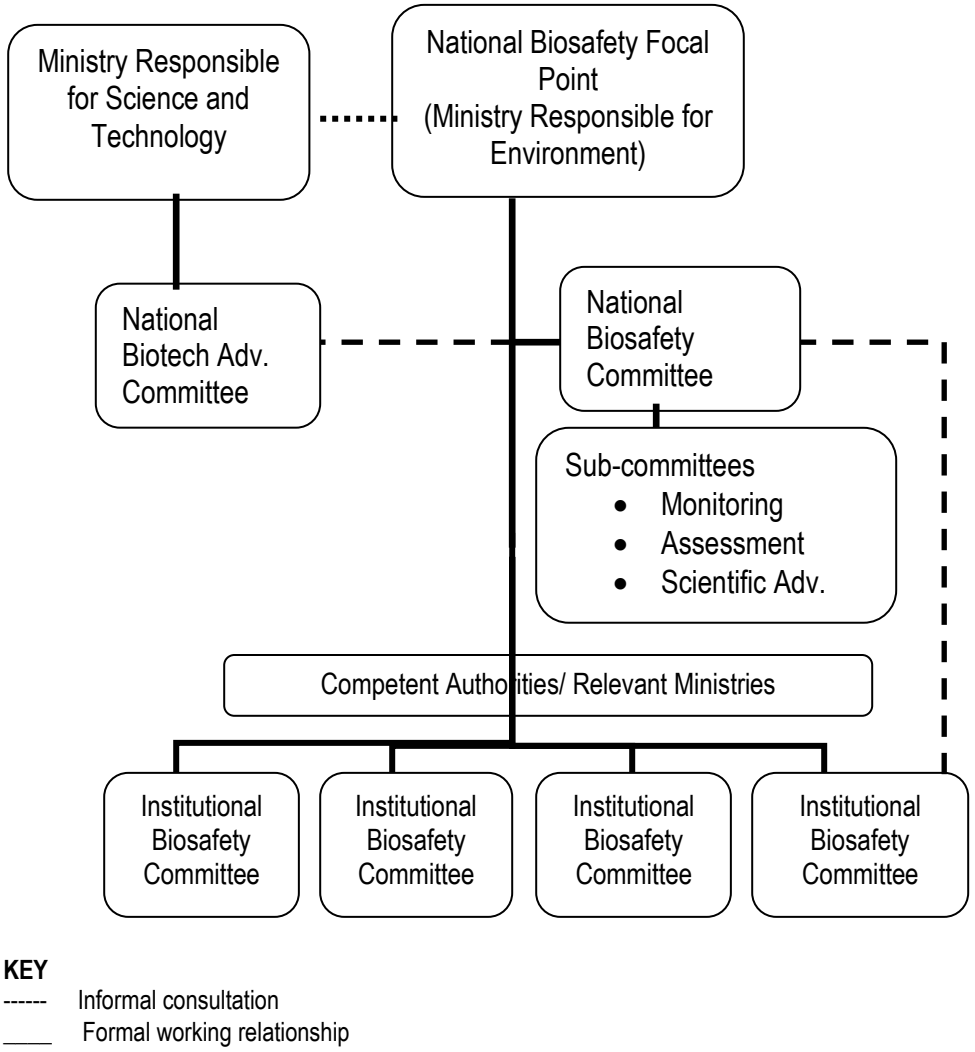

Figure 1: Proposed biosafety institutional structure

4.1.2 National Biosafety Committee (NBC)

A National Biosafety Committee should comprise of representatives from governmental and non-governmental organizations and the private sector that are relevant to the issues of biotechnology and biosafety.

The NBC should have the following functions:

a) Review relevant applications;

b) Advise on policies, legislation and other policy instruments;

c) Undertake study and evaluation of biotechnology research and control and minimize the concomitant risks and hazards associated with the deliberate release of GMOs in the environment;
d) Advise the NBFP and Competent Authorities; and
e) Involve fully the participation of the private sector and the public at large.

In addition, the NBC should perform the following activities:

i) To ensure that adequate testing of GMOs developed elsewhere has been performed in the country of origin before it is introduced in a local trial programme;
ii) To propose mitigation measures to be undertaken in case of any accident;
iii) To review biosafety regulations and guidelines from time to time as necessary;
iv) To facilitate the undertaking of socio-economic impact assessment;
v) To initiate scientific and technical review biosafety applications; and
vi) To perform any other function as may be directed by the NBFP.

The NBFP should designate the National Biosafety Scientific Advisory Sub-Committee comprising of multidisciplinary team of experts in the field of biotechnology and biosafety.

The National Biosafety Scientific Advisory Sub-Committee should be answerable to the NBC. It shall advise the NBC on scientific biosafety concerns. Such functions should include the review and ascertaining of the suitability of both physical and biological containment, confinement and control procedures appropriate at the level of assessed risk involved in relevant research, development and application activities.

4.1.3 Relevant Ministries/ Competent Authorities

The NBFP shall designate Competent Authorities which will be responsible for following up, supervising and controlling the implementation of the biosafety regulations.

The roles and responsibilities of the Competent Authorities shall include:

a) To review relevant applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market;
b) To review, make or have made risk assessments of GMOs or products thereof. When the GMO or products thereof is to be imported, the cost will be borne by the exporter;
c) To advise the NBFP;
d) Designate inspectors and undertake inspection as well as other control measures to ensure compliance with the Biosafety Regulations; and
e) To undertake assessment of socio-economic impacts as well as ethical and cultural impacts.

4.1.4 Institutional Biosafety Committee (IBC)

Institutions that are involved in the import, export, handling, contained use, release or placing on the market of GMOs or products of GMOs should establish IBCs to institute and control safety mechanism and approval procedures at the institutional level. These committees should have multidisciplinary teams.

The roles and responsibilities for IBC shall include:

a) To review the containment and confinement levels required by the Guidelines for the proposed research;

b) To hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purpose/objectives of the proposed GMO and other services;

c) To report immediately to the relevant Ministries/Competent Authorities and appropriate official in the concerned organization, any significant GMO activities, problems with or violations of the regulations and any significant research related accidents and illness; and

d) To perform other functions as may be delegated by the relevant Ministries/Competent Authorities.

4.2 Import of GMOs

4.2.1 Import for GMOs Intended for Intentional Release

4.2.1.1 Notification and Acknowledgement of Receipt of Notification

I. Notification

a) The Party of export shall notify, or require the exporter to ensure notification to, in writing, the NBFP in Tanzania, prior to the importation of GMOs and products thereof into Tanzania including that are intended for direct use as food, feed or for processing. The notification should be submitted to:

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
TANZANIA
E-mail: info@vpdoe.go.tz
Fax: +255 22 2125297
Tel: +255 22 2113983/2118416

b) The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

c) The notification shall contain, at a minimum the information specified in Annex X of the National Biosafety Guidelines for Tanzania.

II. Acknowledgement of Receipt of Notification

a) The NBFP should acknowledge receipt of the notification, in writing, to the Notifier within **ninety (90) days** of its receipt.

b) The acknowledgement should state:-

   i) The date of receipt of the notification;
   ii) Whether the notification, prima facie, contains the information referred to under "Notification" above;
   iii) Whether to proceed according to the regulatory framework of Tanzania.

c) Failure by Tanzania to acknowledge receipt of a notification should not imply its consent to an intentional importation of a GMO into the country.

III. Unintentional and Unauthorized Transboundary Movement of GMOs

a) The applicant shall orally notify the NBFP immediately and in writing within 24 hours of any accident or unintended release of GMOs during transportation and storage, within a contained or confined environments;

b) A notifier, prior to the commencement of any transboundary movement of GMOs, should ensure an emergency plan in the event of accident which among other requirements should contain in a manner and extent of providing information and warning NBFP and competent bodies and the general population in the case of accident or unintended release;

c) In the case of accident or illegal movements, the applicant is required to dispose of the GMOs by repatriation or destruction according to approved procedures and terms provided by the NBFP and the National Biosafety Guidelines and Biosafety Regulations. The NBFP should notify BCH and other relevant international organizations of all cases of illegal transboundary movements.

d) Any notification arising from (c) above, should include:

   i) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMOs;
   ii) Information on the circumstances and estimated date of release, and on the use of the GMOs in the originating Party; and
   iii) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as availabke information about possible risk management measures.

4.2.1.2 Application Procedure

a) Any person who wishes to carry out an import, or transit, or deliberate release, or contained use of, or placing on the market, a GMO or product thereof shall submit an application in writing to NBFP. The application form must be completed and submitted by regular mail or courier delivery to the NBFP through the following address:

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
TANZANIA
E-mail: info@vpdoe.go.tz
Fax: +255 22 2125297
Tel: +255 22 2113983/2118416;

b) No person shall import, transit, carry out the contained use of, or release of, or place on the market, a GMO or a product thereof without an advance informed agreement (AIA) or the explicit written approval of the NBFP;

c) The application shall include:
   i) The information specified in Annex III of the National Biosafety Guidelines for Tanzania and any other information as may be prescribed by Competent Authority ;
   ii) Assessment report on risks that may be posed by the GMO or product thereof on human and animal health, biological diversity and the environment, including the consequences of unintentional release;
   iii) Information from previous or current release of the GMO or product thereof in the country bor in any other country;
   iv) Information on previous approvals or rejections of the GMO or product thereof by any other country;
   v) If the request for approval is for the purposes of research and development, the recommendations of the IBC;
   vi) A clear and sequential description of the steps to be taken in the implementation of the project, and the monitoring and evaluation that will be made at the end of each step, and the method of disposing of any waste;
   vii) The place where and the purpose for which the GMO or product thereof is planned to be developed, used, kept, released or marketed, including detailed instructions for use and a proposed labeling and packaging scheme;
   viii) The applicant shall submit a declaration confirming that the information provided is correct including, where appropriate, an undertaking from the originator of such information affirming its accuracy and completeness

d) Any person who wishes to import, transit, or place on the market a GMO intended for direct use as food or feed, or for processing, shall submit an application in writing with a reference to the information on the item found in the Biosafety Clearing-House, to the NBFP

e) Application should respond to all items listed in the course of action for transboundary movement of GMOs. Application(s) should be submitted four (4) months before importation.

f) If portions of the application contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "Commercial-in-Confidence" or "CIC Copy" by the notifier.

4.2.1.3 Risk Assessment and Management

Before any release is carried out, an evaluation of the impacts and risks posed to human and animal health and the environment by the release should be undertaken. Tanzania shall base its decision on a risk assessment carried out in a scientifically sound manner taking into account socio-economic as well as ethical and cultural considerations.

a) The applicant shall carry out or cause to be carried out an assessment of any risks associated with GMOs or products thereof in respect of GMOs in question;

b) No decision on any applicant to import, transit, make contained use of, release or place on the market a GMO or a product thereof may be made by NBFP without the assessment of risks to human and animal health, biological diversity and the environment, including the socio-economic conditions and cultural norms;

c) The risk assessment of a GMO or a product thereof shall be carried out by the applicant or the Competent Authority as appropriate on a case by case basis and shall be done in accordance with risk assessment procedures as provided in the National Biosafety Guidelines for Tanzania Section 3.0 and Annex VI;

d) The NBFP may require the applicant to bear all the costs for evaluating the risk assessment report or carrying out the risk assessment as the case may be;

e) No person shall be involved in the evaluation of risk assessment in respect of a subject matter in which she/he has any direct or indirect interest of any kind, or if, for any reason, there is , or there is likely to be, a conflict of interest as a result of her/his participation in the evaluation process. A person with a conflict of interest shall declare the fact and withdraw from the evaluation process;

f) If an independent risk assessment can not be undertaken, or if there is no possibility of verifying the independence of the risk assessment, the NBFP may reject the application; and

g) The Competent Authority shall develop, maintain and use, as the need arises, a risk management strategy for protecting human and animal health, biological diversity and the environment, from the accidents of genetic engineering, the use of GMOs and their products. The risk management should be undertaken in accordance with risk management procedures provided in the National Biosafety Guidelines in Section 4.0 and Annex VII;

4.2.1.4 Decision Making Procedure for Import

The decision making process should be based on the best available science taking into account socio-economic, cultural and ethical considerations. Such science must be of the highest quality, inter-disciplinary, peer-reviewed, and consistent with national and international standards. The decision making structure is summarized in Figure 2.

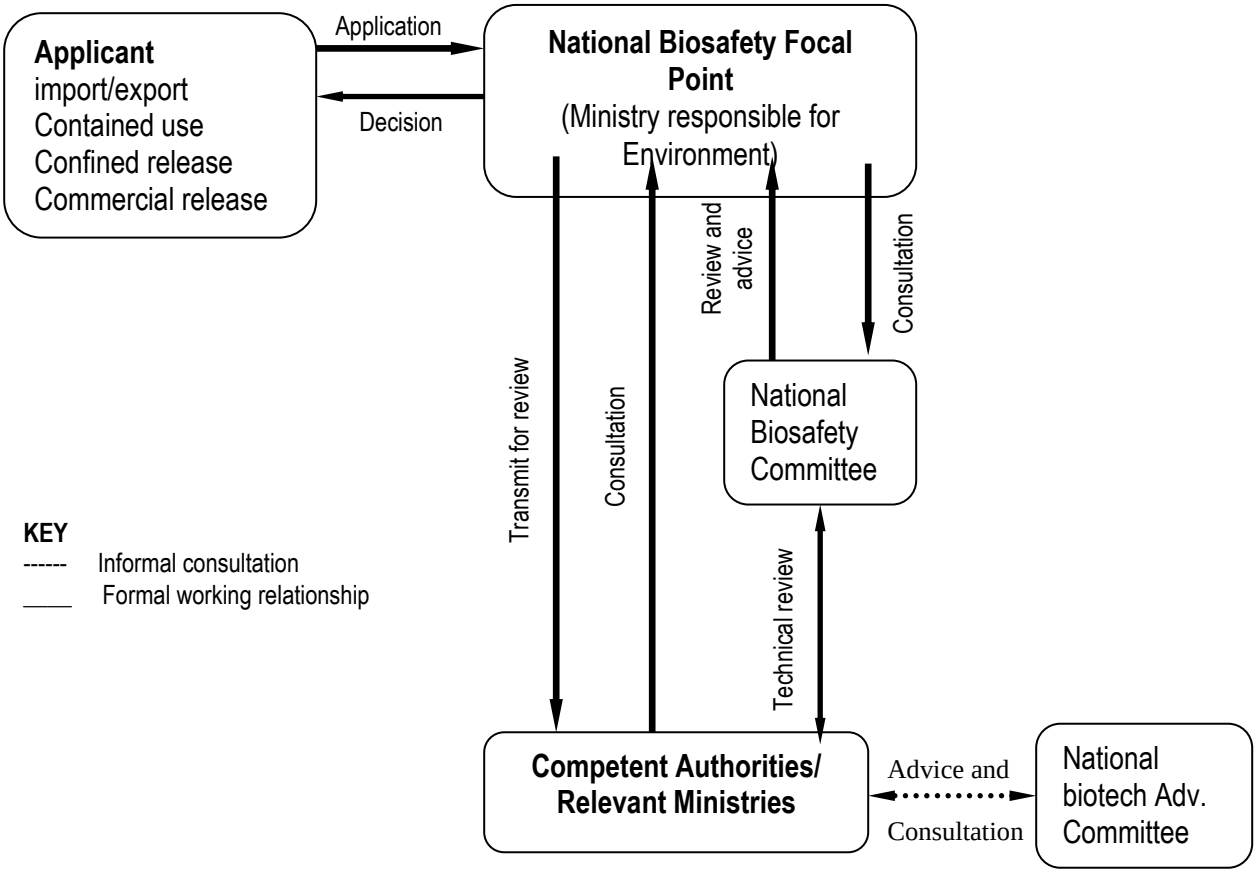

Figure 2: Proposed decision making structure

Decision to import, transit, make contained use of, release, or place on the market a GMO or product thereof should be based on the following procedures:

a) The NBFP shall ensure that the import, transit, contained use, release or placing on the market of a GMO or product thereof is made only after it has given its approval in writing;

b) Decisions taken shall be based on the risk assessment procedures stipulated in the National Biosafety Guidelines

c) The NBFP in collaboration with Competent Authority shall evaluate the information presented by the applicant or in the Biosafety Clearing-House, as the case may be, and may decide that the applicant:
   i) Needs to provide more information to enable decision making;
   ii) May proceed with her/his/its request; or
   iii) May proceed with her/his/its request but only under such conditions as the Competent Authority may specify; or
   iv) Shall not be allowed to proceed with her/his/its request.

d) Within 270 days of the date of receipt of the notification, the NBFP shall notify the applicant in writing and the public of its decisions, copied to the Biosafety Clearing-House;

e) A failure by Tanzania to communicate its decision within 270 days of the date of its receipt of the notification shall not imply its consent to an intentional transboundary movement;

f) The NBFP may, prior to taking a decision, request for further information as it may deem necessary and any applicant who fails to supply the required further information shall be deemed to have withdrawn her/his/its request;

g) Any approval for import, transit, contained use, release or placing on the market of a GMO shall require the applicant to carry out monitoring and evaluation of risks on a continuing basis for a period commensurate with the life cycle of the species, as determined by the NBFP and Competent Authority;

h) In any event, where there is reason to suspect threats of serious damage, lack of scientific evidence shall not be used as a basis for not taking preventive measures;

i) No approval shall be given unless it is considered and duly determined by the NBFP that the import, transit, contained use, release or placing on the market of the GMO will:
   i) Benefit the country without causing any risk/significant risk to human and animal health, biological diversity and the environment;
   ii) Contribute to sustainable development;
   iii) Not have adverse socio-economic impacts;
   iv) Accord with the ethical values and concerns of communities and does not undermine community knowledge and technologies

j) The NBFP shall, as a condition for approval, require the applicant to furnish evidence of insurance cover or some other arrangements sufficient to meet its obligations under this NBF.

4.2.2 Import for Contained Use and GMOs on Transit

4.2.2.1 Contained Use

a) The Cartagena Protocol's AIA procedures does not apply to transboundary movement of GMOs destined for contained use but Tanzania will require risk assessment and prior authorization before the import of GMOs for contained use;

b) Contained use must be undertaken in accordance with standards and terms set by NBFP and Competent Authorities;

c) Tanzania shall require the application of the AIA procedures prior to the first import. In the cases where it is likely GMO initially imported for contained use may subsequently be introduced to the environment;

d) All GMOs for contained use should comply with handling, packaging, identification and other transport safety and health regulatory measures provided by NBFP and Competent Authorities;

e) Contained use of GMO is through physical and biological measures that are classified into four classes:

Class I: no risks on human and animal health, environment and biodiversity;
Class II:low risks on human and animal health, environment and biodiversity;
Class III: intermediate risks on human and animal health, environment and biodiversity; and
Class IV: high risks on human and animal health, environment and biodiversity .

The details of each containment level are available in the National Biosafety Guidelines;

f) Application for contained use shall be submitted to NBFP for approval. Contained use may only be performed in a premise in which the required conditions for the class intended are fulfilled; and

g) Prior to the commencement of contained use, the applicant shall ensure an emergency responce plan in the event of an accident is provided.

4.2.2.2 GMOs on Transit

a) Tanzania will regulate the transport of GMOs through its territory and make available to the BCH, any decision regarding the transit of GMOs through its territory;

b) AIA procedures does not apply to GMOs on transit but Tanzania will subject all GMOs on transit to risk assessment prior to decision on import;

c) All GMOs on transit should comply with handling, packaging, identification and other transport safety and health regulatory measures provided by NBFP and Competent Authorities;

4.2.3 Import of GMOs Intended for Direct Use for Food, Feed or for Processing (GMO-FFPs)

a) Although GMO-FFPs are outside the scope of application of the Cartagena Protocol's AIA procedures, Tanzania will require prior notification and approval of imports or placing on the market of GMO-FFPs;

b) Any exporting Party should provide for the risk assessment of the GMO-FFPs in question, taking into account the characteristics of the GMO, its intended use as well as socio-economic and ethical consideration;

c) Failure by NBFP to communicate its decision shall not imply its consent to the import of GMO-FFPs; and

d) All GMO-FFPs should comply with handling, packaging, identification and other transport safety and health regulatory measures provided by the NBFP and Competent Authorities.

4.2.4 Handling, Transport, Packaging and Identification

a) The notifier/applicant should take necessary measures as stipulated in the National Biosafety Guidelines and Biosafety Regulations for Tanzania that require all GMOs subject to intentional transboundary movement are labelled, handled, packaged and transported

under conditions of safety, taking into consideration relevant national and international rules and standards;

b) Any GMO or product thereof shall be clearly identified and labelled as such, and the identification shall specify the relevant traits and characteristics given in sufficient details for purpose of traceability;

c) Any GMO or product thereof should be clearly labelled and packaged in accordance with National Biosafety Guidelines for Tanzania Annex V part C, and shall comply with such further requirements, if any, imposed by the NBFP and Competent Authority, to indicate that it is, or has been derived from, a GMO, and, where applicable, whether it may cause allergies or pose other risks;

d) GMOs that are made to the third party for contained use or deliberate release should also be labelled even when making available in such a way is not considered placing on the market; and

e) GMOs that are destined for contained use clearly identifies them as GMOs; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the GMOs are consigned.

4.2.5 Review of Decisions

Tanzania may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human and animal health, review and change a decision regarding an intentional transboundary movement.

a) The NBFP shall, within thirty (30) days, inform any notifier that has previously notified movements of the GMOs referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision;

b) A notifier may request the NBFP to review a decision it has made where the notifier considers that:
    i) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
    ii) Additional relevant scientific or technical information has become available.;

c) The NBFP shall respond in writing to such a request within ninety (90) days and set out the reasons for its decision;

d) Where information becomes available after approval of the possible risks to human and animal health, biological diversity and the environment, the notifier should immediately notify the NBFP; and

e) The NBFP could, at its discretion, require a risk assessment for subsequent imports.

4.3 Export of GMOs

a) Any person who intends to export a GMO or a product thereof shall provide to the NBFP a written advance informed agreement (AIA) of the Competent Authority of the importing country;

b) The presentation of the AIA by an exporter shall in no way absolve the exporter from complying with any other laws governing foreign trade;

c) The submission of the AIA shall not preclude Tanzania from taking into account other considerations in deciding whether or not to approve the export; and

d) There shall be no authorization for the re-export of a GMO that has been banned by the laws of Tanzania.

CHAPTER FIVE

MONITORING MECHANISMS

5.1 Introduction

The purpose of monitoring and evaluation is to gather data concerning the GMOs in order to assess the extent, to which transgenic have impacted on the biological diversity, environment and human and animal health. When referring to the environment, the main focus is on confined field trials and commercial release of GMOs. Thus, monitoring would determine effects, which could be categorized as severe, moderate, low, negligible or no harm. In the case of plants, monitoring should be undertaken to determine the level of horizontal gene transfer and to develop a monitoring and evaluation prospectus. Monitoring of the GMOs should be undertaken at different levels. Initial monitoring should be done at the project initiation phase to ensure that all things are organized according to the plan. At several stages during the execution of the project, monitoring should be undertaken to ensure compliance. Two types of evaluations should be undertaken, namely at the formative and the final stages. There are two different types of monitoring which can be associated with the release of GMOs:

a) Monitoring which is required by the government and is intended to confirm any assumptions made in the risk assessment procedures and
b) Voluntary monitoring which is undertaken by the applicant in order to provide further information for his or her own purposes.

5.2 Methodology

It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also important to establish common objectives for the monitoring of GMOs after their deliberate release and/or after placing GMO in the market or products of GMOs. Monitoring of potential cumulative long-term effects should be considered as compulsory part of the monitoring plan. The objective of monitoring plan is to:

a) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
b) identify the occurrence of adverse effects of the GMO or its use on human and animal health or the environment which were not anticipated in the environmental risk assessment.

5.2.1 Monitoring Plan Design

The National Biosafety Focal Point (NBFP) in collaboration with the Competent Authorities should prepare monitoring plan, the mechanism and cost of monitoring for each release of specific GMO. The design of the monitoring plan should:

a) Be detailed on case by case basis taking into account the environmental risk assessment and risk management;

b) Take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released;

c) Incorporate general surveillance for unanticipated adverse effects and, if necessary, (case) specific monitoring focusing on adverse effects identified in the environmental risk assessment;

d) Be carried out for a sufficient period of time to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment;

e) Make use of already established routine surveillance practices such as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder;

f) Facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human and animal health or the environment;

g) Identify who will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human and animal health and the environment.

h) Give consideration to the mechanisms for identifying and confirming any observed adverse effects on biodiversity, human and animal health and environment and enable the consent holder or the Competent Authority, where appropriate, to take the measures necessary to protect human and animal health, biodiversity and the environment.

5.2.2 Types of Monitoring

For the purpose of this NBF, monitoring is used to gather additional scientific data to assist the assessment of risk and decision-making. Monitoring is carried out for specific reasons and at specific times in the development of GMOs. The various types of monitoring that may be used by monitoring agencies are listed below.

a) Case-specific monitoring

Case specific monitoring should be used to confirm any assumption derived from risk assessment regarding potential adverse effects of the GMO or its use on human and animal health or the environment. It deals with the observation of certain adverse effects, i.e. “immediate and direct as well as delayed or indirect effects which have been identified in the environmental risk assessment” relating to individual approvals for placing on the market over a limited period of time.

b) General surveillance monitoring see earlier comment

Used for the long-term observation in Good Manufacturing Practices (GMPs) and covers the observation of adverse effects of the GMO or its use for human and animal health and the environment that were not predicted in the risk assessment for one particular product. To be able to identify these adverse effects, general surveillance should consist of elements based on effect-hypotheses and elements not based on clear defined hypotheses. If changes in the environment are identified further examination is required. An additional component could be existing observation programmes which could be adapted to the needs of monitoring GMPs. In a first range this could be environment observation programmes as well as programmes in the field of agriculture food surveys, nature conservation, soil observation and veterinary surveys.

c) Voluntary monitoring

Might include data collection for the further development of a program of release proposals, e.g. by accumulation of data on survival of the GM plant in the environment. It might also mean obtaining data to better understand the probability or impact of risk and thus allow informed relaxation of unnecessary safeguards in future releases.

d) Monitoring by applicants

Monitoring by an applicant is done at the field level following terms and conditions set by the competent authority. It enables the applicant to take measures to ensure that the implementation of trials/projects on release of GMO are proceeding as expected and if unexpected problems arise, the applicant should immediately take action and notify the authorities.

For the purpose of this NBF, monitoring should cover all types of activities starting from laboratory to commercial release. Some of the important things to consider are:

i) develop monitoring indicators;
ii) develop target outputs ;
iii) develop performance measures;
iv) determine at what stage the evaluation will be undertaken and timelines for both formative and final evaluation; and
v) provide for the resources which will be needed for both monitoring and evaluation.

e) Experimentation

Experimentation refers to that exercise that is part of early stage, research and development procedures. In small scale field tests, monitoring might be designed to answer specific questions about product performance or provide basic information on the biology of organisms and their interactions with the environment. With regard to biosafety issues, a monitoring program might be designed to test pre-release evaluations of gene flow or the potential impacts of gene exchange should it occur. Any of these issues may have been raised at the risk assessment stage of an application review. If there are restrictions imposed as a condition for application approval, a monitoring procedure may be proposed to fulfill some or the entire requirement.

f) Tracking

Tracking is used primarily to monitor the movement and dispersal of the organisms and their genes. For most crop plants which do not survive well beyond cultivated fields, this has not been of great concern. For those crop plants that have close relatives in proximity to the cultivated plots, however, there has been concern for out crossing of the engineered genes. It is the responsibility of the authorized party to ensure that the conditions for reproductive isolation of all trial plants/organism are met during current release period and the post release/harvest periods.

g) Surveillance

For the purpose of this frame work, Surveillance implies post-release observation, often for the survival and dispersal of an organism or for some environmental impact when predetermined sampling regimes are often impractical. The implications of large distances (e.g., kilometers) and long time intervals (e.g., years) to monitor wind driven pollen or seed dispersal, for example, might challenge the most robust budget. Additionally, deciding upon what to look for and devising a meaningful surveillance program may present insurmountable difficulties when there may only be speculation as to what environmental impacts a GMO release might impose. This might result in good faith arguments where responsible investigators suggest 'looking under the lamp post'.

5.2.3 Monitoring During Release

Monitoring during release aims to assess the efficacy of any risk management safeguards applied to the release. This should detect whether there is any risk of harm, caused for example by introgression with potential recipients. For example, if the presence of available pollen recipients within the dispersal area is essential to be a risk, their number should be kept below the level at which harm might occur.

The frequency of monitoring should take account of the nature of GMOs. Monitoring data obtained during and after the release from such voluntary experiments to test survival could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal, and consequently, could allow risk management safeguards to be reduced.

It is possible that, despite a thorough risk assessment, unforeseen events will still occur. The monitoring regime may or may not be able to detect whether this is the case. If an unforeseen effect is detected, its significance should be assessed. If there is a significant adverse impact on the environment, pre-planned emergency control will be required.

5.2.4 Post Release Monitoring

Monitoring of post emergence should be implemented following post emergency time periods established by the NBFP.

Post release/harvesting monitoring is necessary where the risk assessment determines that the continuous presence of the released GMO presents risk of harm. Post-release monitoring will need to concentrate on confirming the removal of the released GMOs. Where appropriate, monitoring should concentrate on detecting and controlling any volunteer GMOs arising form the release. In some cases there may be uncertainty regarding the risk of harm from continued

presence of an organism, especially over the long term. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved. In case of plants, factors to be taken into account include:

i) Seasonal effects, such as flowering and likely germination times;
ii) Post-trial treatment of the release site; and
iii) Longevity of seed or tubers in soil.

5.3 Reporting Requirements

The authorized party should comply to the reporting format set in the terms and conditions of authorization. However, for every GMO, there is a need to determine when to undertake monitoring and when to evaluate the work. The same process would explicitly identify who would undertake the monitoring and evaluation, and who would receive the reports.

CHAPTER SIX

MECHANISMS FOR PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

6.1 Introduction

Tanzania has experienced lively public debates on a wide range of issues related to science and technology but not on GMOs. However, the debates on GMOs coincided with growing public awareness on societal issues such as environment and sustainable development. This reflects the fact that involvement of the general public is crucial in the formulation and implementation of national policies.

The level of public awareness on biotechnology and biosafety in the country is extremely low, even amongst the scientific community. Possible explanations for low awareness include:

a) Recent nature of GMO technology;
b) Limited knowledge on GMO technology at all levels;
c) Limited access to relevant publications, the internet and other information sources; and
d) Low level of awareness by the general public on benefits and risks associated with GMOs.

Therefore, it is very crucial to involve a wide range of stakeholders through a consultative process in order to promote and facilitate public awareness and public participation as stipulated in Article 23 of the CPB, which states that parties shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs in relation to the conservation of biological diversity, taking into account the risks to human and animal health. Parties shall further endeavor to ensure public awareness and education encompassing access to information on GMOs identified in accordance with this protocol that may be imported, should consult the public in the decision making process regarding GMOs, and should make the results of such decisions available to the public.

6.1.1 Why Public Awareness, Education and Participation

As biotechnology develops rapidly, more and more GMOs and their products will be released into the environment and may thus pose potential risks to the environment and human and animal health. A proper mechanism should be established to create awareness and enable the public to participate in implementation of the biosafety measures. Awareness and participation are important:

a) For consensus-building on issues that affect people directly or indirectly;
b) To build a sense of ownership and collective responsibility;
c) To promote sustainable development;
d) To promote smooth implementation of the decisions;
e) To build transparency and accountability;
f) To provide balanced information in terms of pros and cons; and
g) To harmonize institutions that provide awareness activities.

Proposed Biosafety Regulations compel the NBFP to provide information to the public and provide for public consultation mechanisms. The NBFP shall endeavor to make available to the public:

a) Information on all GMOs or their products which have received, or have been denied, authorization, as the case may be, for import, deliberate release (including the location of the release), placing on the market or contained use;
b) The risk assessment report in respect of the GMOs or products thereof; and
c) The report on the evaluation of the outcome of the risk assessment.

The Competent Authorities and other agencies, in making biosafety decisions, should promote and facilitate public awareness, education, and participation concerning the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. They should incorporate into their respective administrative issuances and processes best practices and mechanisms on public awareness and participation.

6.1.2 Scope of Public Awareness, Education and Participation

Public education and awareness should be promoted in terms of:

a) Imparting relevant information to stakeholders about specific issues;
b) Providing balanced information in terms of pros and cons;
c) Providing universal access to information;
d) Providing relevant information for informed participation;
e) Translating available information;
f) Reviewing curricula and improve training facilities; and
g) Providing short and long-term training on biotechnology and biosafety.

Public participation on the other hand should be promoted in terms of:

a) Involving stakeholders (at all levels of society) in decision-making and all processes
b) Obtaining opinion from other people, passing on the information; and
c) Using a democratic process in reaching a common understanding and coming out with a common solution.

6.2 Access to information

a) **Right of access to information:** The right of the public and the relevant stakeholders to information about applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs shall be respected. Concerned government departments and agencies should, subject to reasonable limitations, protect confidential information as provided in the Proposed Regulations, and should disclose all information on such applications in a prompt and timely manner.

b) **Confidential Business Information (CBI):** All ministries agencies and institutions handling GMO applications shall ensure that they have procedures to protect confidential business information. The protection of confidential business information is subject to the following requirements:
    i) The declaration of confidentiality of commercial information is subject to proof that the information specified in the application is: a trade secret; or any other information that has a commercial or other value that could be destroyed or diminished if the information were disclosed; or other information that concerns the

lawful financial and commercial affairs of a legal or physical person and that if it were disclosed it could reasonably affect that person;

ii) The NBFP, Competent Authorities and other agencies may refuse declaring the confidentiality of such information if it is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person;

iii) If an application is withdrawn, the concerned NBFP, Competent Authorities and other agencies should respect the confidentiality of commercial and industrial information, including research and development information;

iv) In no case shall the following information be considered confidential:

- The name and address of the applicant.
- A general description of the GMOs.
- A summary of the scientific risk assessment conducted by the applicant.
- Where applicable, any methods and plans for emergency response; and

v) For information claimed as CBI, applicant must provide written justification.

c) **Information on Biosafety Decisions:** The public and relevant stakeholders should have access to all biosafety decisions approving or denying applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. Such decisions need to summarize the application; the results of the scientific risk assessment and the evaluation of socio-economic risks; the public participation process followed; and the basis for approval or denial of the application.

6.3 Minimum Requirements

Public awareness and participation shall apply to all stages of the biosafety decision-making process from the time the application is received. In conducting these processes, the following minimum requirements should be followed:

a) Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective.
b) Adequate and reasonable time frames for public participation procedures.
c) Public consultations, as a way to secure wide input into the decisions that are to be made. These could include public hearings in certain cases, particularly where there is public concern about the proposed measures. These consultations should encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus building among all stakeholders should be encouraged.
d) Procedures for public participation should include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions.

Public opinion as gauged through the procedures for public participation must be taken into account in the decision. The public must be informed of the final decision promptly, have access

to the decision, and must be provided with the reasons and considerations resulting in the decision.

6.4 Tools and Processes

Tools that are used for both public awareness, education and participation are inter-linked; a mix of tools and processes will assist in achieving the goals. Following are the mechanisms that will be used:

a) **National Biosafety Clearing House:** National Biosafety Clearing House should be established in order to facilitate exchange of scientific, technical, legal and administrative information.

b) **Public consultative meetings:** Public meetings and open days in accordance with the local practice in each community, such as Farmers' Day, stakeholder tours, and demonstration projects. Other public gatherings for meetings with local leaders could also be used to disseminate information. Public meetings should be age and gender-sensitive, accessible, convenient to all and as much as possible use the *Kiswahili* language.

c) **Workshops and seminars:** Workshops and seminars targeted at particular stakeholders e.g., awareness workshops involving groups of consumers, farmers, scientists etc..

d) **Public debates and forums:** Provision of information and public debate should be encouraged between companies and institutions working with GMOs and public interest groups. Follow-up general meetings should be conducted with smaller groups of opinion leaders (key informants) to further explain and exchange ideas. Independent forums may be conducted to identify particular needs of different groups.

e) **Capacity building for various stakeholders:** Implementation of the NBF requires the building of biosafety capacities by concerned government departments and agencies. (Annex I), capacity building programs on biosafety are needed for relevant stakeholders including policymakers, regulators, research scientists, media, NGOs and the general public.

f) **Supporting NGOs or civil society groups:** Interest groups (NGOs, etc) should be supported in promoting public awareness or mobilizing public involvement.

g) **Create awareness about opportunities to participate**: Advertising events and meetings in local media. Make the public aware of forthcoming events or meetings, so that people can raise issues before the meeting.

h) **Mass media:** Using radio, newspapers and television.
   - Printed information on biosafety e.g., leaflets, brochures, fact-sheets, posters, newsletters in accessible style and format.
   - Electronic communication technologies such as internet discussions and e-mail news-group.

- Theatre art and other performances to raise awareness and convey information in an accessible and engaging way. Information dissemination and advertising.

i) Stakeholders participation in committees

6.5 Enabling environment

Enabling environment for public awareness, education and participation is a requirement to ensure smooth implementation of National Biosafety Framework. There is a need for:-

a) Capacity building;

b) Establishment and implementation of appropriate programmes and policy guidelines on participatory approaches;

c) Networking among stakeholders;

d) Regional/sub-regional and global cooperation; and

e) Effective participation at all levels, public, government and private.

ANNEX

ANNEX: BIOSAFETY CAPACITY BUILDING PROPOSAL

OUTPUT	ACTIVITIES	TARGET GROUP
1. Effective and efficient National Biosafety Framework for Tanzania in place.	1.1 Organize seven zones consultative meetings to review the national Biosafety Framework for Tanzania	Scientists, Regulators, Inspectors, Mass media, Policy makers, Decision makers, CBO's/NGO's, Consumers, Farmers
	1.2 Organize one national consultative workshop to review the national Biosafety Framework for Tanzania	
2. Improved knowledge and increased technical capacity in risk assessment and risk management of GM products.	2.1 Training on risk assessment and risk management and bioethics	Multidisciplinary scientists, Research managers, Policy makers, Key persons in society, Laboratory technologists and Inspectors
	2.2 Training on detection of GMO's	Regulators, Inspectors
	2.3 Training on review for applications for introduction of GMO's in the country	

3. Public understanding of biotechnology and biosafety systems improved.	Foster public participation in decision-making	Scientists, Regulators, Inspectors, Mass media, Policy makers, Decision makers, CBO's/NGO's, Consumers, Farmers
	Develop information materials and outreach programme (Brochures, mass media coverage-briefs for radio, TV and Video programmes, feature articles and news letter)	
	Training on communication skills	Journalist and local authoritative spokespersons
	Conduct seminars on diverse topics relating to GM technology	Parliamentarians
4. Strengthened information sharing and networking among relevant institutions and stakeholders	Establish and operationalize Biosafety Clearing House (BCH)	Biosafety Focal Point, BCH Task Force and Competent Authorities
	Procurement and installation of V-system, IT equipment and software for networking	
5. Academic curricula on biotechnology and biosafety improved.	Review curricula and improve training facilities	Research and training institutions
6. Capacity to conduct confined field trials built.	Review guidelines for confined experimental field trials for implementation	Multidisciplinary scientists, Research managers, decision makers, Laboratory technologists and Inspectors
	Training on designing and conducting confined experimental field trials	
	Incorporating reviewed Protocols to undertake confined experimental field trials into Biosafety Framework for Tanzania	

	Training on Intellectual Property Right (IPR) and Access Benefit Sharing (ABS) as related to biosafety issues	Lawyers, Multidisciplinary scientists, Research managers, Policy makers, Key persons in society,
7. Capacity to undertake analysis of food and feed safety developed	Seminars on GM food and feed safety	Multidisciplinary scientists, Research managers, decision makers, Regulatory bodies, Laboratory technologists, Processors and Inspectors
	Adopt and testing existing food safety protocols	
	Incorporating Food Safety protocols into Biosafety Framework for Tanzania	
8. Establish funding mechanism for biotechnology and biosafety R&D activities	Develop collaborative research activities	Multidisciplinary scientists, Research managers, decision makers, policy makers, Regulatory bodies, Laboratory technologists, Processors and Inspectors
	Establish internal funding mechanism for undertaking biotechnology and biosafety activities	
	Provide for an enabling environment to encourage investment and participation of private sector	