Republic of Zambia

MINISTRY OF SCIENCE TECHNOLOGY AND VOCATIONAL TRAINING

Biotechnology and Biosafety Policy

ABBREVIATIONS AND ACRONYMS

BAC	Biosafety Advisory Committee (s)
CBD	Convention on Biological Diversity
CDT	Cotton Development Trust
COP	Conference of Parties
CVRI	Central Veterinary Research Institute
DST	Department of Science and Technology
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
NAIC	National Artificial Insemination Centre
NBA	National Biosafety Authority
NBSAP	National Biodiversity Strategy and Action Plan
NISIR	National Institute for Scientific and Industrial Research
NMCC	National Malaria Control Centre
SCCI	Seed Control and Certification Institute
SCRB	Soils and Crops Research Branch
SPS	Sanitary and Phytosanitary Measures
UNCED	United Nations Conference on the Environment and Development
UNEP	United Nations Environmental Programme
UNZA	University of Zambia
UTH	University Teaching Hospital
WTO	World Trade Organisation

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FOREWORD

I am honoured to present this Draft National Biotechnology and Biosafety Policy. In developing this policy, care was taken to balance the need to sustainably use biotechnology in the nations' quest for socio-economic development on one hand, and the need to protect human and animal health as well as the environment, including biological diversity, on the other hand. The National Biotechnology and Biosafety Policy is built on the position Zambia, along with other African countries, took on the negotiations that led to the development of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity.

My Ministry made deliberate efforts to involve a wide spectrum of stakeholders from various sectors of our economy in the process of developing this policy. This is in recognition of the fact that issues pertaining to Biotechnology and Biosafety cut across all sectors of the economy in the country.

Zambia signed the Convention on Biological Diversity (CBD) on June 11, 1992 and ratified it on May 28, 1993. The implementation of this National Biotechnology and Biosafety Policy, therefore, will enable Zambia to fulfil some of its obligations to the CBD. Article 8 (g) of the CBD states that: "Each Contracting Party shall, as far as possible and as appropriate establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from modern biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health".

Finally, I wish to convey my unreserved gratitude to all individuals, institutions and organisations that supported the development of the Policy. I also acknowledge the UNEP/GEF Pilot Biosafety Enabling Activity Project, whose assistance made it possible to initiate the process of developing this Policy.

It is my Ministry's desire and wish that a participatory approach, embracing the widest possible spectrum of stakeholders, will be applied in the implementation of this policy.

Hon. A.M. Chambeshi, MP
MINISTER OF SCIENCE, TECHNOLOGY AND VOCATIONAL TRAINING

EXECUTIVE SUMMARY

Biotechnology and products of Biotechnology can contribute significantly to economic development of Zambia, especially in the areas of agriculture, health care, environment as well as industry. However, maximal benefits from modern biotechnology can only be realized if it is applied judiciously and in a sustainable manner.

An aspect of modern biotechnology that requires particular attention is the development of Genetically Modified Organisms (GMOs). GMOs are created by altering the genetic material through the introduction of foreign genetic material from an organism belonging to a different species in order to make them capable of producing new substances or to perform new functions. Development of GMOs has attracted attention from various stakeholders regarding concerns over risks to human health, animal and environment safety. Biosafety is a term used to describe a set of measures used to assess and manage any risks associated with processes and/or products of Biotechnology.

There are a number of instruments and agreements at the international level that directly or indirectly address the issue of Biosafety. They are, however, limited in scope and/or do not adequately address the cross-border movement and handling of GMOs. In addition, these instruments and agreements are not legally binding unless ratified. There is therefore, a need for Zambia to have a Biosafety Policy and Legislation.

The mission of the Biotechnology and Biosafety Policy is to guide the judicious use and regulation of modern Biotechnology for the sustainable development of the nation, with minimum risks to human and animal health as well as the environment, including Zambia's biological diversity.

The objectives of the Biotechnology and Biosafety Policy are to support the development of research and industrial capacity to safely apply biotechnology techniques for the enhancement of Zambia's socio-economic and environmental well being.

The guiding principles of the Biotechnology and Biosafety policy are; the Precautionary Principle; Advance Informed Agreement; recognition of undesirable effects of GMOs; Risk Assessment; Socio-economic Impact; Public Participation; Liability and Redress; recognition of possible conflict between conservation of biodiversity and trade; as well as recognition of rights of both developers and innovators over genetic resources and technologies.

The establishment of a National Biosafety Authority (NBA) and Biosafety Advisory Committee(s) (BAC) will constitute the institutional framework for the national decision-making and international co-operation on Biosafety.

The promotion of safe research, development, application and commercialization of Biotechnology products in Zambia will require strengthening of relevant institutions, both in terms of human resource development and upgrading of physical and laboratory infrastructure.

1. INTRODUCTION

Biotechnology is any technological application that uses biological systems (living organisms, or derivatives thereof), to make or modify products or processes for specific use. There is a universal recognition and realisation that biotechnology can contribute significantly to the social and economic development of developing countries such as Zambia. This is particularly so in the areas of agriculture, health, environment as well as industry. However, maximal benefits from biotechnology can only be achieved if it is applied judiciously and in a sustainable manner.

There are risks that are associated with the introduction of Genetically Modified Organisms (GMOs) into the environment. GMOs are created by altering the genetic material through the introduction of foreign genetic material from an organism belonging to a different species in order to make them capable of producing new substances or to perform new functions. Genetic material is material of a plant, animal, microbial or other origin containing functional units of heredity. The genetic material is transferred from one organism, across species boundaries, into another.

Introduction of GMOs into a new environment may be harmful and dangerous to the environment. Similarly, handling of pathogenic or non-pathogenic microorganisms or their fragments can be dangerous. The chemicals that are used in these manipulations can also be highly harmful to life. Thus, although biotechnology has demonstrated its

utility, there are concerns about potential risks to biodiversity, human and animal health and the environment.

Biosafety issues in human and animal medical biotechnology involve the consideration of possible toxic or allergenic effects arising from introduced gene product(s) and production of new strains that are more virulent and resistant to drugs. Environmental considerations involve the potential for uncontrolled spread of the modified organisms and/or the introduced gene. Issues such as the existence of other hosts in the area, and the potential for gene spreading to such unintended hosts are also of importance.

The CBD negotiated under UNEPs auspices, was adopted on 22nd May 1992, and entered into force on 29th December 1993. Article 8 (g) of the CBD states that: "Each Contracting Party shall, as far as possible and as appropriate: establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from modern biotechnology, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health".

2. BACKGROUND

The safe research, development, application and commercialisation of biotechnology, has generated a lot of interest and attention world-wide, especially following the United Nations Conference on the Environment and Development (UNCED) which took place in Rio de Janeiro, Brazil in 1992, resulting in Agenda 21.

Chapter 16 of Agenda 21, "Environmentally Sound Management of Biotechnology", is devoted to Biosafety. The term Biosafety describes a set of measures used to assess and manage any risks associated with processes and products of biotechnology. Such risks may transcend or be inherent in the technology itself and need to be managed accordingly. Biosafety also features prominently in the Convention on Biological Diversity (CBD) through the sustainable use of Biotechnology. The CBD has gone further by developing a Protocol on Biosafety that has been adopted by the Conference of the Parties. The United Nations Environment Programme (UNEP) went a step further, and developed the UNEP International Technical Guidelines for Safety in Biotechnology. Similarly, there are a number of instruments and agreements at regional and international levels that directly or indirectly address the issue of Biosafety. Among these are:

- The United Nations Food and Agriculture Organisation Code of Conduct on Plant Biotechnology
- The Office of International Des Episooties
- United Nations Industrial Organisation Voluntary Code of Conduct for the Release of Organisms into the Environment

- Codex Alimentarius
- The World Trade Organisation (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS).

These instruments however, are limited in scope and/or do not adequately address trans-boundary movements and handling of living modified organisms. Also, most of the existing international instruments are voluntary and are not legally binding unless ratified.

The Government of the Republic of Zambia has signed and ratified both Agenda 21 and the CBD and in 1997 developed the National Biodiversity Strategy and Action Plan (NBSAP). The Zambian Government adopted this NBSAP in 2001. In addition, Zambia has participated fully in the meeting of the Open-ended *Ad Hoc* Working Group of Experts on Biosafety, which has developed a Protocol on Biosafety under the auspices of the CBD. Zambia, also, actively participated in the development of the UNEP International Technical Guidelines for Safety in Biotechnology.

The rate of development and level of success of Biotechnology, as with any new technology, are dependent not only on the scientific and technological capacities of a country, but also on a supporting infrastructure and accepting environment in which it is to be introduced and used. As concerns about safety in biotechnology and its products are being raised worldwide, a key component in the establishment of a "biotechnology accepting" environment is the formulation of a Biosafety Regulatory Legal Framework, creating a

National Biosafety Authority and the required infrastructure. The cornerstone of the Biosafety Regulatory Legal Framework is Biosafety regulations and guidelines.

Biosafety legislation in itself cannot ensure the safe research, development, application and commercialisation of Biotechnology. Equally important, however, is acquiring the capacity to implement regulations and guidelines via environmental impact assessment and risk management, taking into consideration socio-economic factors. Biosafety guidelines and regulations must be developed with a clear understanding that their implementation depends on the availability of human resources (in terms of quantity and quality), financial resources, as well as institutional and infrastructural capacities at national, regional and global levels.

It is possible under the current scenario in Zambia to ensure that biotechnology research, development, application and commercialisation is carried out with minimum adverse effects both to human health and the environment. In the absence of Biosafety legislation, some Zambian laws can be used to ensure minimum risks to human health and environment from biotechnology. These laws basically deal with the transfer, handling, release and use of animals and plants. The other laws are concerned with protecting the general public and the environment from possible effects of industrial activities. There are, however, no laws, which deal specifically with the transfer, handling and use of
microorganisms.

The non-existence of legislation on GMOs poses risks as Zambia could be attractive to foreign biotechnology companies or institutions wishing to test products that cannot be tested in the tougher regulatory climates of their countries. Furthermore, with the liberalised economy, Zambia has become a promising market of pharmaceuticals and agro products some of which may be products of gene manipulation.

3 MISSION STATEMENT

The mission of the Biotechnology and Biosafety Policy is to guide the judicious use and regulation of modern biotechnology for sustainable development of the nation, with minimum risks to human and animal health, the environment and biological diversity.

4. OBJECTIVES

4.1 To support safe application of biotechnology techniques for the enhancement of Zambia's socio-economic and environmental well being.

4.2 To support the development of regulatory capacity to assess, test, monitor and control for the safe research, development, application and commercialisation of Biotechnology in accordance with agreed Biosafety legislation and guidelines.

4.3 To ensure effective control of trans-boundary movements of Genetically Modified Organisms (GMOs) or products thereof

resulting from modern biotechnology, through the exchange of information and risk assessment as well as a transparent system of advance informed agreement.

4.4 To ensure the safe and judicious use of biotechnology, with a view to maximising its potential benefits while avoiding to the maximum extent possible, any adverse effects on human and animal health as well as to the environment.

5 GUIDING PRINCIPLES

5.1 The Precautionary Principle: No approval for transfer, use and release of GMO(s) shall be given unless there is firm and sufficient evidence that the GMO(s) or products thereof pose no risk to human and animal health, biological diversity or the environment. Approval shall not be given where there is reason to believe that harm or damage may result, even when there is lack of scientific evidence or certainty.

5.2 Advance Informed Agreement: Any person who intends to conduct research, develop, apply, release and commercialise GMO(s) and products thereof shall submit an application in writing to the National Biosafety Authority (NBA) for authorisation. There shall be no research, development, application, release and commercialisation of GMO(s), combinations of GMO(s) and products thereof without the prior approval of the NBA.

5.3 Undesirable Effects of GMO(s) and Products Thereof: The following are considered "potentially harmful effects on human and animal health as well as the environment": disease to humans, including allergenic or toxic effects, disease to plants, animals or other organisms; adverse effects resulting from the inability to treat disease or other effective prophylaxis; adverse effects resulting from establishment or dissemination in the environment; adverse effects resulting from the natural transfer of inserted genetic material to other non-target organisms.

5.4 Risk Assessment: No research, development, application, release and commercialisation of GMO(s), combinations of GMO(s) and products thereof shall be undertaken without a risk assessment report. It is the responsibility of the applicant to conduct and/or have an assessment of the impacts and risks posed by GMO(s) and products thereof to human and animal health, the environment and biological diversity, under the supervision of the NBA.

5.5 Socio-economic Impact: The Risk Assessment Report shall include the direct or indirect effects to the economy, socio or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, contained use, deliberate release or placing on the market of GMO(s) or products thereof.

5.6 Public Participation: The NBA shall make available to the public, information pertaining to applications for the research, development, use and commercialisation of GMO(s), combinations of GMOs and products thereof. The public may make comments within such period as may be specified by the NBA.

5.7 Liability and Redress: The liability for any damage caused by the use or release of GMO(s) and products shall be borne by the user and or importer concerned. Where the GMO(s) or products thereof cause damage to the environment, the user concerned shall take remedial measures towards restoring the environment to its original state or harm shall be fully compensated for.

5.8 Conservation of the Biological Diversity and Trade: Should there be a conflict between issues pertaining to the conservation of the Biological Diversity and Trade, the conservation of the Biological Diversity shall prevail.

5.9 Rights Over Genetic Resources and Technologies: The implementation of the Biotechnology and Biosafety Policy shall be based on the fair and equitable sharing of benefits (by all stakeholders), arising out of the utilisation of genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to the technologies.

6 LEGAL FRAMEWORK

6.1 There is no law in the existing Zambian statutes that can be used to protect human and animal health as well as the environment, including biological diversity from potential risks posed by GMOs and products thereof. The laws that are there basically deal with the transfer, handling, release and use of animals and plants. There are, however, no laws, which deal specifically with the transfer, handling and use of microorganisms. Some laws cover the quality of food and foodstuffs as well as pharmaceutical products. The other laws are concerned with protecting the general public and the environment from possible negative effects of industrial activities.

6.2 New Legislation shall be enacted and where necessary, existing laws shall be amended and/or modified in line with the Biotechnology and Biosafety Policy. Some of these laws are:

CAP 303 - The Food and Drug Act
CAP 231 - Noxious weeds Act
CAP 233 - Plant Pest and Diseases Act
CAP 236 - Plant Variety and Seeds Act
CAP 237 - Tobacco Act
CAP 238 - Cotton Act
CAP 351 - Agriculture (fertiliser and Feed) Act of 1966
CAP - Environment Protection Act

6.3 The NBA shall be established and the Biosafety Advisory Committee (BAC) constituted under the Act.

7 IMPLEMENTATION

7.1 Establishment of the NBA and BAC will constitute the institutional framework for national decision-making and international co-operation on biosafety. The NBA shall:

7.1.1 Support the development of regulatory capacity to assess, test, monitor and control for the safe research, development, application and commercialisation of Biotechnology in accordance with agreed Biosafety Legislation.

7.1.2 Support the development of research and industrial capacity to safely apply biotechnology techniques for the enhancement of Zambia's socio-economic and environmental well being.

7.1.3 Ensure effective control of trans-boundary movements of GMO(s) or products thereof resulting from modern biotechnology, through the exchange of information and risk assessment as well as a transparent system of advance informed agreement.

7.1.4 Ensure effective application of bioethical control in research related to biotechnology.

8 SCOPE OF THE BIOTECHNOLOGY AND BIOSAFETY POLICY

Biotechnology and Biosafety Policy shall:

8.1 apply to the research, development, application, release and commercialisation of GMO(s), combinations of GMO(s) and products thereof.

8.2 occupational safety at workplaces where biotechnology procedures are used or products handled;

8.3 labelling of GMO(s) or products thereof developed in or imported into Zambia.

8.4 any other measures deemed necessary to ensure protection of human and animal health as well as the environment with respect to the use of biotechnology in Zambia.

9 IMPLEMENTATION STRATEGY

9.1 The Biotechnology and Biosafety Policy will be implemented through the NBA.

9.2 The regulatory and administrative processes will include notification, information transfer and review, risk assessment, approval or refusal, risk management, including monitoring and enforcement measures pertaining to laboratory use, research and development activities, or field release procedures including handling, containment, monitoring, agreed disposal or destruction procedures and contingency plans for spillage or accidental release.

9.3 In order to trace GMOs and products thereof at the point of import, sectoral legislation related to import control shall require appropriate amendment and enforcement.

10 CURRENT INSTITUTIONAL STRUCTURES

10.1 The Ministry responsible for environment and natural resources is the Focal Point for the CBD while the national institute for scientific and industrial research is the National Biosafety Focal Point. The Ministry responsible for science and technology is charged with the formulation and ensuring the adoption of the policy on the Biotechnology and Biosafety.

10.2 Other key stakeholders are the line ministries and the Statutory Boards responsible for agriculture; health; commerce, trade and industry; legal affairs; finance; home affairs; information and broadcasting; local government and housing; transport and communications; institutions of higher learning; research institutions; civil society; industry and traditional administration authorities.

11 PROPOSED INSTITUTIONAL STRUCTURES

11.1 Upon acceptance of this Policy and the enactment of the supporting legislation, the Government shall establish the NBA to implement, and enforce the legislation. In addition, the BAC and Institutional Biosafety Committees (IBC) shall be established. The BACs shall provide technical advice to the NBA.

11.2 The NBA shall advise the Government of the Republic of Zambia on all aspects concerning the research, development, application, release and commercialisation of GMO(s) and products thereof, to ensure that all operations are carried out in accordance with the provisions of the Biotechnology and Biosafety Policy.

11.3 The NBA shall formulate and review Biosafety legislation and guidelines.

11.4 The NBA shall prescribe laboratory facilities capable of verifying the presence of GMO(s), combinations of GMOs and products thereof.

11.5 The BAC shall advise the NBA on prohibitions, authorisation and the exercise of necessary control of imports, authorisation or notification of contained uses, authorisation of trial or general releases; and control measures to be taken where an intentional release of GMO(s) may occur.

11.6 The IBC shall implement recommendations from the NBA.

12 CAPACITY BUILDING IN BIOTECHNOLOGY AND BIOSAFETY

12.1 Promotion of the safe use of biotechnology in Zambia will involve the strengthening of biotechnology research, development of biosafety capacities and capabilities of institutions in the country including:

12.1.1 National Institute for Scientific and Industrial Research (NISIR)

12.1.2 Tropical Diseases Research Centre (TDRC)

12.1.3 The University of Zambia (UNZA)

12.1.4 The University Teaching Hospital (UTH)

12.1.5 Soil and Crop Research Branch (SCRB)

12.1.6 Golden Valley Agricultural Research Trust (GART)

12.1.7 The Seed Control and Certification Institute (SCCI)

12.1.8 Cotton Development Trust (CDT)

12.1.9 National Artificial Insemination Centre (Animal Genetic Resource (Centre) (NAIC)

12.1.10 Central Veterinary Research Institute (Balmoral) (CVRI)

12.1.11 National Malaria Control Centre (NMCC)

12.2 Human Resource Development

12.2.1 The Government of the Republic of Zambia through the NBA shall work with regional and international training bodies to determine a cost-effective strategy for training scientists and science students in biotechnology, biosafety procedures, such as risk assessment and management.

12.2.2 Zambia shall rationalize its investment by making maximum use of existing regional, international and other educational and training bodies in biotechnology and Biosafety, and by preparing its undergraduate students for easy entry into such programmes by means of curriculum stream options.

12.2.3 Government ministries, regulatory agencies shall, endeavour as a matter of urgency, to identify and implement appropriate in-house or continuing education and training on Biotechnology and Biosafety for their existing staff.

12.3 Infrastructure

12.3.1 Rehabilitation of laboratories to suit accreditation to international standards.

12.3.2 Provision of basic equipment for biotechnology

13 FINANCIAL IMPLICATIONS

13.1 Biotechnology and Biosafety is an exceptionally expensive and specialized field of technology. If taken as an important component of a national science and technology strategy, it involves investment in infrastructure, equipment and specialist training. Equally, the regulation and monitoring of Biotechnology is costly for governments, irrespective of their own Biotechnology capacity.

13.2 Government shall provide financial incentives to support institutional development.

13.3 Investment will become necessary to build capacity for low, medium and high-level biotechnology applications and regulation on a needs-driven basis, through training, research and partnership at the national regional and international level.