

National Biosafety Framework for Zimbabwe

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Table of Contents

Foreword

Introduction

National Policy on Biotechnology and Biosafety

National Biosafety Regulatory Framework

Administrative Arrangements

Decision Making System

Mechanisms for Monitoring and Enforcement

Mechanisms for Public Awareness and Participation

Capacity Building Plan

Foreword

Zimbabwe is a country that is richly endowed with mineral and biological resources. However, the country is yet to benefit fully from the exploitation of its abundant resources. In order for the country to take advantage of its rich resource base to bring about socio-economic transformation, it must harness both conventional and new emerging technologies such as Information and Communication Technologies (ICTs) and biotechnology.

Biotechnology refers to a suite of technologies that are applied to living organisms to produce goods and services to improve quality of life. These technologies include, but are not limited to fermentation, bio-augmentation, composting, the development of vaccines, the production of antibiotics for various ailments, micro-propagation, cloning, bioinformatics, protein engineering, breeding, and genetic modification. Both conventional and modern biotechnologies have a key role to play in Zimbabwe's agricultural, medical, environmental and processing industries.

It is for the reasons above, that Zimbabwe has embraced biotechnology as a tool for sustainable economic and social development. Biotechnology will therefore be applied in all fields of human development in line with national development priorities. Suffice to say that deliberate effort will be applied to the systematic application of biotechnology in agricultural development, the improvement of the country's health delivery system, provision of environmentally friendly energy, sustainable environmental management and the sustainable exploitation of the country's abundant biological diversity.

However, biotechnology is a double edged sword. Whereas there are serious prospects of applying this technology to improve the human condition, there are also real threats that can arise from the unsound and unsafe application of the technology. Such applications could pose a threat to human health, biodiversity, the environment in general, national security, and the general welfare of the people of Zimbabwe. It is against this background that Zimbabwe developed a comprehensive biosafety framework, a framework to enable the economically viable, scientifically sound, environmentally sustainable, and socially acceptable application of both conventional and modern biotechnology.

The National Biosafety Framework comprises of: a national policy on biotechnology and its safe use (The National Biotechnology Policy), an Act of Parliament - the National Biotechnology Authority Act, Institutional arrangements in the form of the National Biotechnology Authority (NBA) and Institutional Biosafety Committees (IBCs), mechanisms for risk assessment (reviews), mechanisms for decision making (NBA), mechanisms for public participation, mechanisms for monitoring and enforcement (Biosafety Inspectorate), and supporting guidelines and standards.

The National Biosafety Framework I believe will enable Zimbabwe to benefit fully from its biological resources whilst ensuring national safety and security.

Professor H. Dzinotyiweyi, Minister for Science and Technology Development (MP)

Introduction

Science, technology and innovation are centrally to a country's development. Both conventional technologies like plant breeding and new cutting edge technologies like genetic modification can play a key role in promoting agricultural production, food security, the provision of sustainable and affordable energy, better means of health delivery, sustainable environmental management and broadening the scope of industrial development.

Zimbabwe has a well established history in the use of conventional biotechnologies such as breeding, fermentation, development of vaccines especially for animal diseases, artificial insemination, embryo transfer, tissue culture and the use of organic pesticides. The country's leadership in conventional biotechnologies such as plant and animal breeding transformed it into the bread basket of Southern Africa before the end of the last century.

It is believed that Zimbabwe possesses a lot of potential to harness new biotechnologies for its own socio-economic development. To achieve this potential, there is need for investment in human and infrastructural development. Some human capital capacity is already present. However, this does not match with its capacity needs. In addition, there is a great need to put in place appropriate policy, legal, institutional arrangement for the safe and responsible application of biotechnology. This must of necessity be achieved if the country is to safe guard its long term human health, environmental and socio-economic interests.

It is for the foregoing that a comprehensive biosafety framework in the form of the National Biotechnology Policy, the National Biotechnology Authority Act and the National Biotechnology Authority of Zimbabwe were put in place. These provisions allow the country to take advantage of breakthroughs in molecular and engineering technologies without compromising its long term human health, environmental and socio-economic interests.

This document therefore provides a summary of the country's biosafety framework.

1. National Policy on Biotechnology and Biosafety

Zimbabwe's national policy on the safe application of biotechnology – the National Biotechnology Policy was developed in 2005 under the United Nations Environment Programme (UNEP)/Global Environment Facility (GEF) Global Project for the Development of National Biosafety Frameworks. The policy recognizes the need for the country to harness biotechnology for agricultural development, improve human health, promote industrial development including the provision of environmentally friendly and affordable energy, and environmental management.

Biotechnology is envisioned to play a critical role in national and household food security, the sustainable exploitation of the country's rich biological resource base, climate change mitigation and adaptation, improving health delivery, provision of renewable bioenergy, food and beverage industries, and biodiversity conservation.

However, the policy also takes note of the fact that there are some aspects of modern biotechnology that are likely to pose adverse effects on human health, biodiversity, the environment in general, national security and other socio-economic interests. Consequently, it proposes under section 7 a set of measures to assess and manage new biotechnologies like genetic modification. These set of measures are centred on the need to balance research and development interests and safety and security.

The policy document is divided into eight main sections. The first section gives an overview of the status of biotechnology in Zimbabwe. Section two gives a brief overview of the socio-economic context for biotechnology in Zimbabwe, and identifies key problems and issues. The third section presents the overall policy framework, detailing the vision, principles and objectives. Section four identifies key priority sectors for biotechnology application. The fifth section identifies instruments for promoting the policy. Section six establishes institutional arrangements for the effective implementation of the policy. The seventh section puts in place financial arrangements. And finally, section eight provides for the ratification and domestication of international agreements on biotechnology and biosafety.

Vision and Objectives of the Policy

The national biotechnology policy envisions a conducive environment for harnessing biotechnology to meet the development needs of the country, whilst affording appropriate protection to the country's biodiversity, health, and economic wellbeing.

Guiding Principles

- Research, development and commercialization of modern biotechnology to address national development imperative
- Development arising from applied biotechnology applications to be socially, environmentally and economically sustainable
- An endeavor by Government to strike a balance between promoting biotechnology and regulating its use
- The use, import, sale, or transit of biotechnology applications and products shall respect national, regional and international regulatory instruments
- The precautionary approach highlighted in the Cartagena Protocol on Biosafety shall be central to biosafety decision making
- The right of the public to participate fully in decisions that affect them shall be upheld
- The benefits from biotechnology applications shall be shared equitably with the providers of genetic resources and /or associated information

Objectives

- To ensure that Zimbabweans have access to, confidence in and benefit from the safe and effective use of biotechnology based products and services

- To position Zimbabwe as an ethically and socially responsible country in the development, commercialization, sale and use of biotechnology products and services
- To improve the public's awareness, understanding and participation in biotechnology and biosafety through education, communication and dialogue
- To support the development of the country's biotechnology human capital base and ensure an adequate supply of highly qualified and relevant personnel
- To promote the conservation of biodiversity and the sustainable exploitation of its components through biotechnology applications
- To promote the development of high quality national infrastructure for supporting biotechnology research, development and innovation
- To promote biotechnology financing through various policy instruments
- To provide for the establishment of regulatory regimes in biosafety, biosecurity, intellectual property, farmers' rights, bio-surveillance and bioethics

Priority Sectors for Biotechnology Application

The following are identified as key priority sectors for biotechnology application:

- Agriculture
- Health
- Environment
- Industry
- Energy

Instruments for promoting policy

The national biotechnology policy highlights the following instruments for policy implementation:

- Encouraging biotechnology research and development
- Developing and reforming intellectual property regimes
- Developing biotechnology research and development infrastructure
- Building the human capital necessary for biotechnology-led development
- Ensuring safety and security in biotechnology practice (biosafety)
- Public awareness, education and participation in biotechnology and biosafety
- Funding biotechnology and biosafety related activities

Institutional Arrangements

The policy proposes the establishment of an autonomous National Focal Point and Competent Authority on Biosafety – The National Biotechnology Authority. The policy and guidance of the authority will be provided by the National Biotechnology Board. The main responsibilities of the authority are highlighted as:

- To champion all national efforts towards biotechnology research, development and management
- To regulate biotechnology research in Zimbabwe
- To administer the Biotechnology Fund
- To manage the National Biosafety Clearing House
- To enforce standards and any regulations pertaining to biotechnology and its safe use

The national biotechnology policy vision, principles and objectives are in line with the country's long term development strategy (Vision 2020), Science and Technology Policy (2002), and the National Environmental Policy and Strategy (2009)

Science and Technology Policy

The science and technology policy of 2002 seeks to promote national scientific and technological self-reliance through a number of strategies. It also identifies agriculture, health, industry, energy and the environment as key sectors that require technological interventions.

Section 13 of the Science and Technology policy focuses on biotechnology. Biotechnology is perceived to be a tool with enormous potential to provide new products and services in human health, crop and livestock production, veterinary medicine, and pollution control. However, whilst the policy fully embraces biotechnology including modern biotechnology, it also underscores the need for putting in place measures to minimize the possible adverse effects of the technology to the health, safety and welfare of the public and the environment in general. Consequently, it calls for responsible and timely measures to be taken to ensure that the sovereignty of the country, the health and safety of the public, and the environment are protected, and that societal concerns about the impact of biotechnology are promptly addressed, while allowing biotechnology research to advance.

The Policy upholds Zimbabwe's commitments to the principles of the 1992 Rio Declaration on Environment and Development, and the aims and objectives of the Convention on Biological Diversity. It empowers the National Biotechnology Authority (formerly Biosafety Board) to:

- Enforce the provisions of the 1972 Biological and Toxin Weapons Convention
- Manage the application of biotechnology in all fields of human development
- Co-operate with relevant authorities in other countries to ensure the safe use of biotechnology in Zimbabwe

National Environment Policy and Strategy

The goal of the National Environmental Policy is to avoid irreversible environmental damage, maintain essential environmental processes, and preserve the broad spectrum of biological diversity so as to sustain the long-term ability of natural resources to meet the basic needs of people, enhance food security, reduce poverty, and improve the standard of living of Zimbabweans through long-term economic growth and employment creation.

The national environmental policy objectives include:

- To conserve biodiversity and maintain the natural resource base and basic environmental processes to enhance environmental sustainability
- To promote equitable access to and sustainable use of natural and cultural resources with an emphasis on satisfying basic needs, improving people's standards of living, enhancing food security, and reducing poverty
- To encourage sustainable development by optimizing the use of resources and energy, and minimizing irreversible environmental damage, waste production and pollution, through incorporating provisions for environmental impact assessment and management in all economic and development activities
- To promote public participation and a sense of responsibility for the environment through environmental education and awareness, and promoting environmentally sustainable life styles

2. National Biotechnology Regulatory Regime

Zimbabwe's regulatory framework on biosafety dates back to the early 1990s when the country's scientists approached the then Scientific Liaison Office in the Office of the President and Cabinet requesting that Government put in place legal measures to manage breakthroughs in molecular biology in particular modern biotechnology. The local scientists appreciated the critical role on cutting edge sciences like modern biotechnology in promoting human development. They however, realized the human health, environmental, national security and

socio-economic challenges that usually come with such breakthroughs. They felt that a standard code of practice without a legal framework would not provide the necessary safeguards in modern biotechnology practice. To fast track the regulatory process it was agreed to amend the Research Act, which was being administered by the Scientific Liaison Office, and allow it to provide for the regulation of modern biotechnology.

Consequently, the Research Act was amended in 1998 so as to provide for the management of potentially harmful technologies and undertakings through Safety Boards. To implement the new law, the Vice President developed and gazetted supporting regulations in 2000 – the Research (Biosafety) Regulations. By the end of 2000 institutional arrangements to manage the research, development, application, import, export, sale and use of modern biotechnology (genetic modification) and its products were in place. These interim arrangements allowed Zimbabwean scientists to undertake laboratory and field trials with genetically modified organism. This framework was also used to manage the import of food and feed containing GMOs.

When the UNEP/GEF project for building capacity for developing biosafety frameworks came on line, Zimbabwe applied for support with a view to revisit the interim national biosafety arrangements to come up with a more comprehensive and standalone regime. Using UNEP/GEF and Government support, a comprehensive national policy on biotechnology and its safe use was developed (2005) and a new Act of Parliament – the National Biotechnology Authority Act passed into law (2006).

The current national biotechnology regulatory regime (National Biotechnology Authority Act of 2006 and its supporting guidelines, regulations and standards) was developed as a means to implement the biotechnology and biosafety provisions contained in the National Biotechnology Policy and other national policy documents, and also to repeal earlier biosafety legal arrangements (The Research (Biosafety) Regulations of 2000. This Act transformed the Biosafety Board into the National Biotechnology Authority

Scope of the Law

The National Biotechnology Authority Act provides for:

- (a) all activities aimed at research, development, importation, exportation and use of biotechnological processes;
- (b) the import export, contained use, release or placing on the market of any products of biotechnological processes that are likely to have adverse effect on human health, environment, economy, national security and social norms and values;
- (c) any activity involving biological and molecular engineering technologies such as metabolic engineering, proteomics, metabolomics, nanotechnology, genetic modification, cloning, DNA-chip technology and bioinformatics; and such other technologies as may be declared by the Authority to constitute potentially harmful research or undertaking;
- (d) all measures aimed at minimising the impact of biotechnological processes on national security, human, animal and plant health, and the environment.

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. The general function of the Authority shall be to advise the Minister on all aspects concerning the development, production, use, application and release of products of biotechnology, and ensure that all activities with regard to such development, production, use, application and release are performed in accordance with this Act.

(1) The Authority shall have the following specific functions—

- (a) to evolve a long-term policy for safety in modern biotechnology in Zimbabwe;
- (b) to actively promote biotechnology research, development and application in Zimbabwe;
- (c) to review project proposals concerning high risk category organisms and controlled experimental trials involving them, and make decisions on whether to approve, prohibit or restrict such trials;
- (d) to review reports of all ongoing approved projects and controlled experimental trials involving high risk category organisms;
- (e) to approve deliberate releases of properly evaluated products of biotechnology;
- (f) to approve the large-scale use of products of biotechnology in industrial production and application;
- (g) to assist in the clearance of applications for setting up industries based on the use of products of biotechnology;
- (h) to monitor and approve the discharge of biological waste from laboratories and hospitals into the environment;

- (i) to ensure that biotechnology guidelines and standards are adhered to generally and in the execution of projects or controlled experimental trials involving high risk category organisms;
- (j) to recommend a training programme for biosafety officers;
- (k) to identify, prioritise and propose areas for standardisation of products of biotechnology to the Standards Association of Zimbabwe, the Medicines Control Authority of Zimbabwe, the Hazardous Substances Control Board and other relevant bodies;
- (l) to approve the safety aspects of the import, export, manufacture, processing and selling of any products of biotechnology, including substances, foodstuffs and additives containing products of genetic engineering;
- (m) to advise the customs authorities on the import and export of biologically active material and genetically engineered organisms, substances or products;
- (n) to collect and disseminate information pertaining to safety procedures associated with work on or research into modern biotechnology;
- (o) to establish contact and maintain liaison with bodies in other countries and international organisations concerned with monitoring work on or research into biotechnology;
- (p) to perform such other functions as are provided for in this Act.

(2) For the better exercise of its functions, the Authority shall have the power, subject to this Act, to do or cause to be done, either by itself or through its agents, all or any of the things specified in the Schedule either absolutely or conditionally and either solely or jointly with others.

(3) The Research Council of Zimbabwe shall maintain the overall responsibility for the promotion, direction, supervision and coordination of research in Zimbabwe and the Authority shall report to it from time to time at the request of the Council in relation to matters related to biotechnology research, development and application.

Board of Authority

(1) Subject to this Act, the operations of the Authority shall be directed and controlled by a board consisting of—

- (a) a chairperson and vice-chairperson appointed by the Minister; and
- (b) the Chief Executive Officer, *ex officio*; and
- (c) not fewer than four and not more than nine other members appointed by the Minister after consultation with the President and in accordance with any directions the President may give him or her.

(2) Of the persons appointed in terms of paragraph (c) of subsection (1)—

- (a) one shall be a member of the Health Professions Council employed by the Ministry responsible for health; and
 - (b) the remainder, as well as the chairman, shall be appointed for their expertise and experience in biotechnology research and development, environmental management, agriculture, business or administration and law.
- (3) Members of the board shall elect one of their number to be deputy chairperson of the Board.

Power of Board to regulate modern biotechnology practices

(1) The Board may, issue to persons owning or controlling facilities registered in terms of this Part, or carrying on any research or undertaking any activity that is permitted in terms of this Part, biotechnology guidelines and standards of practice and procedure that shall be binding on them and all users of products of biotechnology, and may revise them from time to time.

(2) The matters in respect of which the Board may issue biotechnology guidelines or standards include but are not restricted to—

- (a) the contents of risk assessments and environmental impact assessments referred to in section 25(1) (i) and (ii);
- (b) the classification or categorisation of organisms on the basis of the level of risk or degree of hazard, if any, attaching to each class or type of such organism; and the procedures for biotechnology research for each class or type of such organism;
- (c) the level of risk at which the prior approval by the Board for project proposals involving research into specified classes or types of products of biotechnology shall be required;
- (d) the requirements for the contained use of products of biotechnology and the types of containment facility appropriate to specified classes or types of such organisms;
- (e) the requirements for the laboratory development of biotechnology;
- (f) the standards to which facilities utilised for the development, production, use or application of biotechnology should conform;
- (g) the requirements for the general release and trial release of products of biotechnology;
- (h) the requirements for the effective management of biotechnology waste;
- (i) the procedures to be followed and control measures to be taken in the event of accidents, and the information required to be disclosed to the Authority on notification of any release or accident;
- (j) the requirements for the marketing of products of biotechnology;
- (k) the requirements and procedures for the importation and exportation of products of biotechnology that are likely to have an adverse effect on human health, the environment, the economy, national security and social norms and values;

- (l) the identities or classes of products of biotechnology exempted from control for the purposes of this Act;
- (m) generally, the control measures to be complied with by users of products of modern biotechnology;
- (n) the authorisation of persons by the Board for the purpose of enabling such persons to sell, market or utilise any class or type of product of biotechnology.

(3) The Authority may cause a notice to be published in the *Gazette* setting out any biotechnology guidelines and standards:

Provided that the publication in the *Gazette* of such biotechnology guidelines and standards shall be for public information only and their validity shall not depend on publication in the *Gazette*.

(4) Any person may inspect a copy of any biotechnology guidelines and standards issued in terms of subsection (1) free of charge at all reasonable times at the premises of the Authority or such other place as the Authority may direct.

(5) The Authority may, by notice in the *Gazette*—

- (a) prohibit any activity involving genetically modified organisms or its products; or
- (b) declare that any activities involving certain organisms shall constitute potentially harmful research or undertakings for the purposes of this Act.

(6) Any person who contravenes any biotechnology guideline or standard issued in terms of subsection (1) that is binding on him or her, or any prohibition referred to in subsection (5), shall be guilty of an offence and liable to a fine not exceeding level nine or imprisonment for a period not exceeding three years or both.

Register of facilities and permits

(1) The Authority shall establish a register for the purpose of—

- (a) registering facilities utilised for the development, production, use or application of biotechnology; and
- (b) recording permits issued for the utilisation of such facilities.

(2) The Chief Executive Officer of the Authority shall be responsible, subject to any directions given to him or her by the Board, for maintaining the register and ensuring that entries are made in the register recording—

- (a) the name, identity or description and such other particulars as required by the Authority of each facility which the Authority has directed shall be registered; and
- (b) the fact that a permit has been issued to any person to utilise the registered facility for the development, production, use or application of products of biotechnology, or to release such product into the environment, or that any such permit has ceased to be valid, and the name and address of the person concerned; and

- (c) the particulars of the cancellation or suspension of any registration or permit, and of the restoration of any such cancelled registration or permit, or the termination of any such suspension; and
- (d) any necessary corrections or alterations to any particulars or facts referred to in paragraph (a), (b) or (c); and
- (e) any other particulars that may be required by the Authority.

(3) Any person may inspect the register free of charge at all reasonable times at the premises of the Authority or such other place as the Authority may direct.

Certain facilities and research to be registered or permitted by Authority

(1) No person shall—

- (a) own or control any facility utilised or to be utilised for any potentially harmful research, or generally for the development, production, use or application of products of biotechnology, including any facility utilised or to be utilised in connection with the contained use or trial release of such products, unless such facility is registered; or
- (b) carry on potentially harmful research, or undertake the contained use or trial release of product of biotechnology, without a permit; or
- (c) carry on research or undertake any activity referred to in paragraph (b) otherwise than in a registered facility except in circumstances approved in a permit or in writing by the Authority.
- (d) without a permit, develop, produce, stockpile, acquire or retain, import or export any microbial or biological agents or toxins in quantities that have no justification for prophylactic, protective or other peaceful purposes; or
- (e) without a permit, enter into an agreement with any person so as to transfer any microbial or biological agents or toxins if the microbiological agents or toxins is likely to be used or kept otherwise than for prophylactic, protective or other peaceful purposes.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level fourteen or imprisonment for a period not exceeding ten years or both such fine and such imprisonment.

Application for and grant or refusal of registration or permission

(1) A person who wishes to—

- (a) own or control any facility utilised or to be utilised for any potentially harmful research, or generally for the development, production, use or application of product of biotechnology, including any facility utilised or to be utilised in connection with the contained use or trial release of such product; or
- (b) carry on any potentially harmful research, or undertake the contained use or trial release of product of biotechnology;

shall apply to the Chief Executive Officer in the form provided by the Authority and shall, in the case of an application for a permit, submit with his or her application—

- (i) an assessment of the risk; and
- (ii) an assessment of the impact on the environment;

involved in carrying on the research or activity in question.

(2) On receipt of an application made in terms of subsection (1) the Chief Executive Officer shall submit the application to the Board for consideration at its next meeting after the application was received.

(3) Within four months of receiving an application the Board may, after—

- (a) examining the conformity of the application to any applicable biotechnology guidelines and procedures; and
- (b) considering the assessments of risk and of the impact of the environment, if any, submitted in terms of subsection (1); and
- (c) conducting such inspections as it thinks necessary;

grant or refuse to grant the application or grant it subject to such conditions as it may impose.

(4) Any person who is aggrieved by a refusal of the Board to grant an application may, within thirty days, appeal to the Minister against such refusal in the form provided by the Authority, and the Minister on appeal may grant or refuse to grant the application or grant it subject to such conditions as he or she may impose.

(5) Where an application is granted or granted subject to conditions, the Chief Executive Officer shall, at the direction of the Board, make the appropriate entries in the register and confirm the registration in writing or issue the permit to the applicant or both, as the case may be.

(6) The Authority may register any facility or issue any permit for a fixed or indefinite period.

General duty of care to be observed by users of products of biotechnology

(1) Every user of products of biotechnology shall, in addition to the requirements of this Act and any biotechnology guidelines or standards, ensure that appropriate measures are taken to prevent or minimise any foreseeable danger to persons, animals or plants or to the environment generally that may arise from the use of such products.

(2) Any user of a product of biotechnology who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level five or imprisonment for a period not exceeding one year or both.

Notification of releases and accidents

(1) Subject to the terms of any permit, a user of a product of biotechnology shall notify the Authority both orally and in writing in advance of any general or trial release of such product, and shall not release such product until the Authority has approved the same in writing.

(2) A user of a product of biotechnology shall immediately notify the Authority both orally and in writing of any accident involving the product of biotechnology, and shall supply to the Authority with information on the circumstances of the accident, the identity and quantity of the product released, and any information necessary to assess the impact of the accident on the environment, including the emergency measures taken or needed to be taken to avoid or mitigate any adverse impact of such accident on the environment.

(3) Any user of a product of biotechnology who contravenes subsection (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level five or imprisonment for a period not exceeding one year or both such fine and such imprisonment.

Returns to be furnished by registered users

(1) Every registered user of a product of biotechnology shall, in the form and manner and within the time required by the Authority, furnish the Authority with such returns or other information in connection with his or her use of the product as the Authority considers will assist it in discharging its functions.

(2) Any registered user of a product of biotechnology who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level five or imprisonment for a period not exceeding one year or both such fine and such imprisonment.

Inspections

(1) Subject to subsection (3), the Authority or any member with the written authority of the Board may, at fixed intervals agreed with the registered user of a product of biotechnology or at any time without giving prior notice, enter upon and inspect the premises of any registered user to determine whether the provisions of this Act, any biotechnology guidelines or standards and the terms or conditions of any registration or permit are being complied with, and, for that purpose, the Board or member may—

- (a) inspect any activity or process carried out in or upon such premises in connection with the use of products of biotechnology;
- (b) request any information regarding any activity or process referred to in paragraph (a) from the registered user or any person carrying out or supervising such activity or process;
- (c) where it is suspected on reasonable grounds that any offence against this Act is being committed—
 - (i) seize any appliance, book, statement, shipping bill, bill of lading or other document and take samples of materials or substances, which may afford proof of such offence; or
 - (ii) require the registered user to produce any appliance, book, statement, shipping bill, bill of lading or other document, or any sample of any material or substance within a specified time and at a specified place.

(2) Subject to subsection (3), the Authority or any member with the written authority of the Board may, at any time without giving prior notice, exercise the powers specified in subsection

(1) in relation to any premises or place owned or controlled by a person other than a registered user where it is known or suspected on reasonable grounds that any potentially harmful research or undertakings to which this Act apply is being or will be carried on.

(3) The powers of entry, inspection and seizure conferred by this section shall not be exercised—

(a) in relation to the premises of any registered user except with his consent, unless there are reasonable grounds for believing that it is necessary to exercise them for the prevention, investigation or detection of an offence against these regulations, or for the obtaining of evidence relating to such an offence;

(b) in relation to any premises or place referred to in subsection (2) except in accordance with a search warrant issued in terms of section 50 of the Criminal Procedure and Evidence Act [*Chapter 9:07*].

(4) Any person who hinders or obstructs the Authority or any member in the exercise of the powers conferred by this section, or refuses to furnish any information, document or article required pursuant to the exercise of such powers, or furnishes information which he knows to be false or misleading or has no reason to believe to be true, shall be guilty of an offence and liable to a fine not exceeding level five or imprisonment for a period not exceeding one year or both such fine and such imprisonment.

Biosafety Committees

(1) At every biotechnology research institute there shall be established a committee, to be called a “biosafety committee” which shall consist of—

(a) a person familiar with the biosafety requirements of work involving biotechnology, to be called a “biosafety officer”;

(b) not less than three scientists with expertise in biotechnology:

Provided that the Authority may, in the absence of a sufficient number of scientists having relevant expertise at the biotechnology research institute, authorise the appointment of at least one scientist with expertise in biotechnology and two other scientists.

(2) The biosafety officer shall be the chairperson of the biosafety committee.

(3) The general function of a committee shall be to ensure that this Act, any biotechnology guidelines or standards, and the terms or conditions of any registration or permit are complied by all persons engaged in the work of the biotechnology research institute.

(4) A committee shall have the following specific functions—

(a) to consider project proposals by the biotechnology research institute;

(b) to approve project proposals that are below a specified level of risk;

(c) to refer to the Authority project proposals that are above a specified level of risk;

- (d) to devise an operating manual for the purpose of standardising safety and emergency procedures to be observed in connection with projects undertaken at the biotechnology research institute;
- (e) to keep a list of the project supervisors responsible for, and the records and files of, every project;
- (f) to ensure that there are provided suitable safe storage facilities of donor, vector, recipient and other materials involved in experimental work, and from time to time to inspect such facilities;
- (g) to provide annual reports to the Authority on the progress of ongoing projects;
- (h) to ensure that all personnel at the biotechnology research institute involved in project have adequate training in biosafety in accordance with such standards as the Authority may establish;
- (i) to monitor the health and safety of the personnel referred to in paragraph (h).

Project supervisors

(1) For each project there shall be designated by the biotechnology research institute a project supervisor approved by the committee as having the requisite competence, experience or qualifications for supervising the project participants and all aspects of the project.

(2) The project supervisor shall be responsible for describing the project proposal verbally and in writing to the committee.

(3) The project supervisor shall ensure that project participants are suitably trained for the tasks they will perform and that any operating manual referred to in paragraph (d) of subsection (4) of section 18 is complied with.

INSPECTORS OF AUTHORITY

Appointment and functions of inspectors

(1) The Authority may employ, upon such terms and conditions as may be determined by it and approved by the Minister, any person having suitable qualifications and experience to be an inspector.

(2) An inspector, if any is appointed, shall assume the functions of the Board referred to in section 29, and thereupon any reference in that section to the Board or any member of the Board shall be construed as a reference to such inspector:

Provided that—

- (a) the Authority shall not be divested of its power of inspection in terms of section 29; and
- (b) an inspector shall be subject to the control and direction of the Authority.

(3) Upon appointment an inspector shall be provided with a certificate signed by the Chief Executive Officer stating that he or she is an inspector, and shall, on request, exhibit such certificate to any person affected by the performance of the his or her functions in terms of this Act.

3.0 Administrative Arrangements

Section 7 of the National Biotechnology Policy and section 4 of the National biotechnology Authority Act provide for the established of the National Biotechnology Authority of Zimbabwe as the National Focal Point and Competent Authority for Biosafety. The National Biotechnology Authority of Zimbabwe is comprised of the National Biotechnology Board, the agency headed by a Chief Executive Officer and an inspectorate. To help the Authority execute its mandate, it is empowered to establish committees to perform some of its functions. In addition, Biosafety Committees are established at every biotechnology research institute reporting to the Authority.

The National Biotechnology Board, which includes the Chief Executive Officer of the Authority is appointed by the Minister responsible for Science and Technology Development in consultation with The President.

4.0 Decision Making System

Section 5 of the National Biotechnology Authority Act provides powers to the National Biotechnology Board to advise Government on all aspects concerning the development, production, use, application and release of Living Modified Organisms, and to ensure that such activities are performed in accordance with the law. Section 25 of the same Act provides for the application for and grant or refusal of registration or permission. An applicant is required to tender an application for a permit to the Chief Executive Officer of the Authority. In addition, the applicant is also required to submit with their application a risk assessment and an environmental impact assessment dossier. The Chief Executive Officer will then submit the application to the National Biotechnology Board for consideration at its next meeting. The Board would then examine the conformity of the application to any applicable guidelines and standards, consider the risk and impact assessments, and after conducting such inspections as

necessary , grant or refuse to grant the application or grant it subject to such conditions as it might impose.

Any person who is aggrieved by the decision of the board may appeal to the Minister. The Minister on appeal may grant or refuse to grant permission, or grant it subject to such conditions he/she might deem fit, or cancel or re-affirm the conditions.

5.0 Mechanisms for Monitoring and Enforcement

Section 5 of the national Biotechnology Authority Act empowers the Authority to monitor work involving high risk category organisms. Section 28 of the same Act requires that registered users of permit holders report to the Authority in a manner and frequency determined by the Authority. Section 30 empowers institutional biosafety committees at a biotechnology institution to monitor biotechnology work on behalf of the Authority.

Sections 32 of the Act provides for the appointment and functions of the Authority's inspectors. Section 33 provides for the enforcement and monitoring work of inspectors of the Authority.

6.0 Mechanisms for Public Awareness and Participation

Section 6.7 of the National Biotechnology Policy highlights the lack of public understanding of biotechnology and the issues surrounding it. It argues that this has resulted in a negative backlash in many regions of the world. The issue of GMO food aid is said to have raised a lot of controversy in Zimbabwe and other parts of the Southern Africa region. The uncertainties regarding the trade related issues are also a cause for concern. It is further argued that this situation can only be solved through improved communication and better understanding of the possible impacts of the technology on the human well being and the country's economy.

The policy therefore calls for a single biotechnology vision for the country and continuous dialogue amongst stakeholders. These dialogues should be supported by scientific evidence. To enhance the broader understanding, biotechnology should be included in school curriculum. Encouraging debate on the potential benefits, risks and ethical and environmental issues will help create public awareness on the technology. The media, it is underscored, must be provided with unbiased information and encouraged to convey issues to the public in a responsible manner.

Section 59(h) empowers the Minister responsible for the Act to develop regulations to support the provisions of international agreements on ensuring public participation in any aspect in which public participation is necessary or desirable. It also calls for the development of regulations on initiatives and steps regarding research, education, training, raising awareness and capacity building.

7.0 Capacity Building Plan

Although the comprehensive National Biosafety Framework is now in place, there are a number of capacity limitations that are still to be addressed if the country is to ensure the effective implementation of the framework. These include:

- Building a critical mass of risk assessors through risk assessment training
- Building a critical mass of inspectors through training
- Developing supporting regulations for the National Biotechnology Authority Act
- Developing guidelines and standard operating procedures for contained/field trials and deliberate releases
- Building laboratory and skills in LMO detection and identification
- Developing instruments for public participation
- Creating awareness and education on the safe use, handling and transfer of LMOs