



TANZANIA

NATIONAL PROGRESS REPORT SUBMITTED TO THE THIRD SERIES OF SUBREGIONAL WORKSHOPS (2003/2004):

1.0 Introduction

The potentials of modern biotechnology in improving agricultural, industrial, and health sectors as well as environmental conservation cannot be overemphasized. However, there are concerns over the potential adverse effects of modern biotechnology to human health and the environment. In view of this reality, Tanzania acceded to the Cartagena Protocol on Biosafety of the Convention on Biological Diversity (CBD) 2003, supporting the need for instituting to ensure safety and minimize the risks likely to occur, encountered or subsequently beyond expectation with regard to modern biotechnology.

The Vice President's Office, in collaboration with stakeholders at level and UNEP is developing a National Framework for the implementation of the Cartagena Protocol on Biosafety. The involves establishment of a system of technical, and administrative mechanisms address safety in the field of modern biotechnology in the country.

"...aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health...the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements"

Cartagena Protocol on Biosafety, 2000, Article 1

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In the process to develop NBF, stakeholder's workshops and six surveys were conducted in 2003 to ensure public participation. Existing local infrastructure and resources were identified in order to establish the status to what extent Tanzania meets the requirements for safe application of modern biotechnology. In addition to that the draft country report on Biosafety and Biotechnology, Biosafety Guidelines and Biosafety Regulations were produced in January 2004. This report gives an overview of these aspects.

2.0 Overview Status of Biosafety and Biotechnology in Tanzania

It is worth mentioning that, a number of key institutions involved in biotechnology R&D were identified, despite having deficiency in resources, they possess potential foundation, upon which future development can be built without having to start from scratch. The potential institutions identified are the following:

- Mikocheni Agricultural Research Institute (MARI) – *Agriculture*
- Sokoine University of Agriculture (SUA) – *Agriculture and Veterinary Medicine*
- Animal Disease Research Institute (ADRI) - *livestock*

- Muhimbili University College of Health Sciences – *Human health*
- Ifakara Health Research Center – *Human Health*
- Applied Microbiology Unit (AMU), University of Dar-es-salaam – *Industry and environmental protection*

Apart from the above-mentioned institutions, special focus should also be extended to those institutions that perform key mandates such as quality assurance, standardization and forensic services including:

- Tanzania Food and Nutrition Center (TFNC)
- Tanzania Bureau of Standards (TBS)
- Tanzania Food and Drug Agency (TFDA)
- Government Chemist Laboratory Agency (GCLA) and
- Tanzania Pesticide Research Institute (TPRI).

These institutions could be supported to serve as centers of excellence in biotechnology and biosafety in their respective fields of emphasis.

2.1 The Involvement of Private Sector in Biotechnology R&D

Public sector institutions dominate most of the biotechnology R&D in the country. In Tanzania, the current involvement of the private sector on biotechnology is mainly in agriculture and to a limited extent in health. So far attention has focused on coffee, pyrethrum, sisal, cotton, tobacco and sugar. The private sector has shown interest, for application of biotechnology through collaboration with the public sector. Specific examples in the agricultural sector are:-

The newly established Tanzania Coffee Research Institute (TACRI) is in the process of establishing tissue culture capacity for mass production of improved coffee planting materials through somatic embryogenesis; Mlingano ARI is working on micro propagation of sisal planting materials through tissue culture in collaboration with KATANI Ltd. For rehabilitation of the sisal industry in the country; Example of the health sector is IHDR that undertakes molecular diseases diagnostics and DNA finger printing for studies on the epidemiology of malaria drug resistance of *plasmodium falciparum*.

2.2 Existing Policies Related to Biosafety and Biotechnology

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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 significant reduction or loss of biological It further states, "Strategic measures shall be put for the development of biotechnology, especially fair and equitable sharing of the results and arising out of utilization by foreign recipients, of resources originating from Tanzania, and biosafety".

"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 issues"

National Environmental Policy, 1997, paragraph 32

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In October 2001 the Vice President's Office collaboration with the Tanzania Commission for Technology (COSTECH) organized the First National Biotechnology Stakeholders' Workshop to chart out the way forward for promoting biotechnology research and development in the country.

(VPO) in Science

During this workshop it became apparent that, one of the major constraints to biotechnology development in the country is lack of a national policy, strategies and commitment by the government to support biotechnology activities in the country. One of the recommendations of this workshop was for the Government to consider establishing a body responsible for advising the Government and promoting biotechnology in the country. In response, the Government of Tanzania established the National Biotechnology Advisory Committee (NBAC).

It is worth noting that the Ministry of Science, Technology and Higher Education is coordinating the formulation of the National Biotechnology Policy for Tanzania. The draft policy document sets a number of strategic objectives, among them are: establishment and implementation of biosafety regulations and guidelines; and conservation and development of genetic resources.

In view of the fact that modern biotechnology is a new development, other national sectoral policies do not directly reflect issues of biosafety.

2.4 Biosafety concern (National Biosafety Framework -NBF)

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National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that is set in place to address safety issue in the context of modern biotechnology. As already mentioned in the introduction of this report, that modern biotechnology is a new and promising tool for improvement and novel uses in agricultural, industrial, health and environmental fields. However, there are concerns over the risks of GMOs to human health and the environment taking into account socio-economic, cultural and ethical concern. As a result, the need to build National Biosafety Frameworks and Guidelines has emerged as one of the priorities.

The NBF Project is steered by the National Coordinating Committee (NCC) that is comprised of 17 members from different ministries and institutions. Members are from the Vice President's Office; Ministries of: Agriculture and Food Security; Natural Resources and Tourism; Industries and Trade; Justice and Constitutional Affairs; Health; Science, Technology and Higher Education; Water and Livestock Development; and Agriculture, Natural Resources, Environment and Cooperatives (Zanzibar). Other members are from the Commission for Science and Technology (COSTECH); National Environment Management Council (NEMC); and Tanzania Revenue Authority (TRA).

The process to develop National Biosafety Framework involves analysis of the existing situation, that is national assessment and public awareness and participation in the biosafety framework development process. The approach involves surveys and consultative workshops with appropriate stakeholders. The impetus for the surveys and workshops lies on adopting a participatory process in order to create ownership, constituency and legitimacy by all stakeholders in the development and implementation of NBF.

2.3.1 Biosafety Guidelines and Regulations

The drafts of the **national biosafety guidelines and regulations** have been prepared in January 2004, and now are waiting for stakeholder's comments and acceptance. In order to ensure public participation, the drafts will be taken to the stakeholders at zonal level for review. This process will take place up to April 2004. Thereafter the documents will be discussed at the national forum.

Simultaneously, the draft on '**Environmental Management Act 2004**' will be tabled in the Parliament in February 2004. The '**Environment Management Act 2004**' incorporates issues on biosafety. There is a section on biosafety that states clearly on the "regulation of the development,

handling, and use of Genetically Modified Organisms (GMOs) and products thereof”, and this would provide a platform for effecting promulgation of the **biosafety regulations and guidelines**.

2.3.1.1 Interim biosafety measures

On top of that two types of institutional structures are suggested, namely interim arrangement that could be applied before the enactment of a framework legislation on biosafety matters; and the permanent one that would operate after putting in place the legislative framework. Under an interim arrangement, it is proposed that the developed **biosafety guidelines and regulations** by the National Biosafety Framework project, overseen by the Vice President’s Office shall be used or incorporated in policies at sectoral level.

3.0 Existing Legislation Related to Biosafety and Biotechnology

There is yet no single legislative instrument that concerns biosafety in the country. Rather there are various pieces of sectoral legislation that include plant protection, animal health and human health. They include the issues on plant protection, pesticides, herbicides, animal health, and food quality and health control.

In general, many sectors have reviewed their policies. Some sectors have already revised their legal instruments to be in line with the reviewed sectoral policies. However, modern biotechnology industry that necessitates the need for national regulatory frameworks is very recent in Tanzania. As such, most of the national policies and pieces of legislation have not, unsurprisingly so, considered biosafety issues.

The following are examples, of some, of such legislation and other legal instruments that regulate biotechnology application in the country. Their strengths, weaknesses and opportunities are briefly assessed such as:-

a) The Plant Protection Act No. 3 of 1997; The main thrust of this Act is prevention and control of attacks by, or spread of harmful organisms or diseases in Tanzania (URT, 1997).

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

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

As regards pesticides, the Tropical Pesticides Research Institute (TPRI) Act No. 18 of 1979 stipulates that TPRI shall provide the following technical services:- Pesticides registration and control; National plant quarantine services; National herbarium; and Serves as the National Centre for Plant Genetic Resources.

b) The Veterinary Act of 2003;

Despite the silence in issues regarding biosafety the powers vested on the veterinarians, could play a very important role in the future implementation of the National Biosafety Framework.

c) The Animal Diseases Act, of 2003;

In spite of other Act being silence on genetically modified organisms, the animal disease Act of 2003 noted the issues on GMOs. The Act put restriction on GMOs, it states “no person shall make or import or use GMOs of animal origin without permit from the Director of Livestock”.

d) *Fertilisers and Animal Feedstuffs Ordinance Cap. 467 of 1962*, amendment Act No. 19 of 1962; This piece of legislation seeks to regulate the importation, manufacture and sale of agricultural fertilisers and animal foodstuffs (Tanganyika, 1963). Like many other sectoral laws, this legislation is aimed at taking care of the sanitary aspect of feeds for animals, and not so much on the GMOs biosafety and human health concerns. In order for this sectoral law to take on board biosafety concerns, major amendments need to be made to it.

e) *The Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003*; This act repeals among others, the Food (Control of Quality) Act of 1978. The current piece of legislation establishes the Tanzania Food and Drugs Authority (TFDA), which, among others, approves registration of herbal drug “if it considers that the availability of such drug is in the public interest and it is safe, efficacious and of acceptable quality” (URT, 2003). Notably, TFDA is established to control the quality, safety and effectiveness of food, drugs, cosmetics and medical devices. The legislation sets out the procedure for controlling the importation, manufacture, labelling, marking or identification, storage, selling and distribution of these products or any material or substances used in their manufacture. Despite the fact that this Act is very recent, it does not mention biosafety issues. Further, regulations for the implementation of the law have not yet been developed. The Authority, however, has inspectors who could be used to enforce biosafety requirements under its mandate, particularly in respect of Articles 5 and 11 of the Biosafety Protocol, on pharmaceuticals and procedure for GMOs intended for direct use as food or feed, or for processing.

It is therefore recommended that a national biosafety legal framework be put in place. The National Biosafety framework shall be part and parcel of the national Environmental Legal Framework. On the basis of the legal framework, the relevant sectoral policies and legal instruments be revised to be in congruence with the national biosafety framework. The revisions should reflect the mandates and roles of the sectoral ministries and statutory bodies as competent authorities towards the implementation of the biosafety regulation to be formulated.

4.0 International and Regional Context

The International Treaty on Plant Genetic Resources for Food and Agriculture is another important relevant initiative. It seeks, among other things, to provide for conservation and sustainable utilisation of such plant genetic resources. With regard to food safety and control, the “Codex Alimentarius” established under FAO of the United Nations, sets relevant international standards. Its mandates include the development of international guidelines on the labelling of food and feed products derived from genetically modified organisms.

Tanzania also recognises the “African Model Law on Safety in Biotechnology” that was recently adopted by the African Union. The law applies to the import, export, transit, contained use, release or placing on the market of any genetically modified organism, whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing, or a product of a genetically modified organism.

5.0 Challenges and Way forward

Arguably, in order to conduct work of a highly technical nature, such as modern biotechnology, in a manner that is safe and which contribute to sustainable development; caution has to be exercised not to perpetuate economic dependency.

In that respect, perhaps the key question is, **are we ready?** Certainly, this country study has clearly shown that, like many developing countries, Tanzania is still under equipped in terms of technical capacity to conduct biotechnology and biosafety R&D while safeguarding biodiversity, human

“To be truly effective, knowledge and infrastructure are a necessary precondition for safety in biotechnology”.

Permanent Secretary, Vice President's Office at the National Biosafety Framework Stakeholders' Workshop, Bagamoyo, 2003

health and the environment taking into account socio-economic, cultural and ethical concerns. Currently, the available resources and capacity are severely limited and donor-dependent.

The identified major limiting factors in application of biotechnology and biosafety R&D in the country include the following:

- Lack of biotechnology policy and Biosafety legal framework;
- Inadequate infrastructure;
- Funding; and
- Lack of public awareness.

Certainly, modern biotechnology brings new challenges for policy and regulatory framework for the years ahead.

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