NATIONAL BIOSAFETY FRAMEWORK

Republic of Botswana

Final Draft - July 2006

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Preface

This document is comprised of three components. The first component provides an overview of the background that went into developing the National Biosafety Framework (NBF) for Botswana; The second component is the Biosafety and Biotechnology Policy for Botswana and the last component covers the Consultant's Draft Bill. The Policy articulates the position of Botswana regarding the different areas that can be impacted by biotechnology or biosafety activities, and these include the areas of agriculture, commerce and industry, education, environment, health and ethics. The Biosafety Draft Bill expounds both the Policy and the Cartagena Protocol on Biosafety (CPB) to practical measures and activities that can be implemented to achieve the intended objectives of the Policy and the CPB. It contains all the essential elements for biosafety legislation such as the objective, the subject matter for regulation, the measures to be taken for modern biotechnology application, risk assessment and management, monitoring and evaluation and the relevant institutional framework.

BACKGROUND INFORMATION

CHAPTER ONE - THE HISTORY OF BIOTECHNOLOGY REGULATION

The discussions on the need for the regulation of biotechnology activities dates back to the early 1970s when there was recognition at international level of the potential adverse impacts of modern biotechnology on the environment and human health. The emergence of biotechnology and the concerns regarding biosafety started to intensify in the late 1970s to1980s as questions on the impact of biotechnology on sustainable development arose in various fields.

In the early 1990s, significant milestones in the international regulation of biotechnology included Agenda 21, from the RIO Declaration on Environment and Development Symposium in 1992. Agenda 21 outlined the environmentally sound management of biotechnology. Chapter 16, section 4 calls for the development of compatible safety procedures into a framework of internationally agreed principles as a basis for safety guidelines in biotechnology, including considerations of the need for and the possibility of an international agreement for the safe application of biotechnology. The guiding principle to the objective of the Cartagena Protocol on Biosafety is Principle 15 of the RIO Declaration, which is on the precautionary approach.

One of the decisions of the United Nations Conference on Environment and Development (UNCED) in 1992 was the adoption of the Convention on Biological Diversity (CBD), which was then opened for signature. The CBD refers to the regulation of Biotechnology in Articles 8 (g) and 19. Article 19 (3) calls for Parties to consider modalities of a protocol setting out appropriate procedures, including advance informed agreement, in the field of safe transfer, handling and use of any Living Modified Organisms (Biotechnology products) resulting from biotechnology.

In response to Article 19.3, a decision was made during the Fifth Conference of Parties (COP5) in 1995 to develop a protocol on biosafety. The Cartagena Protocol on Biosafety (CPB) was therefore a direct international legal response to the CBD, contributing towards the conservation and sustainable use of biological resources. The Protocol was to focus specifically on transboundary movement of any Biotechnology products resulting from modern biotechnology that may have adverse impact on the environment and human health.

The actual negotiations of the Protocol took place from July 1996 to 2000 when the Protocol was signed. The entry into force of the Protocol occurred on 11 September 2003. This then obligated signatories to the Protocol to localise it within their national laws. Botswana as a signatory therefore undertook this obligation.

CHAPTER TWO - INTRODUCTION

2.1 What is Biotechnology?

Biotechnology is an old technology that has been used over several years. It is a science that aims to modify the natural processes of living organisms. Biotechnology is therefore defined as the use of living organisms or substances from these organisms to make or modify a product, improve plants or animals or develop products for specific uses. The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Biotechnology in a broad sense covers many tools and techniques for agricultural, industrial, medicinal and environmental purposes. Some of the methods/techniques used in biotechnology include fermentation, breeding, hybridization, mutagenesis, tissue culture, artificial insemination, molecular markers, genetic engineering, genomics and cloning.

Fermentation: Anaerobic breakdown of complex organic substances, especially carbohydrates, by micro organisms, producing energy. It is often referred to as the first generation biotechnology.

Selective breeding: The crossing and selection of plants and animals to produce offspring with desired traits. The offspring with the desired traits are then used as breeding stock for the next generation and so on, until offspring that express the desired traits are obtained.

Hybridization: The production of offspring, known as hybrids, from genetically dissimilar parents. The object of hybridization is to combine desirable genes found in two or more different varieties to produce pure-breeding offspring superior in many respects to the parental types.

Mutagenesis: The use of mutagens (such as exposure to radiation, temperature extremes and certain chemicals), to cause changes in the genetic make-up of cells, possibly resulting in new desirable and heritable traits.

Tissue culture: *In vitro* propagation of cells, tissues or organs in a nutrient medium under sterile conditions.

Artificial Insemination: Deposition of semen, using a syringe, at the mouth of the uterus to make conception possible.

Molecular marker: The use of identifiable DNA sequences found at specific locations of the genome.

Genetic Engineering/Modification: Removal of gene(s) from a plant or animal cell and insertion into another plant or animal cell, to give it a desired

characteristic. The technique allows the transfer of genes between species, between animals and plants, and micro organisms. Once the genes are inserted into another organism, they will be transferred to the offspring of the modified individual through the normal reproductive process.

Genetic engineering is also referred to as modern biotechnology. 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 taxonomic family, that overcomes natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection*."

The products of modern biotechnology are referred to as Genetically Modified Organisms (GMOs) or Living Modified Organisms (Biotechnology products).

Genomics: Molecular characterization of the whole genome to understand the structure, functions and evolution of genes.

Cloning: The synthesis of multiple copies of a selected DNA sequences using bacterial cell or another organism as a host.

2.2 Advantages of Biotechnology

Biotechnology is a powerful tool that offers opportunities to mankind. It is used in the field of medicine, agriculture as well as environmental protection. It is used in human and veterinary medicine such as in the development of drugs and vaccines. In agriculture the technology has been used in the improvement of both crop cultivars and livestock breeds. The key areas in agriculture are food security, sustainable yield increase, reduced water shortage and agrochemicals. In environmental protection, biotechnology has been applied in areas such as remediation of polluted sites as well as waste treatment.

Biotechnology has also been used in the mining and energy sectors; as well as industrial processing. Some useful industrial products include enzymes, feedstocks, fibre, fuel and micro biological mining. The advantages in the application of biotechnology techniques are numerous, with potential for even further development for sustainability.

2.3 Potential Detrimental Effects of Biotechnology

Although biotechnology in general is a powerful tool for sustainable development, with great potential benefits, there are uncertainties and possible risks associated particularly with the application of modern biotechnology. Issues of concern that have been associated with the application of modern biotechnology are on the safety of its products for human consumption, and the impact on the environment, as well as non-safety or social possible effects.

The safety concerns on human health and animal welfare include toxicity, allergenecity and nutritional composition. The question on toxicity is whether the levels of naturally occurring toxins in genetically modified organisms have not been increased to toxic levels. Similarly the concern with allergenecity is whether potential allergens have not been introduced into genetically modified organisms. Other safety issues of concern are

pathogenecity, digestibility, stability of proteins and unexpected secondary metabolites/products.

Environmental safety issues due to the application of modern biotechnology include gene spread through hybridisation between genetically modified (GM) organisms and related species; population growth, spreading and invasion of GM plants into the natural ecosystem; spreading of genes through horizontal gene transfer from GM organisms to related species in the environment; introduction of super weeds; development of insect resistance to insecticide; effects of non target organisms; and secondary environmental effects as a consequence of changed agricultural practices.

The socio-economic concerns raised against the application of modern biotechnology include; loss of traditional knowledge, disruption of small scale farming system, displacement of traditional crops, incompatibility with ethical/religious beliefs, equitable access or affordability of the GM products as well as the impact on world trade.

2.4 What is Biosafety?

The previous section highlighted the key concerns in the application of modern biotechnology. It is due to these concerns that extra care has to be taken to ensure that safety measures are put in place during the use of modern biotechnology. Biosafety is therefore a term used to describe efforts to reduce or eliminate the potential risks resulting from modern biotechnology and its products.

The issues of Biosafety are addressed through the Cartagena Protocol on Biosafety (CPB), whose objective 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 into account risks to human health, and specifically on transboundary movement"*.

The key elements of the Protocol include procedures on Advanced Informed Agreement, and transboundary movement of Biotechnology products that are to be intentionally introduced into the environment and for Biotechnology products that are intended to be used directly as food or feed or for processing (Biotechnology products – FFP). The Party of import makes its decision in accordance with scientifically sound risk assessment. The Protocol sets out principles and methodologies on how to conduct risk assessment and requires Parties to have a plan on risk management.

The Protocol also requires Parties to ensure that Biotechnology products subject to intentional transboundary movement be handled, packaged and transported under conditions of safety and be accompanied by appropriate documentation. Lastly, the Protocol establishes a Biosafety Clearing House (BCH) to exchange information, and also contains a number of important provisions including capacity building, financial mechanisms, liability and redress, compliance procedures; and public awareness and participation.

Full articles of the CPB can be accessed at www.biodiv.org.

2.5 National Biosafety Framework

A National Biosafety Framework (NBF) is a combination of policy, legal, administrative and technical instruments that are put in place to address safety for the environment and human health in the application of modern biotechnology. The key components of an NBF are the biosafety policy, regulatory regime, system to handle requests (administrative, risk assessment and management, decision making), follow-up activities (enforcement, monitoring); public awareness and participation.

An NBF is also a tool to be used in the implementation of the Cartagena Protocol on Biosafety. Botswana as a signatory to the Protocol has to implement it, hence the need to develop the NBF.

The summarised articles of the Protocol in the previous section are what the NBF at a minimum will provide for effective biosafety regulation in Botswana. The national policy and legal framework will localize the Cartagena Protocol on Biosafety by observing its minimum standards. The NBF for Botswana will reflect the elements enumerated below, either through law or policy as well as supporting guidelines for implementation. It should be noted that these elements are not exhaustive and are not exclusive but guided in the design of the NBF.

2.5.1 Scope

The scope of the NBF will among others include internal/national and transboundary, movements, handling and placing on the market of all products of modern biotechnology. The NBF will also make exclusions, if any (e.g. pharmaceuticals), to avoid uncertainty in policy or law.

2.5.2 Requirements for Application

The NBF will lay out what the requirements for an application are; these will include information on the nature of the modern biotechnology products, the intended use, the sites for use, the risk assessment and management information and the producer. The applicant will also need to provide information on how monitoring will be done after the release of the GMO into the environment or market. The NBF will spell out why the information is needed, who should monitor, what environmental, human and animal health effects, what pre-commercialization protocols ought to be followed to assess risks adequately and the responsibility for the costs of monitoring.

2.5.3 Conditions for Approvals

The NBF will provide for the conditions for approvals of application for the importation of GMOs and also conditions for release into the environment in Botswana. These conditions include the ecosystem to which release will be made, the interests and priorities of the country, the social setting, independent scientific views, public participation, economic considerations, environment and resource conservation, risk management measures, measures for observance of changes to the environment and other factors.

2.5.4 Monitoring

The NBF will spell out the minimum conditions for the design of the monitoring plan, that will include monitoring and evaluation procedures.

2.5.5 Accidents

The NBF will provide for the conditions for emergency procedures; capacity and personnel for dealing with emergencies in containment; during transit; food and feed production; deliberate release into the environment of organisms. There will be need to put in place steps for emergency planning which will include establishment of facts/verification sourcing; collection of material to prevent spreading; assessment of damage and follow up health and environmental checks.

2.5.6 Liability

The NBF will cover the issues of damage such as adverse effects on conservation and sustainable use of biological diversity; damage to property or person; adverse economic effects. Furthermore, the NBF will cover; causation, channelling of liability; the nature of liability; scope and nature of redress; limitation of liability; financial security and prescription periods.

2.5.7 Information management and institutional arrangements

The NBF will focus on the most practical institutional arrangements for effective implementation of a biosafety policy and legal framework including information management.

CHAPTER THREE - METHODOLOGY

The development of the National Biosafety Framework was done in three phases as follows:

Phase 1: This consisted of information gathering in the form of a survey. The information gathered was on the current uses of modern biotechnology, existing legislation or legal instruments related to biotechnology/biosafety, active or planned national projects for capacity building related to the safe use of biotechnology, existing sub-regional biosafety frameworks and mechanisms for harmonization of risk assessment/management, roster of relevant experts within the country, identifying their experience and expertise so that adequate coverage in all areas of expertise is obtained and potential gaps can be identified.

A report of the surveys was published, and is also accessible on DAR website: www.dar.gov.bw

Phase 2: The second phase involved analysis of the findings of the surveys and consultation with stakeholders. A national workshop for stakeholders to review the findings, identify gaps and set priorities for the NBF was held in April 2004.

An external reviewer from Namibia was invited to assist in the analysis of the report to ensure that all the elements of the NBF had been incorporated.

The proceedings of the workshop were published and can also be accessed on DAR website: www.dar.gov.bw

The development of the National Biosafety database and linkages to the Biosafety Clearing House was also undertaken.

During the two phases, public awareness campaign was conducted to sensitize stakeholders on issues of modern biotechnology and biosafety. This was done to empower the public so that they can effectively participate in the national discussions on the issues, hence contribute in the development of the NBF.

A pamphlet on biotechnology and biosafety was published and can also be accessed on DAR website: www.dar.gov.bw

Phase 3: The final phase involved the actual preparation of the draft National Biosafety Framework. The draft NBF was then given to an external reviewer to comment on.

A second national stakeholder consultative workshop was conducted in April 2006 to discuss the draft NBF. The proceedings of the second workshop were published and can also be accessed on DAR website: www.dar.gov.bw

The final NBF was prepared after the workshop, incorporating the comments from the stakeholders.

CHAPTER FOUR – GUIDING PRINCIPLES FOR THE DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK (NBF)

Various national policies were reviewed during the development of the NBF in order to align the NBF to them. The national policies reviewed were Vision 2016, National Development Plant 9 (NDP 9), the revised National Policy on Rural Development, the National Policy on Natural Resources Conservation and Development (NPRCD, 1990), Science and Technology Policy for Botswana, 1998 and the National Agriculture Policy. In addition, Principle 15 of the Rio Declaration on the Precautionary Approach was also taken into consideration.

4.1 Precautionary Principle

The Precautionary Principle can be understood thus:

> "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically." *from the January 1998 Wingspread Statement on the Precautionary Principle.*

One of the most important expressions of the precautionary principle internationally is the Rio Declaration from the 1992 United Nations Conference on Environment and Development, also known as Agenda 21. The declaration states:

> "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The development of the NBF should therefore take into account the role of the precautionary principle in biotechnology management or biosafety measures, as biotechnology may be uncertain regarding some adverse effects on the environment.

4.2 Vision 2016

Vision 2016 encourages Botswana to position herself strategically for global trade using science and technology to effectively address issues of poverty and sustainable economic and human development. Primary to social development is food security, and to this end an NBF is needed, to guide in matters where GM products are to be used. The essential elements that emerge from the Vision to guide the development of the NBF include the following:

a) Effective management of scientific research and development for economic diversification and social/human development in order to contribute to poverty management and employment creation;
b) The development of agriculture for food security at household, national and export levels to enable Botswana to cushion itself and to compete within the global market;

c) Development of scientific and technological capacity by contributing to strengthening the policy, legal, scientific and institutional capacities for scientific innovation, which in this context includes biotechnology and biosafety research;
d) Strengthening public awareness and participation in decision-making by ensuring public education, information and awareness.

4.3 National Development Plan 9

The NDP9 document provides guidance for:

a) Identification of the local and national priorities in social, scientific and economic development to enhance food security through application of technologies that will raise production of food;

b) Botswana needs to protect traditional crops by regulating the use of GM crops.

c) Identification of potential niche markets.

4.4 The Revised National Policy on Rural Development

The Revised National Policy on Rural Development is a framework policy to link and facilitate coordination of the various sectoral policies, and to engender a common vision and unity in pursuit of rural development.

The development of the NBF should therefore take into account the potential contribution of biotechnology to creating opportunities for improving rural livelihoods. This can be achieved by a number of factors including improving agriculture, and research into medicinal plants with the full involvement of the rural communities.

4.5 The National Policy on Natural Resources Conservation and Development (NPNRCD) 1990

The NPNRCD addresses amongst other issues, the depletion of fuel wood resources, groundwater resources, wildlife species and indigenous veld product resources; land erosion; urban and rural population; and rangeland degradation.

The strategy goals of this Policy are to:

- Increase the effectiveness with which natural resources are used and managed, so that beneficial interactions are optimised and harmful environmental side effects are minimised*;*
- Integrate the work of the many sectors, ministries and interest groups throughout Botswana, thereby improving the development of natural resources through conservation.

A number of considerations emerge from this Policy which should guide the development of the NBF and these include:

a) Assessment of benefits of biotechnology and their relevance to Botswana's developmental and environmental needs. This will inform the policy, which can be subject to revision when priorities and needs change;

b) Consideration for risk assessment and management in order to minimise any potentially harmful effects on the environment;
c) Involvement of the broader public in the implementation of the NBF.

4.6 Science and Technology Policy for Botswana, 1998

The overall goal of the Policy is to achieve sustainable social and economic development to meet the present and future needs of the nation, through co-ordinated and integrated application of science and technology for the upliftment of quality of life of the people of Botswana and conservation of the environment. The core policy objectives are to:

- Establish and strengthen national capacity to research, evaluate, select, acquire, adapt, develop, generate, apply and disseminate suitable technologies;
- Develop and raise the national productive capacity and improve competitiveness through efficient application of S&T;
- Promote and develop traditional, endogenous, new and innovative technologies;
- Create knowledge and awareness, improve and develop the scientific and technological culture of Botswana.

The science and Technology Policy is geared towards the promotion of the development of science and technology for the general development of the country, while contributing towards environmental sustainability. This then means that the NBF should cover the following:

a) Regulate the activities relating to science and technology for balanced and equitable environmental and human development;
b) Ensure development of scientific and technological capacity for biotechnology and biosafety research in the country and trade in such knowledge and services;
c) Ensure that issues of intellectual property rights are taken into consideration.

4.7 National Agricultural Policy

The National Agricultural Policy promotes agricultural development through research, training, extension, provision of infrastructure, and access to credit. The core policy objectives are to:

- Improve food security at household and national levels;
- Diversify agricultural production base;
- Increase agricultural output and productivity;
- Increase employment opportunities for the fast growing labour force;

- Provide a secure and productive environment for agricultural producers;
- Conserve scarce agricultural and land resources;

The strategy goals of this policy relevant to the development of the NBF are:

- Development of techniques for conservation and utilization of biodiversity;
- Initiation of biotechnology research that has potential for higher production and productivity; and the safe use of biotechnology.

NATIONAL POLICY ON BIOSAFETY AND BIOTECHNOLOGY

CHAPTER ONE – POLICY PRINCIPLES

Botswana recognises the potential of biotechnology in the advancement of the economy and the improvement of livelihoods. The country further recognises that to fully exploit the advantages of biotechnology there is need to build and enhance the capacity in biotechnology, harness benefits of biotechnology and ensure the application of biosafety measures to safeguard the environment, biological diversity and human health against possible adverse effects biotechnology. Botswana also recognises and emphasizes the precautionary principle in the regulation of any undertaking for the import, contained use, release or placing in the market of genetically modified organisms and their products.

This Policy:

a) Recognises that biotechnology promises improvement of human well-being, including economic advancement of the country;
b) Recognizes the potential risks and adverse effects of modern biotechnology and the need to ensure the safe application thereof;
c) Emphasizes that it is important to enhance capacity to generate and apply modern biotechnology and biosafety;
d) Endorses the principles of democracy as contained in Vision 2016, including the principle of *therisanyo* (consultation) in decision-making pertaining to the approval for the use of genetically modified organisms and their products;
e) Recognises that the management of modern biotechnology through biosafety research and regulation must be multi-dimensional and multi-sectoral;
f) Recognises the need to promote and protect traditional biotechnology by ensuring that there is adequate investment in those technologies that are deemed to be of local, social, communal and national value towards alternative and diversified development of the country;
g) Emphasizes the need to ensure that biotechnology is used in an equitable and beneficial manner for overall socio-economic development.
h) Acknowledges the importance of other sectoral policies and programmes and their linkages with biosafety management and biotechnology development and application.
i) Recognizes the current regional and international initiatives for the safe application of biotechnology including the SADC Guidelines on Biotechnology, the African Model Law on Biosafety and the Cartagena Protocol on Biosafety.

CHAPTER TWO – OVERALL GOAL, OBJECTIVES AND STRATEGIES

2.1 Goal

The overall goal of the Policy is to regulate and monitor the application and development of biotechnology by ensuring the application of biosafety measures to guarantee the protection of biological resources, to ensure sustainable use of biological resources, protection of human health, and to minimize the adverse socio-economic impacts of biotechnology.

2.2 Objectives

In order to achieve the goal of the Policy, the objectives are:

a) To promote and ensure the application of biosafety measures in the development and use of biotechnology;
b) To promote the development and application of biotechnology;
c) To regulate the importation, use, handling, transfer, introduction in to the environment and contained use of genetically modified organisms and the products thereof;
d) To ensure public participation and access to information;
e) To establish and strengthen national capacity for biotechnology, development, application and biosafety regulation;
f) To raise public awareness on modern biotechnology and biosafety;
g) To protect human health, the environment and social values from potentially adverse effects of modern biotechnology.

2.3 Strategies

The Policy strategies are intended to contribute to the realisation of the set of objectives above and these strategies are:

a) Development of legislation to promote research and application of biotechnology.
b) Development of legislation and other measures to regulate the importation, safe use, handling, transfer, introduction into the environment and contained use of modern biotechnology product and products thereof;
c) Encourage and support non-governmental organisations, community based organisations, professional bodies, practice associations and other appropriate legitimate interest group entities to enhance community participation and access to information on biosafety regulation, biotechnological development and application and related activities;
d) Development of a strategy for infrastructural and human resource capacity building for the regulation of modern biotechnology;
e) Introduction of biotechnology and biosafety in all relevant fields of education and ensure their systematic institutionalisation.
f) Encourage private sector participation in the development and application of biotechnology and biosafety;
g) Development of a biosafety regulatory framework that ensures the protection of human health and the environment;

CHAPTER THREE – SECTOR OBJECTIVES AND STRATEGIES

The introduction, promotion, development and safe application of modern biotechnology, require the active participation of all sectors due to its cross cutting and multi-sectoral nature.

3.1 Political Context

3.1.1 Key Issues

Biotechnology has the potential to contribute meaningfully to economic development and poverty alleviation. However political commitment, leadership and awareness remain a challenge to realising this potential.

3.1.2 Objectives

a) To promote political commitment to biotechnology and biosafety

3.1.3 Strategies

a) Support the development of an environment that will boost the status of biosafety and its techniques through:
   - Creation of a national fund for development and application of biotechnology and biosafety activities supported by all stakeholders.
   - Establishment and supporting fora where there can be dialogue with the public in modern biotechnology and biosafety issues.

b) Engage the legislature on biotechnology developments and the regulation of such developments on regular basis.

3.2 Agriculture

3.2.1 Key Issues

Biotechnology has the potential to contribute meaningfully to the development of agriculture. The key issues within both the arable and livestock agriculture are low productivity due to harsh environmental conditions and high cost of inputs, unexplored niche markets demands/preferences and limited diversity of agricultural products. In response to this, biotechnology is regarded as being a possible choice in the field of agriculture to transform and enhance value creation of the agricultural sector. However there is recognition of the potential adverse impacts of the use of modern biotechnology in agriculture such as genetic pollution and genetic erosion and changes to soil, air and water quality.

3.2.2 Objectives

a) To promote development and application of biotechnology (conventional and modern) as well as biosafety regulation and sustainable use of agricultural genetic resources for enhanced food security at national and household level;
b) To promote agricultural R&D in the field of biotechnology;

c) To support the promotion of niche market for Botswana's agricultural products and other potential markets for GM free food, feed and products.
d) To promote the safe use of modern biotechnology in agriculture in order to conserve and sustainably use agro-biodiversity and genetic resources for food and agriculture.

3.2.3 Strategies

a) Strengthen the capacity of agricultural research institutions to enable well co-ordinated research activities in biotechnology and biosafety;
b) Carry out capacity building activities within the agricultural research institutions on the development and application of biotechnology and biosafety;
c) Conserve agro-biological resources and support research that improves their quality and utilisation;
d) Promote research on domestication and production of useful indigenous, traditional and non-GM plants and animals;
e) Promote application of biotechnology to increase production.
f) Promote the implementation of biosafety measures in the field of agriculture.

3.3 Commerce and Industry

3.3.1 Key Issues

Biotechnology has the potential to contribute meaningfully to economic development and poverty alleviation. Science and technology, including biotechnology are important driving forces in industrial development and productivity. In order to diversify the economy, it is essential to support research innovation and development (RI&D). All modern biotechnology products and products thereof introduced in the market should be labelled to respect consumers' rights to choice.

3.3.2 Objectives

a) To develop packaging standards for products of modern biotechnology and products thereof;
b) To promote and increase opportunities in bio-manufacturing.
c) To develop labelling and identification standards for modern biotechnology products and products thereof placed on the market.

3.3.3 Strategies

a) Promote the development and implementation of standards necessary for effective commercialisation of products of modern biotechnology;
b) Encourage collaborative projects amongst stakeholders in commercial and industrial application of modern biotechnology and biosafety.
c) Develop standards and specifications for labelling and identification of modern biotechnology products.

3.4 Education

3.4.1 Key Issues

Modern biotechnology has the potential to contribute meaningfully to economic development and poverty alleviation. It is essential that education in biosafety and biotechnology and its potential be part of the educational curricula. The challenges in the educational sector are the integration of biotechnology in the school curriculum and the provision of adequate training facilities. In order to fully benefit from the contribution of modern biotechnology to economic development and poverty alleviation it is also necessary that modern biotechnology and its regulation be included in non-formal education structures.

3.4.2 Objectives

a) To promote integration of biotechnology and biosafety in the education curricula at all levels;
b) To encourage the development of well equipped training facilities.
c) To promote the integration of information on biosafety and biotechnology in the non formal education sector.

3.4.3 Strategies

a) Integrate traditional issues, knowledge and technology in the teaching of modern biotechnology and biosafety;
b) Develop and strengthen existing manpower in line with the modern biotechnology and biosafety trends;
c) Identify and develop strategic centres of excellence in areas of modern biotechnology and biosafety.
d) Integrate Information, Education and Communication (IEC) strategies into the education sector.

3.5 Environment

3.5.1 Key Issues

Botswana has an abundance of biological resources, some of which are rare and endemic to the country. Modern biotechnology has the potential to be used meaningfully in environmental conservation, however it brings about risks and challenges for the environment sector. These include genetic contamination, genetic erosion, and loss of biological diversity that may result in negative socio-economic consequences and human health.

3.5.2 Objectives

a) To develop measures for the protection of the environment and biological resources.
b) To develop regulations on liability and redress for damage resulting from the use and application of modern biotechnology and its products.

3.5.3 Strategies

a) Develop measures to minimise the potential harm of modern biotechnology to the environment;
b) Monitor and evaluate the impact of products of modern biotechnology on the environment.
c) Elaborate on elements for liability and remedies for damage resulting from the use of modern biotechnology and its products.

3.6 Health

3.6.1 Key Issues

Biotechnology has the potential to contribute meaningfully to human health. The challenges in the development and application of biotechnology include concerns on food safety, use of modern biotechnology to improve food nutrition, the capacity to use modern biotechnology in the development of vaccines and medicines and use in disease diagnosis.

3.6.2 Objectives

a) To improve public health by application of biotechnology;
b) To ensure safety in food production through modern biotechnology.

3.6.3 Strategies

a) Conduct institutional research on medicinal plants;
b) Promote and support research geared towards producing feasible and safe technologies for the prevention and management of diseases;
c) Monitor and evaluate the risk to human health that may occur through the application of modern biotechnology;
c) Exploit traditional plants using biotechnology to develop health related natural products.

3.7 Ethical Issues

3.7.1 Key Issues

While modern biotechnology has the potential to enhance economic and social development, there are ethical issues that need to be addressed. The development and application of modern biotechnology has raised a number of ethical issues. The ethical aspects of modern biotechnology across all sectors have to be considered from moral, social, justice, animal welfare perspective and religious grounds, all these ethical concerns need to be addressed and discussed openly.

3.7.2 Objectives

a) To address ethical concerns relating to modern biotechnology research and application;
b) To consult and liaise widely with the public on ethical issues.

3.7.3 Strategy

Develop an effective Information, Education and Communication (IEC) strategy on ethical issues.

CHAPTER FOUR - CROSS CUTTING ISSUES

4.1 Financing Biotechnology and Biosafety Development

4.1.1 Key Issues

The challenge facing biotechnology development and application, as well as biosafety is lack of private and public partnership funding.

4.1.2 Objective

To promote public and private financial support for the development and application of modern biotechnology and biosafety.

4.1.3 Strategies

a) Promote establishment of a target goal – as a percentage of the total annual GDP for research and redevelopment in biotechnology and biosafety;
b) Encourage the private sector through various incentives to make effective financial contribution into modern biotechnology development and application;
c) Promote the flow of funds from bilateral and multilateral sources for the support of biosafety technology development and application.

4.2 Public Awareness

4.2.1 Key Issues

There is limited public awareness and knowledge on the issues pertaining to the merits of biotechnology, including possible adverse impacts.

4.2.2 Objective

To ensure that the public is aware, sensitised and educated on biotechnology and biosafety issues

4.2.3 Strategy

a) Generate specific biotechnology market sector information;
b) Undertake IEC activities in order to increase the public's general awareness of biotechnology and applications, and of the regulatory system;
c) Build community confidence in biotechnology, its regulation, the industry, and the way risks are assessed and managed;
d) Inform consumer discussions through media and publication of information booklets and listen to community concerns;

e) Encourage public contribution to policy decisions;
f) Facilitate the development and implementation of a biosafety and biotechnology communications strategy;
g) Encourage public participation in modern biotechnology and biosafety issues.

4.3 Capacity Building

4.3.1 Key Issues

The key challenges in the development and application of biotechnology and biosafety are the limited capacity in biotechnology development and biosafety regulation.

4.3.2 Objective

To build capacity in the development and application of modern biotechnology and biosafety**.**

4.3.3 Strategies

a) Establish and strengthen research in biotechnology and biosafety development and application;
b) Promote commercialization and application of modern biotechnology and biosafety through the development of clusters, incubators and networks;
c) Develop and strengthen capacity in manpower and infrastructure in line with emerging modern biotechnology and biosafety.
d) (d) socio-economic security

BIOSAFETY DRAFT BILL

PART I – *Preliminary*

1. Short title

This Act may be cited as the Biosafety Act of 2006.

2. Intent of Act (Scope)

An Act to provide for the safe application of modern biotechnology by regulating and managing its products through the implementation of the Cartagena Protocol on Biosafety, the establishment of the Biosafety institutional framework, risk assessment, risk management plan and a licensing system and matters incidental thereto.

3. Exemption

Notwithstanding the scope of this Act and without prejudice to any right of a party to subject all genetically modified organisms to risk assessment prior to the making of decisions on import, this Act shall not apply to the transboundary movement of genetically modified products which are pharmaceuticals for humans and which are subject to any other enactment.

PART II - *Interpretation*

4. In this Act, unless the context otherwise requires:

Advance informed agreement means the consent obtained before any activity is undertaken based upon full disclosure of all relevant matters as required under the provisions of this Act.

Applicant means any natural or legal person making an application to undertake activities on modern biotechnology as regulated under the provisions of this Act.

Biosafety Authority means the institution responsible for the implementation of this Act.

Authorised biotechnology activities in relation to premises or a facility, means modern biotechnology activities being undertaken at the premises or facility:

(a) that are authorised to be undertaken at the premises or facility by a GMO or modern biotechnology activity licence; or

(b) that are modern biotechnology activities in contained use.

Biosafety Clearing House **(BCH)** refers to an information exchange mechanism established under Article 20 of the Cartagena Protocol on Biosafety.

Cartagena Protocol is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Contained use refers to any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, external environment and the general population.

Corporation means a body corporate including an external or foreign company or partnership formed or existing in Botswana or elsewhere.

Export means intentional transboundary movement from the area of national jurisdiction of Botswana to the area of national jurisdiction of another country.

Exporter is any natural or legal person who arranges for GMOs or products of GMOs to be intentionally moved from Botswana to a given country.

Genetically Modified Organism (GMO) is an organism that has been modified through modern biotechnology.

Import into Botswana means the intentional transboundary movement from a given country into Botswana.

Importer is any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be brought into Botswana.

Intentional introduction into the environment" means any deliberate release of Living Modified Organisms into the environment.

Licence holder means the holder of a licence of modern biotechnology activities or products thereof.

Living modified organism **(LMO)** means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living organism means any biological entity that is:

(a) viable; or
(b) capable of reproduction; or
(c) capable of transferring genetic material.

Minister means the Minister responsible for implementing this Act.

Modern biotechnology means 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,
that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Parties means the Countries that have acceded to the Cartagena Protocol on Biosafety

Products thereof means products derived from living modified organisms.

Person means a juridical or natural person

Placing on the market means making a modern biotechnology product available to third parties

Premises means any building or tent or other structures permanent or otherwise, together with the land on which the same is situated and any adjoining land used in connection therewith and includes any vehicle, conveyance or vessel.

Relevant conviction means a conviction for an offence against laws of Botswana, or a foreign country, being a law relating to the health and safety of people, biological diversity, socio-economic security or the environment, if:

(a) the offence was committed within the period of 10 years immediately before the making of the application for the licence; and
(b) the offence was punishable on conviction by a fine or by a term of imprisonment.

Risks to human health means the potential impact on human beings as a direct result of use, handling, and introduction to the environment of products of modern biotechnology.

Risk assessment means the evaluation of the direct and indirect adverse impacts to human and animal health, the environment, biological diversity, ethics and socio-economic considerations which may be posed by application of modern biotechnology or products thereof. This includes the evaluation of secondary and long term effects.

Sectoral laws mean laws found in the different fields of biodiversity, environment and trade and are administered by specific designated organs of Government.

Socio-economic impact means the direct or indirect effects to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, national or traditional technologies as a result of modern biotechnology activities and products derived from biotechnology.

PART III – *Institutional Arrangements*

5. Establishment of the Biosafety Authority

There is hereby established an authority, to be known as Biosafety Authority of Botswana hereinafter referred to as 'Authority", which shall be a body corporate, with perpetual succession and a common seal, and capable, in its corporate name of:

a) suing and being sued;
b) purchasing or otherwise acquiring, holding, charging, and disposing of property, movable or immovable;
c) entering into contracts, and doing or performing all such other things as may be necessary, and as may lawfully be done or performed by a body corporate.

6. Functions of the Biosafety Authority

(a) The functions of the Biosafety Authority shall be to implement the provisions of this Act, which include:

(i) serving as the National Focal Point on Biosafety issues;
(ii) performing functions relating to modern biotechnology applications and licensing;
(iii) ensuring implementation of technical and procedural guidelines on risk assessment and risk management in relation to products of modern biotechnology;
(iv) providing the public with information on modern biotechnology and its regulation;
(v) creating an environment for public participation in the evaluation of applications of modern biotechnology;
(vi) promoting public awareness and education concerning activities regulated in this Act.
(vii) developing the terms and conditions of employment of the general staff.
(viii) performing any functions incidental to any of the foregoing functions

(b) The Authority shall

(i) establish and maintain a National Biosafety Clearing House (BCH) which shall:
- facilitate the exchange of scientific, technical, environmental and legal information on, and experience with living modified organisms;
- provide access to information made available by the parties relevant to the implementation of the Cartagena Protocol;
- provide access where possible to other international biosafety information exchange mechanisms

(ii) ensure that the BCH is accessible to the public.

7. Establishment of the Biosafety Authority Board (BAB)

(a) There shall be a Board to be known as the Biosafety Authority Board hereinafter referred to as the 'Board', which shall consist of not less than 10 and not more than 15 members as may from time to time be determined and appointed by the Minister.
(b) At the first meeting of the Board convened by the Minister, the Minister shall cause the Board to elect a chairperson and a vice chairperson from among themselves.
(c) The Board shall, subject to the special or general direction of the Minister, be responsible for the overall direction of the affairs of the Authority, and for such other matters as may be specified in this Act.
(d) Appointments to the Board, and of the Chairperson, shall be signified by notice in the Gazette.
(e) The Chief Executive of the Authority shall be the secretary of the Board but will have no voting powers.

8. Tenure of Office of Members

(a) A Board member shall be appointed for such period, not exceeding five years, as shall be specified in the notice of appointment, and at the termination of such period such member shall be eligible for reappointment:

Provided that, in appointing members to the Board, the Minister shall specify such periods of appointment as to ensure that the appointments of not more than one third of the members expire in any one year.

(b) The appointment of the Chairperson shall be for a period of three years, but such Chairperson shall be eligible for reappointment.

(c) If at any time the Minister is satisfied that a member is temporarily incapacitated by illness, absence or other sufficient cause from satisfactorily performing the duties of such member, he may appoint some fit and duly qualified person to be a temporary member in place of the incapacitated member during the period of his incapacity, and the person so appointed shall, whilst so appointed, be deemed to be a full member of the Board.

9. Powers of the Biosafety Authority Board

For the better exercise of its functions the Board shall, subject to this Act, have powers to do or cause to be done all or any of the duties specified in this Act and the Regulations.

10. Disqualification, Removal and Resignation of Board Members

(a) No person shall be appointed to be a member who:

(i). has been declared insolvent or bankrupt under any law in any country, and has not been rehabilitated or discharged, or who has made a composition with his creditors and has not paid his debts in full;

(ii) is incapacitated by physical or mental illness or infirmity from performing their functions;

(iii) is a member of the National Assembly;

(iv) has been convicted of an offence for which the prescribed sentence is a term of imprisonment, with or without the option of a fine, or who has been convicted of an offence involving dishonesty;

(v) has such financial or other interests, as is likely, in the opinion of the Minister, to prejudicially affect the discharge of the functions of a member.

(b) If the Minister is satisfied that a member:

(i) has become subject to any of the disabilities specified in subsection (a);

(ii) has been absent from three consecutive meetings of the Board without the consent of the Chairperson;

(iii) is otherwise unable or unfit to carry out the functions of a member;

(iv) contravenes the provisions of this Act or otherwise commits an act of misconduct to the detriment of any of the objectives of the Authority;

the Minister may declare their office as a member to be vacant, and may thereupon appoint another fit and qualified person to assume such office

(c) Notwithstanding the provisions of subsection (b), the Minister may at any time, for reasons that appear to warrant such action, remove a member from office.

(d) A member may resign from office by giving 30 days notice in writing to the Minister.

(e) The office of a member shall become vacant after:

(i) a period of 30 days has elapsed from the date the member gave a notice in writing to the Minister in accordance with subsection (d), of the member's intention to resign;
(ii) a period of 30 days has elapsed from the date the member is given a notice in writing by the Minister to vacate office; or
(iii) a member is summarily dismissed by the Minister on the grounds of contravening the provisions of this Act or for misconduct in accordance with subsection (b)(iv).

11. Meetings and Proceedings of the Board

(a) **Presiding officer**

(i) The chairperson, or in his absence the vice-chairperson, or in the absence of both, a member elected by the Board from among their number, shall preside at all meetings of the Board, and the vice-chairperson or person presiding at any meeting shall, with respect to such meeting or any business transacted thereat, have all the powers of, and be deemed to be, the chairperson of the Biosafety Authority Board under this Act.

(b) **Meetings of the Board**

(i) The chairperson of the Board shall convene ordinary meetings of the Board at least every quarter, and shall appoint a suitable time, place and date for the holding of each such meeting.
(ii) At least seven days notice shall be given of any meeting of the Board except in the case of emergency.
(iii) The chairperson of the Board may convene a special meeting of the Board at any time, and shall cause a special meeting of the Board to be held within twenty-one days after receiving a written request to do so signed by not fewer than five members of the Board, or as need arises.
(iv) A majority of the members shall constitute a quorum.
(v) Issues arising at a meeting of the Board shall be determined by consensus or, if there is no consensus, by a majority of the votes of members with the chairperson having deliberative vote, or if necessary, also casting vote.

12. Sitting Allowance of the Board

Members may be paid by the Authority such sitting allowances as shall be approved by the Minister.

13. Appointment of the Chief Executive Officer (CEO)

The Minister shall, after consultation with the Board, appoint a person, suitably qualified technically and scientifically, to be the Chief Executive Officer of the Authority.

14. Responsibilities of the Chief Executive Officer (CEO)

(a) The Chief Executive Officer shall be responsible for ensuring that the activities of the Authority as prescribed in this Act are carried out efficiently and effectively under the direction of the Board.
(b) The CEO shall undertake any other duties as prescribed by the Board of Directors and the regulations.

15. Appointment of Other Staff Members

(a) The Board shall, after consultation with the Chief Executive Officer appoint such members of staff of the Authority as it deems necessary for the proper performance of the functions, and carrying out the duties of the Authority.
(b) Members of staff shall perform their functions according to terms and conditions of service as determined by the Board.

16. Disclosure of interest by Board and Committee members

(a) If a member is present at a meeting of the Authority or any committee of the Authority at which any matter is the subject of consideration and in which matter the member is directly or indirectly interested in a private capacity, he shall as soon as practicable after the commencement of the meeting, disclose such interest and shall not, unless the Authority otherwise directs, take part in any consideration or discussion of, or vote on, any question touching such matter.
(b) A disclosure of interest made under subsection (a) shall be recorded in the minutes of the meeting at which it is made.

17. Protection from personal liability

No matter or thing done or omitted by any member of the Board or by any officer or employee of the Authority shall, if the matter or thing is done or omitted bona fide in the course of the operations of the Board or the Authority, render such person, or any other person acting under the first person's direction, personally liable to any action, claim or demand.

18. Establishment of Biosafety Authority Account (BAA)

(a) The Biosafety Authority Account is hereby established

19. Purposes of Account

The purposes of the Account are to make payments to further the intent of this Act; and other activities in connection with the performance of the Authority's functions under this Act, the regulations or a corresponding national law.

20. Authority shall charge for services

The Biosafety Authority shall charge for services provided by, or on behalf of, the Biosafety Authority in the performance of the Authority's functions.

21. Credits to account

(a) The funds and resources of the authority shall consist of:
(i) such moneys as may be provided for the purpose of the Authority by the Government;
(ii) such moneys or assets as may, from time to time, vest in the Authority from other sources by way of fees, grants or otherwise; provided that the Authority shall not accept any donation or bequest without the approval of the Minister in consultation with the Minister responsible for finance; and
(iii) such moneys as the Board may, in accordance with the stated provisions, borrow for the purpose of the Authority.

(b) With prior approval of the Minister for the time being responsible for finance, the Board may, from time to time, borrow moneys on behalf of and for the purposes of the Authority, by way of loans or overdrafts, upon such security, and on such terms and conditions relating to the repayment of the principal and the payment of interest as the Board may, subject to any directions given by the Minister, deem fit.

(c) The Board may, from time to time, invest any moneys standing to the credit of the Authority in securities and property approved, either generally or specifically, by the Minister for the time being responsible for finance, and may, from time to time with his approval, sell or vary such securities or property.

22. Recovery of Amount

The following amounts may be recovered in a court of competent jurisdiction as debts due to the Authority:

(a) fees payable to the Authority under this Act, the regulations or a corresponding national law;
(b) amounts payable to the Authority in connection with the performance of the Authority's functions.

23. Funds

Amounts standing to the credit of the Account may be expended:

(a) in payment or discharge of the costs, expenses and other obligations incurred by the Biosafety Authority in the performance of the Biosafety Authority's functions or in the exercise of the Biosafety Authority's powers under this Act, the Regulations or a corresponding Ministry law; or
(b) in payment of any remuneration and allowances payable to any person under this Act or the regulations.

24. Financial Year

The financial year of the Biosafety Account shall be a period of twelve months commencing on the 1st of April and ending on the 31st of March each year.

25. Accounts and Audit

(a) The Biosafety Authority shall maintain proper books of accounts in respect of each financial year relating to the expenditure of the Authority and shall in each financial year prepare a statement of such accounts.

(b) The statement of accounts produced in accordance with sub-section (a) in respect of each financial year shall, within four months of the end of such year be examined and audited by a person who is registered as public auditor in terms of the Finance and Auditing Act appointed by the Board with approval, of the Minister.

(c) The auditors appointed under subsection (b) shall, in respect of the accounts of each financial year, and in addition to any other matters on which they deem pertinent to report to the Board of Directors.

(d) The Board shall, within six months of the end of each financial year, or such longer period as the Minister may approve, prepare and submit a comprehensive report on the operations of the Authority during such year, together with the auditor's report and audited accounts, the Minister shall lay before the Parliament, and require them to be published in such manner as he may specify.

26. Establishment of the National Biosafety Committee (NBC)

(a) The National Biosafety Committee is hereby established.

(b) The Board of Directors is to appoint up to 10 members of the Committee.

(c) The members hold office on a part-time basis.

(d) The Board of Directors must not appoint a person as a member of the Committee unless the Board of Directors is satisfied that the person has relevant skills or experience.

(e) The Board of Directors must appoint a layperson as a member of the Committee. The Board of Directors is not required to be satisfied that the person has relevant skills or experience.

(f) In appointing the members of the Committee, the Board of Directors must ensure, as far as practicable, that among the members as a whole is a broad range of relevant skills and experience, as per regulations.

(g) The chairperson and vice chairperson shall be selected from among the members on their first meeting.

(h) The term of service of the members of the NBC shall be 5 years.

27. Function of the National Biosafety Committee

The function of the National Biosafety Committee is to provide scientific, technical, ethical, socio-economic or any other advice, on the request of the Biosafety Authority or the Minister, regarding Biosafety issues such as:

(a) modern biotechnology and products thereof;

(b) applications made under this Act;

(c) the Biosafety aspects of modern biotechnology;

(d) the establishment, functions and monitoring of Institutional Biosafety Committee as per the regulations;

(e) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to biotechnology and products thereof, and the content of such principles, guidelines and codes.

28. Sitting Allowance

Any person who is a member of the National Biosafety Committee shall receive a sitting allowance that is determined by the Minister.

29. Members and procedures

(a) The regulations made under the Act may prescribe matters relating to the members of the National Biosafety Committee and including, but not limited to the following:

(i) term of appointment;
(ii) resignation;
(iii) disclosure of interests;
(iv) termination of appointment;

(b) The regulations may prescribe matters relating to the operation of the National Biosafety Committee, including, but not limited to:

(i) procedures for convening meetings of the Committee; and
(ii) the constitution of a quorum for a meeting of the Committee; and
(iii) the way in which matters are to be resolved by the Committee; and
(iv) Committee records; and
(v) reporting requirements, including, but not limited to, reports to the Authority and to the public.

(c) If no regulations are in force, the Committee must operate in the way determined by the Authority in writing.
(d) If no regulations are in force and no determination is in force, the Committee may operate in the way it determines.

30. Subcommittees

(a) The National Biosafety Committee may, with the Biosafety Authority's consent, establish *ad hoc* committees to assist in the performance of its functions.
(b) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

31. Establishment of the Appeals Tribunal

There is hereby established a Biosafety Appeals Tribunal which shall consist of not more than five members all of whom shall be appointed by the Minister as follows:-

(a) a Chairman, who shall be a qualified legal practitioner;
(b) an expert on environmental matters;
(c) an expert on biosafety or biotechnology
(d) an expert on health matters; and
(e) any other member.

32. Application for assessment

Any person aggrieved by a decision of the Authority may appeal against such decision to the Biosafety Appeals Tribunal.

33. Proceedings in application for assessment

(a) Where an application for assessment has been made, the Tribunal shall cause notice of the date, time and place fixed for the holding of the hearing of the application to be given, by registered post, to the applicant and to the Authority.

(b) Where, on the date, time and place fixed for the holding of the hearing, the Authority or its agent, as the case may be, and the applicant appear, the Tribunal shall hold the hearing and shall, for such purpose, have the power to direct such adjournments and postponements as the Tribunal may from time to time think proper.

(c) Where notice under subsection (a) has been received by the Authority or its agent, as the case may be, and the applicant and either party fails to appear on the date and at the time fixed for the holding of the hearing the Tribunal may proceed with the holding of the hearing or may postpone it.

(d) At any hearing held by the Tribunal the Authority or his agent, as the case may be, and the applicant may give evidence, produce documents and call witnesses, and each party to the hearing may cross-examine the other party and witnesses.

(e) The Tribunal may summon any person to give oral evidence which it considers may assist in the hearing and may call for any written evidence or documents necessary in order to conduct such hearing.

(f) A member of the Tribunal or any other person duly authorized in that behalf by the Chairman of the Tribunal may enter into any premises in respect of which an application has been made under subsection (a) in order to carry out an investigation and inspection of such premises:

(g) The Biosafety Appeals Tribunal, after giving both parties to the dispute an opportunity to appear before it and present arguments or evidence, may uphold the decision of the Authority, reject it or amend it as it deems fit, and shall thereafter cause the decision of the Authority, if upheld, or as amended, to be enforced as a decision of the Biosafety Appeals Tribunal.

34. Appeal from Tribunal

(a) The Authority and any applicant who is dissatisfied with the decision of the Tribunal under this Act may appeal therefrom to the High Court in the manner and subject to the conditions hereinafter provided.

(b) An appellant shall, within 14 days after the announcement of the Tribunal of its ruling-

  (i) give written notice of the appeal and the grounds therefore to the Registrar of the High Court; and

  (ii) send by registered post a copy of such written notice of appeal to the other party and to the Tribunal.

(c) Where an appellant has complied with the provisions of subsection (b), the Tribunal shall, within 21 days after the written notice of appeal was lodged with the Registrar of the High Court, transmit to the Registrar of the High Court-

(i) one copy of the proceedings recorded by the Tribunal, duly authenticated by the signature of the Chairman; and
(ii) a copy of the reasons for the Tribunal's decision with regard to the controlled rent, duly authenticated by the signature of the Chairman.

(d) The Registrar of the High Court shall cause notice of the dates and the hour fixed for the appeal to be sent by registered post to the appellant and to the opposite party.

(e) Every appeal under this section shall be heard by a judge sitting in Chambers who shall have power-

(i) to order that evidence be adduced before the judge on a day to be fixed for the purpose;
(ii) to refer the matter to the Tribunal to make a fresh hearing subject to such direction of law as the judge thinks fit; or
(iii) to affirm, increase or decrease the controlled rent.

(f) The decision of the judge shall be final.

PART IV – *Licensing System*

35. Application for a Licence

(a) A person shall apply to the authority for a licence authorising any of the following use and handling of products of modern biotechnology.

(i) contained use
(ii) intentional introduction into the environment
(iii) import or placing in the market
(iv) export
(v) GMOs on transit

36. Application Procedure

(a) The application shall be in writing and shall contain such information as prescribed in the relevant schedule.
(b) The application shall be accompanied by an application fee prescribed by the Authority.
(c) The applicant shall provide a declaration that the information contained in the application is factually correct.
(d) An applicant may withdraw the application at any time prior to the issuance of a final decision by the Authority.
(e) The application fee is not refundable if the applicant withdraws the application.

38. Conditions for Licensing

Application for Contained Use

(a) A person shall not conduct a contained use activity involving genetically modified organisms without the licence of the Authority.

(b) The application shall include:

(i) the details that are set out in the First Schedule;
(ii) any other additional information that the applicant may consider necessary for an assessment of the potential risk and benefits of the requested activity.

Application for intentional introduction into the environment

(a) A person shall not introduce into the environment a genetically modified organism without the licence of the Authority.

(b) The application shall include:

(i) the information set out in the Second Schedule
(ii) a risk assessment as set out in the Third Schedule
(iii) any other additional information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

Application to import or place on the market

(a) A person shall not, without the written approval of the Authority, import or place on the market a GMO.
(b) The application shall include:

(i) the information set out in the Second Schedule
(ii) a risk assessment as set out in the Third Schedule
(iii) any other additional information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

Application to export

A person intending to export a GMO shall provide the Authority with a written advance informed agreement of, or the appropriate certification from, the competent authority of the importing country.

Genetically modified organisms on transit

A person intending to transport a genetically modified organism through the Republic of Botswana which is not destined for use in Botswana shall:

(a) apply to the Authority for a written approval for the transportation, and
(b) ensure that the GMO is properly packaged and transported in accordance with the regulations and international standards.

39. Confidential Information

The Biosafety Authority shall:

(a) permit the Applicant to identify information provided to the Authority in accordance with the requirements of this Act and any Regulations promulgated hereunder, including information contained in notifications, applications and other written submissions, that is to be treated as confidential, with justification for claims of confidentiality to be provided;

(b) decide whether it accepts as confidential the information designated by the Applicant;

(c) prior to any disclosure of information identified by the Applicant as confidential, inform the Applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure;

(d) in the event that an Applicant withdraws or has withdrawn an application, respect the Applicant's claims of confidentiality, including claims for that information on which the Authority and the Applicant disagree as to its confidentiality.

(e) the Authority shall neither use nor permit the use of confidential information accepted as confidential under Sub-section (a) for any purpose not specifically authorized under this Act except with the written consent of the Applicant and shall ensure that such information is protected by all persons involved in handling or reviewing applications or other written submissions under this Act.

(f) the following information shall not be considered confidential

(i) the name and address of the Applicant;
(ii) a general description of the or biotechnology activity;
(iii) a summary of risk assessments performed on the GMO or biotechnology activity; and
(iv) any methods and plans for emergency response.

(g) The Authority shall not use confidential information for a purpose not authorised under this Act and shall ensure that the information is protected by the person involved in handling applications under this Act.

40. Acknowledgement of Application

(a) Upon receipt of an application, submitted under Section 35, the Biosafety Authority shall immediately refer the application to NBC for prompt screening for *prima facie* technical completeness.

(b) Within ninety (90) days of receipt of the application, the Biosafety Authority shall acknowledge receipt of the application and respond, in writing, to the Applicant.

(c) The preliminary response shall include:
(i) The date of receipt of the application; and
(ii) Whether the application, *prima faci*e, contains the required information or, if not, what additional information within the scope of the Regulations is required.

(d) If additional information is required, the number of days the Competent Authority must wait for the information shall not be included in calculating the timeframe for making a final decision.

41. Public Notification of Applications

(a) The Authority shall publish a notice for all applications on modern biotechnology activities:
  (i) in the Government Gazette;
  (ii) in a newspaper(s) circulating throughout the whole country;
  (iii) on the Authority's website; or
  (vi) other such public notification and consultation mechanism as may be established by the regulations or any other relevant sectoral law.

(b) The notice shall:
  (i) invite written submissions in relation to the applications from the public
  (ii) specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.
  (iii) not contain information declared confidential

(c) If the Authority holds a public hearing, the Authority may, having regard to the requirements of this Act in relation to confidential business information, direct that any part of the hearing be held in private, and may determine who can attend.

(d) The Authority may give directions prohibiting or restricting the publication of evidence given, or material contained in documents produced, at a public hearing.

42. Licence Decision Making

In reaching a final decision on an application, the Authority shall take into account.

(a) information submitted by the applicant;
(b) the risk assessment report;
(c) relevant comments submitted by the public, and
(d) socio-economic considerations arising from the impact of a proposed activity and the genetically modified organisms on the environment.

43. Communication of Decision

(a) The Authority shall communicate its final decision to the applicant
  (i) as soon as possible, but in any case not later than two hundred and seventy days of the receipt of the application, or
  (ii) within such time that the Board may in special circumstances determine.

(b) The approval shall clearly set out the specific conditions related to the approval.

(c) The approval shall be specific and limited to the activity authorised as set out in the decision document.

44. Public Notification of Final Decision

The Authority shall publish a notice of the final decision of an application in:

(a) Government Gazette;
(b) a newspaper(s) circulating throughout the whole country;

(c) the Authority website;
(d) or other such public notification and consultation;
(e) mechanism as may be established by the regulations or any other relevant sectoral law.

45. Review of Approval

Any changes of the conditions of the licence shall be published as in section 44

(a) The Authority may review its decision of an application at any time on obtaining significant new scientific information indicating that the genetically organism or approved activity involved may adversely affect human health, plant health, animal health or the environment.
(b) Any person or an applicant may request the Authority to review its decision with respect to an activity conducted by the applicant on the ground.
    (i) a change in the circumstances has occurred that may have a material effect on the outcome of the risk assessment on which the decision was based; or
    (ii) additional scientific or technical information is available which may have a material effect on the decision including the conditions, limitations or requirement imposed under an approval.
(c) Where after a review the Authority is satisfied that a change is warranted, it shall vary the licence.
(d) The Authority shall take a decision on a review within one hundred and fifty days from the date of notification of the review and shall set out the reasons for the decision.

46. Suitability to hold license

(a) Without limiting the matters to which the Authority may have regard in deciding whether a natural person is a suitable person to hold a licence, the Authority must have regard to:
    (i) any relevant conviction of the person; and
    (ii) any revocation or suspension of a licence or permit (however described) held by the person under any laws of Botswana, or a foreign country, being a law relating to the health and safety of people, biological diversity, socio-economic security or the environment; and
    (iii) the capacity of the person to meet the conditions of the licence.

(b) Without limiting the matters to which the Authority may have regard in deciding whether a body corporate is a suitable person to hold a licence, the Authority must have regard to the following:
    (i) any relevant conviction of the body corporate; and
    (ii) if there is a relevant conviction of the body corporate:
        - whether the offence concerned was committed at a time when any person who is presently a director of the body corporate was a director; and
        - whether that offence was committed at a time when any officer or shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such an officer or shareholder; and

(c) any revocation or suspension of a licence or permit (however described) held by the body corporate under any law of the Botswana, or a foreign country, being a law relating to the health and safety of people or the environment; and
(d) the capacity of the body corporate to meet the conditions of the licence.

47. Period of License

(a) A licence shall be specific to an activity of modern biotechnology and should there be any change of activity the licence shall cease to be valid.
(b) A licence is not in force throughout any period of suspension.

48. License is subject to conditions

A modern biotechnology and/or products thereof licence is subject to the following conditions:
(a) the conditions set out in this Act;
(b) any conditions prescribed by the regulations;
(c) any conditions imposed by the Authority at the time of issuing the licence;
(d) any conditions imposed by the Authority after the licence is issued

49. Condition about additional information

(a) It is a condition of a licence that the licence holder or any third party informs the Authority if he or she:
  (i) becomes aware of additional information as to any risks to the health and safety of people, biological diversity, socio-economic security or to the environment, associated with the activity authorised by the licence; or
  (ii) becomes aware of any contraventions of the licence by a person covered by the licence; or
  (iii) becomes aware of any unintended effects of the activity authorised by the licence.
(b) For the purposes of subsection (a):
  (i) the licence holder is taken to have become aware of additional information of a kind mentioned in subsection (a) if he or she was reckless as to whether such information existed; and
  (ii) the licence holder is taken to have become aware of contraventions, or unintended effects, of a kind mentioned in subsection a(1) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

50. Suspension and cancellation of licence

The Authority may, by notice in writing given to the holder of a modern biotechnology and/or products thereof licence, suspend or cancel the licence if:
(a) the Authority believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or by a person covered by the licence; or
(b) the Authority believes on reasonable grounds that the licence holder, or a person covered by the licence, has committed an offence against this Act or the regulations; or

(c) any annual charge payable in respect of the licence remains unpaid after the due date; or

(d) the licence was obtained in a manner not consistent with this Act or any other Law; or

(e) the Authority becomes aware of risks associated with the continuation of the activities authorised by the licence, and is satisfied that the licence holder has not proposed, or is not in a position to implement, adequate measures to deal with those risks; or

(f) the Authority is satisfied that the licence holder is no longer a suitable person to hold the licence.

51. Surrender of license

The licence holder may, with the consent of the Authority, surrender the licence.

52. Transfer of license

(a) The licence holder and another person (the transferee) may jointly apply to the Authority for the licence to be transferred from the licence holder to the transferee.

(b) The application must be in writing, and must contain:
  (i) such information as is prescribed by the regulations; and
  (ii) such information as is specified in writing by the Authority.

(c) The Authority must not transfer the licence unless the Authority is satisfied that, if the licence is transferred, any risks posed by the activities authorised by the licence will continue to be able to be managed in such a way as to protect:
  (i) the health and safety of people;
  (ii) biological diversity;
  (iii) socio-economic security
  (iv) the environment.

(d) The Authority must not transfer the licence unless the Authority is satisfied that the transferee is a suitable person to hold the licence.

(e) The Authority must give written notice of the decision on the application to the licence holder and the transferee.

(f) If the Authority decides to transfer the licence:
  (i) the transfer takes effect on the date specified in the notice; and
  (ii) the licence continues in force as mentioned in section 60; and
  (iii) the licence is subject to the same conditions as those in force immediately before the transfer.

53. Variation of license

(a) The Authority may, at any time, by notice in writing given to the licence holder, vary a licence.

(b) Without limiting subsection (a), the Authority may:
  (i) impose licence conditions or additional licence conditions; or
  (ii) remove or vary licence conditions that were imposed by the Authority; or
  (iii) extend or reduce the authority granted by the licence.

(c) However, the Authority must not vary the licence unless the Authority is satisfied that any risks posed by the activities proposed to be authorised by the licence as varied are able to be managed in such a way as to protect:
(i) the health and safety of people;
(ii) biological diversity
(iii) socio-economic security
(iv) the environment.

PART V – *Inspection*

54. Appointment of Inspectors

(a) The Minister shall, in consultation with the Board, and by Gazette notice, appoint duly qualified persons to be Biosafety inspectors of the Authority;
(b) A qualified individual or a company incorporated in Botswana may be appointed as an inspector, which duly shall be published in the Government Gazette.
(c) Every person appointed as an inspector shall be furnished with, and shall produce on request, a certificate of appointment signed by the CEO, starting that such person is duly appointed and authorised by the Board as an inspector for the purposes of the Act.

55. Powers of Inspectors

(a) A Biosafety inspector may, in the performance of a function under this Act, at a reasonable time and without a warrant,

(i) enter any premises, vessel or property, which the inspector has reason to believe it is necessary to enter, in order to ascertain whether the requirements of this Act or of the Regulations are, or an approval under this Act is, being complied with, and may be accompanied by a person duly authorised by the Authority;
(ii) take possession of the equipment or material required for the purpose for which the power of entry is being exercised;
(iii) carry out the tests and inspection and make the recordings that are necessary in the circumstances;
(iv) direct that a part of the premises, or anything in the premises, shall be left undisturbed for so long as it is reasonably necessary for the purposes of the test or inspection;
(v) take appropriate samples of the organisms, articles or substances found in the premises, and an analysis or any other thing relevant for the purposes of this Act;
(vi) in the case of anything found in the premises which appears to contain a genetically modified organism which has adversely affected or is likely to adversely affect the environment, the inspector may cause it to be dismantled or subjected to a process or test but not so as to damage or destroy it, unless it is necessary; or inevitable;
(vii) require the production of the records which are required to be kept under this Act.

(b) In the performance of a function under this Act, a biosafety inspector shall supply the appropriate identification.

56. Obligations of the Person Incharge of the Premises

Any owner, occupier or person in charge of any premises entered by an authorised inspector or any person found therein, shall give to the authorised officer all reasonable assistance which is in his power to give, and shall furnish him with such information as the officer may reasonably require.

PART VI – *Identification and Labelling*

Any living modified organism or product of a genetically modified organism intended for food, feed and processing shall be clearly identified and labelled as such.

PART VII – *Offences and Penalties*

57. Operation without a license

(a) A person is guilty of an offence if he/she undertakes modern biotechnology activities without a licence.
(b) An offence under subsection (a) is punishable on conviction of imprisonment for a term not exceeding 5 years or liable to a fine not exceeding P100 000.00.
(c) A person who is guilty of an offence under subsection (a) or (b) is guilty of a separate offence in respect of each day (including the day of a conviction for the offence or any later day) on which the person is guilty of the offence.

58. Failure to Comply with a Licence

(a) A person is guilty of an offence if he/she fails to comply with the conditions of the licence.
(b) Such an offence is punishable on conviction by whichever of imprisonment of a term not exceeding 3 years or a fine not exceeding P60 000.00.

59. Unintentional release

(a) A licence holder for contained use is guilty of an offence if he/she unintentionally releases LMOs or GMOs into the environment.
(b) Such an offence is punishable on conviction by whichever of imprisonment for 1 year or a fine of P20 000.00.

60. Failure to provide required information and Miscellaneous Offences

A person commits an offence and is liable on conviction by whichever imprisonment for 3 years or a fine of P60 000.00, if that person

(a) fails to furnish an information as required by or under this Act, or
(b) uses confidential information for a purpose not authorised by or under this Act, or
(c) obstructs or fails to assist the Authority or officers of the Authority in the performance of a function under this Act, or

(d) contravenes any other provision of this Act
(e) gives false or misleading information to the Authority

61. Annual Licence/Inspection Fee

If the Authority incurs costs because of arrangements made by the Authority, the licence holder or the person, as the case requires, is liable to pay to the Government an amount equal to the cost, and the amount may be recovered by the Government as a debt due to the Government in a court of competent jurisdiction.

PART VIII – *Liability and Redress*

62. Civil liability and redress

Liability or redress for a damage that occurs as a result of an activity under this Act is subject to the applicable Laws.

PART IX – *General Provisions*

63. Minister's power to make regulations

The Authority may, with the approval of the Minister, make regulations for the better carrying out of its functions under this Act and in particular for prescribing.

(a) Anything required by this Act to be prescribed;
(b) Procedures for conducting contained used activities involving genetically modified organisms;
(c) Procedures for release of genetically modified organisms into the environment;
(d) Procedures for importation and exportation of genetically modified organisms;
(e) Procedures for genetically modified organisms in transit;
(f) Procedures for appeals;
(g) Forms to be used for applications for approvals;
(h) Schedules of fees to cover administrative costs of processing applications and notices
(i) The Minister in consultation with the Board shall prescribe regulations on specifications of identification and labelling of LMOs and GMOs.

64. Transitional Provisions

(a) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.
(b) Activities that were ongoing at the date of the entry into force of this Act shall be permitted to continue but shall be subject to the review procedure set forth in the Act.

65. Public Awareness and Participation

The Authority shall promote public awareness, participation and education concerning Biosafety matters through the implementation of the National Biosafety Strategy for Public Participation.

SCHEDULES

FIRST SCHEDULE

INFORMATION REQUIRED IN APPLICATIONS FOR CONTAINED USE

(a) the name and contact address of the applicant;
(b) the location where the contained or confined use activities are to be undertaken;
(c) the nature and identity of the genetically modified organisms to be involved;
(d) the nature and purpose of the activities including storing, transporting, producing, processing, disposing or use of the genetically modified organisms in any other way;
(e) a description of the potential risks associated with the genetically modified organism activities to be undertaken, and
(f) a description of the remedial management plan measures for the activities to be undertaken for unintentional release and at the end of the activity.

SECOND SCHEDULE

INFORMATION REQUIRED IN APPLICATIONS FOR RELEASE INTO THE ENVIRONMENT, IMPORTATION AND PLACING ON THE MARKET

(a) Name, address and contact details of the exporter
(b) Name, address and contact details of the importer
(c) Name and identity of the genetically modified organism as well as the domestic classification of the biosafety level of the genetically modified organism in the country of export
(d) Intended date of the transboundary movement
(e) Taxonomic status, scientific and technical names, common name, unique identifier, transformation code or event, point of collection or acquisition and characteristics of the recipient organism or parental organism related to biosafety
(f) Center of origin and center of genetic diversity, of the recipient organism and the parental organism and the description of the habitat where the organism is related to biosafety
(g) Taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the genetically modified organism.
(h) Intended use of the genetically modified and the products of the genetically modified organism
(i) Quantity or volume of the genetically modified to be transferred and released
(j) Suggested methods for the safe handling, storage, transport and use, including procedures for unintentional or accidental release
(k) A sworn declaration of the applicant that the above mentioned information is factually correct.

THIRD SCHEDULE

RISK ASSESSMENT

Objective

(1) The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of genetically modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

(2) The risk assessment shall, *inter alia*, be used by the Authority to make informed decisions regarding genetically modified organism.

General principles

(3) Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, guidelines developed by, relevant international organisations.

(4) Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

(5) Risks associated with genetically modified organisms or products thereof, namely, processed materials that are of genetically modified organisms origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

(6) Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the genetically modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

(7) To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the genetically modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the genetically modified organism;

(c) An evaluation of the consequences should these adverse effects be realised;

(d) An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the genetically modified organism in the receiving environment.

Points to consider

(8) Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) *Recipient organism or parental organisms*. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Genetically modified organism.* Identity of the genetically modified organism, and the differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the genetically modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use.* Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centre of origin of the likely potential receiving environment.

FOURTH SCHEDULE

RISK MANAGEMENT

(1) In preparing the risk management plan, the applicant must take into account the means of managing any risks posed by the dealings proposed in such a way as to protect:

(a) the health and safety of humans, animals and plants;

(b) biological diversity;

(c) the environment;

(d) socio-economic security