

TABLE OF CONTENT

PREFACE	3
ACKNOWLEDGEMENT	4
1. INTRODUCTION	6
1.1 Background and rationale	6
1.2 Objective	7
1.3 Specific objectives/terms of reference	7
2. METHODOLOGICAL FRAMEWORK	7
2.1 Approach	7
2.2 Selection criteria	8
3. FUNCTIONS OF THE NATIONAL COE FOR BIOSAFETY	9
4. THE PROPOSED NATIONAL CENTRE EXCELLENCE FOR BIOSAFETY	10
4.1 The proposed model for CoE for Biosafety in Tanzania	10
4.1.1 Background4.1.2 The recommended model for CoE	10 12
4.2 Coordination of the CoE activities	12
4.2.1 The National Coordinating Centre (NCC)	12
4.2.2 The Technical committee of the Centre	13
4.3 Institutional arrangements for the CoE	15
4.3.1 University of Dar Es Salaam	15
4.3.2 Tropical Pest Research Institute	15
4.3.3 Ifakara Health Institute (IHI)	16
4.3.4 Mikocheni Agricultural Research Institute (MARI)	16
4.3.5 Tanzania Food and Drug Authority (TFDA)	16
4.3.6 Sokoine University of Agriculture (SUA)	16
4.3.7 National Institute of Medical research (NIMR)4.3.8 Government Chemist Laboratory Agency (GCLA)	17 17
4.3.9 Tanzania Bureau of Standards (TBS)	17
4.3.10 Central Veterinary laboratory (CVL)	17
5. RECOMENDATIONS	18
6. APPENDICES	21

PREFACE

The United Republic of Tanzania ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity on 16th March 2003. The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Modern biotechnology has the potential to provide answers to some of the most intractable development challenges facing developing countries, including agricultural production, health, nutrition and the protection of environment. The development and application of this technology has opened up a wide range of possibilities, including the production of genetically modified plants, animal and microorganisms. These developments are, however, characterized by increasing scientific complexity, policy uncertainty and public anxiety over real and perceived potential benefits and risks to human health, animal health, biodiversity, and environment as well as social, economic and ethical issues. The concerns and opportunities surrounding modern biotechnology dictate the need to have policies and capacities to guide the safe use of biotechnology to prevent or effectively reduce its risks. The perceived promises and risks of biotechnology are now under intense public scrutiny. The debate is wide, complex and often inconclusive.

The challenge in implementing the Protocol arises from limited capacity in terms of skilled human and financial resources, infrastructure as well as limited public awareness. The Government of the United Republic of Tanzania is committed to build the necessary capacity for effective and efficient implementation of the Protocol. Enactment and operationalization of the Environmental Management Act of 2004 paved the way for the establishment of a functional National Framework for Biosafety in the country. The Framework provides a regulatory regime, administrative and decision making, monitoring and public awareness and participation mechanisms. Tanzania has started to build capacity in risk assessment and risk management, detection of GMOs, enforcement of the regulatory regime and public awareness.

Tanzania, has very limited capacity in biosafety. Very few institutions have all the capacity to address the levels of complexity to successfully carry out all agreed tasks under the Cartagena Protocol on Biosafety (CPB). Many would need substantive training and technical backstopping. Given the limited capacity in place and the high level of skills needed, ranging from the safety and regulatory aspects to technical and scientific issues, the need for establishing a National Centre of excellence (CoE) that would help strengthen cooperation in biosafety and provide the necessary backstopping to institutions involved in biotechnology and biosafety is critical.

I am grateful to the Global Environmental Facility (GEF) through the United Nations Environment Programme (UNEP) for providing financial and technical support.

Dr. Batilda S. Burian (MP) Minister of State (Environment) Vice President's Office

ACKNOWLEDGEMENT

The success of establishment of Biosafety Centre of Excellency for Tanzania is the result of joint efforts of several experts and institutions that deserve a vote of appreciation. Due to space limitation we cannot mention all of them. However, we assure them of our heartfelt appreciation and that we value their continued cooperation and support.

We would like to express our gratitude to government ministries, institutions, civil society and individuals who were involved in thepreliminary survey that formed the basis for the establishment of Biosafety Centre of Excellency for Tanzania. We are indebted to all institutions that sent their representatives to the technical retreats that took considerable time to provide additional information and came up with the draft MOU (Mninstry of Agriculture food Security and Cooperatives MARI, TPRI; Ministry of Health and Social Wellfare (NIMR, GCLA, TFDA), University of Dar es Salaam, Sokoine University of agricultur, Ministry of Agriculture and Environment Zanzibar (Kizimbani agricultural Research Centre), and Ifakara Health Institute)

We are grateful to the Director of Environment, Vice President's Office, Mr. E.K. Mugurusi, for the role he played as the Designated National Executing Agency Officer and his contribution to this document. Many thanks as well go to Dr. Alex Owusu-Biney UNEP Regional Biosafety Coordinator for participating in visiting and assessing the institution and reviewing this document.

Gratitude is equally due to the team of experts that prepared this document for their commendable effort and input towards its completion. First and foremost is to Dr. E. Mneney (MARI), the lead expert who did preliminary assessment and prepared the first draft document; Prof. Susan Nchimbi- Msolla (SUA), Dr. S.R. Mwinjaka, National Project Coordinator, Mr. S.R. Nkondokaya, Mr. T Bwana, Mr. O.M. Kamukuru, all from Vice President's Office.

Last but not least we are grateful to UNEP/GEF for funding the implementation phase of National Biosafety Framework for Tanzania.

Ruth H. Mollel Permanent Secretary Vice President's Office

ABBREVIATIONS AND ACRONYMS

ASARECA	Association for Strengthening Agricultural Research in Eastern and Central
	Africa
AIA	Advance Informed Agreement
BIOEARN	East African Regional Programme and Research Network for Biotechnology,
	Biosafety and Biotechnology Policy Development
CBD	Convention on Biological Diversity
CoE	Centre of Excellency
CPB	Cartagena Protocol on Biosafety
DMBB	Department of Molecular Biology and Biotechnology
EAC	East African Community
GCLA	Government Chemist Laboratory Agency
GEF	Global Environment Facility
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
ICE	Institute of Continuous Education
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICIPE	International Centre for Insect Physiology and Ecology
IHI	Ifakara Health Institute
MARI	Mikocheni Agricultural Research Institute
NRIs	National Research Institutes
NBAC	National Biotechnology Advisory Committee
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBFP	National Biosafety Focal Point
NIMR	National Institute of Medical research
PBS	Programme on Biosafety Systems
SUA	Sokoine University of Agriculture
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drug Authority
TPRI	Tropical Pesticides Research Institute
UDSM	University of Dar Es Salaam
UNEP	United Nations Environment Programme
VPO	Vice President's Office

1. INTRODUCTION

1.1 Background and rationale

Modern biotechnology has the potential to provide answers to some of the most intractable development challenges facing developing countries, including agricultural production, health, nutrition and the environment. The development and application of this technology has opened up a wide range of possibilities, including the production of genetically modified plants, animal and microorganisms. These developments are, however, characterized by increasing scientific complexity, policy uncertainty and public anxiety over real and perceived potential benefits and risks to human health, animal health, biodiversity, and environment, social economic and ethical issues. The concerns and opportunities surrounding modern biotechnology dictate the need to have policies and capacities to guide the safe of biotechnology to prevent or effectively reduce its risks. The perceived promises and risks of biotechnology are now under intense public scrutiny. The debate is wide, complex and often inconclusive.

Tanzania, like many African countries, has very limited capacity in biosafety. Very few institutions have all the capacity to address the levels of complexity to successfully carry out all agreed tasks under the Cartagena Protocol on Biosafety (CPB). Many would need substantive training and technical backstopping. Given the limited capacity in place and the high level of skills needed, ranging from the safety and regulatory aspects to technical and scientific issues, there is a need for establishing a National Centre of excellence (CoE) that would help strengthen cooperation in biosafety and provide the necessary backstopping to institutions involved in biotechnology and biosafety.

The CoE would be responsible for conducting biosafety research and building capacity in risk assessment, risk management, risk communication, detection of GMOs and other biosafety related issues. The Centre would also provide scientific advice on emerging social cultural, ethical, economic, legal and political issues that surround the development, dissemination and marketing of biotechnology and its products. In addition the CoE would also provide a forum for scientists, policy makers, civil society, farmers, NGOs, private sector players and other stakeholders to objectively debate the issues, share knowledge, experiences on the potential benefits and risks of biotechnology.

1.2 Objective

In view of the above, the main objective of the study was to assess the physical, technical, managerial and financial capacity of the existing biotechnology organisation in Tanzania in order identify the institution that is capable of hosting/becoming the National Centres of Excellence (CoE) for Biosafety.

1.3 Specific objectives/terms of reference

- To assess the physical human and laboratory infrastructure capacity of biotechnology organisation in Tanzania;
- Do literature search on the experiences of other countries in the establishment of a National CoE for biotechnology/ biosafety;
- Develop criteria for selecting the National CoE for biosafety;
- Recommend the most suitable organisation for hosting the National Centre of Excellence for biosafety;
- To propose the feasible governance structure and institutional arrangement of the CoE;
- Propose major functions that will be performed by the National CoE for biosafety.

2. METHODOLOGICAL FRAMEWORK

2.1 Approach

The study adopted a combination of approaches including surveys, interviews with key informants in institutions and relevant Ministries, visits to different institutions in the country to assess facilities available and literature search on previous surveys. The candidate institutions included agricultural institutions, universities, and other institutions dealing with biological researches in fisheries, forestry, medicine and environment. This study was done in two phases.

The first phase involved visiting all biotechnology institutions in Tanzania (Annex 1) to get a broad picture on the available capacities. The data from this study and other

previous surveys was used to shortlist the institutions. The second phase involved making an in-depth study on the shortlisted institutions in order to select the most suitable based on its technical, managerial and financial capability. The short listed institutions were: Mikocheni Agricultural Research Institute (MARI), Sokoine University of Agriculture (SUA), Tropical Pesticides Research Institute (TPRI), University of Dar Es Salaam, Ifakara Health Institute (IHI), Tanzania Food and Drug Authority (TFDA) National Institute of Medical research (NIMR), Government Chemist Laboratory Agency (GCLA), Tanzania Bureau of Standards (TBS) and Central Veterinary laboratory (CVL).

2.2 Selection criteria

The selection and evaluation criteria for the CoE for biosafety were based on selection criteria developed by the consultant together with the National Biosafety Focal Point (NBFP) Team. The selection criteria was based on scientific merits, research competence, and availability infrastructure to support research and capacity building needs of different stakeholders. Specific selection criteria for the proposed CoE are:

- The CoE should demonstrate support for the centre from higher levels;
- The proposed CoE should have researchers with all the necessary skills required to carry out quality research in biosafety;
- The CoE should have adequate and qualified staff to support the national and regional demands on capacity building in areas of risk assessment, risk management and risk communication; GMO detection and other biosafety skills;
- The centre should have biosafety facilities (eg biosafety level 2 laboratory/screen house) and equipment (eg GMO detection equipment) to support multidisciplinary research in biosafety;
- Centre must demonstrate the potential for attracting local and international financial and technical support;
- The CoE should be able to offer higher level/advanced training (MSc and PhD) in biosafety and related fields;
- CoE should be able to act as a central resource centre where individuals and institutions can access and exchange information, including guidelines/procedures and other resource materials related to biosafety;
- Have close links with other biosafety institutions in the region/sub-region;

- Have the support and trust of the network members/collaborating institutions;
- Have considerable experience and strong leadership on biosafety issues;
- Have, or be able to access, multidisciplinary expertise; and
- Be supportive of the Cartagena Protocol on Biosafety.

3. FUNCTIONS OF THE NATIONAL COE FOR BIOSAFETY

The CoE shall:

- i. Carry out capacity building needs assessments at the national and regional level in order for CoE to design demand-driven training and awareness creation programmes on biosafety;
- ii. Develop capacity building programmes that impart knowledge and skills needed for effective implementation of the Cartagena Protocol as key players like the regulatory scientist in the NBC and competent authorities lack the competence in biosafety risk assessment and management. Biosafety risk assessment and risk management is a knowledge-based activity requiring many types of expertise and access to high quality technical information about safety and environmental interactions;
- iii. Provide advanced training in biosafety at MSc and PhD levels; Conduct handson short courses on biosafety assessment, GMO detection, risk communication and other biosafety issues. The NBC and NBFP (the decision making bodies) must have a backing of local scientific capacity to screen applications and make decisions on import. The training and capacity building of local scientists in biosafety assessment is therefore critical. Government scientists, university scientists, scientists from NRIs and scientists from civil society organisations should all be part of the local scientific pool of expertise;
- iv. In collaboration with NBFP develop and maintain a database of national biosafety experts;
- Mobilise funding for the development and delivery of the biosafety programmes, either through local budgeting or by fundraising from external sources A large number of opportunities exists, not least through the GEF-UNEP, ICGEB, BIO-EARN, PBS, ASARECA and many others;

- vi. Foster and facilitate exchange of experiences and best safety practices among collaborating institutes;
- vii. Facilitate the sharing of biosafety information and resources, including educational materials; and
- viii. liaise and collaborate closely with the relevant national authorities, particularly the NFP for the Cartagena Protocol, NBC and competent authorities in order to adapt existing and/or develop new programmes that address national capacity needs in biosafety.

4. THE PROPOSED NATIONAL CENTRE EXCELLENCE FOR BIOSAFETY

4.1 The proposed model for CoE for Biosafety in Tanzania

4.1.1 Background

There are three possible models for establishing a National CoE for Biosafety in Tanzania as discussed below:

Option 1: Single Centred Model

Under this model the centre is established as a single physical unit comprising of different sub-units carrying out different programs. An example of such a model is the International Centre for Insect Physiology and Ecology (ICIPE), located in Nairobi, Kenya.

The advantages of this model include:

- ease of administration and management, and
- low running costs.

The disadvantages include:

- high initial investments in human resources and infrastructure and
- Inefficient utilization of existing human resources and facilities in other institutions in the country.

Under this model the centre is established as multiple physical units or centres in different geographical locations. The units or centres are involved in different programs and the centres are semi-autonomous in terms of administration and management. An example of such a model is the National Institute for Medical Research (NIMR) in Tanzania.

The advantages of this model include:

- Ease of administration and management as the centres are affiliated to each other through a coordinating centre/institution; and
- Broader scope of research activities with stations at different locations thus increasing relevance.

The disadvantages include:

- The running costs are relatively higher than the single centre model;
- Higher initial investments in human resources and infrastructure; and
- Inefficient utilization of existing human resources and facilities in other institutions in the different locations.

Option 3: Network Model

Under this model, a number of existing institutions are organized into a network of centres of excellence each involved in a specific program. The centres may be in different geographical locations but attached to relevant existing institutions. The centres are semi-autonomous but linked through an administrative structure that is coordinated at national level. An example of such a model is BioNexus of Malaysia which is a network of different centres of excellence in specific biotechnology fields. The advantages of this model include:

- Initial investment costs are relatively low;
- Efficient utilization of existing human resources and infrastructure;
- Broader scope of research activities at different locations thus increasing relevance; and

 Higher potential for multidisciplinary approach in formulation and implementation of R & D activities.

The disadvantages include:

- Administration and management of the network is more complex than in other two models.
- •

4.1.2 The recommended model for CoE

Considering the analysis of the various models above and the current capacity in the available institution, the adoption of the Network Model is recommended. This model will insure efficient utilization of existing human resources and infrastructure in the available institution and hence make the initial investment costs to be relatively low. Furthermore, the model insures multidisciplinary approach in formulation and implementation of the centres activities. The broader scope of research activities at different locations within the network increases relevance and quality of work done. Efforts for pgrading these centres should be selective to avoid stretching resources too thinly. One out of the ten biotechnology centres one will be upgraded to become the national coordinating centre for biosafety in Tanzania.

4.2 Coordination of the CoE activities 4.2.1 The National Coordinating Centre (NCC)

There will be a national co-coordinating centre (leading institution) which will coordinate and provide overall administration of the CoE. Based on the selection criteria adopted for this study, the University of Dar Es Salaam, Department of Molecular Biology and Biotechnology has capacity to become national coordinating centre for Biosafety.

Competitive advantage of National coordinating centre (DMBB)

The proposed National coordinating centre for biosafety has the following comparative advantage

• The DMBB combines agricultural, medical, industrial and environmental biotechnology in one centre;

- DMBB, University of Dar Es Salaam is currently the only institute offering advanced training in biosafety (MSc and PhD level programmes);
- The institute also runs a series of hands on short courses in GMO detection, biosafety and ecological risk assessment for researchers from East and Central Africa Region;
- The institute has developed curriculum for environmental biosafety and food safety for two undergraduate courses;
- The institute has a biosafely level two laboratory including physical containment structures that are required for experimentation, testing and / or release of transgenic materials and biocontrol agents;
- The institute has about 5 PhD holders with vast experience in Biosafety, ecological risk assessment and bioethics;
- Have strong collaborative links with regional and international research institutes; and
- The institute is currently implementing two collaborative projects on capacity building with financial assistance from BiosafeTrain Project (2006- 2010) and Programme on Biosafety Systems (PBS).
- •

4.2.2 The Technical committee of the Centre

There will be a technical committee of the centre. This will be composed of lead experts from each collaborating institution. The technical committee will responsible for overseeing all technical issues of the CoE. The VPO will host the secretariat to the technical committee and will be responsible for running the committee's activities

Figure 1: ORGANISATIONAL STRUCTURE OF NATIONAL COE FOR BIOSAFETY



4.3 Institutional arrangements for the CoE

The CoE for Tanzania will consist of 10 centres organised/operating in a net work model The VPO will provide policy guidance and oversee the activities of the CoE (Figure 1). The suggested division of responsibilities of the CoE among the research organisations is as follows:

4.3.1 University of Dar Es Salaam

- The UDSM will be the leading institution for biosafety activities related to environmental and industrial biotechnology
- The UDSM, specifically the Department of Molecular Biology and Biotechnology (DMBB) will be the National Coordinating Centre for the CoE for biosafety and network headquarters responsible for CoE strengthening and Coordination; The network headquarters will be responsible for the following activities:
 - Backstopping all Biosafety R&D activities in all the collaborating centres including regulatory and competent authorities;
 - Host equipment which is otherwise too expensive and sensitive to be installed at each network centre for use by all the network fraternity;
 - Secure core funding from the government and other sources for the activities of the collaborating institutes;
 - Provide overall administration of the CoE;
 - Create public awareness and maintain public relations;
 - Provide logistical support to the collaborating Institutes;
 - Establish and maintain linkages among the collaborating centres and other national and international collaborators; and

4.3.2 Tropical Pest Research Institute

The TPRI is an institute under the ministry of agriculture in charge for monitoring and enforcement plant health. TPRI is also the Plant Biosafety Office of the Ministry of Agriculture, Food Security and Cooperatives (MAFC) and the Secretariat of the Agricultural Biosafety Scientific Advisory Committee (ABSAC). The ABSAC is the competent authority under the MAFC. The TPRI will be responsible for monitoring and regulating biosafety activities under the MAFC.

4.3.3 Ifakara Health Institute (IHI)

The IHI is an independent, non-profit foundation that operates as a Trust under the leadership of the Ministry of Health. The vision of IHI is to be a centre of innovations in health R&D in the areas of molecular epidemiology, diagnostic immunology and parasitology. The Centre has state-of the art facilities including microarray and Real Time PCR. In collaboration with NIMR, the institute will be responsible for biosafety Research and development activities in health.

4.3.4 Mikocheni Agricultural Research Institute (MARI)

The MARI is the leading centre for biotechnology R&D in the MAFC. The institute has modern equipments for molecular biology and diagnostics. MARI will be responsible for R&D in biosafety, GM detection and hands-on/short term training on biosafety.

4.3.5 Tanzania Food and Drug Authority (TFDA)

Tanzania Food and Drugs Authority (TFDA) is a regulatory body under the Ministry of Health and Social Welfare which is responsible for regulating the quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices in the country. TFDAs main role will be in regulating food and drugs biosafety.

4.3.6 Sokoine University of Agriculture (SUA)

The SUA is a public university with a mandate to teach and conduct research in agriculture, veterinary medicine, forestry, nature conservation. The institute has other academic units including, Institute of Continuing Education (ICE), Pest Management Centre (PMC), SUA Centre for Sustainable Rural Development (SCSRD) and the

genome centre. SUA will be responsible for Agricultural R&D in biosafety, training, public awareness and participation.

4.3.7 National Institute of Medical research (NIMR)

The National Institute for Medical Research (NIMR) is a parastatal service organization under the Ministry of Health mandated to conduct and coordinate health research in Tanzania. The establishment of this institute was in recognition by the government of the need to generate scientific data and information required in the development of better methods and techniques of enhancing disease management, prevention and control in the country. The institute will be responsible for overseeing biosafety R&D and providing technical advice on matters relating to biosafety regulation in health.

4.3.8 Government Chemist Laboratory Agency (GCLA)

The Government Chemist Laboratory Agency is a semi-autonomous, commercially oriented Executive Agency that provide comprehensive services of specialized scientific analysis, expert opinion and advice including quality control of food and drugs, Water, cosmetics and chemicals management and forensic science services. The Forensic Science Division has acquired an automatic DNA Sequencer (Gen Scan ABI 3100) and a thermocycler (9700 GENE AMP), which are mainly used for forensic and paternity cases. However, the facilities are underutilized, and can be used to support biosafety activities of the CoE. The GCLA will be the Appellate Lab for Health and food biosafety.

4.3.9 Tanzania Bureau of Standards (TBS)

Tanzania Bureau of Standards was established by the Act of Parliament in 1975 and has a mandate to undertake measures for quality control of products of all descriptions and promote standardization in industry and commerce. The TBS has well equipped laboratories for testing chemicals, materials, food and agricultural products. Tests are carried out to detect contaminants of all types and prove wholesomeness and safety. In addition the Food Laboratory provides special service to exporters of fish and fish. TBS will be responsible for setting thresholds and biosafety standards.

4.3.10 Central Veterinary laboratory (CVL)

The Central Veterinary laboratory (CVL) is an R& D centre of the Ministry of Livestock Development that has a national mandate to conduct research on animal diseases. The CVL has fully furnished laboratories with standard equipment for disease diagnosis and research in microbiology, parasitology, chemistry and pathology. The centre in collaboration with SUA will be responsible of animal/livestock biosafety.

5. RECOMENDATIONS

The CoE for biosafety in Tanzania will be organised in a network model. The network will consist of 10 collaborating centres coordinated by one lead institution. Based on the selection criteria adopted for this study, the institute that has capacity to become national coordinating centre for Biosafety is the University of Dar Es Salaam, Department of Molecular Biology and Biotechnology (DMBB). The national co-coordinating centre (leading institution) will coordinate the biosafety activities of collaborating centres and provide administration support for the network. The Efforts of upgrading these centres should be selective to avoid stretching resources too thinly. Given the limited resources available, it is recommended that, in the short term, high priority for investment be given to the University of Dar Es Salaam, Department of Molecular Biology (DMBB).

Table 1: Suitability assessment of the proposed biotechnology centres

	UDSM	SUA	MARI	TPRI	IHI	TFDA	TBS	NIMR	CVL	GCLA
Biosafety laboratory level 2	\checkmark	Х	\checkmark	х	х	Х	Х	х	x	x
Offer advanced level training (MSc/PhD)	\checkmark	Х	Х	Х	Х	Х	Х	Х	Х	Х
Number of biosafety experts (PhD level)	6	1	0	2	0	0	0	0	0	0
Quality of the biosafety experts	Excellent	Good	Good	V good	Fair	Fair	Fair	Fair	Fair	Fair
Capacity to offer hands on short courses on biosafety	Excellent	V/Good	Good	Good	Fair	Fair	Fair	Fair	Fair	Poor
Multidisciplinary	V Good	Good	Poor	Poor	Poor	Poor	Poor	Poor	Poor	Poor
Potential for attracting support	Excellent	Good	Good	Excellent	Good	Excellent	V.Good	Excellent	Good	Good
Availability of support services ICT, Library molecular labs etc	V Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Linkage with regional and international biosafety institution	V Strong	Moderate	Moderate	Strong	Moderate	Moderate	Moderate	moderate	Weak	Weak
Space for expansion	\checkmark	\checkmark	Х	√	√	1	1	1	1	√
Have Institutional Biosafety Committee	\checkmark	Х	\checkmark	х	Х	Х	Х	х	Х	Х
Accessibility	Excellent	Good	Excellent	Good	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Suitability score	5	3	3	4	1	1	1	2	1	1

Key: √ = Available;

X = Not available

Table 2: Gap analysis of the proposed CoE institutes/centres

S/N	Institution	Roles and responsibilities	Бар	Requirement
1	UDSM	 GM detection Long term training Short term training of trainers and CoE members Research & Development (Industry & Environment) 	Equipments for GMO quantification	Real time PCR
2	TFDA	 Regulation of GM food, drugs and cosmetics 	 Basic equipment for GMO detection Biosafety skills 	 Equipments Rapid test kits, Thermocyclers, Electrophoresis Imaging system Training
3	NIMR	R & D (Biosafety R&D in health)	Skills	Training
4	IHI	R & D (Biosafety R&D in health)	Skills	Training
5	TPRI	 Regulatory (Agriculture) Training of biosafety inspectors GMO detection (basic) 	Skills	Training
6	GCLA	Appellate Lab for Health and food biosafety	 Equipment and skills and equipment 	 Equipment Diagnostic Software Training
7	TBS	Set Biosafety standard/Threshold	Skills	Training
8	SUA	 R&D (biosafety R&D in Crops and Livestock) Training Public awareness and participation 	Biosafety skills	Training
9	MARI	 R&D on crop biosafety GMO detection training	Skills	Training
10	CVL	 R&D (livestock biosafety) 	Skills	Training

6. APPENDICES

Appendix 1: Current status of the potential Laboratory available in various Institutions

Institute/Faculty	Section	Human	Facilities	Size of Lab	Remarks
/Department		resource	/equipment		
UDSM	Molecular	Researchers - 7	Basic equipments are	One room of 10m x 8m	Highly potential.
	Biology	Technicians - 5	available, but missing	(80sq.metres)	Students can take part
			Sequencer and/Micro array		in biosafety activities
			for DNA analysis.		as part of their
					research
	Tissue Culture	Researchers - 3	Missing important facilities	Two rooms, each one of	
	Lab.	Technicians -1	like, power security, HPLC,	12sq.metres and a growth	
			Infrared, Atomic absorption	chamber with four cubicles of	
			mechanism & bioreactors	5sq.metres.	
			And no green houses.	-	
	Biosafety Lab.	On	~		
		construction			
Sokoine	Tissue culture	Researchers -3	Moderately equipped,	Four chambers each of size	Highly potential as an
University of	Lab.	Technicians - 2	needing more like	24sq.metres	overall center. The
Agriculture			Biorectors, power security		Institute of
			systems.		Continuous
			Two screen houses		Education) (ICE)
	Seed	Researchers-01	Moderate, Some are still	Big room of 42sq.metres	could be ideal public
	Pathology	Technicians- 02	needed like Polaroid		awareness
	Lab.		documentation systems for		programmes.
			molecular diagnostics and		
			Sequencer for DNA		Students can take part
			fragment analysis.		in biosafety activities
			One Screen house		as part of their

Institute/Faculty /Department	Section	Human resource	Facilities /equipment	Size of Lab	Remarks
	Plant Breeding Molecular Lab	Researchers – 3 Technicians - 2	Well equipped, more equipment have been ordered	Room 32 sq. metres	research
	Molecular Lab. (Veterinary Medicine)	Researchers-07 Technicians-02	Moderately equipped, lacking, sequencer and Polaroid documentation (computer system) for DNA band analysis.	Three chambers of 24sq.metres each	
	Genome Science Centre.	Researchers-02 Technicians-02	Well equipped only lacking de-ionizer (machine for making de-ionize water).	Five rooms of 42sq.metres	
	Institute of Continuous Education (ICE)	Researchers- 04 Technicians - 04	One big conference room and two small meeting rooms; well equipped with visual aid facilities; meal facilities are available	Can accommodate up to 150 people at a time	
Animal Diseases Research Institute (ADRI)	Molecular Lab.	Researchers-04 Technicians-02	Moderately equipped, missing sequencer and or Micro array	Six rooms with (42sq.metres)	Moderate potential (ideal for animal science/diseases work)
National Medical Research Institute (NMRI)	Molecular Lab. (Mwanza branch.)	Researchers-01 Technicians-03	Equipped with limitations on DNA analysis.	A laboratory with three chambers, one for preparations, second for mixing and the third for processing.	Moderate potential (ideal for human diseases work)
Ifakara Health Research and Development	Molecular Lab.	Researchers – Technicians -	Well equipped for molecular biology work	Several rooms	Highly potential for human disease work

Institute/Faculty /Department Centre (IHRDC)	Section	Human resource	Facilities /equipment	Size of Lab	Remarks
Mikocheni Agricultural Research Institute	Molecular biology	Researchers-05 Technicians-01	Basic equipments are available but missing sequencer and or micro array	Two chambers, one with (35sq.m) and the other (15sq.m)	High potential
	Tissue Culture Lab.	Researchers-05 Technicians-01	Moderately equipped, no bioreactors, Infrared and atomic absorption mechanism.	Two chambers, preparation and culture room (42sq.m) and incubation room (35sq.m). 4 screen house	
	Transformatio n Lab.	Under construction			
Seliani Agricultural Institute	No molecular biology or tissue culture labs				Moderately potential
	Pathology lab	Researchers – 02 Technicians- 04	Moderately equipped	Two rooms of 24sq.m each, 4 screen houses. One cold room	
	Soil Science lab	Researchers- Technician- several	Very well equipped lab	One big lab (40sq.m) and two small rooms (24sq.m)	
	Breeding	Researchers- 04 Technicians- 03		4 Screen houses, seed cleaning room	
Horticultural Research Institute Tengeru	Tissue culture	Researcher- 0 Technician - 01	Well equipped	3 rooms, one of size 24sq.m and the other two of 18sq.m; 2 screen houses – need repair	Low potential

Institute/Faculty /Department	Section	Human resource	Facilities /equipment	Size of Lab	Remarks
Uyole Agricultural Research Institute	Tissue culture lab.	Researcher-0 Technician-01	Moderately equipped	One room with big space. One screen house constructions not completed	Low potential
	Pathology lab	Researchers-03 Technicians- several	Moderately equipped		
	Breeding	Researchers- 07 Technicians- 03	Moderately equipped	2 screen houses, seed cleaning room	
TPRI	Molecular lab.	Researchers – 06 Technicians - 03	Moderately equipped	1 room lab. but rooms are available if needed for molecular lab; 2 greenhouse- need repair; 2 screen houses	Moderately potential
	Breeding	Researcher -01			

Appendix 2: Report of National Coordinator visit on COE

1.0 Introduction

The Regional Coordinator for UNEP Biosafety project for Africa Dr.Alex Owusu- Biney visited Tanzania from 22nd June to 30th June 2009. The mission was aimed at undertaking midterm internal review and self assessment on the National Biosafety Framework implementation phase. During the visit, a project review was done by comparing the original planned activities, achieved project outputs, progress and expenditure reports, work plans and current revised work plan. A discussion on the current progress report for June 2009 was also done to prepare input data for the Project Implementation Review (PIR). The team also had opportunity to discuss the new proposed follow-up project which aims at filling the identified gaps in the current project and discuss possible plans to start the Project Preparation Grant process while the PIF is in the approval process.

Secondly, the Regional Coordinator had opportunity to meet Permanent secretary, Ag.DE, PSO, IT expert to highlight the objective of his visit to and made brief discussion on NBF issues.

Furthermore, the Regional Coordinator and a team of national experts made Field visit to potential laboratory and institutions earmarked to form a network centre of excellence on biosafety in Dar es salaam, Morogoro, Ifakara and Zanzibar.

2.0 Outcomes

2.1 NBF Office

Review of project was undertaken to access status of execution as at June 2009, identify targeted activities till completion of the project 2010. In reviewing project progress, the Coordinator and the NBF team went through the project activities and it was revealed that project progress is in the right track. However, some of the core project activities are not in line with the project timing as some activities are overdue, these include:- zonal workshops for public awareness, translation of the biosafety regulation, upgrading of identified laboratories, purchase of field tool kits for biosafety inspectors, establishment of specific biosafety units within the Competent Authorities for handling GMO issue.

Discussions with PS, Ag.DE and Project team

During the discussion it was revealed that some of the project activities are overdue and the Coordinator insisted on the need to facilitate procedural bottlenecks which delays execution of project activities including meetings, training activities and upgrading identified laboratories. A discussion was also made with Procurement and IT team to address issues on execution of procurement activities and installation of wireless backup system to facilitate access to the net including speedy reporting on Anubis. The PSO and IT personnel updated the team on the progress of installation of backup wireless internet and purchase of the computers for competent authority. The PSO assured the meeting that the installation was in final stage and it will be working before the coordinator leaves on 30th June 2009. However this was not the case.

The NBF team together with the Coordinator discussed the prepared Biosafety manuals which were under review by regional adviser. (Risk Assessment manual, Risk management manual, GMO testing protocol, Manual for Confined field trials Procedures for Handling Request). A general comment to the manuals was that the manuals mostly covered issues in that area of agriculture other areas like industry and health are not well covered. It was suggested that these two areas are very important and need to be well covered in the manuals.

For Management reporting a review of Anubis to discuss on site issues related to reporting, time targets set and procedural approaches were discussed.

Other issue raised was possibility of developing regional Biosafety project for EAC. Since EAC community is in the process of Harmonization of regulatory instruments on Biosafety, the EAC countries could explore a possibility of utilizing GEF RAF-5 funding for a regional project on harmonization of biosafety instruments.

2.2 Field visit for (COE)

The Regional Coordinator and a team of national experts made Field visit to potential laboratory and institutions earmarked to form a network centre of excellence on biosafety in Dar es salaam, Morogoro, Ifakara and Zanzibar. The aim of this visit was to assess the capacity of the institution in terms of human resource base, laboratory equipments for GMO detection, training and research on biosafety.

Ministry of Agriculture Research Institute (MARI) - Mikocheni

MARI conducts all biotechnology research for Coconut, Cashew, cassava and other crops. The team visited Molecular biology laboratory, Disease molecular laboratory, Gell documentation room, Media preparation room, Tissue culture rooms and containment facility which are biosafety level 2. The biosafety facilities are in the final stage of accomplishment. In general MARI has the capacity to handle biosafety research, GM detection and training on biosafety though have limited space for expansion.

University of Dar es Salaam (UDSM)

Visit to department of Molecular Biology and Biotechnology was done; it was revealed that the department is in a the process of finalizing a biosafety lab level 2. Have a screen house and have develop courses on biosafety.

Sokoine university of Agriculture (SUA)

The team had a brief meeting with the Dean faculty of agriculture and heads of departments. It was noted that the department of crop science have molecular laboratory for isolation of plant pathogen. It also have tissue culture lab with ample space which can accommodate more facilities in future. Food science laboratory has also space which is planned to handle food assessments. Furthermore, faculty of Veterinary medicine has a Genome Centre with modern facilities for genomics and bioinformatics. The lab is equipped with a modern Microarray which can be used for both animal and plant genetic printing. The faculty also has a biosafety level 2 facilities. Though there is a gap in experts on bioinformatics, SUA can provide support for Genomics and Bioinformatics. Furthermore, SUA is going to be the National Centre of Excellence on Agricultural Biotechnology and therefore be able to handle more issues on agricultural biotechnology.

In term of public awareness, the institute of Continuing education at SUA has a big potential to undertake public awareness activities on Biosafety.

Ifakara Health Institute (IHI)

The institution has modern laboratory for molecular biology, Parasitology, Immunology. The molecular biology laboratory supports research, training, diagnostic and consultancy services. The institute has a both conventional and real time PCR which can do both quantitative and qualitative gene amplification.

Kizimbani Agricultural Research Centre - Zanzibar

Is a pure tissue culture laboratory which by now needs to be improved or make strong link with other canters in the mainland like MARI, SUA and UDSM. This is important because Zanzibar is an important port of entry and handles a number of transhipments.

3.0 Recommendation and way forward

3.1 Key recommendations

- i. There is a need to look upon consistency between the biosafety regulation and the technical instruments (Biosafety manuals)
- ii. There is an urgent need for updating equipments in the competent institution to facilitate regulatory mandate in managing biosafety in Tanzania
- iii. The network of centers of excellence will be extremely dependent on the commitment of Government and the designated institutions

- iv. The identified center of excellence if assigned their duties and monitored accordingly will help in achieving a functional biosafety system in the country.
- v. There is a need to have well defined system for monitoring GMO product at Zanzibar port as the Zanzibar port is major port of entry in the country.

3.2 Way forward

- i. Project activities targeted to complete with tangible outputs by December 2010 and the first quarter of 2011 to be used for terminal reporting and project closure
- ii. Finalize and agree on the center of excellence and assign duties
- iii. Complete installation of wireless internet and insure timely reporting in Anubis
- iv. Cross check and incorporate in the developed manuals or develop new manuals on inpection procedure, drug related issues and industrial products.
- v. Prepare operational matrix with timelines for the execution of the project till termination

Appendix 1: MEMORANDUM OF UNDERSTANDINGMEMORANDUM OF UNDERSTANDING BETWEEN THE NATIONAL BIOSAFTY FOCAL POINT AND THE NETWORK MEMBERS OF THE NATIONAL CENTER OF EXCELLENCY FOR BIOSAFETY FOR COLLABORATION AND MUTUAL SUPPORT IN PROMOTING BIOSAFETY IN TANZANIA

This memorandum of Understanding (hereinafter referred as "MOU") is made and entered into on this---

day of ----- 200-- between:

National Biosafety Focal Point -Vice Presidents Office (VPO)

(Hereinafter referred as NBFP)

And

The Network Members of National Centre of Excellency (CoE) for biosafety

(Hereinafter referred as network members/partner institutions)

The Network Members of the National Centre of Excellency (CoE) for biosafety are:

University of Dar Es Salaam (UDSM); Mikocheni Agricultural Research Institute (MARI); Sokoine University of Agriculture (SUA); Tropical Pesticides Research Institute (TPRI); Ifakara Health Institute (IHI); Tanzania Food and Drug Authority (TFDA); National Institute of Medical research (NIMR); Government Chemist Laboratory Agency (GCLA); Tanzania Bureau of Standards (TBS) and Central Veterinary laboratory (CVL)

PREAMBLE

With the current development and increase in use of Genetic modified organisms, there is an urgent need to effectively take necessary measures to ensure that the adaptation of such bio technologies do not bring harmful effects to both human health and environment.

Recognising that Tanzania has limited capacity to adequately address GMOs challenges, it was deemed necessary that different institutions should work collateral to each other in a bid to ensure that Tanzania does not fall behind in the adaptation of bio technology but also ensure that the adaptation of such technologies do not bring harm to human health and the environment. In order to achieve this goal, it was imperative that there was need of having a legal instrument which will bring different institutions with

different capabilities to work hand in hand to ensure safe application of modern biotechnology. The Biosafety centre of Excellence will not only set a forum for addressing pertinent issues on bio technologies but also provide for framework whereby different institutions will collaborate. This memorandum will foster commitments for joint approach geared at establishing and maintaining collaboration between the "NBFP" and the "network members" of the National Centre of Excellency (CoE). The objective of this agreement is to create a mutually beneficial partnership that will seek to promote biosafety in Tanzania. This MoU will also focus on jointly addressing the effective implementation of the Cartagena Protocol in Tanzania through conducting biosafety research and building capacity in risk assessment, risk management, risk communication, detection of GMOs and other biosafety related issues.

WHEREAS The objective of the National Bio safety Focal Point (NBFP) is to put in place an effective policy framework as well as administrative and legal instruments for assessing the management and and enhancing the safe application of modern biotechnology in Tanzania particularly on biosafety issues, such as health, environmental, social-cultural and ethical impacts.

ACKNOWLEDGING that collaboration between the CoE network members will contribute to optimize utilization of limited resources, minimize duplication of efforts, and maximize the use of available technical, financial and other opportunities within each other.

REALISING that mutual benefit can be derived from scholarly interaction, co-operative planning and implementation and other forms of technical and scientific collaboration based on mutual understanding; reciprocity and equal partnership

COGNISANT of the fact that parties posses certain skills and technology which can complement each other in achieving the objective of this collaboration and hence collaborating institutions will contribute to optimize the utilization of limited resources, minimize duplication of efforts, and maximize the use of available technical, financial and other opportunities within each other.

NOW THEREFORE, in consideration of the mutual covenants and premises set forth herein, the parties hereby agree as follows:

Clause One: The objective

1.1 The objective of this agreement is to provide the framework for a partnership arrangement between "NBFP" and the "Network Members" of the National Centre of Excellency (CoE) for

biosafety (hereinafter referred as network members/partner institutions) to create a national capacity for conducting biosafety research and regulate the safe application of GM technology in Tanzania.

Clause Two: The scope of collaboration

The parties undertake to jointly perform the following actions to the extent possible within their individual capacities;

- 2.1 Provide scientific advice on emerging technical, social cultural, ethical, economic, legal and political issues that surround the development, dissemination and marketing of GMO and its products in Tanzania;
- 2.2 Foster and facilitate exchange of experiences and best safety practices among collaborating institutes;
- 2.3 Build a network of Tanzanian practitioners and experts on biosafety, maintaining relation and facilitate the sharing of biosafety information and resources, including educational materials;
- 2.4 liaise and collaborate closely with the relevant national authorities, particularly the NFP for the Cartagena Protocol, NBC and competent authorities in order to adapt existing and/or develop new programmes that address national capacity needs in biosafety;
- 2.5 Carry out capacity building needs assessments at the institutional, national and regional level in order to design demand-driven training and awareness creation programmes on biosafety;
- 2.6 Develop capacity building programmes that impart knowledge and skills needed for effective implementation of the Cartagena Protocol to key players such as the regulatory scientist in the NBC and competent authorities;
- 2.7 provide a forum for scientists, policy makers, civil society, farmers, NGOs, private sector players and other stakeholders to objectively debate the issues, share knowledge and experiences on the potential benefits and risks of GMOs;
- 2.8 Provide advanced training in biosafety at MSc and PhD levels;
- 2.9 Conduct hands-on short courses on biosafety assessment, GMO detection, risk communication and other biosafety issues to scientists from Government university, NRIs and civil society organizations;
- 2.10 In collaboration with NBFP develop and maintain a database of national biosafety experts;
- 2.11 Plan and collaborate in joint publications and presentations as a result of service monitoring and operational research in biosafety and
- 2.12 Mobilize funding for the development and delivery of the biosafety programmes, either through local budgeting or by fundraising from external sources.

Clause Three: Implementation

- 3.1 Each party shall offer some of its research facilities including quality research laboratories/equipments to facilitate CoE activities;
- 3.2 Network members shall offer their research platform laboratory and expertise to perform GMO testing and other biosafety related activities;
- 3.3 Network members shall offer their senior researchers to facilitate training and participate as resource persons as per agreed CoE training plans;
- 3.4 Most of the activities envisaged in clause two will take place on an on-going basis, to the extent that parties find it possible within their current human resource and financial capabilities.
- 3.5 The MOU carries no financial commitment on either party and does not obligate either part to work exclusively with the ether or constitute either organization the agent of the other
- 3.6 All activities pursuant to the above CoE objectives shall be implemented through specific agreements supplemental to this MOU. Each such agreement shall specify:
 - Objective and duration of the particular activity
 - The terms of reference for activities to be undertaken by each party
 - Financial terms and conditions as applicable t each party
 - Any other provisions as may be applicable

Clause Four: Biological materials

- 4.1 Joint ownership: All Biological Materials arising from, produced from, discovered in connection with or developed under this contract, or obtained by a partner for furtherance of the research shall be jointly owned by the collaborating parties. Notwithstanding the expiration or determination of this memorandum all material shall be kept in safe custody in accordance with and under any conditions mutually agreed by the parties in writing.
- 4.2 Right to use: Subject to the provision of this MOU, each party shall have the right to use the Biological Materials for its own Academic, Non-Commercial Research purposes.
- 4.3 Distribution to Third Parties: Distribution or transfer of Biological Materials to third parties shall be done only for Academic, Non-Commercial Research purposes, upon consultation with all parties.

Clause FIVE: Material transfer Agreement

5.1 Any and all materials transferred between the parties shall be subject to an acceptable material transfer agreement signed by the parties.

Clause Six: Publications

- 6.1 Parties to this MoU shall review each publication or material to be presented in order to;
 - (i) prevent disclosure of patentable inventions before applications can be filed, or
 - (ii) identify and correct any inadvertent disclosure of Proprietary Information or use of institution's name which each institution, in its sole discretion, considers inappropriate.
- 6.2 In all activities, publications and seminar presentations undertaken or which arise from or pursuant to any project under this MoU, all the names of the parties involved must be acknowledged. Such acknowledgement shall include but will not be limited to display in equal prominence of the full names and symbols and/or logos of all parties on all materials.

Clause Seven: Proprietary Information

- 7.1 Parties herein agree not to disclose Proprietary Information except on a need to know basis to persons subject to terms of confidentiality (or with the consent of the holder of the Proprietary Information). Parties' further agree not to use the Proprietary Information except for purposes contemplated by this MOU and to equally take necessary measures to prevent disclosure of the proprietary information to third parties.
- 7.2 Each party agrees not to do or omit to do anything which might prejudice the filing of patent applications, including (but not limited to) using, publishing, disclosing or making available to the public anywhere in the world whether in writing or orally and whether in whole or in any part any invention and/or Proprietary Information.

Clause Seven: Dispute settlement

8.1 Any dispute between the Parties regarding the interpretation or implementation of this Memorandum shall be settled amicably by consultation or negotiation within the spirit of collaboration. In the event that parties have failed to amicably settle any dispute, the matter shall be assigned to a single arbitrator as may be agreed upon by the parties whereas further recourse may be settled by two arbitrators and an umpire. If parties are still not satisfied with the award issued by the arbitrators, parties may proceed to seek redress from the courts of law.

Clause Nine: Force Majeure

9.1 Either party shall promptly notify the other party, in writing, of any situation or event arising from circumstances beyond their control, which they could not have reasonably foreseen, and which make the performance of all or part of the parties' obligations under this contract impossible. Upon notification of the occurrence of such a situation or event, the performance of this contract shall be deemed to be postponed for a period of time.

Clause Ten: Review and Amendments

10.1 This Memorandum of Understanding may be reviewed and/or amended from time to time on mutual agreement as need may arise; and all such mutual agreements shall be ADDEDUMS to this Memorandum.

Clause Eleven: Duration of the Memorandum

11.1 This Memorandum of Understanding will come into force on the date of its signature by all parties and will be valid for a period of five years and may be renewed for a further period on terms to be agreed by all parties.

Clause Twelve: Termination

12.1 The Memorandum may be terminated at any time by either party giving the other six months notice, provided such termination shall be effective only after settlement of all liabilities and benefits and mutually accepted settlement of partially completed activities.

IN WITNESS WHEREOF, the Parties, acting through their duly authorized representative, have signed this Memorandum of Understanding in eleven identical copies in English language, all copies being equally authentic, on the date first above written:

National Biosafety	Focal Point (NBFP)		
Name	Signature	Designation	date
And			
University of Dar I	Es Salaam (UDSM)		
Name	Signature	Designation	date

Mikocheni Agricultural Research Institute (MARI)

Name	Signature	Designation	date			
Sokoine University of Agricul	ture (SUA)					
Name	Signature	Designation	date			
Tropical Pesticides Research	Institute (TPRI)					
Name	Signature	Designation	date			
Ifakara Health Institute (IHI)						
Name	Signature	Designation	date			
Tanzania Food and Drug Aut	hority (TFDA)					
Name	Signature	Designation	date			
National Institute of Medical	research (NIMR),					
Name	Signature	Designation	date			
Government Chemist Labora	Government Chemist Laboratory Agency (GCLA)					

Name	Signature	Designation	date
Tanzania Bureau of Standards	s (TBS) and		
Name	Signature	Designation	date
Central Veterinary laboratory	(CVL)		
Name	Signature	Designation	date

