



GOVERNMENT OF MALAWI

**STATUS OF BIOSAFETY INTEGRATION INTO EXISTING NATIONAL
POLICIES, STRATEGIES AND ACTIVITIES ACROSS VARIOUS
MINISTRIES, DEPARTMENTS AND SECTORS IN MALAWI**



ENVIRONMENTAL AFFAIRS DEPARTMENT

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ACRONYMS

ABNE	African Biosafety Network of Expertise
CBD	Convention on Biological Diversity
CFT	Confined Field Trial
DNA	Deoxy Ribonucleic Acid
EAD	Environmental Affairs Department
EIA	Environmental Impact Assessment
EMA	Environment Management Act
FAO	Food and Agriculture Organization
GDP	Gross Domestic Product
GEF	Global Environment Facility
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
LMO	Living Modified Organism
MBS	Malawi Bureau of Standards
MGDS	Malawi Growth and Development Strategy
MLFT	Multi-Location Field Trial
NBRC	National Biosafety Regulatory Committee
NBSAP	National Biodiversity Strategy and Action Plan
NCE	National Council for Environment
NCST	National Commission for Science and Technology
NEPAD	New Partnership for Africa's Development
RNAi	Ribonucleic Acid interference
SOP	Standard Operating Procedure

EXECUTIVE SUMMARY

This report provides an overview of the status of biosafety mainstreaming in Malawi. It outlines laws and policies relevant for biosafety mainstreaming and examples of mainstreaming processes; and future entry points for mainstreaming biosafety although current practices and examples of mainstreaming in these instruments appear to be limited. The report indicates that mainstreaming biosafety in Malawi has happened in two ways; as a process, through engaging various stakeholders in biosafety activities; and as an output through inclusion of biosafety in relevant sectoral strategies and legislation

Malawi has taken advantage of various ongoing activities including revision of policies, strategies and development of national budgets to mainstream biosafety issues. A notable example of mainstreaming biosafety is seen in Malawi's National Biodiversity Strategy and Action Plan, where biosafety issues have been included in the document and the National Focal Point for Biosafety was included in the task team that revised the NBSAP. Further, a number of stakeholders from institutions dealing with issues related to biosafety were consulted during the process and biosafety reports and needs assessment documents were used to determine biosafety issues to be included in the NBSAP. In addition to the NBSAP, biosafety has also been included in Malawi's annual budgets, the GEF-5 and relevant laws and policies in the fields of environment and agriculture. There are also various cross-sectoral institutions, notably the National Biosafety Regulatory Committee, which includes government representatives from cross-sectoral and sectoral departments, NGOs and private institutions which also ensures sustainability of mainstreaming efforts.

Despite these achievements, key challenges in the mainstreaming process relate to limited capacity and insufficient knowledge which have led to inadequate integration of biosafety in other sectors; low budgetary support for implementation of biosafety activities and inadequate technical infrastructural capacity for regulating biotechnology activities.

As a way forward, Malawi needs to come up with strategies to address the challenges identified in order to ensure effective and innovative ways of bringing biosafety issues and objectives into

the national development agenda. The country recognizes that mainstreaming is an ongoing process, and hence the need to prioritize sectors to mainstream and develop guidelines on how and when mainstreaming will be done in sectors. There is also a need to develop indicators for measuring mainstreaming to ensure that mainstreaming efforts produce desired results.

1.0 INTRODUCTION

The natural environment in Malawi supports high levels of biodiversity. Its inland waters hold the most diverse freshwater fish species in the world, with over 800 species of fish, 90% of which are endemic, and 15% of the world's freshwater fish species can be found in Lake Malawi. The Protected Area Network in Malawi totals over 1.8million hectares and includes five national parks, four wildlife reserves, three nature sanctuaries and 87 forest reserves. Genetic resources used for food and agriculture are conserved on-farm as well as in National and Community Seed Banks, Agricultural Research Stations, Botanical Gardens and Academic Institutions. If conserved and managed sustainably, Malawi's biodiversity could effectively contribute to sustainable socio-economic development of the country.

Malawi's economy is highly dependent on agriculture and natural resources. The agriculture and natural resource sector employs over 80% of the workforce and contributes over 80% of the foreign exchange earnings (MGDS II). The sector also contributes over 33% of the GDP with agriculture being the main contributor (IMF, 2015). The natural environment is also a source of food and income for a large percentage of the population. As such, the conservation of biodiversity and sustainable management of natural resources is very important for the livelihood of people. Natural resources therefore have a direct effect on economic empowerment of the population and in the country's efforts on poverty eradication and food security. The mainstreaming of biosafety and biodiversity in the various sectors can help ensure that natural resources are properly managed and effectively contribute to the economic growth of the country.

Food insecurity and poverty eradication being among major challenges affecting the country, triggered discussion at policy and technical level on various options for addressing them including the use of Genetically Modified Organisms (GMOs). Malawi has biosafety legislation, specifically the National Biotechnology and Biosafety Policy of 2008, the Biosafety Act No. 13 of 2002 and Biosafety (Management of Genetically Modified Organisms) Regulations of 2007. The legislation has provided an enabling framework to promote and regulate the development,

acquisition, and dissemination of relevant biotechnology to fulfil the needs of Malawi and provide a springboard for development in the agricultural, nutrition, health, environment, industry and trade sectors.

The National Biodiversity Strategy and Action Plan (NBSAP, 2015) is a tool for achieving long-term goals on conservation and sustainable use of biodiversity in accordance with Malawi's Constitution and National Environmental Policy (NEP, 2004). The NBSAP has action plans to promote the safe transfer, handling and use of living modified organisms as a prerequisite in the use of biotechnology for economic growth and social development to ensure that there are no adverse impacts to biodiversity and human health.

Malawi is participating in the **Capacity-Building Project to promote Integrated Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the National Level**. The purpose of the project is to develop and test practical measures to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity. Malawi has already ensured mainstreaming of Biosafety in the NBSAP, what remains is to ensure that implementation of the target on biosafety is done in an integrated approach with other strategies in the document. Through the project Malawi has identified entry points for biosafety mainstreaming, gaps and future activities to enhance the mainstreaming process to ensure that the country has enough capacity to implement the Cartagena Protocol on Biosafety and the Convention.

2.0 METHODOLOGY

The process of preparing the status report was coordinated by Environmental Affairs Department, which is the national focal point for the Cartagena Protocol on Biosafety as well as the Convention on Biological Diversity (CBD). A number of steps were followed during preparation including stakeholder mapping, formation of a task team, assessment of the existing legal instruments and strategies to identify those that integrate biosafety and the extent to which biosafety is integrated in sectoral policies and plans as well as conducting stakeholder consultations. Comprehensive desk reviews of the NBSAP and other relevant national documents were done to identify strategic and implementation gaps that would need to be addressed at stakeholder consultative meetings.

To promote participation of stakeholders in the process, workshops were conducted to generate information from government Ministries, departments and agencies, the academia, non-governmental organizations and the private sector. In addition, a draft report on the findings of the desk study on the assessment of the status of integration of biosafety at various levels in the country was presented to stakeholders.

3.0 OVERVIEW OF THE NATIONAL BIOSAFETY-RELATED LEGAL, POLICY AND INSTITUTIONAL FRAMEWORKS AND CROSS-SECTORAL MECHANISMS

Overview

Section 13 (d) of the Constitution of the Republic of Malawi provides that the environment should be managed in order to: prevent the degradation of the environment; provide a healthy living and working environment for the people; accord full recognition of the rights of future generations by means of environmental protection; and conserve and enhance the biological diversity in order to promote the welfare and development of the people of Malawi.

Malawi has several Acts, Regulations and Policies relating to biological diversity including legislation which specifically address biotechnology and biosafety. These include; the Biosafety Act of 2002; the Biosafety (Management of Genetically Modified Organisms) Regulations, 2007; the National Biosafety and Biotechnology Policy as well as various Handbooks and Guidelines.

Malawi also has other sectoral legislations which are not specifically intended to address biotechnology or biosafety but have a bearing on these issues including; National Environmental Policy, 2004; Environment Management Act, 1996; National Forestry Policy, 1996; National Forestry Act, 1997; Fisheries and Aquaculture Policy, 2001; Fisheries Conservation and Management Act, 1997; Wildlife Policy, 2000; National Parks and Wildlife Amendment Act, 2004; The National Herbarium and Botanic Gardens Act, 1987; Water Resources Act, 2013; Science and Technology Act, 2003; Seed Act 1988 as amended in 1996 ;Consumer Protection Act 2003; the Pharmacy, Medicines and Poisons Act (year); the Malawi Bureau of Standards Act (); and the Pesticides Act, 2002 These relate to issues of science and technology, environment and natural resources, variety release, food and feed safety, advertising and labelling.

Definitions

Malawian legislation has not provided a definition of biosafety but according to the Cartagena Protocol on Biosafety website ‘biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products.’ Article 3 of the

Cartagena Protocol on Biosafety defines modern biotechnology as the application of: a).In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) fusion of cells beyond the taxonomic family. Another definition for biotechnology used on the Cartagena Protocol website is ‘any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.’ The Biosafety Act of 2002 defines biotechnology as any technique that uses living organisms or parts of organisms to (a) make or modify products; (b) improve plants or animals; or (c) develop micro-organisms for specific purposes.

3.1 BIOSAFETY AND BIOTECHNOLOGY

Biosafety Act, 2002

Background

The framework Act for the management of Genetically Modified Organisms in Malawi is the Biosafety Act which was passed in 2002 to provide for the safe management of biotechnological activities.

The government of Malawi published the Biosafety Act in the Malawi Gazette Supplement dated 13th September 2002 at the height of the genetically modified food aid controversy when several countries in Southern Africa imposed restrictions on the acceptance of genetically modified food aid from the United States. The Government of Malawi accepted the maize on condition that it would be milled prior to distribution.

Provisions

The Biosafety Act is administered by the Minister responsible for environmental affairs and other public officers. The Minister has several functions including approving safety aspects of import, export, manufacture, processing and selling of genetically modified organisms and products thereof and advising generally on all biosafety activities. Section 30 of the Biosafety

Act empowers the Minister to appoint inspectors for purposes of ensuring compliance with the provisions of the Act.

The Act provides for the issuance of various categories of licenses and permits depending on the activities to be conducted. Section 17 (b) of the Act provides that no person shall engage in; (a) the genetic modification of organisms; (b) the importation, development, production, testing, release, use and application of genetically modified organisms' and (c) the use of gene therapy in animals, including human beings except in accordance with a license granted under section 17. The section 17 licenses are referred to as GMO licenses. Section 18 provides that permits may be issued to engage in the activities mentioned in section 17 but only for scientific research or experimental purposes and emergency supply of food for human beings. Section 19 of the Act provides for other classes of licenses known as 'product licences', 'manufacturer's license, 'wholesale dealer's license and "dispensing license". These are licenses that are issued to persons conducting businesses involving GMOs.

Observations

The Biosafety Act was developed quickly in response to the food crisis on 2002 in order to enable the government to import GM maize for human consumption. In as much as the provisions of the Biosafety Act attempted to reduce and eliminate the potential risks resulting from biotechnology and its products, it had some shortfalls and gaps such as the absence of a clear institutional infrastructure for biosafety, limited provisions on public participation, risk assessment, social economic considerations and liability. The Act did not provide sufficient information on how licenses and permits could be processed. This necessitated the development of Biosafety Regulations to ensure effective implementation of the Act.

Biosafety (Management of Genetically Modified Organisms) Regulations, 2007

Background

The Biosafety (Management of Genetically Modified Organisms) Regulations were gazetted in 2007 to ensure effective implementation of the Biosafety Act and to provide technical information on the administration of the Biosafety Act.

Provisions

Regulation 3 of the Biosafety Regulations creates a National Biosafety Regulatory Committee (NBRC) whose functions include; evaluating all applications concerning or related to GMOs and products thereof and making recommendations to the Minister in that regard; and advising, on request or of its own accord, the Minister on matters concerning genetic modification of organisms.

Regulation 8 provides for the appointment of a Biosafety Registrar who acts as the Secretariat for the NBRC. The office of the Biosafety Registrar is based at the EAD. Some of the functions of the Biosafety Registrar include; receiving all documents relating to applications and appeals and transmitting them to the NBRC and the Minister and maintaining a register of all biotechnological activities in Malawi and all licenses and permits issued under the Act.

Regulation 11 provides for the appointment of reviewers. The NBRC may, before it considers any application for a license or a permit, appoint one or more experts in any relevant field to review the application so as to provide the NBRC with sufficient information to enable it make an informed decision about what recommendation to make to the Minister on the license or permit. The reviewers are responsible for reviewing risk assessment reports and auditing processes in order to establish the impact of the biotechnological activities on the environment and human health and they submit reports to the Committee, in respect of any assessment undertaken.

The Regulations also elaborate on the types of GMO licenses and permits that a person can apply for. Regulation 12 provides for licenses and permits for trial release and contained use and Regulation 14 provides for licenses for general release of GMOs. Regulation 16 provides for licensing and/or registration of facilities that carry out genetic modification.

Observations

The Regulations addressed a majority of the shortfalls and gaps identified in the Biosafety Act and contribute significantly by providing more detailed and practical information on reducing and eliminating the potential risks resulting from biotechnology and its products. The Act and

the Regulations were both published before Malawi became a Party to the Cartagena Protocol on Biosafety but it is evident that some of the provisions of the Biosafety Regulations are based on what is contained in the Biosafety Protocol

National Biotechnology and Biosafety Policy of 2008

Background

The National Biotechnology and Biosafety Policy of 2008 provides a framework for effective implementation of biotechnology programmes and activities. The goal of the policy is to attain sustainable socio-economic development through research, acquisition and use of traditional and modern biotechnology.

Provisions

The objectives of the Policy include; building and strengthening national capacity in biotechnology research, development and application; promoting the utilization of biotechnology products and processes as tools for national development; providing a regulatory and institutional framework for safe utilization and sustainable biotechnology development and application; and promoting ethical standards in biotechnology research and development.

Observations

The Policy makes a distinction between the functions of the National Commission for Science and Technology (NCST) which are to promote biotechnology and those of the EAD which are to regulate biotechnology activities.

Guidelines and Handbooks

Malawi has several Guidelines and Handbooks including; the Trial Managers Handbook, Inspectors Handbook and Guidelines for Confined Field Trials (CFTs) and Multi Location Field Trials (MLFTs). The Trial Managers Handbook provides instructions in the form of Standard Operating Procedures (SOPs) for all aspects of biosafety for confined field trials. The SOPs give detailed instructions for shipping and storage; establishment, maintenance and conduct of CFTs; sampling of plant tissues; termination and post-harvest management of the trial site; and

reporting of results to the Regulatory Authority. The Handbook also contains forms for collecting typical information required for documentation of compliance requirements. The procedures provided in the Handbook are for the use of all principal investigators, trial managers, technical personnel, agents of the authorized party, and government officials engaged in planning, conducting or overseeing confined field trials of GM plants in Malawi.

The Inspectors Handbook provides instruction and guidance to Inspectors of confined field trials. It provides a basis for a logical and step-wise approach to preparing for inspection, conducting inspection of the field site and documentation, interviewing field personnel for pertinent information, obtaining necessary confirmation of key information, writing the inspection report, notifying the Regulatory Authority of inspection results and findings, and implementing any corrective actions that may be required resulting from the inspection.

The Guidelines for conducting CFTs and MLFTs provide a summary of the regulatory requirements governing CFTs and MLFTs of GMOs, in accordance with the Biosafety Act and the Biosafety Regulations.

3.2 ENVIRONMENT, NATURAL RESOURCES AND BIOLOGICAL DIVERSITY

National Environmental Policy 2004

Background

Malawi adopted the National Environmental Policy (NEP) of 1996 in order to promote sustainable social and economic development through sound management of the environment. The NEP provides guidance and set standards for development of sector policies in environment and natural resources. However, the 1996 NEP was revised as a result of policy gaps, conflicts and duplication, which adversely affected effective implementation of the policy. The revision was also necessary to ensure that the NEP would remain current and responsive to new challenges and incorporate lessons learned.

The 2004 revised NEP recognizes the importance of creating an enabling policy and legal framework for cross sector coordination, participation of non -state sectors, strengthening the enforcement machinery and decentralizing natural resources and environmental management and

governance. The overall policy goal is promotion of sustainable, social and economic development through sound management of the environment and natural resources.

Provisions

The NEP (2004) contains a section on the conservation of biological diversity, which is general in nature. One of the key objectives of the Policy set out in section 4.12 is to manage, conserve and utilize sustainably the country's biological diversity, (ecosystems, genetic resources and species) for the preservation of national heritage.

The Policy also contains sections, which deal specifically with other environment and natural resources sector. Section 5.1 provides for Agriculture and Livestock, section 5.2 provides for the forestry sector, section 5.3 provides for the fisheries sector, section 5.4 provides for parks and wildlife and section 5.5 provides for the water sector. These sections contain strategies on protection, conservation and sustainable utilization of resources.

Observations

The policy has general provisions dealing with environmental management and protection however it does not have provisions which specifically refer to biotechnology or biosafety. This is not necessarily a gap as the Policy is intended to be a key instrument and standard for environment and natural resources policies and legislation and to act as a guide for all sectoral activities at all levels, including biosafety.

The Environment Management Act No.23 of 1996

Background

The Environment Management Act No.23 of 1996 (EMA) was enacted to make provision for the protection and management of the environment and the conservation and sustainable utilization of natural resources.

Provisions

Section 35 of the Act provides for conservation of biological diversity and empowers the Minister responsible for the Environment, on the advice of the National Council on Environment to, amongst others, determine actual and potential threats to the biological diversity of Malawi and devise necessary measures for preventing, removing or mitigating the effect of those threats.

Observations

The EMA (1996) aimed at protection and management of the environment and conservation and sustainable utilization of natural resources. This includes the impact of the biotechnological activities on the environment and biological diversity. The Act does not specifically mention biosafety however the provisions of section 35 can be broadly interpreted to include biosafety.

The Act contains provisions on Environmental Impact Assessment (EIA) for activities that are likely to have adverse impacts of the physical and social environment. Malawi has Guidelines for conducting EIAs which include a prescribed list of project that may require to undergo an EIA, however, activities involving biotechnology are not included on that list.

Forestry Act No. 11 of 1997

Background

The Forestry Act provides for the conservation and management of forests and specifically for participatory forestry, forest management, forestry research, forestry education, forest industries and protection and rehabilitation of environmentally fragile areas and international co-operation in forestry.

Provisions

The purposes of the Act are set out in section 3 and they include;

- (a) to identify and manage areas of permanent forest cover as protection or production forest in order to maintain environmental stability; to prevent resource degradation and to increase social and economic benefits;

- (b) to augment, protect and manage trees and forest on customary land in order to meet basic fuelwood and forest produce needs of local communities and for the conservation of soil and water;
- (e) to promote sustainable utilization of timber, fuelwood and other forest produce;
- (f) to promote optimal and land use through agroforestry in smallholder farming systems;
- (g) to upgrade the capability of forestry institutions in the implementation of their resource management responsibilities and in development of human resources in forestry;
- (i) to protect fragile areas such as steep slopes, river banks, water catchment and to conserve and enhance biodiversity;
- (j) to provide guidelines in planning and implementation of forestry research and forestry education;
- (l) to promote bilateral, regional and international co-operation in forest augmentation and conservation

Observations

The Forestry Act does not specifically mention biotechnology or biosafety but the broad provisions of the Act can apply to issues of biosafety.

Fisheries Conservation and Management Act No.25 of 1997

Background

The principal statute governing fisheries is the Fisheries Conservation and Management Act, 1997. The purpose of the Act is to make provision for the regulation, conservation and management of the fisheries of Malawi. The Act strengthens institutional capacity by involving various stakeholders in the management of fisheries; promotes community participation and protection of fish; and provides for establishment and operation of aquaculture.

Provisions

Section 3 of the Act creates the position of the Director of Fisheries who is assigned with various responsibilities including; the conservation of fish stocks; taking measures as he may consider appropriate for the protection of fish stocks from the effects of pollution and siltation; the development and management of fisheries; and the regulation and control of fishing operations, including aquaculture and operations ancillary thereto;

Observations

The Act does not specifically mention biotechnology, biosafety or GMOs. The broad provisions of the Act can be applied to biosafety.

National Fisheries Policy (2012-2017)

Background

The 2001 National Fisheries and Aquaculture Policy document guided management of the fisheries resources in Malawi up until 2012 when the National Fisheries Policy (2012-2017) was prepared. The development of the 2012 Policy was a response to policy shifts from natural resources conservation and management to promoting sustainable production of fish for food security as well as income generation.

The revised Policy seeks to provide guidance to all stakeholders in the implementation and provision of fisheries services as well as interventions that will continue rendering the sector as a key source of food and wealth in Malawi. The Policy focuses on increasing sustainable fish production from capture fisheries and aquaculture, enhancing fish quality and value addition for domestic and export trade to create wealth, promoting technology development and its transfer to the users, enhancing capacity for the sector's development and promoting social development, decent employment and fisheries governance through participatory resource management regimes.

Provisions

The goal of the Policy, as set out in section 2.1, is to promote sustainable fisheries and aquaculture development in order to contribute to economic growth in Malawi. Some of the expected outcomes of the Policy are enhanced capacity to sustainably manage and develop fisheries and aquaculture in Malawi and improved protein and micronutrients intake for Malawians.

One of the priority policies set out in section 3.6 is research and information. According to the Policy, fisheries research involves the generation of knowledge, information and technologies necessary for sustainable exploitation, management, conservation of biodiversity, utilization processes and marketing and investment in the fisheries sector.

Observations

The Fisheries Policy has shifted from natural resources conservation and management to promoting sustainable production of fish for food security as well as income generation. This means that there is less emphasis on issues of conservation of biodiversity in the Policy even though this is a mandate of the sector. In this case, issues of biosafety are better covered by the Act than the Policy.

The provisions of section 3.6 could be interpreted to include research using biotechnology.

The National Herbarium and Botanic Gardens Act (1987)

Background

The Act was established in 1987 and provides for the development and management of herbarium and botanic gardens as national heritage for Malawi and the establishment of the National Herbarium & Botanic Gardens of Malawi. Among other things the Act was established to:

- Establish herbaria and botanic gardens as a centre for assemblage, growth, curation and classification of plants of Malawi;

- Conduct investigations and research into the science of plants and related subjects and disseminate the results;
- Provide advice, instructions and education in relation to those aspects of the science of plants; and;
- Keep the collections as national reference collections and ensure that collections are available to interested persons for the purposes of study

No observations for HBG

Water Resources Act No.2 of 2013

Background

The purpose of the Water Resources Act of 2013 is to provide for the management, conservation, use and control of water resources; for the acquisition and regulation of rights to use water.

Provisions

The Act defines water resources as any lake, pond, swamp, marsh, stream, watercourse, estuary, aquifer, artesian basin or other body of flowing or standing water whether below or above ground.

Section 7 (2) of the Act provides that the Minister for water shall promote conservation and proper use of water resources in Malawi.

Section 33 (3) states that a National Water Policy shall be developed which shall prescribe objectives, procedures and institutional arrangements for the management, protection, use, development, conservation and control of water resources.

Section 37 provides that the Minister may in consultation with district councils in a notice published in the Government Gazette reserve part or all of the flow of a watercourse to reasonably protect aquatic and wetland ecosystems, including their biological diversity, and to maintain essential ecosystem functions.

Observations

The provisions of the Act do not specifically mention biosafety however reference is made to biological diversity. The linkage between the Act and biosafety is weak as the Act barely mentions the protection of aquatic resources.

Science and Technology Act No.16 of 2003

Background

The Science and Technology Act No.16 of 2003 provides for the advancement of science and technology; to establish the National Commission for science and Technology. The functions of the Commission are to advise the Government and other stakeholders on all science and technology matters in order to achieve science and technology-led development.

Provisions

Section 37 of the Science and Technology Act which deals with licenses and permits stipulates that 'no person shall engage in any matter related to biotechnology without prior consent of the Commission'. This means that any person intending to conduct research activities or trials involving biotechnology is required to obtain consent from NCST before applying for a license or permit under the Biosafety Act and Biosafety Regulations.

Observations

The Science and Technology Act, by its mandate, has provided for issues of biotechnology without having to explicitly include the word biotechnology. However, issues specifically on biotechnology and biosafety are elaborated on in the National Biosafety and Biotechnology Policy of 2008.

Variety Release

It is important to note that in Malawi once an applicant has obtained approval under the Biosafety Act and Regulations to conduct confined field trials (CFTs) and multi-location field trials, if the applicant wants to commercially release (to sell or grow commercially) a genetically modified plant variety, an applicant must obtain authorization from two institutions. The first of

such is a license for general release of the genetically modified organism or the event (trait) which will be introduced into multiple varieties by conventional breeding methods. This is done under the provisions of the Biosafety Act and Regulations. If the NBRC makes a recommendation to the Minister to issue a license, it implies that the event is considered safe for large-scale (unconfined) use. The second license would be for plant varieties that contain the trait for commercial grain production. This is done by Ministry responsible for Agriculture using relevant legislation and/or Guidelines.

Seed Act No. 5 of 1988

Background

Malawi is currently using the Seed Act No.5 of 1988 as amended in 1996.

Provisions

The amended Act defines seed as ‘the part of any plant, customarily referred to as seed, intended for planting and includes other propagating materials’.

Section 3 of the Act creates the position of a Controller of Seeds to be responsible for the administration of the Act. The Controller is also mandated to consider and examine all applications for the recognition of a variety or varieties. According to the Act an application for recognition of a variety should be made to the Controller of Seeds in a prescribed form and manner and upon payment of a prescribed fee.

Section 4 (a) provides that upon receipt of an application the Controller shall by notice in a Gazette publish the particulars of the application and any person has two months to submit comments to the Controller which should provide reasons. The Controller is mandated to hear the objectors before making a decision on the application for recognition of a variety. Sections 10 and 11 of the Act provide for the grounds of rejection and approval of an application.

Section 9 provides that the Controller shall either conduct such verification tests and trials of a variety or use the results of the tests and trials conducted on that variety and obtained by him in

order to determine whether such variety may be recognized. A controller can reject an application if instructed to do so by the Minister after a section 13 evaluation. Section 13 provides that the Minister responsible for Agriculture may, if he deems it necessary, investigate a variety in which an application for recognition has been submitted or a variety of which the denomination has been entered into the variety list in order for the usefulness for agricultural and industrial purposes should be evaluated.

Observations

The provisions of the Seed Act do not specifically mention GMOs or biotechnology.

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3.3 FOOD AND FEED SAFETY

Malawi Bureau of Standards Act 1972 as amended in 2010

Background

The Malawi Bureau of Standards (MBS) is a statutory organization established in 1972 by an Act of Parliament, Malawi Bureau of Standards Act, (Cap 51:02) of the Laws of Malawi.

Provisions

The MBS is responsible for the development and enforcement of standards. The MBS has not yet developed standards on GMOs in Malawi however, it uses the Codex Alimentarius Commission Principles and Guidelines on GMOs which can be adopted as Malawi standards.

The Codex Alimentarius or Food Code is the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. The Commission is the body responsible for compiling the standards, codes of practice, guidelines and recommendations that constitute the Codex Alimentarius. It was established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) with the purpose of protecting the health of consumers and ensuring fair practices in the food trade.

According to the ‘Foods Derived from Modern Biotechnology’ the hazards associated with foods are subjected to the risk analysis process of the Codex Alimentarius Commission to assess potential risks and, if necessary, to develop approaches to managing these risks. The conduct of risk analysis is guided by general decisions of the Codex Alimentarius Commission as well as the Working Principles for Risk Analysis.

The MBS adopts Codex standards, guidelines and principles by rewriting them in the format of a Malawi standard. The MBS Act however has a provision that MBS can adopt such international standards by mere referencing, but this option has never been used. Once MBS standards have been adopted the international standards become national standards, with a clear indication that it is equivalent to a particular international standard.

Malawi as a member of the Codex can use the following standards on GMOs which can be used for risk assessment of foods and food safety analysis;

1. CAC/GL 44:2003; Principles for the risk analysis of foods derived from modern biotechnology;
2. CAC/GL 45:2003; Guideline for the conduct of food safety assessment of foods Derived from recombinant-DNA plants; and
3. CAC/GL 46:2003, Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms.

These principles provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.

Observations

Malawi don't have specific legislation on food safety but the MBS Act can be used to ensure compliance in accordance with the codex.

3.6 PESTICIDES

The Pesticides Act, 2002

Background

The Pesticides Act No.12 of 2002 provides for the control and management of the importation, exportation, manufacture, distribution, storage, disposal, sales, repackaging and use of all pesticides in Malawi.

Provisions

The Act defines a pesticide as “any substance or mixture of substances intended to be administered on animals, plants, or humans for preventing, destroying or controlling any pest and includes any substance intended for use as a plant growth, regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport”.

Section 17 to 27 of the Pesticides Act deal with issues of registration and licensing of pesticides. Section 17(1) stipulates that “no person shall import, manufacture or sell a pesticide, which has not been registered under this Act”.

Section 31 prohibits and restricts the use of certain pesticides products and establishes standards on maximum residue limits of pesticides in food and feed products.

Section 37 prohibits the disposal of any pesticides container or packaging in a manner that is unduly hazardous to human or animal health or the environment or that is contrary to any written law.

Observations

The Act does not specifically refer to bio pesticides, however the provisions of this Act can be used to include bio pesticides.

Other relevant legislation

In addition to the Biosafety legislation, the Malawi Government has also passed various other pieces of legislation that have a bearing on biotechnology and biosafety. These are elaborated on in Table 1 below and they relate to issues of environment, variety release, food and feed safety, advertising and labeling.

However, it is important to note that once an applicant has obtained approval under the Biosafety Act and Regulations to conduct confined field trials (CFTs) and multi-location field trials, if the applicant wants to commercially release (to sell or grow commercially) a genetically modified plant variety, an applicant must obtain licenses from two institutions. The first of such is a license for general release of the genetically modified organism or the event (trait) which will be introduced into multiple varieties by conventional breeding methods. This is done under the provisions of the Biosafety Act and Regulations. If the NBRC makes a recommendation to the Minister to issue a license, it implies that the event is considered safe for large-scale (unconfined) use. The second license would be for plant varieties that contain the trait for commercial grain production. This is done by the Department of Agricultural Research Services (DARS) under the Ministry Agriculture, Irrigation and Water Development (MoAIWD) using their relevant legislation.

Table 1: Other Legislation that has a bearing on Biotechnology and Biosafety

ACT	RESPONSIBLE INSTITUTION	RELEVANT PROVISIONS
Science and Technology Act No.16 of 2003	National Commission for Science and Technology (NCST).	The Act states that subject to the provisions of the Act, no person shall engage in any matter related to biotechnology without prior consent of the Commission. The provision means that an applicant must obtain a prior approval from the NCST before applying for a license or permit under the Biosafety Act and Regulations.

Environment Management Act No.23 of 1996	Environmental Affairs Department	The objective of the EMA is the protection and management of the environment and the conservation and sustainable utilization of natural resources. This includes assessing the impact of the biotechnological activities on the environment.
Malawi Bureau of Standards Act, 1972 as amended in 2012	Malawi Bureau of Standards	The MBS is responsible for the development and enforcement of standards. The MBS has not yet developed standards on GMOs in Malawi however it can use the Codex Alimentarius Commission Principles and Guidelines for feed and food safety of GMOs which can be adopted as Malawi standards.

Malawi's National Biodiversity Strategy and Action Plan

Target 14 of Malawi's National Biodiversity Strategy and Action Plan has strategies to ensure the safe transfer, handling and use of living modified organisms (LMOs) as a prerequisite in the use of biotechnology for economic growth and social development to ensure that there are no impacts to biodiversity and human health. The strategy has the following actions and output indicators to be achieved by 2025 on biosafety.

Actions

- a) Revise the Biosafety Act and Regulations;
- b) Conduct public awareness campaigns on biosafety legislation;
- c) Develop and implement a National Biosafety Capacity Building Plan;
- d) Establish national systems for documentation, management and information sharing on biosafety;

e) Establish an effective detection and monitoring system for biotechnology.

Output Indicators

- a) Biosafety Act and Regulations revised;
- b) Public awareness campaigns on biosafety legislation conducted;
- c) A national biosafety capacity-building plan developed and implemented;
- d) A biosafety clearing house mechanism developed and operational;
- e) An effective monitoring system in place

The National Biodiversity Strategy and Action Plan has focused on priority areas for Malawi's implementation of the Cartagena Protocol. The NBSAP has also determined how much resources will be required to implement such activities and proposed potential sources of funding. The extent to which biosafety issues have been integrated in the NBSAP is adequate although more information on how it links with other strategies and targets would have helped to promote mainstreaming during implementation.

Cross-Sectoral Mechanisms

Malawi has established various cross-sectoral coordinating mechanisms. These mechanisms are in the form of Boards, Councils and Technical Committees. Membership is from government, private sector and the civil society. Their functions range from dealing specifically with biosafety issues in the case of the NBRC to dealing with issues on the environment for the National Council for the Environment (NCE). Table 2 below is a summary of the cross-sectoral coordinating mechanisms in Malawi.

Table 2: Cross-Sectoral Mechanisms for Coordinating Biosafety Activities in Malawi

Institutional Body	Composition	Roles and Responsibilities with respect to Biosafety
National Biosafety Regulatory Committee	<ul style="list-style-type: none"> i. Ministry of Agriculture and Food Security ii. Ministry of Health iii. Ministry of Industry and Trade Malawi Bureau of 	<ul style="list-style-type: none"> 1. evaluating all applications concerning or related to genetically modified organisms and products and making recommendations to

	<p>Standards</p> <p>iv. Ministry of Labour</p> <p>v. Ministry of Justice</p> <p>vi. Department of Forestry</p> <p>vii. Ministry of Women and Child Welfare</p> <p>viii. Ministry of Nutrition, HIV and Aids</p> <p>ix. Director of Parks and Wildlife</p> <p>x. Council for Non-Governmental Organizations</p> <p>xi. Malawi Revenue Authority</p> <p>xii. Malawi Police Services</p> <p>xiii. Consumer Association of Malawi</p>	<p>the Minister;</p> <p>2. advising the Minister on matters concerning genetic modification of organisms including; all aspects relating to the introduction of GMOs into the environment, proposals for specific activities or projects concerning GMOs, all aspects of confined field trials, import and export of GMOs and amendments or withdrawals of licenses and permits issued</p> <p>3. liaising, through the relevant institutions, with international groups or organizations concerned with biosafety and biotechnology;</p> <p>4. inviting knowledgeable persons to assist the Committee on any aspects related to genetically modified organisms; and</p> <p>5. carrying out such other functions that are necessary for the effective implementation of these Regulations.</p>
National Council on Environment	<p>i. Office of President and Cabinet;</p>	<p>1. Advising the Minister on all matters and issues</p>

	<ul style="list-style-type: none"> ii. all Principal Secretaries of Ministries, or their representatives; iii. the General Manager of the Malawi Bureau of Standards, or his representative; iv. the General Manager of the National Herbarium and Botanical Gardens of Malawi, or his representative; v. one member nominated by the Malawi Chamber of Commerce and Industry representing the industrial sector vi. one member nominated by and representing non-governmental organizations concerned with the protection and management of the environment and the conservation of natural resources vii. one representative of the University of Malawi viii. one member nominated by and representing the 	<p>affecting the protection and management of the environment and the conservation and sustainable utilization of natural resources;</p> <ol style="list-style-type: none"> 2. Recommending to the Minister measures necessary for the integration of environmental considerations in all aspects of economics planning and development; 3. Recommending to the Minister measures necessary for the harmonization of activities, plans and policies of lead agencies and non-governmental organizations concerned with the protection and management of the environment and the conservation and sustainable utilization of natural resources.
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	National Commission for Women in Development	
Technical Committee on the Environment (TCE)	<ul style="list-style-type: none"> i. Environmental Affairs Department ii. Fisheries Department iii. Ministry of Labour iv. Department of Water Resources v. Department of Mines vi. Geological Surveys Department vii. National Botanic Gardens viii. Malawi Bureau of Standards ix. Department of Parks and Wildlife x. City Councils xi. Forestry Department xii. Department of Physical Planning xiii. Department of Nutrition, HIV and AIDS xiv. Ministry of Gender and Women Empowerment 	<ol style="list-style-type: none"> 1. Examine any scientific issue which may be referred to it by the Minister responsible for Environment, National Council on Environment, the Director of Environmental Affairs or any lead agency relating to the protection and management of the environment and sustainable utilization of natural resources and recommend necessary action. 2. Carry out investigations and conduct studies into the scientific, social and economic aspects of any activity, occurrence, product or substance which may be referred to it by the Minister responsible for Environment, National Council on Environment, the Director of Environmental Affairs or any lead agency 3. Recommend to the Council the criteria, standards and

		guidelines for environmental control and regulation, including the form and content of environmental impact assessment
Biodiversity Steering Committee	<ul style="list-style-type: none"> i. Environmental Affairs Department ii. Department of Climate Change and Meteorological Services iii. National Herbarium and Botanic Gardens iv. Forestry Department v. Fisheries Department vi. Department of Agricultural Research Services vii. Crop Production Department viii. Department of Livestock and Animal Health ix. Department of Tourism x. Museums of Malawi xi. Ministry of Local Government and Rural Development xii. Malawi Revenue Authority xiii. Ministry of Industry and 	<ul style="list-style-type: none"> a) Advises Government, NGOs, private sector and other stakeholders on mainstreaming biodiversity into national development and sectoral planning processes; b) Promoting investment in biodiversity conservation and coordinating support by development partners; c) facilitating the implementation of the country's obligations to the CBD; d) Promoting awareness and access to information to the general public, researchers, private sector, civil society, NGOs and academia among others

	Trade	
	xiv. Ministry of Finance, Economic planning and Development	
	xv. NGOs and CSOs	
	xvi. Coordination Union for the Rehabilitation of the Environment	
	xvii. Wildlife and Environmental Society of Malawi	
	xviii. Department of National Parks and Wildlife	
	xix. National Commission for Science and Technology	
	xx. Mulanje Mountain Conservation Trust	
	xxi. The Academia	

Institutional Biosafety Committees

In addition to the institutions mentioned in Table 2 above, Institutional Biosafety Committees (IBCs) are also important in ensuring integration of biosafety within institutions. An IBC is a committee set up at institutional level to review research activities that involve the use of biotechnology. The Biosafety Act and the Regulations do not contain provisions on IBCs. However, the Guidelines for conducting CFTs and MLFTs do provide for IBCs. Section 3.1.1. of the Guidelines provides that submission of an application to the Biosafety Registrar, and thereafter to the NBRC, shall be through the IBC, whose officers shall ensure completeness of the application form and verify availability of the proposed facilities before endorsing and forwarding the application to the regulatory authority.

In practice, this has not been implemented in Malawi and applications have been processed without the considering the recommendations of the IBCs. However initiatives are underway to ensure that IBCs are set up in institutions that are considering undertaking biotechnology and biosafety activities. This will ensure that biosafety issues have been discussed at institutional level prior to submitting an application.

4.0 RECENT AND ONGOING NATIONAL BIOTECHNOLOGY ACTIVITIES AND PROJECTS

Malawi conducted CFTs and MLFTs of genetically modified insect resistant cotton. The cotton, modified to contain the *Bacillus thuringiensis* (*Bt*) gene was tested to determine efficacy of the *Bt* in controlling cotton bollworm. The *Bt* gene has now been deregulated and the trials are at on-farm trial stage under the supervision of the Ministry of Agriculture.

Currently, Malawi is conducting CFTs of genetically modified cowpea (*Bt*-cowpea). The trials are being conducted by Lilongwe University of Science and Technology through its Bunda College in collaboration with African Agricultural Technology Foundation (AATF). The trial is intended to evaluate the agronomic performance of the crop and to test the efficacy of *Bt* in inferring resistance against the maruca pod borer (*Maruca vitrata*) which is a common pest in cowpea. The trial will run for a period of 3 years, from 2015 to 2017.

Another confined field trial that was authorized and is currently being conducted in Malawi is for transgenic banana. This trial is being conducted by Bvumbwe Agricultural Research Station in the Department of Agricultural Research Services (DARS) of the Ministry of Agriculture, Irrigation and Water Development (MoAIWD) in partnership with Queensland University of Technology in Australia. The approval to conduct the confined field trial was granted in February 2016. The CFT has the objective of using RNAi technology to genetically modify bananas to display resistance to the banana bunchy top virus.

5.0 PROCESSES AND PRACTICAL STEPS TAKEN TO SUPPORT MAINSTREAMING OF BIOSAFETY

Environmental Affairs Department by virtue of its mandate and the fact that it houses the office of the Biosafety Registrar has taken steps to support mainstreaming of biosafety into national frameworks. The following steps have been taken;

1. Engagement of the National Biosafety Regulatory Committee which is multi sectoral (Refer to table 2). The NBRC creates an opportunity to share information, raise awareness and build capacity on biosafety. From the NBRC various sectors get an understanding of the expectations of their institutions in implementing the Cartagena Protocol on Biosafety.
2. Inclusion of biosafety activities in the national budget such as monitoring of CFTs and MLFTs, meetings of NBRC, capacity building workshops for regulators, scientists, media and the public. Currently resources allocated to the sector are not sufficient as they are not adequately prioritized in the development agenda. Consequently, most sectors have not incorporated biosafety issues in their annual work plans and budgets. There is a need to raise awareness and ascertain that finances have been allocated to biosafety activities in the sectors expected to participate in the implementation.
3. Engagement of partners to support biosafety activities through technical and financial assistance. This ensures that the implementation requirements are distributed over a number of sectors and resources are mobilized from various sources.
4. The approval process for activities involving biotechnology which includes public participation that is likely to contribute to public awareness on biosafety. By ensuring that a number of stakeholders including the public participate in the approval processes of applications, awareness is raised and interaction amongst stakeholders is enhanced.

5. Development and dissemination of a Biosafety Communication Strategy. This is an important awareness tool that when implemented will increase knowledge on biosafety and create an understanding on how various sectors and stakeholders can participate in implementation of biosafety activities.
6. The regulatory system that provides for licensing and compliance monitoring by inspectors from different sectors enables continuous consideration of biosafety issues. Undergoing biotechnology activities are inspected in a coordinated way, where trained inspectors from relevant sectors undertake the inspection. This ensures that all sectors are involved and that decision making on biosafety is done in a coordinated manner.

Target 14 of Malawi's revised National Biodiversity Strategy and Action Plan (2015-2025) recognizes the safe transfer, handling and use of living modified organisms as a prerequisite in the use of biotechnology for economic growth and social development to ensure that there are no adverse impacts to biodiversity and human health. As part of the revision process of the NBSAP:

- Malawi included in the task team the National Focal Point for Biosafety to ensure that the development of targets on biosafety could be linked to the whole strategy.
- Public consultations were conducted during which, institutions dealing with issues related to biosafety were consulted so as to give input on biosafety in the NBSAP.
- Reports on biosafety and needs assessment also contributed to the development of biosafety strategies that were fed into the NBSAP.

Mainstreaming biosafety in the NBSAP was both as a process, through the inclusion of the focal point and use of biosafety information and as an output through the inclusion of actions and outcomes to be undertaken for biosafety.

In addition, Malawi has taken advantage of the revision and development of legislation and regulations to ensure that biosafety is incorporated in upcoming legislative documents. A good example is the revision of the Environment Management Act (1996) which created an

opportunity to integrate provisions on biosafety into the Bill as a result of extensive stakeholder consultations. Section 71(g) of the Environment Management Bill (2016) states that “The Authority shall, in consultation with relevant lead agencies, prescribe measures and issue guidelines to promote the conservation of biological diversity *in situ* in relation to safe handling, transfer and use of living modified organisms resulting from modern biotechnology that may have adverse impact on biodiversity, human health and the environment. This provision was included in the Bill despite having a specific legislation on Biosafety to ensure that the role of biosafety is considered in environmental management. During the revision of the Environmental Management Act, both the National Biosafety Focal Point and the CBD Focal point were part of the team that was consulted on the EMA. This involvement gave the officers an opportunity to ensure that their areas of interest are addressed in the Bill.

Malawi is also revising its guidelines for Environmental Impact Assessment. Biosafety issues in the guidelines were incorporated when the draft guidelines were sent to various relevant stakeholders for comments including to the CBD focal point. The CBD Focal point in consultation with the National Focal Point for the Cartagena Protocol included biosafety issues under Section 2.1.5.1 of the Draft guidelines that focuses on impact identification and analysis of projects. The included text was on the need to screen projects for their risk of spreading transgenic organisms or genes from such organisms; risk of introducing genetically engineered crops and their impact on crop diversity and their wild relatives.

Finally, Malawi together with other selected SADC countries are participating in a Sub-Regional Project on LMO detection and testing in cooperation with RAEIN Africa under GEF 5. Through the project, Malawi and other countries have assessed their needs in detection and testing of LMO's. It is hoped that by participating in the project, Malawi will improve its infrastructure for detecting, testing and monitoring LMOs; upgrade institutional laboratories and lobby government to finance infrastructure for biosafety. Malawi will involve other stakeholders from customs, Agriculture, Academia, trade among others in the implementation process to enhance participation and capacity building on biosafety there by ensuring that these sectors participate in future biosafety programmes. Malawi can learn from this experience and ensure that it includes biosafety activities in future GEF projects.

6.0 LESSONS LEARNT AND STRENGTHS IN MAINSTREAMING BIOSAFETY

The following are the strengths and lessons learnt;

- Mainstreaming biosafety in NBSAP was effective due to the inclusion of the biosafety focal point and other relevant biosafety practitioners in the task team that developed the NBSAP.
- Inclusion of Biosafety issues in the national budget has raised the profile of biosafety in the country.
- Multisectoral assessment of applications by the NBRC and multisectoral compliance monitoring by inspectors has improved coordination amongst sectors on biosafety. The assessments and monitoring processes have also improved over time through capacity building initiatives thereby contributing to enhanced regulation of biotechnology activities.
- Engagement of partners in biosafety activities mobilizes the much needed technical and financial support to enable effective implementation. Malawi's participation in a Sub-Regional Project on LMO detection and testing under GEF 5 is one such example.
- Inadequate awareness and communication has a negative impact on successful mainstreaming of biosafety. This has been evidenced by lack of mainstreaming of biosafety in most sectoral policies because of lack of an understanding of how biosafety impact their sectors and how there sectors can benefit from biosafety mainstreaming.
- Revision and development of legislation and other relevant policy documents provides opportunities to raise awareness and incorporate issues of biosafety. The revision of Environment Management Act and EIA Regulations are examples.

7.0 DESCRIPTION OF NATIONAL CAPACITY NEEDS AND SKILL GAPS

The major capacity needs for Malawi to ensure effective implementation of biosafety issues include;

- Inadequate human resources that possess sufficient knowledge and skills in communication on such matters. Insufficient technical capacity in terms of human resources capable of conducting thorough risk assessments and awareness activities.
- Low levels of awareness and insufficient information sharing amongst stakeholders that are meant to implement biosafety activities. Although a biosafety communication strategy was developed, there has been no funding to ensure its implementation and this has led to low levels of awareness on biosafety issues. As such, other sectors have not been knowledgeable enough to mainstream biosafety into their planning and development initiatives. There is a need for government to support effective implementation of the Communication Strategy on Biosafety and ensure good data management and information exchange amongst institutions including the effective use of the biosafety clearing house mechanism.
- Inadequate financial resources for Biosafety activities is another challenge the country is facing. Inadequate funds have been allocated for the implementation of the biosafety legislation, thereby weakening biosafety programs. The funding challenges have also been compounded by the absence of adequate innovative activities to raise funds for biosafety activities in Malawi. Most of the activities have been conducted with assistance from international partners like Program for Biosafety Systems (PBS), African Biosafety Network of Expertise (ABNE) and New Partnership for Africa's Development (NEPAD) for training Biosafety Inspectors and NBRC members. Minimal resources have been generated from government to spearhead capacity building, procurement of detection infrastructure and conducting assessments of biotechnology. Continuous lobbying with government to raise the importance of biosafety can influence decision makers in allocating more resources for biosafety. Also ensuring that

partnerships are built for implementation will distribute the financial and infrastructure resource burden.

- Inadequate infrastructure for the effective detection, testing, monitoring of LMOs. The country does not have adequate facilities with sufficient equipment to conduct the required biosafety analyses. It is hoped that by participating in the Sub-Regional Project on LMO detection and testing, Malawi will improve how it detects, tests and monitors for LMOs.

8.0 RECOMMENDATIONS TO FURTHER IMPROVE MAINSTREAMING BIOSAFETY

The assessment of the current status of integration of biosafety into the various relevant sectors in the country identified gaps and capacity deficiencies. This has also helped determine measures to be implemented to ensure the effective mainstreaming and implementation of biosafety strategies and legislation in the country. Malawi should therefore implement the following to ensure this is done:

- Develop a Mainstreaming strategy that will provide guidelines to promote effective mainstreaming of biosafety into existing sectoral policies and plans.
- Develop indicators for measuring mainstreaming outcomes in various sectors based on what changes we want to see.
- Enhance synergies through coordination mechanisms among stakeholders involved in aspects of biotechnology and biosafety in the country through promotion of coordination committees at National and Institutional level.
- Enhance information sharing, awareness activities and access to information on biosafety in the country through implementation of the Biosafety Communication Strategy.
- Prioritize mainstreaming efforts on sectors like Trade, Education that have the potential to raise the profile of biosafety in the country.

- Conduct a training needs assessment on biosafety and develop and implement a national biosafety capacity-building plan which includes long term training at local institutions.
- Develop funding mechanisms for biosafety programmes in the various sectors including the use of economic instruments such as license fees and taxes.

9.0 CONCLUSION

The assessment of Malawi's current status on integration of biosafety into relevant sectoral policies, plans and strategies has identified existing strengths that need to be enhanced and gaps that need to be addressed to ensure effective mainstreaming and implementation of biosafety issues in the country. It has also assisted in the determination of measures to be implemented by various sectors to ensure that biosafety is awarded the prominence it deserves.

It is clear from the assessment that most of the mainstreaming has taken place in the environment and natural resources sectors. Malawi therefore has to focus its mainstreaming efforts in other sectors such as trade, health, education, customs, labour.

It is very important to ensure that biosafety considerations are integrated into relevant sectoral policies, plans and programmes and national growth and development strategies as it creates an opportunity to raise awareness and sensitize the public and decision makers on biosafety.

ANNEX 1 - LIST OF STAKEHOLDERS CONSULTED

NAME	INSTITUTION
Ms. Tessia Kamoto	Forestry Department
Mr. Titus Zulu	Forestry Department
Mr. Matias Elisa	Department of National Parks and Wildlife
Mr. E. Banda	Department of Disaster Management Affairs
Ms. Charity Gambatula	Department of Economic Planning and Development
Mr. Kefasi Kamoyo	Department of Land Resources Conservation
Mr. Isaac Chirwa	Malawi Bureau of Standards (MBS)
Mr. Christopher Mwambene	Coordination Union for the Rehabilitation of the Environment (CURE)
Mr. Yohane Chimbalanga	National Commission for Science and Technology (NCST)
Ms. Modester Kachapila - Millinyu	Department of Agriculture Research (Gene Bank)
Mr. Geoffrey Kanyerere	Fisheries Department
Mr. Gerald Meke	Forestry Research Institute of Malawi
Mr. Elisa Mazuma	Department of Agricultural Research Services
Mr. Isaac Chiundira	Ministry of Justice
Mr. Francis Mponda	Malawi Revenue Authority
Mr. Henry Mandere	Ministry of Industry and Trade
Dr. Benson Chilima	Public Health Institute of Malawi (PHIM)