MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEF SEC PROJECT ID: 3012
COUNTRY: The United Republic of Tanzania
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of the United Republic of Tanzania
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES): Vice President's Office
DURATION: 48 months
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: 1st January 2005
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	777,300.00
PDF A*	
Sub-Total GEF	777,300.00
CO-FINANCING**	
GEF Agency	
Government	614,300.00
Bilateral	0.00
NGOs	0.00
Others	0.00
Sub-Total Co-financing:	614,300.00
Total Project Financing:	1,391,600.00
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

R.O.S Mollel
Senior Permanent Secretary
Vice President's Office

GEF Focal Point of The United Republic of Tanzania, Vice President's Office - Division of Environment, IPS Building, 1st Floor, Samora Avenue/Azikiwe street, PO BOX 5380, Dar Es Salaam, Tanzania
E-mail: info@vpdoe.go.tz; biosafetytz@vpdoe.go.tz
Tel: 255 22 2113983/2118416
Fax: 255 22 2125297/2124637

August 15, 2005

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

Ahmed Djoghlaf, Director, DGEF, UNEP
Assistant Executive Director
Director, Division of GEF Coordination
United Nations Environment Programmes
P .O. BOX 30552
Nairobi
Tel: 254 20 624166
Fax: 254 20 624041/42

Mr. Eric K. Mugurusi
Director
Vice President's Office
Project contact Person
E-mail: info@vpdoe.go.tz; biosafetytz@vpdoe.go.tz
Tel: 255 22 2113983/2118416
Fax: 255 22 2125297/2124637

Date:

LIST OF ACRONYMS

AIA	Advance Informed Agreement
ABSAC	Agriculture Biosafety Steering Committee
BCH	Biosafety Clearing House
BL	Biosafety Level
CBD	Convention on Biological Diversity
CBI	Commercial Business Information
CNDD	The National commission for Sustainable Development
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
NEA	National Executing Agency
NPC	National Project Coordinator
NCC	National Coordinating Committee
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

A. PROJECT SUMMARY

A1. Relevant Policies and Legislation

a) Tanzania has a number of policies, strategies and programmes that relate to conservation and management of biodiversity. The Government commitment on conservation and management of biodiversity has increased in the recent years by enacting Environmental Law (Environmental Management Act 2004) by the Parliament in September 2004 acceded to by the President on 8th February 2005 and operationalised by the Minister responsible for Environment on the 1st July 2005. Also a number of sector policies have been reviewed to accommodate biotechnology and biosafety issues. The National Environment Policy (1997) and the National Environment Action Plan-NEAP (1994) recognise the need to conserve biodiversity at the same time utilise components of biodiversity in a sustainable manner. The NEAP identifies loss of wildlife habitat and biodiversity as one among six major environmental problems in Tanzania, and seeks to conserve and enhance natural and man-made heritage including the biological diversity of the unique ecosystems of Tanzania. Other related policies and strategies include the National Wildlife Policy (1998), the National Forest Policy (1998), the National Fisheries Policy and Strategy (1997), the National Agriculture and Livestock Policy (1997), all of which complement one another and seek for the sustainable management of biodiversity. In addition to these policies, Tanzania has a number of programmes, projects and activities geared towards implementing these policies. Most of these are sectorally administered at national, and/or local levels.

b) The President of the United of Republic of Tanzania acceded to Environmental Management Act, 2004 in February 2005 while the Minister responsible for Environment operationalised the law in the 1st July 2005. The Environmental Management Act, 2004 provides for the legal and institutional framework for sustainable management of the environment. The Environmental Management Act, 2004 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. It is on the basis of the Environmental Management Act 2004, that the proposed draft *Environmental Management (Biosafety) Regulations* will be established and made operational by the Minister responsible for Environment.

c) The draft Biosafety Regulations amply provide for tools to facilitate decision making in terms of risk assessment and risk management. They also provide for liability and redress and places strict liability on the one who carries out activity in relation to GMOs.

A2. The NBF Development Process and Institutional Arrangement

The Vice President's Office, as Focal Point for Biosafety in the country, coordinated the NBF development process through a participatory bottom-up approach that involved key stakeholders. Non-governmental organisations and the private sector also participated in this process. The process involved national surveys, consultative workshops, retreats of experts and national workshops.

The NBF for Tanzania is a system of policy, legal, technical and administrative instruments set in place to address safety for the environment, including the safety of humans, in the field of modern biotechnology. The institutional arrangement for effective implementation of National Biosafety Framework for Tanzania has four components proposed to regulate the import or export of GMOs. It is important to note that the proposed structure recognizes mandates of Competent Authorities in their respective disciplines.

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

Details on roles and functions of these institutions as well as the institutional structure are presented in Annex H.

A3. Project Significance

The United Republic of Tanzania is one of the 41 countries that have completed their National Biosafety Framework as part of the UNEP-GEF project for the development of NBFs. The main outcomes of the development phase include, among others, the setting up of the NBF, Biosafety issues enshrined in the Environmental Management Act 2004, Draft Biosafety Regulations and Guidelines, establishing public awareness, education and information dissemination mechanisms and monitoring mechanisms. This project will help the United Republic of Tanzania to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol and have a National Biosafety Framework fully operational. This project will contribute to:-

i) Development and implementation of Biosafety Regulations;
ii) The implementation of the United Republic of Tanzania's legislative framework on the safe use of biotechnology through decrees, orders, guidelines and manuals;
iii) The preparation of specific technical guidelines;
iv) The strengthening of appropriate institutional structures for risk assessment, risk management, detection of GMOs and decision making;
v) The development and implementation of policies for biotechnology and biosafety;
vi) The training of regulators, decision makers, scientists, and administrative and technical staff on legal and technical matters relates to GMO application;
vii) The reinforcement of the existing infrastructures (laboratories) to strengthen monitoring and detection of GMOs';
viii) The setting up of a mechanism for monitoring and enforcement;
ix) The strengthening of communication and information exchange relating to biosafety both at the national level as well as through the global BCH; and
x) Putting in place systems for strengthening public awareness, education and participation in decision making on GMOs.

A4. Goal and Objectives

Goal: Functional and transparent national biosafety framework in place in accordance with national development priorities and international obligations.

Specific Objectives:

A. To assist The United Republic of Tanzania to establish and consolidate a fully functional and responsive regulatory regime in line with Cartagena Protocol and national needs and priorities*;*

B. To assist The United Republic of Tanzania to establish and consolidate a functional national system for handling request, perform risk assessment, testing of GMOs, decision-making, perform administrative tasks;

C. To assist The United Republic of Tanzania to establish and consolidate a functional national system for "follow-up", namely monitoring of environmental effects and enforcement; and

D. To assist The United Republic of Tanzania to establish and consolidate a functional national system for public awareness, education, participation and access to information.

Indicators for objectives : see logframe in Annex D

A5. Project Outcomes

A. The United Republic of Tanzania has a fully functional and responsive regulatory regime in line with CPB and national needs;
   - *A1. A regulatory regime in place consistent with CPB and other obligations*
   - *A2. Regulatory regime fully enforced*

B. The United Republic of Tanzania has a functional national system for handling requests and decision-making as well as performing or cause to perform risk assessment and management associated to with LMOs, and has a capacity to detect GMOs;
   - *B1. A fully functional risk assessment and risk management system in place*
   - *B2. A functional decision making system established*
   - *B3. A functional administrative system established*

C. The United Republic of Tanzania has a functional national system for "follow-up" activities, namely monitoring of environmental effects and enforcement; and
   - *C1 Strengthened system for monitoring of environmental effects and inspection*
     - *Monitoring of environmental effects and enforcement actions are defined and in place*
     - *Technical means for monitoring and inspections are in place*
     - *Increased national competence on monitoring and inspection is in place and equipped with equipment for additional capacity building*
   - *C2. Emergency procedures established and operationalized*

D. The United Republic of Tanzania has a functional national system for public awareness, education, participation and access to information.
   - *D1. Public education, awareness and participation in decision making strengthened.*

Indicators for outcomes : see logframe in Annex D

A6. Estimated budget (in US$)

GEF: Project Cost: 777,300

Co-financing: (Government of the United Republic of Tanzania)
In- kind US $ 614,300.00

Total: budget US $ 1,391,600.00

A7. Information on Project Proposer:

Director, Vice President's Office - Division of Environment,

Contact person:
Mr. Eric K. Mugurusi
IPS Building, 1st Floor, Samora Avenue/Azikiwe street,
P. O. Box 5380, Dar es Salaam, Tanzania
E-mail: info@vpdoe.go.tz; biosafetytz@vpdoe.go.tz
Tel: 255 22 2113983/2118416
Fax: 255 22 2125297/2124637

B. COUNTRY OWNERSHIP

B1. Country eligibility

The United Republic of Tanzania is a Party to the Convention on Biological Diversity and ratified it on March 1996 while the Cartagena Protocol on Biosafety was acceded to 16 March 2003.

B2. Country Driveness

In promulgating the document “Vision 2025”, the Government of Tanzania postulated that by the year 2025, "the economy of Tanzania should be transformed from a low productivity predominantly rural based subsistence agriculture to diversified semi industrial economy with a modern rural sector and high productivity agriculture which ensures food security and food self sufficiency". To realize this vision, Tanzania considers science and technology to be central to creating wealth and improving the quality of life and bringing sustainable development in contemporary society. Sustainable development depends upon the application of new technologies such as rDNA technology and utilization of inexhaustible supply of renewable resources. On the other hand, the safe application of modern biotechnology needs to be guaranteed through a clear and effective national biotechnology policy, functional biosafety system and government commitment.

In view of the above, it is now momentous for Tanzania to take steps such as incorporating biosafety issues into sectoral policies, national biotechnology strategies and national action plan in order to conserve and manage biodiversity; protect human health. It is very crucial now for the country to collaborate with development partners to implement a functional National Biosafety Framework that would facilitate the safe application of modern biotechnology in the country.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to the third priority that relates to capacity building for the Implementation of the Cartagena Protocol on Biosafety.

The global project will assist Parties to the Protocol to meet their obligations by building or strengthening the capacity needed to have an operative NBF in their respective countries including Biosafety Clearing House and enabling activities such as training in risk assessment and risk management of GMOs. This will be done in collaboration with other relevant government sectors, NGOs, private sector, academic and research institutions and CBOs.

It is therefore most relevant to the implementation of GEF Operational Programs 1-4 and 13.

C2. PROJECT DESIGN

C2.A Background and context

Agenda 21 adopted at the 1992 Conference on Environment and Development states that modern biotechnology "promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improve supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes". According to the Convention on Biological Diversity (CBD), biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Often biotechnology is categorized into traditional and modern biotechnology. Traditional biotechnology refers to techniques that have historically been applied including selective breeding, hybridization and fermentation. On the other hand, modern biotechnology, frequently referred to as *genetic engineering,* refers to a number of techniques that involve the intentional manipulation of genes, cells and living tissue in a relatively predictable and controlled manner to generate changes in the genetic make-up of an organism or production of new tissue.

However, the evolution and growth of modern biotechnology, including its application, has raised concerns on potential side effects to human health, environment, including risks to biological diversity and taking into account socio-economic, cultural and ethical concerns. Particularly serious consequences are associated with the unintentional gene transfer, increased chemical use, reduced agricultural efficiencies, enhanced insect tolerance to biopesticides, adverse impact on indigenous species (non-target), toxic bioremediation products, and increased antibiotic resistance. In response to these concerns, the need to build National Biosafety Frameworks and Guidelines has emerged as one of the priorities from the Convention on Biological Diversity (CBD), as laid out in a supplementary agreement known as Cartagena Protocol on Biosafety that was adopted in 2000. Tanzania acceded to it on 16 March 2003.

It is from this context that, in June 2001, UNEP in collaboration with the GEF initiated a global project to assist up to 100 countries to develop their National Biosafety Frameworks (NBF) so that they can comply with the Cartagena Protocol. The Protocol requires Parties to establish national frameworks for independent scientific review and decision-making on GMOs. A National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that is set in place to address safety for the environment and human health in the context of modern biotechnology. Tanzania has successfully completed the development of National Biosafety Framework in March 2005 (See Annex A).

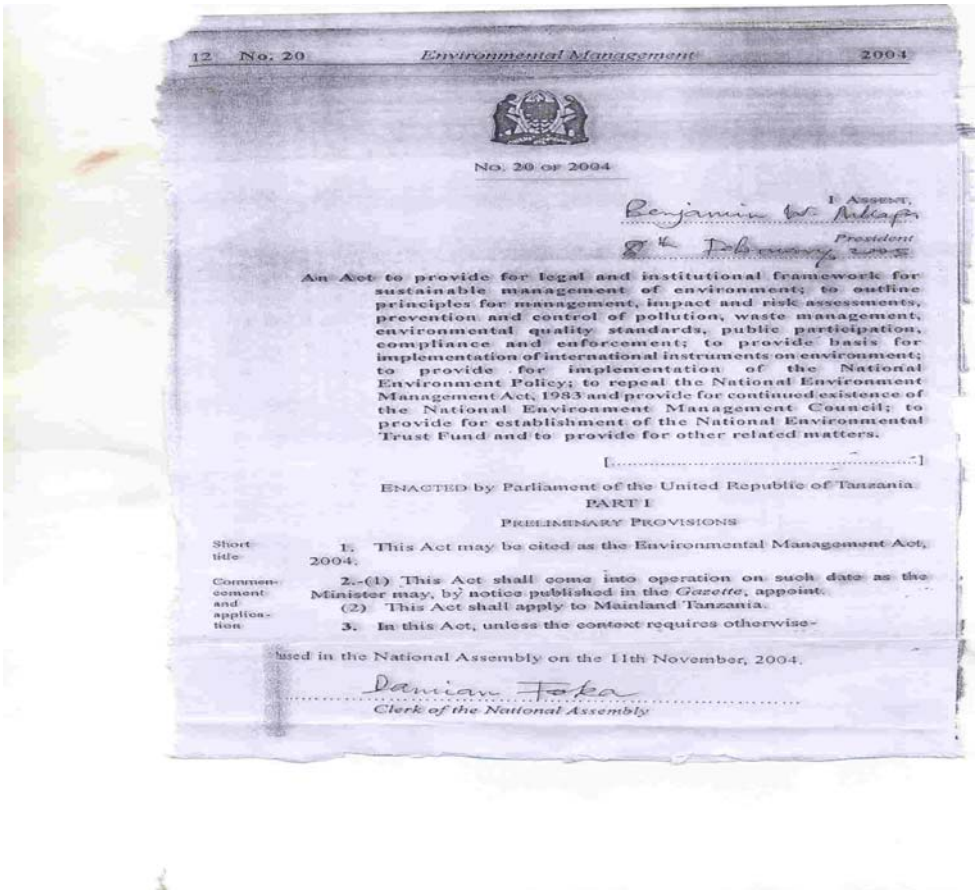
BIOSAFETY REGULATORY REGIME

The National Biosafety Regulatory Regime consists of the Environmental Management Act No. 20 of 2004 (EMA 2004), the National Biosafety Framework (2005), and the Biosafety guidelines (2005). Regulations on Biosafety are in draft form that needs further consultation with stakeholders to finalize the draft.

The approach used in developing biosafety regulatory regime in the United Republic of Tanzania is that of subsidiary legislation. In this respect, the Environmental Management Act No. 20 of 2004 (EMA, 2004) serves as the principal legislation as it empowers the Minister Responsible for Environment to promulgate, among others, biosafety regulations. This is to say, the developed Draft Biosafety Regulations will be operational under the auspices of EMA (2004). The draft Biosafety Regulations provide for tools to facilitate decision making in terms of risk assessment and risk management. They also provide for liability and redress and places strict liability on the one who carries out an activity in relation to GMOs.

ENVIRONMENTAL MANAGEMENT ACT, 2004

As a major output of the development of NBF process in Tanzania, the President of the United Republic of Tanzania has recently accent to a framework law on environment on the 8th February 2005 while the Minister responsible for Environment operationalised the law on the 1st July 2005. The EMA, 2004 is found in parliament website (www.parliament.go.tz). In this context, the components and activities of this project will to fully integrate biosafety into the development agenda of Tanzania.



12 No. 20 *Environmental Management* 2004

No. 20 OF 2004

I Assent,
Benjamin W. Mkapa
President
8th February, 2005

An Act to provide for legal and institutional framework for sustainable management of environment; to outline principles for management, impact and risk assessments, prevention and control of pollution, waste management, environmental quality standards, public participation, compliance and enforcement; to provide basis for implementation of international instruments on environment; to provide for implementation of the National Environment Policy; to repeal the National Environment Management Act, 1983 and provide for continued existence of the National Environment Management Council; to provide for establishment of the National Environmental Trust Fund and to provide for other related matters.

[.....]

ENACTED by Parliament of the United Republic of Tanzania

PART I

PRELIMINARY PROVISIONS

Short title
1. This Act may be cited as the Environmental Management Act, 2004.

Commencement and application
2.-(1) This Act shall come into operation on such date as the Minister may, by notice published in the *Gazette*, appoint.
(2) This Act shall apply to Mainland Tanzania.

3. In this Act, unless the context requires otherwise-

...used in the National Assembly on the 11th November, 2004.

Damian Foka
Clerk of the National Assembly

The Environmental Management Act, 2004 provides for the legal and institutional framework for sustainable management of the environment as well as the regulation of development, handling and use of GMOs and products thereof. It empowers 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 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 ENVIRONMENTAL MANAGEMENT (BIOSAFETY) REGULATIONS

On the basis of the Environmental Management Act 2004, the proposed draft *Environmental Management (Biosafety) Regulations* will be prepared and made operational by the Minister responsible for Environment without being taken to the Parliament. This approach has added advantage because of the nature of the technology. There is fast development on this technology therefore; the Minister responsible for Environment is given mandate by EMA, 2004 to amend regulation according to the new developments in modern biotechnology without taking them back to the parliament.

The draft Biosafety Regulations (see Annex J for brief description of the Draft Regulations) amply provide for tools to facilitate decision making in terms of risk assessment and risk management. They also provide for liability and redress and places strict liability on the one who carries out an activity in relation to GMOs.

BIOSAFETY GUIDELINES

The Biosafety Guidelines call for Risk Assessment and Risk Management. They require that before any release is carried out, an evaluation of the likely impacts and risks posed to human and animal health and the environment by the release should be undertaken. Decision-making shall be made on the basis of risk assessment carried out in a scientifically sound manner taking into account socio-economic as well as ethical and cultural considerations. The Guidelines stipulate as follows:

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.
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.

ADMINISTRATIVE AND DECISION MAKING-MECHANISMS

THE DRAFT BIOSAFETY REGULATIONS PROPOSE THE FOLLOWING FOUR INSTITUTIONS FOR THE REGULATION OF GMOS:

- National Biosafety Focal Point (Vice President's Office)
- 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).

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 Biosafety institutional structure is summarized in Figure 1 (see annex I). On the onset, it is important to note that the proposed structure recognize mandates of Competent Authorities in their respective disciplines.

C2.B CURRENT situation (in the country with respect to the NBF)

The current situation in the country with respect to biosafety can be summarised as follows:

a) Biosafety Policy

Although the United Republic of Tanzania does not have a biosafety policy, it has several national policies related to it. The Constitution of the United Republic of Tanzania recognizes the right of inhabitants of Tanzania to enjoy and protect 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.

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 "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.

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) acknowledge 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 Environmental Management Act (2004), will provide a basis for further revision of related policies and sectoral laws so as to take on board biosafety concerns.

b) Existing legislation on Biosafety

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.

c) System for Handling Request for Permits

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. The details are described in the NBF for Tanzania (Annex A).

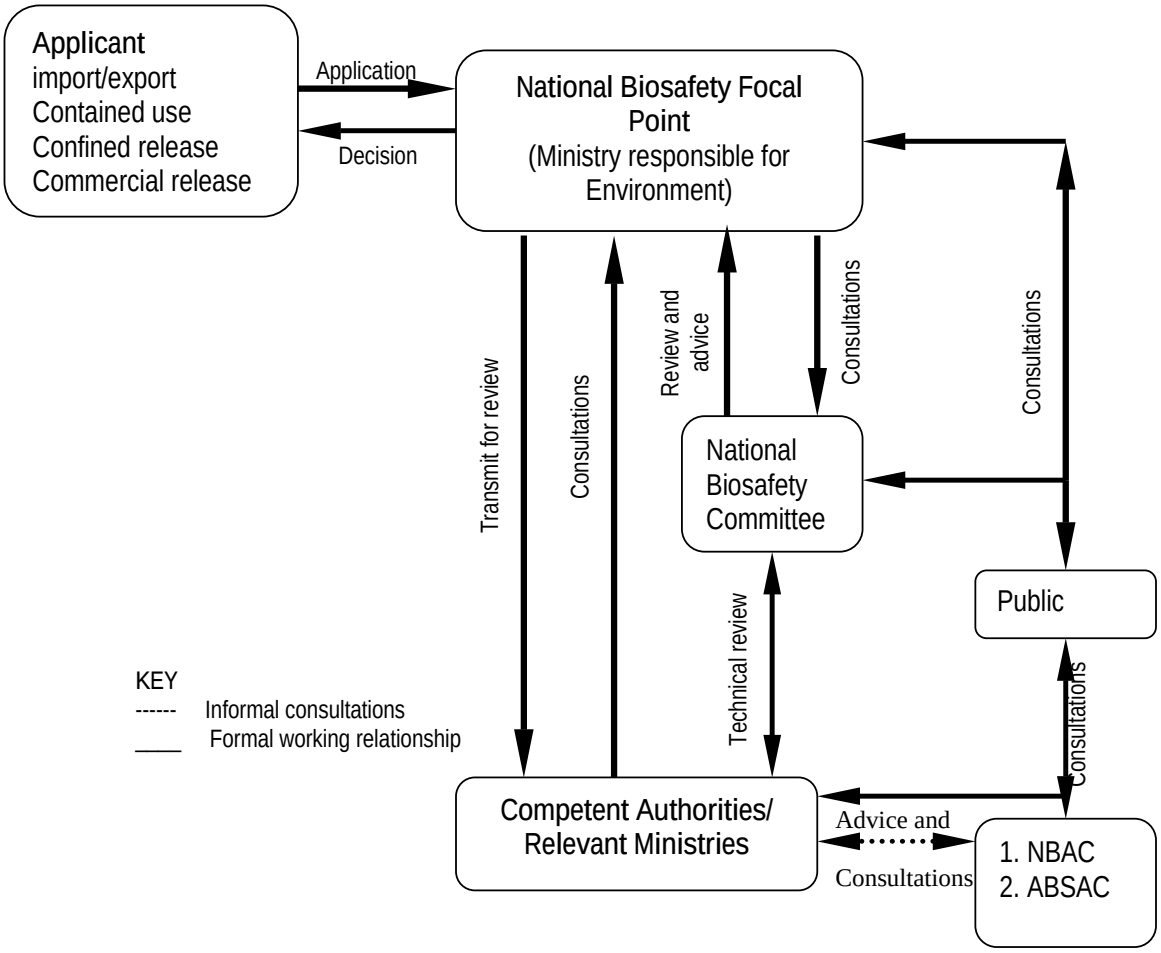


Figure 2: Decision making structure

d) Systems for Monitoring of Environmental Effects and Enforcement

In accordance with the Environmental Management Act, 2004 and draft Biosafety Regulations, the Inspectorate of Competent Authorities (see under Table 1.Stakeholders, page 21) shall perform inspection and supervision. Authorized party shall pay inspection fees that will be established by Competent Authorities. Inspectors have the authority to inspect sites containing GMOs such as field trial sites 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. The proposed system has flexibility to appoint different competent inspectorates on the case-by-case basis.

e) Public Information 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.

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, shall promote and facilitate public awareness, education and participation concerning research, development, handling, transboundary movement, transport, use, transfer, release, management of GMOs and incorporate biosafety issues in teaching curricula. The Competent Authorities shall also incorporate into their respective administrative issuances and processes best practices and mechanisms on public awareness and participation.

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. Government departments and agencies shall, subject to reasonable limitations, protect confidential information as provided in the Proposed Regulations, and shall disclose all information on such applications in a prompt and timely manner.

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. Public awareness and participation shall apply to all stages of the biosafety decision-making process from the time the application is received.

Public opinion as gauged through the procedures for public participation must be taken into account in the decision. The public shall be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision.

C2.C RATIONALE

A baseline situation analysis on biotechnology and biosafety in the country carried out in 2004 revealed that the challenge in implementing the Cartagena Protocol in Tanzania lies on limited capacity in terms of equipment, skilled human resource base, funding, as well as limited public awareness and lack of comprehensive legal framework in dealing with modern biotechnology.

The need for a functional biosafety system is made more urgent by the fact that modern biotechnology applications and products of genetic engineering are increasingly becoming available on the market, especially agricultural products. The use of genetically engineered/modified (GM) crops in agriculture is now a reality and we are now beginning to see them being grown commercially worldwide. In East Africa, Kenya is already conducting confined field trials of genetically engineered crops such as the virus-resistant sweet potatoes, insect resistant *Bt* Cotton and insect resistant *Bt* Maize. In Tanzania there is already a growing demand for introducing *Bt* cotton varieties in the Southern Highlands where cotton cultivation have been banned because of red bollworm.

The application of GM technology to solve such problems requires capacity building in the field of risk assessment and risk management, detection of GMOs as well as socio-economic and ethical aspects associated with adoption of the GM technology. It is therefore, important to strengthen the national capacity in all subjects related to safe application of modern biotechnology in order to protect consumers and the environment as well as addressing socio-economic, cultural and ethical concerns.

The project does undertake activities for BCH project (namely a Training Component and an Equipment Component), needed to guarantee the operationalisation of the national BCH. Currently, the BCH project is not operational in Tanzania.

In the absence of GEF contribution, the baseline scenario is as follows:

a) Implementation of Protocol

The United Republic of Tanzania being a Party to the Biosafety Protocol is deeply committed to meet its obligations despite limited financial resources.

GEF project proposal and its financial assistance will contribute greatly to the initial effort of implementatining the Protocol This intervention and its financial contribution will speedily put in place fully functional/operational regulatory regime . When the system will be operational, the United Republic of Tanzania will cover the cost of maintaining the process.

b) Economic, Environmental and Development Viewpoint

Despite Government commitment to boost agricultural production, yet still the challenge lies on producing enough food for the ever-growing population. This has been aggravated by erratic rainfall, depleted soil fertility, pest and diseases, inadequate improved seed varieties etc. In this respect, biotechnology applications, if properly integrated into the agricultural production system, may avail opportunities to increase production and productivity and release pressure on natural resources and hence their degradation. However, the challenge will remain on the issues pertaining to trade and access to market of GMOs.

C2.D Expected project outcomes, with underlying assumptions and context to be according to final activities

The Overall Goal of the project is that by 2009, Tanzania has a functional and transparent national biosafety framework in place and consistent with its international obligations and national development priorities.

Component A	To establish and make fully operational the regulatory regime on biosafety in Tanzania by 2009
Outputs	• Biosafety Regulations reviewed and finalized • Four 2-day sensitisation zonal workshops on regulatory regime for GMOs (CAs, NGOs, Private sector, civil society) conducted • The NBF and Biosafety Regulations translated into *swahili* language • Two, 3-days workshops for the Biosafety units of the Competent Authorities for sharing experience and information for effective enforcement of the regulatory regime carried out. • Operational manual for GMO inspectorates prepared. • Four, 3-day training workshops for Competent Authorities and Inspectorates on inspection procedures (2 workshops) and related legal issues (2 workshops) carried out. • Cessation or revocation order for non-compliance established • GMO inspection facilities (field tool kits)
Component B	Tanzania has in place operational procedures to handle requests for permits, including systems for administrative processing, risk assessment and decision making, by 2009
Outputs	• National Biosafety Guidelines and training manuals on risk assessment and risk management developed. • Two 3-day training workshops for 30 participants each from Competent Authorities and other biosafety regulatory personnel on risk assessment and risk management conducted • Laboratory equipped with necessary facilities for risk assessment and risk management (it is already under component C) (see Annex B) • Two 5-day training workshops held for 30 participants each (NBC members, NBFP, private sector) on handling of requests conducted • A 2-day workshop held for identification of socio-economical priorities to be taken into consideration for decision making conducted • An internal manual on procedures for handling requests of GMOs in Tanzania prepared • Specific biosafety units within the seven Competent Authorities (see Section A2 for the list of CAs) for handling GMO issues strengthened • Two, 3-days training workshops on GMO administrative issues (responsible

	personnel within CAs, NGOs, Private sector) conducted • A networking mechanism for cooperation and information exchange among CAs, NGOs, private sector etc developed
Component C	Tanzania has an operational system for monitoring of environmental effects and enforcement on biosafety by 2009
Outputs	• Three 2-days training workshops for 15 Inspectors from each CAs, 40 Custom officers and 20 Judiciary officials (dispute settlement, handling of court cases and enforcement) conducted • One of the potential laboratories into a center of excellence for R&D on biosafety upgraded • Equipment for detection of GMOs (see Activity A1 (c)) purchased • GMO testing protocol developed • Two, 5-days training workshops for 8 laboratory technicians from each CAs for GMO detection conducted • On-the-job training provided to officials from different authorities with real case studies to make sure that the system for handling requests is functioning • Guidelines for monitoring (in cooperation with sector ministries) environmental effects developed • Guidelines and rules for emergency cases (including remediation), develop TORs for responsible persons developed • Training for emergency operations for all principal actors (including high ranking officials – see risk management) provided • An updated inventory of emergency equipment and ensure replacement/procurement of any additional requirements maintained • Emergency response procedures (hotline etc, contact details, including international ones) for NBFP and Competent Authorities established
Component D	Tanzania has a functional national system for promoting public awareness and involvement in biosafety decision-making by 2009
Outputs	• Government agency/responsible institutions for managing public awareness and education campaigns relating to Biosafety identified • Surveys for public opinion carried out • Public debates to create awareness organized

	• Public education and involvement plan prepared • Outreach material (e.g. leaflets, Newsletter, Biosafety website) developed and disseminated • Three 2-day awareness raising workshops for parliamentarians, media, NGOs and other stakeholders conducted • Public debates (biannual) and meetings (biannual) including educational competitions (annually) or events (annually) organized • Entry points for public participation in decision-making on GMOs identified and institutionalized • Institution/agency specializing in developing and delivering public service campaign identified • National website for dissemination of biosafety information established and updated regularly

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

Planned activities to achieve outcomes

A. Regulatory regime

A.1 Establishment of a regulatory regime consistent with CPB and other obligations

a) Reviewing and finalizing draft Biosafety Regulations[1] (consultancy, 2 national workshops, gazetting by the Minister responsible for Environment)
b) Conducting four 2-day sensitisation zonal workshops on regulatory regime for GMOs (CAs, NGOs, Private sector, civil society). Taking into account the vastness of the country, zonal workshops would be appropriate in reaching out a wide spectrum of key stakeholders.
c) Translation of the NBF and Biosafety Regulations into swahili language
d) Conducting two 3-days national fora of Biosafety units of the Competent Authorities for sharing experience and information for effective enforcement of the regulatory regime.

A2. Enforcement of the regulatory regime

a) Preparation of operational manual for GMO inspectorates
b) Conducting four 3-day training workshops for Competent Authorities and Inspectorates on inspection procedures (2 workshops) and related legal issues (2 workshops)
c) Establishment of cessation or revocation order for non-compliance

Total costs A (TOT: USD 186,000; GEF: USD 110,000.00; Government: USD 76,000.00)

B. Handling requests for permits [include costs]

B1. Development of a fully functional risk assessment and risk management system

a) Development of National Biosafety Guidelines and training manuals on risk assessment and risk management.
b) Conducting two 3-day training workshops for 30 participants each from Competent Authorities and other biosafety regulatory personnel on risk assessment and risk management
c) Strengthening and improving necessary facilities for risk assessment and risk management and GMO detection. (Please refer to Annex B for a provisional list of equipment and related cost)

B2. Establishment of a functional decision making system

d) Conducting two 5-day training workshops for 30 participants each (NBC members, NBFP, private sector) on handling of requests
e) Conducting 2-day workshop for identification of socio-economical priorities to be taken into consideration for decision making
f) Preparation of internal manual on procedures for handling requests of GMOs in Tanzania

[1] The approach used in developing biosafety regulatory regime in the United Republic of Tanzania is that of subsidiary legislation. In this respect, the Environmental Management Act (EMA) (2004) serves as the principal legislation as it empowers the Minister Responsible for Environment to promulgate, among others, biosafety regulations. This is to say, the developed Draft Biosafety Regulations will be operational under the auspices of EMA (2004).

B3. Establishment of functional administrative system

g) Strengthening specific biosafety units within the seven Competent Authorities (see Section A2 for the list of CAs) for handling GMO issues
h) Conducting two 3-days, 2 training workshops on GMO administrative issues (responsible personnel within CAs, NGOs, Private sector)
i) Development of a networking mechanism for cooperation and information exchange among CAs, NGOs, private sector etc

Total costs B (TOT: USD 190,000; GEF: USD 102,500 USD; Government: USD 87,500)

C. System for Follow-up

C1. Strengthening systems for monitoring and inspection

a) Conducting three 2-day training workshops for:
   - 15 Inspectors from each Competent Authority ·
   - 40 Custom officers ·
   - 20 Judiciary officials (dispute settlement, handling of court cases and enforcement)
b) Upgrading of one of the potential laboratories into a centre of excellence for biosafety.[2]
c) Purchase of equipment for detection of GMOs.
d) Acquisition of GMO inspection facilities.
e) Development of GMO testing protocol
f) Conducting two 5-days training workshop for 30 laboratory technicians on GMO detection
g) Provide on the job training for officials from different authorities with real case studies to make sure that the monitoring and inspection system is functioning
h) Develop guidelines for monitoring (in cooperation with sector ministries) environmental effects

C2. Establishment and operationalization of emergency procedures

i) Develop guidelines and rules for emergency cases (including remediation), develop TORs for responsible persons
j) Provide training (how many how long etc) for emergency operations for all principal actors (including high ranking officials – see risk management)
k) Maintain an updated inventory of emergency equipment and ensure replacement/procurement of any additional requirements
l) Establish emergency response procedures (hotline etc, contact details, including international ones) for NBFP and Competent Authorities

Total costs C (TOT: USD 555,000; GEF: USD 252,000; Government: USD 303,000)

[2] The center will have full capacity in terms of human and infrastructure to provide full scientific back up for scientific activities in the form of GMO detection and general monitoring activities. The proposed center will act as a referral to other laboratories in the country. This may be a cost-effective approach.

D. Public education, awareness and participation

D1 Strengthening system for public education, awareness and participation in decision-making

a) Identify government agency/responsible institutions for managing public awareness and education campaigns relating to Biosafety
b) Identify an institution/agency specializing in developing and delivering public service campaign
c) Identify and institutionalize entry points for public participation in decision-making on GMOs
d) Conducting 2 surveys for public opinion
e) Preparation of public education and involvement plan
f) Development and dissemination of outreach material (e.g. leaflets, Newsletter, Biosafety website)
g) Organise public debates (biannual) and meetings (biannnual) including educational competitions (annually) or events (annually)
h) Conducting three 2-day awareness raising workshops for 30 parliamentarians, 20 media, 30 NGOs, 15 private sector and 30 other stakeholders
i) User-friendly National website for biosafety established and regularly updated for public access and awareness raising.

Total costs D (TOT: USD 159,000; GEF: USD 84,000; Government: USD 75,000)

C.3 SUSTAINABILITY

a) Institutional sustainability

The United Republic of Tanzania has demonstrated its commitment by acceding to the CPB on 16 March 2003. The enactment of the Environmental Management Act (2004) strengthens Tanzania's commitment to sustainable environmental management including biosafety issues. The EMA operationalize NBF, Biosafety Regulations, Guidelines and Manuals for addressing biosafety in the country. Further, the NBF provides for biosafety institutional arrangement principally based on the existing institutional structure, mandates and roles and responsibilities. The set up ensures long-term sustainability and effective utilization of available resources through strengthening and building capacity of the existing institutions. Also the National Strategy for Growth and reduction Poverty (NSRGP, 2005) emphasizes the urgent need of Ministries Development Agencies (MDAs) and Local Government Authorities to mainstream environmental issues in their planning and Budgeting process.

b) Financial sustainability

Government budgetary allocations will be made through the Medium Term Expenditure Framework (MTEF), this guarantees the availability of financial resources on annual basis. Also EMA 2004 and NSGRP (2005) urged MDAs and Local Government authorities to mainstream environmental issues in the planning and budgeting process. Currently, the Vice President's Office is preparing a guideline for mainstreaming environment into sector and local government authorities' plans and budget. EMA, 2004 provide for the establishment of the National Environmental Trust Fund that will support initiatives on environmental management. Additional finances will be accrued from application fees and penalties as well as from other development

partners. The EMA, 2004 provide for compliance and enforcement. Anybody who commits an offence and is liable on conviction to a fine that will vary depending on the offence made. Fees are legally binding but the amount required for a particular activity will be decided by competent authorities in collaboration with the focal point. For example, risk assessment fee will be paid by the applicant. This is indicated in the draft biosafety regulations.

c) Environmental sustainability

EMA, 2004 provide for the establishment of the regulations and guidelines for the development, handling and use of GMOs, Environmental Impact Assessment, Strategic Impact Assessment, pollution, waste management, biodiversity conservation etc (Section 230 of EMA, 2004). Currently, Vice President's office has prepared Environmental Impact Assessment Regulations and Draft Guidelines. Also Biosafety Guidelines have been prepared and provide procedure and measures to undertake safe application of Modern biotechnology to environment, human health and biodiversity. In addition, already there exist several environmental policies, legislation and strategies that focus on biodiversity conservation at different sector levels. Major policies and strategies that are considered relevant to the environment and biodiversity include: the Forest Policy (1998) and Forest Act (2002); the Fisheries Sector Policy and Strategy Statement (1998); the Water Policy (2002); the Wildlife Policy (1998), the Land Policy, the Village Land Act (1999) and the Land Act (1999) and the National Environment Management Policy (1997); the Poverty Reduction Strategy Paper (2000) and the second version- NSGRP; the Local Government Reform Programme as being implemented under the amended Local Government Act of (1982); as well as the National Agriculture and Livestock Policy (1997), the Agricultural Sector Development Strategy (2001) and the Rural Development Strategy (2001).

Given the current situation all environmental conservation matters have been mainstreamed into national and local government development planning and budgeting processes. This facilitates a broad participation of key stakeholders in environmental conservation for improving their livelihood and sustainable development. Therefore, this builds the motivation for conservation of biodiversity and provides a platform for environmental sustainability at the end of the project.

d) Project risks

Key project risks include inadequate capacity to cope with rapid development of modern biotechnology, weak regulatory regime to address emerging issues of modern biotechnology, and disputes on GMOs and products thereof in international trade which might jeopardize our markets.

e) Project Risk Management

The identified risks will be mitigated by 1) strengthening legal and technical capacity 2) developing programmes that guarantee capacity building beyond the life of the project and 3) setting up a mechanism for reviewing relevant policy and legislation when and how needed.

C. 4 REPLICABILITY

Just as the experience gained and lessons learned from the demonstration projects will be transferred to new implementation projects, the experience gained from this project will produce a similar replicate effect (for example, further developing training material and checklists, producing risk assessments or

environmental reviews of LMOs generated by regulatory processes, taking final decisions on import or release of LMOs, etc.) so as to be used in other areas of the world and under different contexts.

In order to guarantee sharing and dissemination of information and amplify the replicability potential of national projects to other countries in the world, documents, reports, findings of the demonstration projects will be posted and updated regularly on the web. Contacts between National project Coordinators will be facilitated by UNEP.

C. 5 STAKEHOLDER INVOLVEMENT

In June 2003, a national workshop was organized to identify key stakeholders and define their roles and responsibilities in the implementation of NBF. A wide range of stakeholders was identified to include CAs, academic and research institutions; NGOs, private sector etc. (refer Table 1).

A survey was undertaken by local experts to assess the existing physical infrastructure, human resource base, existing use of biotechnology, and national legal framework with regard to biosafety and biotechnology so as to help determine the extent to which Tanzania meets the requirements for safe application of modern biotechnology. A number of technical retreats were organized to further elaborate on the project taking into account the views and inputs by stakeholders.

The first draft of the NBF was prepared by the NBFP and a national consultative workshop involving key stakeholders was organized to solicit their inputs and further improve the NBF.

The initial draft of this project was prepared by NBFP and reviewed by the National Coordinating Committee (NCC) on NBF.

Table 1: Major Stakeholders and their roles and responsibilities

Stakeholders	Roles and Responsibilities
Parliament	• Overall policy guidance
Vice President's Office (Division of Environment)	• Oversee and coordinate environmental management in the country including development and implementation of the NBF • Overall coordinator of the implementation of the Environmental Management Act (2004) and its subsidiary legislation including Draft Biosafety Regulations • National Focal Point for the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety • National Focal Point for Biosafety and BCH • Approval of biosafety applications in consultation with CAs and National Biosafety Committee (NBC) • Promote public awareness on biotechnology and biosafety issues

Ministry of Agriculture and Food Security	• Competent Authority in agriculture • Advise the NBFP on issues related to biosafety in agriculture • Monitoring and inspection of crop plants, seed certification , • Undertake agricultural biotechnology and biosafety R&D • Promote public awareness on biotechnology and biosafety issues
Ministry of Water and Livestock Development	• Competent Authority in livestock • Advise the NBFP on issues related to biosafety in livestock • Monitoring and inspection of livestock and their products • Undertake livestock production, implement breeding programmes relevant to biotechnology and biosafety R&D • Promote public awareness on biotechnology and biosafety issues
Ministry of Health	• Competent Authority in general human health (food and drugs) • Advise the NBFP on issues related to biosafety in food, feed and drugs • Provide analytical services and technical advice through the Government Chemist Laboratory Agency (GCLA), Tanzania Food and Drugs Authority (TFDA) and Tanzania Food and Nutrition Center (TFNC) • Monitoring and inspection of food, drugs and other relevant products • Undertake health R&D relevant to biotechnology and biosafety • Promote public awareness on biotechnology and biosafety issues

Stakeholders	Roles and Responsibilities
Ministry of Science, Technology and Higher Education	• Competent Authority in promoting biotechnology R&D in the country • Advise the NBFP on policy issues related to biotechnology • Mainstreaming of biotechnology and biosafety in higher learning institution curricula • Promote public awareness on biotechnology and biosafety issues
Ministry of Industry and Trade	• Competent Authority in setting and monitoring standard compliance for products of biological origin, industrial products, food, feed and the environmental quality • Regulation and monitoring of foreign trade and intellectual property rights • Promote public awareness on biotechnology and biosafety issues
Ministry of Natural Resources and Tourism	• Competent Authority in wildlife, forestry and fisheries • Advise the NBFP on issues related to biotechnology and biosafety • Undertake biotechnology and biosafety R&D in wildlife, forestry and fisheries • Promote public awareness on biotechnology and biosafety issues
Ministry of Justice and Constitutional Affairs	• Advise the NBFP on legal matters related to biotechnology and biosafety • Technical backstopping in development of Biosafety Regulations and their translation into *swahili* • Train inspectors and the general public on legal matters related to biotechnology and biosafety • Promote public awareness on legal matters related to biotechnology and biosafety
Ministry of Finance	• Mainstreaming of biotechnology and biosafety activities in the government planning process and budgeting • Enforcement of biosafety regulations at entry points including labelling requirements, handling, packaging, inspection, sampling and identity preservation
President's Office – Regional Administration and Local Government	• Promote wider participation and awareness of the general public especially in implementation of the NBF • Enforcement of Biosafety Regulations • Liase with NBFP and CAs on issues related to biotechnology and biosafety • Mainstreaming biotechnology and biosafety in the planning process and budgeting
Ministry of Foreign Affairs and International Cooperation	• Liaise with the NBFP in handling of international disputes on GMOs that involve Tanzania

Stakeholders	Roles and Responsibilities
Scientific community Mikocheni Agricultural Research Institute (MARI); Sokoine University of Agriculture (SUA); Animal Disease Research Institute (ADRI); Muhimbili University College of Health Sciences;· Ifakara Health Research and Development Center; Applied Microbiology Unit (AMU), University of Dar-es-salaam; Tanzania Food and Nutrition Center (TFNC); Tanzania Bureau of Standards (TBS); Tanzania Food and Drug Authority (TFDA); Tanzania Official Seed Certifying Agency (TOSCA); Government Chemist Laboratory Agency (GCLA) and ·Tanzania Pesticide Research Institute (TPRI).	• Conducting trials concerning GMOs • Conducting risk assessment and risk management with respect to food and feed safety and ecology / environment. • Conducting scientific reviews for GMOs applications • Conducting impact studies of GMOs on the general economy, socio-economic welfare of farmers and/or producers, food security, industry and trade, poverty alleviation, etc • Sources of individual expertise, resource persons and consultants on issues of biotechnology and biosafety • Promote public awareness on biotechnology and biosafety issues
Civil society (consumers associations, NGOs) Tanzania Consumers Association, Tanzania Farmers Association (TFA), ENVIROCARE, AGENDA, TANGO, Pelum Tanzania, Journalist Association of Tanzania (JET)	• Complementing the government's efforts especially to promote popular participation by catalyzing participation, organizing and mobilizing groups, obtaining grassroots perspectives, raising awareness and advocacy.

Private sector Tanzania of Commerce, Industry and Agriculture (TCCIA), Confederation of Tanzania Industries (CTI), Tanzania Organic Agriculture Certification (TANCERT)	• Production and trading of GMOs • Support government initiative in public awareness and education on issues of biotechnology and biosafety
Media	• Public awareness, education and advocacy on issues related to biotechnology and biosafety
Development Partners UNEP, GEF, NORAD, SIDA, IFAD, GTZ etc	• Provide financial and technical assistance to biotechnology and biosafety activities in the country. • May participate in the planning and implementation of relevant programmes and strategies.

C.6 MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This process will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs (Annex C, C.6 a) and project impact (Annex C, C6.b) will be measured according to the indicators developed in the project log frame (Annex D), and using this specific Monitoring and Evaluation Plan. The general and specific objectives of the project, and the list of its planned outcomes, provide the basis for this monitoring and evaluation plan. The project co-ordinator, with the assistance of the NCC, will be in charge of the monitoring and evaluation component of the project and will take action whenever needed so as to guarantee that the M&E activities of the project and related indicators adequately reflect the needs of the project.

The Monitoring and Evaluation plan is detailed in Annex C. The monitoring and Evaluation plan includes Table 2 Indicators and Means of Verification, Table 3 reporting and monitoring responsibilities, Table 4 information on reporting requirements.

THE LOG FRAME IS ATTACHED IN ANNEX D. THE MATRIX ON KEY INDICATORS, BASELINE AND METHODS OF DATA COLLECTION IS ATTACHED IN ANNEX I.

D – FINANCING

D1 Incremental Costs Assessment

The Table 5 gives a summary of incremental costs by output/component as well as information on GEF financing and national co-financing. The total baseline expenditure amounts to USD 580,000 and is mainly related to activities in three components namely systems for follow up, public participation and project management. The alternative is estimated to cost USD 1,391,600, with an increment of USD 811,600. The national contribution in kind amounts to 614,300 USD and it mainly caters for infrastructure and personnel for GMO monitoring and inspection as well as project coordination. The remaining total cost of 777,300 USD is requested from GEF.

Table 5: Incremental cost assessment

Activity	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing
Regulatory regime	0	186,000	186,000	110,000	76,000
Handling requests	0	190,000	190,000	102,000	87,500
Systems for follow up (Monitoring and evaluation)	500,000	555,000	55,000	252,000	303,000
Public education, awareness and participation	25,000	159,000	134,000	84,000	75,000

Project management and support	55,000	231,600	176,600	158,800	72,800
Technical support (to be allocated to service provider by country, after project approval)	0	70,000	70,000	70,000	0
TOTAL	580,000	1,391,600	811,600	777,300	614,300

D2 Budget

a) Summary of the budget

The detailed budget of the project is shown in Annex F. A summary of the budget by components with co-financing details and the staff cost are shown in Tables 6 and 7 respectively.

Table 6: Project Budget by components

Component	GEF (US $)	Government in-kind (US $)	Total (US $)
Regulatory regime	110,000	76,000	186,000
Handling requests	102,500	87,500	190,000
Systems for follow op (Monitoring and evaluation)	252,000	303,000	555,000
Public education, awareness and participation	84,000	75,000	159,000
Project management and coordination	158,800	72,800	231,600
Technical support (to be allocated to service provider of choice by country, after project approval)	70,000	0	70,000
TOTAL	777,300	614,300	1,391,600

The National Coordinating Committee will meet on quarterly or when need arise to plan, review and assess and adjust activities. The NPC will be responsible for preparation of NCC meeting and for following activities planned.

b) Project Staff Costs

The total personnel costs of the project (Table 7) amounts to 116,800 USD of which 76,800 USD is requested from GEF and the remaining 40,000 USD is provided by Government (in-kind).

Table 7: Project staff

Personnel	GEF (US $)	National co-financing (US $)	Total (US $)
National Project Coordinator (NPC)	48,000	24,000	72,000
Assistant Project Coordinator	14,400	8,000	22,400
Administrative Assistant (Accountant)	14,400	8,000	22,400
TOTAL	76,800	40,000	116,800

c) Equipment and operating costs

The equipment and operating costs budget (USD) covers the purchase of computers, software upgrades, maintenance and it also caters for stationery and communication cost (Table 8).

Table 8: Equipment and operating costs

Equipment	GEF (US $)	National co-financing (US $)	Total (US $)
Computers, Scanner, Photocopier	20,000	6,000	26,000
Communication	12,000	8,000	20,000
Office supplies	8,000	2,400	10,400
Maintenance	10,000	2,400	12,400
TOTAL	50,000	18,800	68,800

d) Monitoring

Monitoring	GEF (US $)	Government in-kind (US $)	Total (US $)
National Coordinating Committee (NCC) meetings	20,000	8,000	28,000
Auditing	12,000	6,000	18,000
TOTAL	32,000	14,000	46,000

D3 Project Implementation Plan

The project will be carried out over four years (48 months). The implementation plan is provided in Annex E.

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the Cartagena Protocol on Biosafety. These are carried out through the development and implementation of National Biosafety Frameworks respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in the United Republic of Tanzania, where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently in operation under UNEP.

E2 CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IMPLEMENTING AGENCIES, EXECUTING AGENCIES, AND THE GEF SECRETARIAT (WHERE APPROPRIATE)

E2a National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex I.

E2b National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, after consultation with UNEP, for the duration of the National Project. The National Project Coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liase closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex G.

E2c Overall Steering Committee

The Steering Committee for the implementation projects, chaired by UNEP, comprises representatives of the National Executing Agency, two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, *whenever technical and scientific issues related to the implementation of the MSP are to be addressed,* the representative of STAP as well as experts selected in their personal capacity *will be* invited to participate in that meeting of the Steering Committee. The Steering Committee meets once a year and communicates mainly by e-mail and phone.

ANNEXES

LIST OF TABLES

ANNEX A

SUMMARY OF THE NATIONAL BIOSAFETY FRAMEWORK (NBF) FOR TANZANIA

1.0 INTRODUCTION

1.1 Guiding Principles

The following principles shall guide the implementation of the NBF: precautionary principle, preventive principle, a balanced approach, prior informed consent, strict liability, socio-economic and ethical considerations, transparency and public participation and duty to protect the environment.

1.2 Objectives of the NBF

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.

1.3 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. The NBF shall apply in tandem with two important documents, the National Biosafety Guidelines and the Biosafety Regulations.

2.0 NATIONAL POLICIES RELATED TO BIOSAFETY

In addition to the National Environmental Policy (1997) which recognizes the importance of conservation and sustainable utilization of the national biological resources, 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 Environmental Management Act

(2004), will provide a basis for further revision of related policies and sectoral laws so as to take on board biosafety concerns.

3.0 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.

3.2 Regulatory Mechanisms

3.2.1 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.

The Environmental Management Act (EMA) (2004) 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. It is on the basis of EMA (2004), the proposed draft *Environmental Management (Biosafety) Regulations* will be made operational.

3.2.2 Inspection and Enforcement

In accordance to Environmental Management Act (2004) and Draft 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.

4.0 ADMINISTRATIVE AND DECISION MAKING MECHANISMS

4.1 Institutional Structure and Administrative Mechanisms

a) National Biosafety Focal Point (NBFP)

The NBFP shall be the Ministry responsible for environment. Its roles and responsibilities, among others, include the following: to review and approve biosafety applications for research, confined release, pre-commercial release or placing on the market; to oversee the implementation of biosafety issues; and 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.

b) National Biosafety Committee (NBC)

The NBC shall have, among others, the following key functions: review relevant applications; advise on policies, legislation and other policy instruments; and advise the NBFP and Competent Authorities.

The NBFP shall designate the National Biosafety Scientific Advisory Sub-Committee that is answerable to the NBC. It shall advise the NBC on scientific biosafety concerns.

c) Relevant Ministries/ Competent Authorities

The NBFP shall designate Competent Authorities whose roles and responsibilities shall, among others, include: to review relevant applications or proposals; to review, carry out or have made risk assessments, socio-economic impacts as well as ethical and cultural impacts of GMOs or products thereof; to advise the NBFP; and designate inspectors and undertake inspection as well as other control measures.

d) 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.

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

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; and

b) The NBFP should acknowledge receipt of the notification, in writing, to the Notifier within ninety (90) days of its receipt. Failure by Tanzania to acknowledge receipt of a notification should not imply its consent to an intentional importation of a GMO into the country.

4.2.1.2 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; and

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 shall notify BCH and other relevant international organizations of all cases of illegal transboundary movements.

4.2.1.3 Application Procedure

a) 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;

b) 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; and

c) Application(s) should be submitted four (4) months before importation.

4.2.1.4 Risk Assessment and Risk Management

h) 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 risk assessment and risk management in accordance with the National Biosafety Guidelines for Tanzania (Section 3.0 and Annex VI).

i) 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. 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;

4.2.1.5 Decision Making Procedure for Import

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 in collaboration with Competent Authority shall evaluate the information presented by the applicant or in the Biosafety Clearing-House, as the case may be;

b) 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. 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;

c) 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;

d) 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;

e) 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; and

f) 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 the NBF.

4.2.2 Import for Contained Use and GMOs on Transit

4.2.2.1 Contained Use

a) Tanzania shall require risk assessment and prior authorization before the import of GMOs for contained use;

b) 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;

c) 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 safety class intended (Class I to Class IV) are fulfilled; and

d) 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;

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

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 withn \]] 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. 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

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

5.0 MONITORING MECHANISMS

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.

5.1 Types of Monitoring

a) Case-specific monitoring: 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: 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.

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: 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.

e) Experimentation: Experimentation refers to that exercise that is part of early stage, research and development procedures. 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.

f) Tracking: Tracking is used primarily to monitor the movement and dispersal of the organisms and their genes.

g) Surveillance: 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.

5.2 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.

5.3 Post Release Monitoring

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. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved.

5.4 Reporting Requirements

The authorized party should comply to the reporting format set in the terms and conditions of authorization.

6.0 MECHANISMS FOR PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

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:

d) 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;
e) The risk assessment report in respect of the GMOs or products thereof; and
f) 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.

6.1 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.

b) Confidential Business Information (CBI): All ministries agencies and institutions handling GMO applications shall ensure that they have procedures to protect confidential business information.

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.

6.2 Tools and Processes

The mechanisms that will be used include: National Biosafety Clearing House; public consultative meetings; workshops and seminars; Public debates and forums; Capacity building for various stakeholders; supporting NGOs or civil society groups; create awareness about opportunities to participate; mass media: Using radio, newspapers and television; and stakeholders participation in committees

---

ANNEX B

PROVISIONAL LIST OF EQUIPMENT

Equipment	Quantity Needed (n)
1. HPLC	2
2. Protein Analyzer	1
3. Fat Extractor	3
4. ELISA reader	3
5. PCR machines (thermocylers)	4
6. Safety Cabinets	4
7. Cryopreservation equipment	2

*Need Assessment should be conducted to identify the number of equipments required and estimated costs. The unit cost of equipment as quoted from the Internet varies a lot from one supplier to another.

ITEM	QUANTITY	UNIT PRICE
• HPLC	2	29,950 (USD)
• DNA (Protein Analyzer)	1	74,000 (EURO)
• Safety cabinets L1,L2,L3	4	11,565 USD

ANNEX C

MONITORING AND EVALUATION PLAN

C.6 a Execution performance and delivered outputs

Monitoring of the project execution will assess whether the management and supervision of project activities is efficient and seek to improve efficiencies and overall effectiveness of project implementation. It is a continuous process, which will collect information about the execution of the planned activities, allow for improvements in method and performance, and compare accomplished with planned tasks . This activity will be under direct responsibility of the National Coordination Committee (NCC) . The UNEP Task manager will, in collaboration with the NCC, track these indicators (Table 2).

Table 2: Indicators and Means of verification

Indicator	Means of Verification
Half-yearly and annual activity and progress reports are prepared in a timely and satisfactory manner	Arrival of reports to UNEP
Half-yearly disbursement plans and half-year and annual financial reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Yearly GEF Project Implementation Review reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Performance targets, outputs, and outcomes are achieved as specified in the annual work plans.	Semi annual and Annual progress reports
Deviations from the annual work plans are corrected promptly and appropriately.	Work plans, minutes of SC meetings
Disbursements are made on a timely basis, and procurement is achieved according to the procurement plan.	IMIS system at UNEP and Bank Account statements of executing agency
Audit reports and other reviews show sound financial practices.	Audit statements
National Coordinating Committee is tracking implementation progress and project impact, and providing guidance.	Minutes of NCC meetings
National Coordinating Committee is providing policy guidance, especially on achievement of project impact.	Minutes of NCC meetings

Monitoring and evaluation of project execution will be conducted through constant interaction, namely exchange via email and technical support or supervision missions. Throughout the project, approaches will be integrated with feedbacks, lessons learnt and best practices gained. The task manager will facilitate exchange of experiences between countries in the process of implementing their NBF. A meeting of the NPCs of the ongoing implementation projects is expected to be held annually.

The monitoring plan also covers the risks associated to project management. In this respect, special attention will be devoted to:

Management structure	so as to monitor whether stability and responsibilities are clearly understood
Work Flow	so as to verify if the project is maintaining its planned work load (key role in this case is played by quarterly reports and constant contacts)
Co-financing	so as to ensure that disbursements are carried out in time and with ease
Implementation	To verify if work plan is progressing according to schedule
Budget	So as to ensure that the work plan is progressing according to budget plans
Fund management[3]	So as to ensure that funds are wisely spent and correctly and transparently accounted for
Reporting	So as to monitor that work progress is reported comprehensively and on time. Reports contains critical analysis
Stakeholder involvement	So as to ensure that a multi-stakeholder process is in place and active
Communication	So as to guarantee that communication between management team members is fluid
Leadership	So as to ensure that project has an active and committed management team
Short term/long term balance	So as to guarantee that project meets short term need without compromising on long term outlook
Political influence	So as to verify project is making politically motivated decisions

C6.b Project Impact

Evaluation of the project's success in achieving its outcomes will be monitored continuously through the project progress reports, mid-term and final evaluation reports, all of which will use the log-frame presented in Annex H.The full implementation of all components of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main focus for assessing the success of the project.

The Project Management team is responsible for monitoring progress as well as ensuring evaluation of impact. These are described in Tables 3 and 4 (below).

Table 3 Responsibilities of the project management entities regarding monitoring and reporting

UNEP Task Manager	National Executing Agency (NEA)	National Coordinating Committee (NCC)
Monitor the agreed M&E plan in accordance with the terms of agreement with GEFSEC Receive quarterly and annual reports (progress and financial), and copies of all substantive	Prepare quarterly progress reports (operational and financial) annual summary progress reports for UNEP, and forward quarterly operational and financial reports, with supporting documentation as appropriate, in a timely manner to	Meet at least on a quarterly basis and receive quarterly progress and financial reports, annual summary progress reports and all substantive reports and outputs and use them to review the progress of work in the project as a whole

[3] The total expenditures incurred during each year ending 31 December, certified by a duly authorised official, will be reported in an opinion by a recognised firm of public accountants according to UNEP regulations

reports from (National Executing Agency). Task manager to attend and participate fully in meetings of the NCC Task Manager to conduct supervision missions to selected project sites and identify implementation problems and suggest remedies to annual meeting of the NCC. Engage and prepare terms of reference for independent M&E consultants to conduct the mid-term and final evaluations	UNEP. Carry out a programme of regular visits to project sites to supervise activities, and pay special attention to those sites with serious implementation problems	Advise on implementation problems that emerge, and on desirable modifications to the work-plan Monitor progress of the project, and advise on steps to improve it

Table 4: The key content required in the quarterly progress reports and financial reports.

Report	Format and Content	Timing	Responsibility
Progress Reports			
Document the completion of planned activities, and describe progress in relation to the annual operating/work plan. Review any implementation problems that impact on performance Summary of problems and proposed action Provide adequate substantive data outcomes for inclusion in consolidated project half-yearly and annual progress reports Highlights of achievements	Reports will use standard UNEP Progress Report format. The project log frame (Annex H) will be attached to each report and progress reported against outcome and output indicators.	Quarterly, within 30 days of end of each reporting period,	NEA

The Project Implementation Review (PIR) reports	Per GEFSEC format	Yearly (after project has been under implementation for one year)	UNEP Task Manager
Consolidated Annual Summary Progress Reports			
Presents a consolidated summary review of progress in the project as a whole, in each of its activities and in each output Provides summary review and assessment of progress under each activity set out in the annual work plan-, highlighting significant results and progress toward achievement of the overall work programme Provides a general source of information, used in all general project reporting	Reports will use a standard format to be developed following the UNEP Progress Report model The project log-frame will be attached to each report and progress reported against outcome and output indicators. A consolidated summary of the half-yearly reports Summary of progress and of all project activities Description of progress under each activity and in each output Review of delays and problems, and of action proposed to address with these Review of plans for the following period, with report on progress under each heading	Yearly, within 45 days of end of the reporting period	NEA
Financial reports			
Report on co-financing that has been provided to project as originally estimated in project proposal approved by GEF	Use Annex as found in project document with supporting documentation of realized co-financing	Six-monthly	NEA
Details project expenses and disbursements	Standardized UNEP format as found in project document Disbursements and	Quarterly	NEA

	expenses in categories and format as set out in standard UNEP format, together with supporting documents as necessary		
Summary financial reports	(Standardized UNEP format as found in project document)		
Consolidates information on project expenses and disbursements	Disbursements and expenses by category. Requirement for coming period: request for cash advance.	Half-yearly, within 30 days of end of period	Project financial officer
Financial audits			
Annual audit	Audit of accounts for project management and expenditures	Annual	Recognised firm of public accountants according to UNEP regulations.

A summary of the project against key indicators, baseline and method of data collected is presented in Annex D.

ANNEX D

PROJECT LOGFRAME

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
COMPONENT A: REGULATORY REGIME				
OBJECTIVE To have a fully functional and responsive regulatory regime in line with CPB and national needs	- An approved regulatory regime reflecting policies and defining all other NBF components in compliance with CPB and other international obligations - Operationalize NBF, Biosafety Regulations and Biosafety Guidelines - Trained experts - Manuals	- Draft biosafety regulations finalized and operational by year one of the project - Biosafety regulations translated into ' Kiswahili ' by 2006. - Biosafety regulations published and distributed to MDAs and local government by 2006 - Biosafety Guidelines available and operationalzed in year one of the project - Internal manuals available by year 2006 - Capacity programme implemented	- Regulatory regime is not responsive to country's changes (technological, social, political, economic etc) - Regulatory regime cannot be easily adopted because of resistance from interest groups	- Promote cooperation and exchange of information throughout government structure - Develop tools and training for translation of legislation into practice - Support countries to take action in Biosafety - Promote broader public awareness and support for Biosafety and the need for regulatory regime - Promote national consensus on Biosafety - Promote mechanisms for review and adjustment of legislation - Promote consultation with all stakeholders during the initial stages implementation of the regulatory regime. - Promote collection of information on experiences in other countries
OUTCOMES				
A1 Regulatory regime in place consistent with CPB and other obligations	- Compliance with ICCP checklist - [compliance with other international obligations]	- ICCP list filled in and available	- Regulatory regime not translated into practice	- Promote training on CPB and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country - Promote cooperation and exchange of information throughout government structure
ACTIVITIES				
1. Reviewing and finalizing draft Biosafety Regulations (consultancy, 2 national workshops, gazetting by the Minister responsible for Environment) 2. Conducting four 2-day sensitisation zonal workshops on regulatory regime for GMOs (CAs, NGOs, Private sector, civil society) 3. Translation of the NBF and Biosafety Regulations into *swahili* language 4. Conducting two, 3-days national for a of Biosafety units of the Competent Authorities for sharing experience and information for effective enforcement of the regulatory regime				

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
A2 Regulatory regime fully enforced	- Manuals/guidelines produced to operationalize regulatory regime - Mechanism for enforcement of regulatory regime - Cases of non-compliance - Inspections carried out according to agreed procedures - Flexible revision mechanism - Trained enforcement agencies	- Manuals and guidelines developed and operational by year 2006/2007 - At least 60% of inspectors from competent authorities and focal point trained by year 2007 - Number of inspection carried out per year per competent authority	- Lack of trained officials with expertise to enforce and apply the regulatory regime - Absence of clear guidelines and manuals. - Overlapping responsibilities among enforcement agencies. - Weak cooperation between enforcement agencies	- Promote training on possible options and implications of implementing a regulatory regime, options and implications of amending the existing regulatory regime, enforcement measures. - Write and provide clear manuals and guidelines on the regulatory system - Regular meeting of CAs for exchange of information
ACTIVITIES				
1. Preparation of operational manual for GMO inspectorates 2. Conducting four, 3-day training workshops for Competent Authorities and Inspectorates on inspection procedures (2 workshops) and related legal issues (2 workshops) 3. Establishment of cessation or revocation order for non-compliance				

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
COMPONENT B: HANDLING REQUESTS				
OBJECTIVE To have fully functional national systems for handling requests	- Advanced use of BCH - Number of decisions made as a result of requests - NCA(s) nominated and in place with clear distinction of responsibilities - Available set of procedures for handling requests within time frames.	- Reports (financial reports and quarterly reports, workshop reports, meeting minutes) - Functional BCH by year 2006, with decisions and requests recorded on the nBCH - Record of access to nBCH - At least one decision made on application on GMO by 2006 - Procedures for handling requests in place and used by 2006	- Institutional and infra-structure not in place - Inadequate expertise	- Establish interim measures to handle requests - Conduct training for admin. And institutional support personnel - Work within time frames
OUTCOMES				
B1. A fully functional risk assessment and risk management system in place	- National roster of risk assessment experts - Appointed entity for risk assessment - Appointed laboratory for GMO detection and equipped with facilities - Rules for appointments of experts and TORs - Agreed procedures for carrying out risk assessment - Trained personnel - Percentage of assessments completed	- Reports (financial reports and quarterly reports, workshop reports, meeting minutes) - Roster of experts developed and posted to the BCH by year 2006 - Referral laboratory for RA/and GMo detection identified (Biosafety). - Biosafety guidelines and manuals developed and harmonised and operational by 2006 - 20 % of experts trained in year 1 on RA and GMO detection - 40 % of proposed facilities purchased by 2006/2007	- Inadequate expertise in RA/RM - Lack of consensus in RA/RM decision - Insufficient scientific data/information provided - Credibility of data provided for RA/RM - Bureaucratic red tape that hinders decision-making - Inadequate facilites and laboratory to identify GMOs	- Capacity building in RA/RM - Encourage regional cooperation in RA/RM - Encourage dialogue between proponent and regulators with respect to RA/RM applications - Encourage collaboration between institutions for GMO identification
ACTIVITIES				
1. Development of National Biosafety Guidelines and training manuals on risk assessment and risk management. 2. Conducting two 3-day training workshops for 30 participants each from Competent Authorities and other biosafety regulatory personnel on risk assessment and risk management 3. Strengthening and improving necessary facilities for risk assessment and risk management and GMO detection				

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
B2. A fully functional decision-making system established	- Number of decisions reviewed on risk assessment - Clearly defined entity for decision making with clearly defined roles and responsibilities - Percentage of decisions made - Public consultation in decision making based on Article 23.2 of the CPB - Mechanism to include, where applicable, other issues such as socio-economic considerations in decision making	- Reports (financial reports and quarterly reports, workshop reports, meeting minutes) - At least one request handled by 2006 - Socio-economic priorities identified and harmonised among sectors by 2006-2007 - At least one manual developed, harmonised and operationalized by 2006-2007 - An effective mechanisms for public participation in place by 2007	- Trade, politics and other considerations over-ride decision-making - Negative public opinion on GMOs - Conflict of interest between institutions	- Institute a strong decision-making body which enjoys public confidence and credibility - Involve public and other stakeholders in decision-making - Establish an Appeal /Review mechanism for decision-making - Transparency
ACTIVITIES				
1. Conducting two 5-day training workshops for 30 participants each (NBC members, NBFP, private sector) on handling of requests 2. Conducting 2-day workshop for identification of socio-economical priorities to be taken into consideration for decision making 3. Preparation of internal manual on procedures for handling requests of GMOs in Tanzania				
B3. A fully functional administrative system established	- Responsibilities assigned for emergency response, accidental release, illegal movement, transit or for contained use - Compliance with BCH obligations - Clear definition of procedures for handling of notification (AIA) - Percentage of requests handled - Procedures for handling transport, packaging and identification of GMOs in place - Procedures for handling of confidential information established - Decisions made within timeframes of CPB	- Reports (financial reports and quarterly reports, workshop reports, meeting minutes) - Networking mechanism established and operational by 2007 - Biosafety units established and fully functional by 2008 within all Cas - At least one application handled by 2006/2007	- Inadequate staff to carry out administrative tasks - Inadequate financial resources - Delay in administration due to bureaucracy - Inadequate knowledge and capacity	- Training - Provision of adequate financial resources

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
		-		
ACTIVITIES				
1. Strengthening of specific biosafety units within the seven Competent Authorities (see Section A2 for the list of CAs) for handling GMO issues 2. Conducting two, 3-days training workshops on GMO administrative issues (responsible personnel within CAs, NGOs, Private sector) 3. Development of a networking mechanism for cooperation and information exchange among CAs, NGOs, private sector etc				
COMPONENT C: SYSTEMS FOR FOLLOW-UP (E.G. ENFORCEMENT AND MONITORING FOR ENVIRONMENTAL EFFECTS)				
OBJECTIVE To have a fully functional system for monitoring and enforcement	- Number of monitoring reports - Number of cases for complaints - Timeliness and quality of reports received	- Reports (financial reports and quarterly reports, workshop reports, meeting minutes) - Inspectors of all CAs trained by 2007/2008		
OUTCOMES				
C1 Strengthened systems for monitoring for environmental effects and enforcement actions	- Monitoring for environmental effects in place - Enforcement system in place	- Written and approved rules for enforcement by 2006/07 - Trained people on regulatory regime in place who know how to interpret CPB and what are the compliance rules (practical applicability) by 2008 - Center of excellence for R&D for biosafety identified and fully operational 2008	- rules in place, approved, but there is weak enforcement regime due to low awareness and/or low capacity	- train people, especially lawyers (governmental officers in CAs), to correctly interpret CPB and how to comply with CPB - ensure the regular reporting to the CBD Secretariat about the implementation of CPB, make these reports available to other interested parties

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
		- At least 50% of equipment purchased by 2006/07 - GMO testing protocol established and functional by 2006/07 - GMO inspection facilities (field toll kits) purchased for inspectors by 2006/07 - Guidelines for monitoring environmental effects established and operational by 2006/07 - At least 60% of staff of CAs receives on job training by 2006/07 and the last 40% by the end of the project.		

ACTIVITIES

1. Conducting three 2-days training workshops for:·
   a. 15 Inspectors from each CA·
   b. 40 Custom officers ·
   c. 20 Judiciary officials (dispute settlement, handling of court cases and enforcement)
2. Upgrading of one of the potential laboratories into a center of excellence for R&D on biosafety
3. Purchase of equipment for detection of GMOs (see Activity A1 (c))
4. Acquisition of GMO inspection facilities (field tool kits)
5. Development of GMO testing protocol
6. Conducting two, 5-days training workshops for 10 laboratory technicians for each CA for GMO detection
7. Provide on the job training for officials from different authorities with real case studies to make sure that the system is functioning
8. Develop guidelines for monitoring (in cooperation with sector ministries) environmental effects

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
OUTCOMES				
C2. Emergency response procedures established and operational	- rules for emergency procedures in place - Biosafety units within CAs made known to public - trained staff able to deal with emergency issues - Number of trained staff to deal with emergencies - Budget for Emergency Response to mitigate accidental release available - connection to the other countries via BCH - Public educated on warning signals for emergencies and response needed - remedial system in place - number of follow-up actions AFTER the emergency case is solved	- Written and approved rules and guidelines available and functional (also for remediation) by 2006/08 - Biosafety units within CAs in place and opertational by 2006/07 - Staff in these authorities trained and nominated tasks described in their job description by 2006 - Functional BCH and other means of communication by 2008 - Emergency response procedures established and operational by 2007 - At least 50% of principal inspectors trained on risk management by 2007/08	- system exists only on paper, is non-functional or with low capacity (functional when dealing with small cases, but helpless with big cases) - not enough finances (emergency measures, remediation could be very expensive), also there could be no means for eliminating GMOs from environment - connection not functioning (ie somebody who sees an accident cannot access to responsible persons for whatever reasons – bad connection, contact person having holiday etc etc) - responsible staff does not know what to do (could be aware how to behave in case of GM plants, but no awareness in case of GMOs) - emergency cases hidden by government or by companies, blocking information - Competent Authorities not willing to admit that their institutions is/are not able to deal with the issue themselves and hence not seeking assistance from As/ countries / international organizations	- ensure that people responsible for emergency cases are fully aware of their tasks, probably written contracts should be established. - good education/training for responsible persons, duplication of persons so that there is no one single person responsible for everything (in case one contact person is sick, then somebody takes over his task) - ensure that means for emergency responses are available (cars to access the emergency site, means for eliminating GMOs, etc) - develop tools (guidelines) for different emergency cases, possibility to ask for help from other countries/ authoritites/ international organizations - ensure that access to emergency lines is free and operational. Possible options – free emergency line, all the calls are taped, etc - raise awareness so that governments/ companies understand that hiding accidents and delays in eliminating GMOs will lead to bigger disaster than immediate action and that hiding accidents (especially from naighbouring countries) is illegal
ACTIVITIES				
1. Develop guidelines and rules for emergency cases (including remediation), develop TORs for responsible persons 2. Provide training for emergency operations for all principal actors (including high ranking officials – see risk management) 3. Maintain an updated inventory of emergency equipment and ensure replacement/procurement of any additional requirements 4. Establish emergency response procedures (hotline etc, contact details, including international ones) for NBFP and Competent Authorities				

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
COMPONENT D: PUBLIC AWARENESS AND PARTICIPATION				
OBJECTIVE To have fully functional systems for: - Public awareness - Public education - Participation - Access to information	- Public participation for Biosafety-related issues part of the sustainable development plan. - Topics addressing biosafety included in teaching curricula. - Public debate and discussion in media. - National BCH operational and continuously updated. - National website for biosafety regularly visited by the public - Public Awareness strategy developed and executed. - Biosafety mainstreamed into training courses of agricultural, health, customs and other enforcement officers.	- Development Plans and strategies for public participation by 2007 - Topics on Biosafety included in Teaching curricula by 2006/07 - Biosafety issues mainstreamed in the courses for health, agriculture, customs, inspectors and enforcement officers by 2006/07 - Feedback received from public on biosafety issues	- Biosafety not a sustainable development issue - Inadequate capacity to address public participation and awareness issues - Media not willing to promote debate on biosafety.	- Strengthen public participation - Educating the media on the importance of biosafety - Promote awareness on relevant international obligations
OUTCOMES				
D1. Strengthened system for public awareness, education and participation in decision making	- Number of students receiving education on biosafety in higher learning institutions - Strategies and mechanism for public awareness, education and participation - Outreach materials - Number of public debate, meetings and educational competition - Short and long courses - Institution responsible for public awareness identified	- Curricula for Biosafety and Biotechnology established/strengthened and operational in higher learning institutions by 2006/07 - 30 students trained and graduate on Biosafety and Biotechnology by 2007/08 from institutions of higher learning. - Short and long term courses on Biosafety established and taught locally by 2006/07 - Institution for managing public awareness and education campaigns on Biosafety		

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
		identified and fully operational by 2007 - Mechanisms for public participation established and functional by 2006/2008 - Public education and involvement plan established and operational by 2006/07 - Outreach material (two per year) developed and distributed to stakeholders by 2006/2009 - At least public debates (2), meeting(2) and educational competition (2) conducted by 2007/09 - Awareness of Biosafety and GMOs by public, media, MPs, etc. increased by 60% by year 2007/08.		

ACTIVITIES

1. Identify government agency/responsible institutions for managing public awareness and education campaigns relating to Biosafety
2. Identify an institution/agency specializing in developing and delivering public service campaign
3. Identify and institutionalize entry points for public participation in decision-making on GMOs
4. Strengthen teaching curricula by including issues on biosafety
5. Conducting 2 surveys for public opinion
6. Preparation of public education and involvement plan
7. Development and dissemination of outreach material (e.g. leaflets, Newsletter, Biosafety website)
8. Organise public debates (biannual) and meetings (biannnual) including educational competitions (annually) or events (annually)
9. Conducting three 2-day awareness raising workshops for 30 parliamentarians, 20 media, 30 NGOs, 15 private sector and 30 other stakeholders
10. User-friendly National website for biosafety established and regularly updated for public access and enhanced awareness.

ANNEX E

PROJECT IMPLEMENTATION PLAN

PROPOSED WORKPLAN - NBF IMPLEMENTATION PROJECT (UNITED REPUBLIC OF TANZANIA)

MARCH 2005

OUTCOME	ACTIVITIES	Year 1				Year 2				Year 3				Year 4			
	Months(48) Quarters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
COMPONENT A: REGULATORY REGIME																	
A1 Regulatory regime in place consistent with CPB and other obligations	1. Reviewing and finalizing draft Biosafety Regulations (consultancy, 2 national workshops, gazetting by the Minister responsible for Environment)																
	2. Conducting four 2-day sensitisation zonal workshops on regulatory regime for GMOs (CAs, NGOs, Private sector, civil society).																
	3. Translation of the NBF and Biosafety Regulations into *swahili* language																
	4. Conducting two, 3-days national fora of the Biosafety units of the Competent Authorities for sharing experience and information for effective enforcement of the regulatory regime																
A2 Enforcement of the regulatory regime	5. Preparation of operational manual for GMO inspectorates																
	6. Conducting four 3-day training workshops for Competent Authorities on inspection procedures (2 workshops) and related legal issues (2 workshops)																
	7. Establishment of cessation or revocation order for non-compliance																
COMPONENT B: HANDLING REQUESTS																	
B1. A fully functional risk assessment and risk management system	8. Development of National Biosafety Guidelines and training manual on risk assessment and risk management.																
	9. Conducting two, 3-day training workshops for 30 participants each from Competent Authorities and other biosafety regulatory personnel on risk assessment and risk management																

OUTCOME	ACTIVITIES	Year 1				Year 2				Year 3				Year 4			
	Months(48) Quarters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	10. Strengthening and improving necessary facilities for risk assessment and risk management and GMO detection																
A2. A fully functional decision-making system	11. Conducting two, 5-day training workshops for 30 participants each (NBC members, NBFP, private sector) on handling of requests																
	12. Conducting 2-day workshop for identification of socio-economical priorities to be taken into consideration for decision making																
	13. Preparation of internal manual on procedures for handling requests of GMOs in Tanzania																
A3. A fully functional administrative system	14. Strengthening biosafety units within the seven Competent Authorities for handling GMO issues																
	15. Conducting two, 3-days training workshops on GMO administrative issues (responsible personnel within CAs, NGOs, Private sector)																
	16. Development of a networking mechanism for cooperation and information exchange among CAs, NGOs, private sector etc																
COMPONENT C: SYSTEMS FOR FOLLOW-UP (E.G. ENFORCEMENT AND MONITORING FOR ENVIRONMENTAL EFFECTS)																	
C1. Strengthen systems for enforcement	17. Conducting three 2-day training workshops for:· • 100 Inspectors from the seven CAs· • 40 Custom officers · • 20 Judiciary officials (dispute settlement, handling of court cases and enforcement)																
	18. Upgrading one of the potential laboratories into a centerof excellence for R&D on modern biotechnology and biosafety																
	19. Purchase of equipment for detection of GMOs (see activity A1 (c))																
	20. Acquisition of GMO inspection facilities (field tool kits) for the seven CAs																
	21. Development of GMO testing protocol																
	22. Conducting two, 5-days training workshops for 60 laboratory technicians on GMO detection																
	23. Provide on the job training for officials from different authorities with real case studies to make sure that the system is functioning																
	24. Develop guidelines for monitoring (in cooperation with sector ministries) environmental effects																
C2. Emergency response procedures established and operational	25. Develop guidelines and rules for emergency cases (including remediation), develop TORs for responsible persons																
	26. Provide two training workshops, 2-days each for emergency operations for all principal actors (including high ranking officials – see risk management) (60 participants)																

OUTCOME	ACTIVITIES	Year 1				Year 2				Year 3				Year 4			
	Months(48) Quarters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	27. Maintain an updated inventory of emergency equipment and ensure replacement/procurement of any additional requirements																
	28. Establish emergency response procedures (hotline etc, contact details, including international ones) for NBFP and Competent Authorities																
COMPONENT D: PUBLIC EDUCATION, AWARENESS AND PARTICIPATION																	
D1. Strengthen system for public awareness, education and participation in decision making	29. Identify government agency/responsible institutions for managing public awareness and education campaigns relating to Biosafety																
	30. Conducting 2 surveys for public opinion																
	31. Preparation of public education and involvement plan together with improved teaching curricular to include issues on Biosafety																
	32. Development and dissemination of outreach material (e.g. leaflets, Newsletter, Biosafety website)																
	33. Conducting three 1-day awareness raising workshops for 30 parliamentarians, 20 media, 30 NGOs and 30 other stakeholders																
	34. Organise public debates (biannual) and meetings (biannual) including educational competitions (annually) or events (annually)																

ANNEX F

BUDGET AS PER PROJECT ACTIVITY

PROPOSED ACTIVITY-BASED BUDGET (UNITED REPUBLIC OF TANZANIA)

		YEAR 1		YEAR 2		YEAR 3		YEAR 4		TOTAL		GranTotal
		GEF	URT	GEF	URT	GEF	URT	GEF	URT	GEF	URT	
A1 Regulatory regime in place consistent with CPB and other obligations	1. Reviewing and finalizing draft Biosafety Regulations (consultancy, 1 national workshops, gazetting by the Minister responsible for Environment)	13,000	5,000	10,000	5,000	0	0	0	0	23,000	10,000	
	2. Conducting four 2-day sensitisation zonal workshops on regulatory regime for GMOs (CAs, NGOs, Private sector, civil society).	12,000	8,000	12,000	8,000	0	0	0	0	24,000	16,000	
	3. Translation of the NBF and Biosafety Regulations into swahili language (Printing and distribution)	8,000	5,000	8,000	5,000	0	0	0	0	16,000	10,000	
	4. Conducting two, 3-days national fora Biosafety units of the Competent Authorities for sharing experience and information for effective enforcement of the regulatory regime	0	0	8,000	8000	8,000	8,000	0	0	16,000	16,000	
2 Enforcement of the regulatory regime	5. Preparation of operational manual for GMO inspectorates	5,000	3,000	5,000	3,000	0	0	0	0	10,000	6,000	
	6. Conducting four 3-day training workshops for Competent Authorities on inspection procedures (2 workshops) and related legal issues (2 workshops)	9,000	7,000	8,000	7,000	0	0	0	0	17,000	14,000	
	7. Establishment of cessation or revocation order for non-compliance	2,000	2,000	2,000	2,000	0	0	0	0	4,000	4,000	
	Sub total	49,000	30,000	53,000	38,000	8,000	8,000	0	0	110,000	76,000	186,000

COMPONENT B: HANDLING REQUESTS												
B1. A fully functional risk assessment and risk management system	8. Development of National Biosafety Guidelines and training manual on risk assessment and risk management.	2,000	2,000	1,000	1000	0	0	0	0	3,000	3,000	
	9. Conducting two 3-day training workshops for 30 participants each from Competent Authorities and other biosafety regulatory personnel on risk assessment and risk management	10,000	8,000	10,000	8,000	0	0	0	0	20,000	16,000	
	10. Strengthening and improving necessary facilities for risk assessment and risk management and GMO detection	0	0	10,000	10,000	7,000	6,000	0	0	17,000	16,000	

B2. A fully functional decision-making system	11. Conducting two 5-day training workshops for 30 participants each (NBC members, NBFP, private sector) on handling of requests	10,000	8,000	10,000	8,000	0	0	0	0	20,000	16,000	
	12. Conducting 2-day workshop for identification of socio-economical priorities to be taken into consideration for decision making	6,000	5,000	0	0	0	0	0	0	6,000	5,000	
	13. Preparation of internal manual on procedures for handling requests of GMOs in Tanzania	2,500	500	0	0	0	0	0	0	2,500	500	
B3. A fully functional administrative system	14. Strengthening of specific biosafety units within the seven Competent Authorities for handling GMO issue	5,000	5,000	5,000	5,000	0	0	0	0	10,000	10,000	
	15. Conducting two, 3-days training workshop on GMO (30 participants each) administrative issues (responsible personnel within CAs, NGOs, Private sector)	0	0	18,000	17,000	0	0	0	0	18,000	17,000	
	16. Development of a networking mechanism for cooperation and information exchange among CAs, NGOs, private sector etc	0	0	3,000	2,000	3,000	2,000	0	0	6,000	4,000	
	Sub total	35,500	28,500	57,000	51,000	10,000	8,000	0	0	102,500	87,500	190,000

COMPONENT C: SYSTEMS FOR FOLLOW-UP (E.G. ENFORCEMENT AND MONITORING FOR ENVIRONMENTAL EFFECTS)												
C1. Strengthen systems for enforcement	17. Conducting three 2-day training workshops for:·	23,000	20,000	15,000	13,000	0	0	0	0	38,000	33,000	
	a) 15 Inspectors from each CA·											
	b) 40 Custom officers ·											
	c) 20 Judiciary officials (dispute settlement, handling of court cases and enforcement)											
	18. Upgrading one of the potential laboratories into a center of excellence for R&D on biosafety	15,000	15,000	0	0	0	0	0	0	15,000	15,000	
	19. Purchase of equipment for detection of GMOs (see activity A1 (c))	0	0	55,000	90,000	45,000	90,000	0	0	100,000	180,000	
	20. Acquisition of GMO inspection facilities (field tool kits)	8,000	8,000	5,000	9,000	0	0	0	0	13,000	17,000	
	21. Development of GMO testing protocol	2,000	2,000	1,000	1000	1,000	1000	1,000	1000	5,000	5,000	
	22. Conducting two training workshops, 5-day each for GMO detection (40 people)	0	0	14,000	10,000	14,000	10,000	0	0	28,000	20,000	
	23. Provide on-the-job training for officials (20) from different authorities with real case studies to make sure that the system is functioning	4,000	2,000	3,000	1,000	3,000	1,000	3,000	1,000	13,000	5,000	
	24. Develop guidelines and rules for monitoring (in cooperation with sector ministries) environmental effects	0	0	8,000	6,000	0	0	0	0	8,000	6,000	

C2. Emergency response procedures established and operational	25. Develop guidelines and rules for emergency cases (including remediation), develop TORs for responsible persons	0	0	6,000	5,000	0	0	0	0	6,000	5,000	
	26. Provide two training workshops, 2-day each for (60) for emergency operations for all principal actors (including high ranking officials – see risk management)	0	0	8,000	6,000	8,000	6,000	0	0	16,000	12,000	
	27. Maintain an updated inventory of emergency equipment and ensure replacement/procurement of any additional requirements	2,000	500	2,000	500	2,000	500	2,000	500	8,000	2,000	
	28. Establish emergency response procedures (hotline etc, contact details, including international ones) for NBFP and Competent Authorities	0	0	2,000	3,000	0	0	0	0	2,000	3,000	
	Sub total	54,000	47,500	119,000	144,500	73,000	108,500	6,000	2,500	252,000	303,000	555,000

COMPONENT D: PUBLIC AWARENESS, EDUCATION AND PARTICIPATION												
D1. Strengthen system for public awareness, education and participation in decision making	29. Identify government agency/responsible institutions for managing public awareness, education campaigns relating to Biosafety and entry points for public participation in decision making	6,000	6,000	0	0	0	0	0	0	6,000	6,000	
	30. Conducting 2 surveys for public opinion	0	0	4,000	4,000	0	0	4,000	4,000	8,000	8,000	
	31. Preparation of public education and involvement plan together with improved teaching curricular to include issues on Biosafety	0	0	8,000	6,000	0	0	0	0	8,000	8,000	
	32. Development and dissemination of outreach material (e.g. leaflets, Newsletter, Biosafety website)	5,000	4,000	5,000	4,000	5,000	4,000	5,000	4,000	20,000	16,000	
	33. Conducting three 1-day awareness raising workshops for parliamentarians, media, NGOs and other stakeholders	0	0	8,000	7,000	8,000	7,000	8,000	7,000	24,000	21,000	
	34 Organise public debates (biannual) and meetings (biannual) including educational competitions (annually) or events (annually)	0	0	6,000	6,000	6,000	6,000	6,000	6,000	18,000	18,000	
	Sub total	11,000	10,000	31,000	27,000	19,000	17,000	23,000	21,000	84,000	75,000	159,000

COMPONENT E: NATIONAL PROJECT PERSONNEL												
	National Coordinator	12,000	6,000	12,000	6,000	12,000	6,000	12,000	6,000	48,000	24,000	
	One Project Assistant	3,600	2,000	3,600	2,000	3,600	2,000	3,600	2,000	14,400	8,000	
	Administrative assistant (part time on finance)	3,600	2,000	3,600	2,000	3,600	2,000	3,600	2,000	14,400	8,000	
	NCC meeting and travel	5,000	2,000	5,000	2,000	5,000	2,000	5,000	2,000	20,000	8,000	
Miscellaneous component	Computer,Printer, scanner and photocopier	20,000	6,000	0	0	0	0	0	0	20,000	6,000	
	Communication costs	3,000	2,000	3,000	2,000	3,000	2,000	3,000	2,000	12,000	8,000	
	Office supplies	2,000	600	2,000	600	2,000	600	2,000	600	8,000	2,400	
	Equipment maintenance	2,500	600	2,500	600	2,500	600	2,500	600	10,000	2,400	
	Audit of final accounts	3,000	1,500	3,000	1,500	3,000	1,500	3,000	1,500	12,000	6,000	
	Sub total	54,700	22,700	34,700	16,700	34,700	16,700	34,700	16,700	158,800	72,800	
Technical support		17,500	0	17,500	0	17,500	0	17,500	0	70,000	0	
	Total	221,700	138,700	312,200	277,200	162,200	158,200	81,200	40,200	777,300	614,300	1,391,600
	Grand Total GEF	777,300										
	Grand Total Tanzania(In Kind)	614,300										

ANNEX G

INCREMENTAL COST ASSESSMENT

Activity	Baseline	Alternative	Increment
System for handling requests for permits	Tanzania needs to set up procedures for handling requests as per Biosafety Regulations and provide tools and training to staff in charge so as to enable them carry out their tasks effectively	The implementation of the Cartagena Protocol on Biosafety is supported by an operational system for handling requests which include administrative processing, risk assessment and decision making in line with the CPB and national legislation procedures	System for handling request for GMOs including administrative processing, risks assessment and decision making is in place National capacities are strengthened in terms of training courses, training tools and equipment
Regulatory regime	The Environmental Management Act (2004) is about to be in force and once in force, it will operationalize Biosafety Regulations	The implementation of the CPB is sorted by a regulatory regime reflecting existing policies and defining all the elements of the NBF, in line with the CPB and international obligations is in force	A legal regime, which includes Biosafety Regulations, is in place Decision-making and personnel involved in the application of the regulatory regime are trained
System for follow-up (monitoring and enforcement)	Tanzania needs to finalize methodologies/procedures for monitoring environmental effects and procedures for enforcement Technical means and training are needed so as to enable inspectors and technicians to carry out their tasks	The implementation of the Cartagena Protocol on Biosafety is supported by an operational system for monitoring of environmental effects and enforcement	Systems for monitoring of environmental effects and enforcement are in place Reference laboratories are selected and upgraded with facilities for GMO monitoring and inspection
Public education, awareness and participation	Awareness and education on biosafety need to be further raised, involvement of the public need to be part of the system so as to reflect the Article 23 of the CPB	Implementation of the CPB is supported by a strengthened system for public education, awareness and participation	A plan for public education, awareness and participation and access to information is formulated and implemented Outreach materials is prepared and disseminated for different target groups

Broad Development Goals

This project is part of the GEF's wider efforts in assisting countries to implement a biosafety regulatory regime in accordance with Agenda 21 and CBD. More specifically GEF resources will be used to assist URT to meet the objective of the CPB (i.e to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking also into account risks to human health and specifically focusing on transboundary movements) through the full implementation of its NBF.

The project is consistent with and based on, national development priorities, plans and programmes in both development and conservation sectors including National Visio 2025 and the National Biodiversity Strategy and Action Plan.

ANNEX H

INSTITUTIONAL ARRANGEMENT AND ROLES

The institutional arrangement for effective implementation of National Biosafety Framework for Tanzania has four components proposed to regulate the import or export of GMOs. It is important to note that the proposed structure recognizes mandates of Competent Authorities in their respective disciplines.

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

The proposed biosafety institutional structure is summarized in the Figure 1 below.

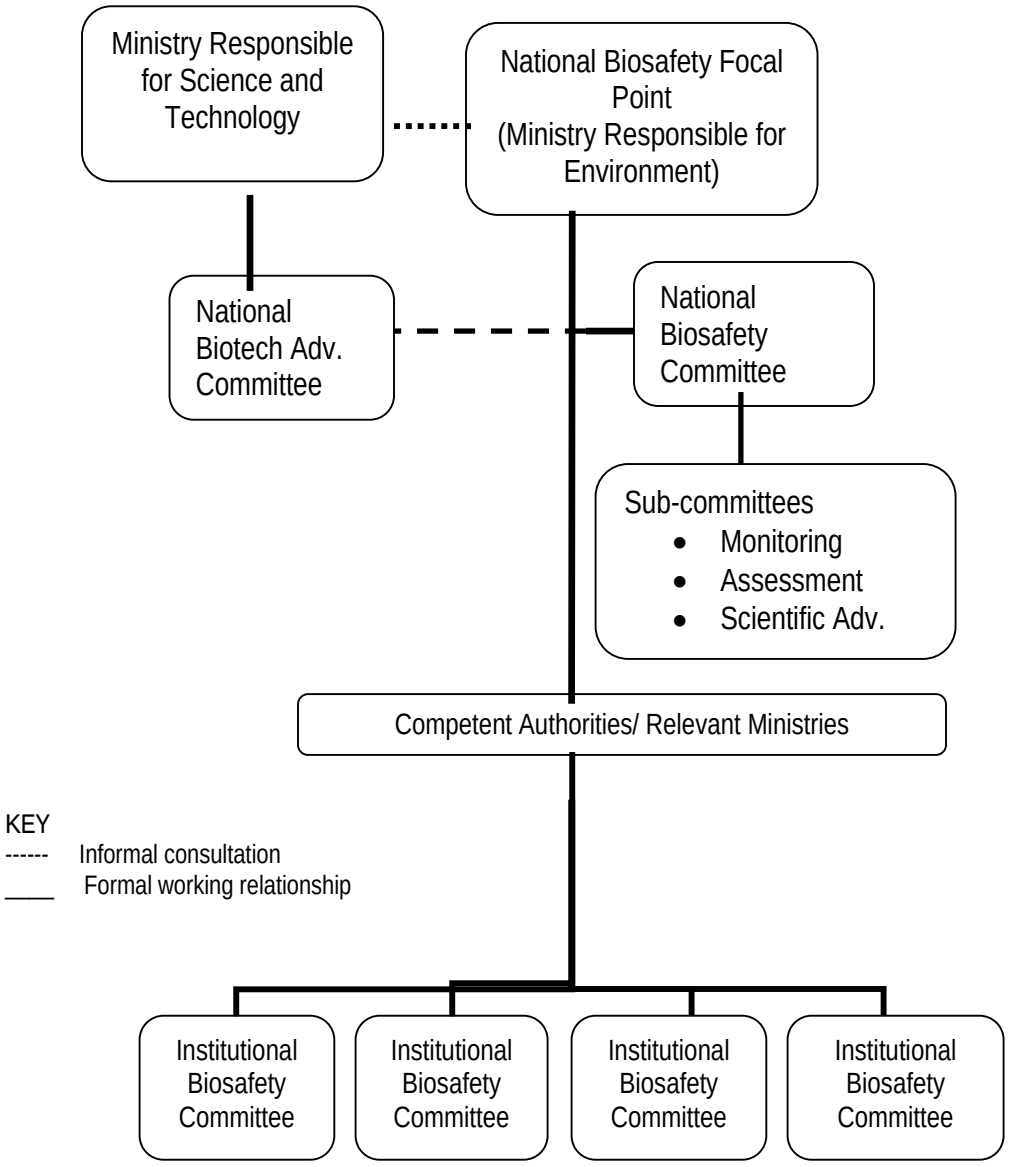


Figure 1: Biosafety institutional structure

National Biosafety Focal Point (NBFP)

The NBFP should be the Ministry responsible for environment. Its roles and responsibilities includes the review and approve of biosafety applications for research, confined release, pre-commercial release or placing on the market; to oversee the implementation of the NBF; to receive and forward applications to Competent Authorities; to collect and disseminate biosafety information to the public; to decide whether to accept or reject an application based on the advice by a Competent Authority and NBC.

National Biosafety Committee (NBC)

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

review relevant applications; advise on policies, legislation and other policy instruments; advise the NBFP and Competent Authorities; and involve fully the participation of the private sector and the public at large.

Relevant Ministries/ Competent Authorities

The NBFP shall designate Competent Authorities which will be responsible for following up, supervising and controlling implementation of the biosafety regulations. The roles and responsibilities of Competent Authorities shall include the review of relevant applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market; review, conduct or cause to conduct risk assessments of GMOs or products thereof. The Competent Authorities shall advise the NBFP, designate inspectors and undertake inspection as well as other control measures to ensure compliance with the Biosafety Regulations; and to undertake assessment of socio-economic impacts as well as ethical and cultural impacts.

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:- to review the containment and confinement levels required by the Guidelines for the proposed research; 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; 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 illnesses; and to perform other functions as may be delegated by the relevant Ministries/Competent Authorities.

ANNEX I

DRAFT TERMS OF REFERENCE FOR NATIONAL EXECUTING AGENCY (NEA), NATIONAL PROJECT COORDINATOR (NPC) AND NATIONAL COORDINATING COMMITTEE (NCC)

F1 NATIONAL EXECUTING AGENCY

The National Executing Agency (NEA), in addition to other duties given to it by the National Government, will:

a) Establish the National Co-ordinating Committee (NCC);
b) Appoint a National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
c) Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
d) Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
e) Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government; and
f) Submit the final version of the National Biosafety Framework no later than eighteen months from signature of this Memorandum of Understanding.

F2 NATIONAL COORDINATING COOMMITTEE (NCC)

The National Coordinating Committee (NCC) will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

a) Develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework;
b) Oversee the preparation of the National Biosafety Framework
c) Approve the detailed workplan and budget produced by the NPC;
d) Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
e) Provide overall policy advice on the implementation of the National Project;
f) Review and advise on the main outputs of the National Project;
g) Ensure that information on the implementation of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
h) Assist in mobilising available data and ensure a constant information flow between all concerned parties;
i) Allow for effective communication and decision-making between the National Project Coordinator and other actors; and
j) Ensure that the environmental policy of the Government is fully reflected in the National Project documentation.

F3 NATIONAL COORDINATING COOMMITTEE (NCC)

The National Project Coordinator (NPC) will carry out the following tasks:

a) The National Project Coordinator (NPC) will act as the secretary of the NCC
b) Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;

c) Organize National Coordinating Committee meetings;
d) Prepare detailed workplan and budget under the guidance of the NCC;
e) Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
f) Foster, establish and maintain links with other related national and international programmes and National Projects;
g) Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
h) Organize, contract and manage the consultants and experts, and supervise their performance;
i) Coordinate and oversee the preparation of the outputs of the NBF;
j) Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
k) Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
l) Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP Global National Project Team;
m) Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology; and
n) Prepare and submit to UNEP and the NCC, regular progress and financial reports

F4 PROJECT ASSISTANTS (PA)

The Project Assistants (PA) will carry out the following tasks

a) Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
b) Assist with the organisation of National Coordinating Committee meetings;
c) Assist with preparation detailed work plan and budget under the guidance of the NCC;
d) Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
e) Inform the NPC of other related national and international programmes and National Projects;
f) Assist in drafting Terms of Reference for National Project components, consultants and experts;
g) Assist with the identification of the consultants and experts, and supervise their performance;
h) Assist in overseeing the preparation of the outputs of the NBF;
i) Assist the National Project Finance Officer providing information as needed;
j) Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
k) Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
l) Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports;
m) Assist with the preparation of a project monitoring and evaluation plan;
n) Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact ;
o) Assist with capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan; and
p) Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines.

ANNEX J

BRIEF DESCRIPTION OF THE DRAFT ENVIRONMENTAL MANAGEMENT (BIOSAFETY) REGULATIONS

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.

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.
k) Attached Schedules