REPUBLIC OF RWANDA

NATIONAL STRATEGY FOR IMPLEMENTATION OF BIOSAFETY FRAMEWORK

SEPTEMBER 2020

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LIST OF ACRONYMS AND ABBREVIATIONS

AU	African Union
CPB	Cartagena Protocol on Biosafety
CSO	Civil Society Organisation
CBD	Convention on Biological Diversity
CoEB	Center of Excellence in Biodiversity and Natural Resources Management
DNA	Deoxyribonucleic Acid
BRD	Development Bank of Rwanda / "Banque Rwandaise de Développement"
EAC	East African Community
GMO	Gender Monitoring Office
INES	Institute of Applied Sciences
IBC	Institutional Biosafety Committee
LMO	Living Modified Organisms
MINAGRI	Ministry of Agriculture and Animal Resources
MINEDUC	Ministry of Education
MoE	Ministry of Environment
MINECOFIN	Ministry of Finance and Economic Planning
MoH	Ministry of Health
MINISANTE	Ministry of Health
MINICT	Ministry of ICT and Innovation
MININFRA	Ministry of Infrastructure
MINIJUST	Ministry of Justice
MINALOC	Ministry of Local Government
MIFOTRA	Ministry of Public Service
MINICOM	Ministry of Trade and Industry
M&E	Monitoring and Evaluation
MEA	Multilateral Environmental Agreements
NAEB	National Agricultural Export Development Board
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NCST	National Council for Science and Technology
NIRDA	National Industrial Research and Development Agency
NISR	National Institute of Statistics Rwanda
NST1	National Strategy for Transformation
NGO	Non-Governmental Organisation
PSF	Private Sector Federation
rDNA	Recombinant Deoxyribonucleic Acid
R&D	Research and Development
RAB	Rwanda Agriculture Board

RALIS	Rwanda Agriculture Livestock Inspection and Certification Services
RBC	Rwanda Biomedical Centre
RDB	Rwanda Development Board
REB	Rwanda Education Board
REMA	Rwanda Environment Management Authority
Rwanda FDA	Rwanda Food and Drugs Authority
RGB	Rwanda Governance Board
FONERWA	Rwanda Green Fund (Fond National de l'Environnement au Rwanda)
RISA	Rwanda Information Society Authority
RICA	Rwanda Institute for Conservation Agriculture
RLUMA	Rwanda Land Management and Use Authority
RNP	Rwanda National Police
RRA	Rwanda Revenue Authority
RSB	Rwanda Standards Board
SSPs	Sector Strategic Plans
SDGs	Sustainable Development Goals
UN	United Nations
UNEP	United Nations Environment Programme
UNCED	United Nations Conference on Environment and Development
UR	University of Rwanda

i. PREFACE

With the awareness that there are potential adverse effects on human health, environment and socio-economic well being resulting from biotechnology applications, particularly the deliberate or accidental release of genetically modified organisms (GMOs), the Cartagena Protocol on Biosafety was signed in Montreal, Canada in May 2000, to ensure the safe development, transfer and use of modern biotechnology products.

As a Party to the Cartagena Protocol on Biosafety, the Government of Rwanda (GoR) has prepared a biosafety law to regulate the development and application of GMOs in Rwanda, including the transit of GMOs through Rwandan territory. This strategy is developed to support the operationalisation of the legal and regulatory framework. Indeed, this strategy has been developed in line with Rwanda's national Environment and Climate Change Policy. It will support the implementation of its second policy objective "Enhancing functional natural ecosystems and managing biosafety", and especially its fifth policy statement which is ensuring biosafety and the cautious adoption and use of biotechnology.

This strategy has been developed for scientists, project supervisors and administrators, regulatory enforcement agents, and all stakeholders involved in conducting genetic manipulation activities, including the importation into and transit through Rwanda. It must be used and followed by all researchers, business people or their agents, regulatory agencies and policymakers as well as institutions and organisations, national and international, involved in genetic manipulation, including transit.

This strategy takes into consideration and is harmonious with the current Environment and Climate Change Policy objectives.

The biosafety in GMOs application is being formulated at a time when biotechnology activities are already on-going in many countries in the world and increasing in Rwanda. It is therefore anticipated that this strategy will be regularly reviewed to make it more effective and efficient due to the dynamism of emerging and future developments in biotechnology and biosafety - in the country and beyond. Thus, appropriate mechanisms will be put in place to facilitate provision for suggestions for modifications and improvement from all stakeholders involved.

ii. GLOSSARY OF TERMS USED

1° **Advance Informed Agreement (AIA)**: agreement, received by the State of Import, prior to the first intentional transboundary transfer, of all necessary information, which engages the full responsibility of the State of Export for the accuracy and comprehensiveness of said information;

2° **applicant**: a person submitting an application pursuant to the provisions of this Law;

3° **application**: submission to the Competent National Authority, of documents containing the required information, with, where applicable, samples attesting the full responsibility of the successful applicant for the accuracy and comprehensiveness of the information submitted;

4° **biological diversity**: the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;

5° **Biosafety Clearing House**: the information exchange mechanism established under the Cartagena Protocol;

6° **Cartagena Protocol**: the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

7° **Competent National Authority**: the entity responsible for the implementation of this strategy;

8° **confined field trials**: an experimental release of a living modified organism into the environment under physical and biological confinement conditions, that effectively limit their impact on human and the environment;

9° **contained use**: 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 the external environment;

10° **damage**: an adverse effect on the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, that:

a) is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines recognized by the Competent Authority that take into account any other human-induced variation and natural variation; and

b) is significant;

11° **ecosystem**: a dynamic complex of plant, animal and microorganism communities and their non-living environment interacting as a functional unit;

12° **export:** the intentional transboundary movement from the area of Rwanda to another country;

13° **food or feed product**: a living modified organism or its product that is used as food or feed, or for processing and is primarily intended for consumption by humans or animals or for the consumption of both humans and animals;

14° **import**: the intentional transboundary movement into Rwanda from another country;

15° **intentional Introduction into the Environment**: any deliberate use, that is not contained use, of living modified organisms subject to this Law and does not include living modified organisms imported for direct use for food or feed or for processing;

16° **living modified organisms (LMOs)**: any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

17° **living organism**: any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses, and viroids;

18° **Minister**: the Minister responsible for Environment;

19° **modern biotechnology**: 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) the 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;

20° **operator**: any person in direct or indirect control of the living modified organism which could, as appropriate and as determined by domestic law, include, *inter alia,* the permit holder, person who placed the LMOs on the market, developer, producer, notifier, exporter, importer, carrier, or supplier;

21° **permit**: authorization granted to an applicant to conduct activities allowed under this law;

22° **permit holder**: a person granted a permit to conduct activities authorized or otherwise allowed under this Law;

23° **person**: any legal or natural individual;

24° **principal investigator:** a trained scientist with thorough knowledge in the codes, regulations and laws applicable to biotechnological work and exhibits an appreciation for the biosafety concerns and is recognized by the institution or organization as the Principal Investigator (PI);

25° **products thereof**: processed materials that are of a living modified organism origin containing detectable novel combinations of replicable genetic material obtained through the use of biotechnology;

26° **register**: the compilation of living modified organisms or activities that are authorized, exempted or subject to simplified procedures in accordance with this Law and regularly published by the Competent National Authority pursuant to the Law;

27° **response measures**: reasonable actions to:

a) prevent, minimize, contain, mitigate, or otherwise avoid Damage, as appropriate; or

b) restore Biological Diversity through actions to be undertaken in the following order of preference:

(i) restoration of Biological Diversity to the condition that existed before the Damage occurred, or its nearest equivalent; and where the Competent Authority determines this is not possible;

(ii) restoration by, inter alia, replacing the loss of Biological Diversity with other components of Biological Diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location;

28° **risks to human health**: the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of Biological Diversity;

29° **significant**: an adverse effect that results in long-term or permanent change, in other words, change that does not have the capacity to self-correct naturally, within a reasonable period of time;

30° **socio-economic considerations**: considerations arising from the impact of living modified organisms on the conservation and sustainable use of Biological Diversity, especially with regard to the value of Biological Diversity and local communities.

1.0 Introduction

1.1 General Overview

Nowadays, modern biotechnology is applied in the fields of agriculture, food and feed production and supply, industry, health care (human and animal), and environmental protection, notwithstanding the global debate surrounding its negative impacts. It is also to be noted that biotechnology is not new. Traditional biotechnology has, in fact, been in use for centuries - notably in brewing and fermentation industries and in the production of animal vaccines. The major exception with modern biotechnology is that it covers, among others, cell and tissue culture, monoclonal antibodies, and recombinant DNA (rDNA) or "genetic engineering" techniques, which has made it more complex with increased precision and shorter time required in producing results.

The development of new techniques of genetic modification in the early 1970s introduced a new dimension to biotechnology. Scientists can now recombine DNA from different organisms, giving rise to Genetically Modified Organisms (GMOs). Recombinant DNA (rDNA) organisms are derived by introducing a section of DNA from a "donor" organism to a "recipient" organism. The genome of the recipient organism is, therefore, modified.

While recognising the potential benefits of this new molecular technique which allows a greater diversity of genes to be introduced into organisms, the relative lack of familiarity with such modified organisms and the gaps in knowledge as regards the effect of interaction of these GMOs with the environment, make it necessary to institute measures to ensure that biotechnology is developed in a precautionary and judicious manner. The results of this modification need to be assessed for risks to human health, conservation of biodiversity and the environment before the intentional release of the modified organism.

This strategy is developed in line with the precautionary approach principle in the use of modern biotechnology and the risks inherent thereto. The guidelines contained in this strategy seek to provide appropriate regulatory measures to assist all stakeholders in the establishment and maintenance of national and institutional capacities to provide for safety in biotechnology, development of expert human resources, coordination, and efficient exchange of information.

1.2 Developments, Applications of Biotechnology and Anticipated Associated risks

Biotechnology development in Rwanda is still limited compared to developed countries and some developing countries. However, biotechnology applications are increasing - especially those that relate to importation into and transit through Rwanda. Genetic manipulation work including embryo transfer and plant breeding is increasingly being developed or planned in key national research institutions. These future applications of biotechnology necessitate putting in place stringent biosafety measures. It is being assumed and anticipated that only the low risks will be accepted in handling and treating all related applications.

2.0 Rationale, Objectives, Guiding Principles And Linkages With Development Agenda

2.1. Rationale and General Context

Rwanda is one of the more than 170 countries that have ratified and are signatories to the United Nations Convention on Biological Diversity (CBD) adopted at the United Nations Conference on Environment and Development (UNCED), codenamed "*The Earth Summit"*, held in Rio de Janeiro, Brazil in 1992 at which Agenda 21 was adopted. Both Agenda 21 and the CBD recognize that biotechnology is essential for the attainment of conservation and sustainable use of biological diversity, particularly in agriculture, food and feed, healthcare, and environmental management but strongly caution that its development and application be pursued judiciously.

The CBD and in particular, Article 8 (g), encourages Parties to the Convention to "establish and/ or maintain means to regulate, manage, or control the risks associated with the use and release of genetically modified organisms (GMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity taking into account risks to human health".

Further, in Article 19 (3), the CBD calls upon Parties "to consider the need for and the modalities of a protocol setting out appropriate procedures, including, in particular, Advance Informed Agreement (AIA) for the safe transfer, handling and use of any GMOs resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity". Article 19(4) makes it obligatory for Parties "to directly or indirectly provide available

information about the use and safe regulations required by these Parties in handling such organisms as well as any available information on the potential adverse impact of the specific organism to the receiving Party".

To facilitate the implementation of the aforementioned objectives, the Cartagena Protocol on Biosafety (CPB) was adopted in Montreal, Canada in May 2000. Rwanda signed the Protocol in 2002. The Protocol, among others, spells out the transboundary movement of GMOs resulting from modern biotechnology that may have effects on the conservation and sustainable use of biological resources, and the adoption of the appropriate procedure for Advance Informed Agreement (AIA).

In order to fulfill Rwanda's commitments under the CPB, and to achieve the goals of ensuring sustainable development while protecting the environment, the Government of Rwanda (GoR) has formulated a draft Biosafety law. Recognizing the complexity of the requirements of safe transfer, movement, and use of biotechnology in Rwanda, this strategy has been prepared to be used by the GoR and other stakeholders as referral guidance. It is also in line with the implementation of Environment and Climate Change Policy.

2.2 Objectives and Guiding Principles

2.2.1 Objectives

Mindful of the precautionary principles embodied in Agenda 21, the CBD and the CPB, this strategy intended to implement the provisions of the current policy on Environment and Climate Change.

It will provide a general framework for safety in research, development, release, trans-boundary movement, use and application of biotechnology products containing organisms with novel traits. It is based on the precautionary principle which emphasizes that preventive action should be taken to preserve, protect and improve the environment and human health irrespective of whether or not such concerns are justified by available scientific data.

The overall objectives of this strategy are to:

(i) Ensure and guarantee public and environmental safety with regard to accident prevention, containment and waste disposal when GMOs are utilized in research and development (R&D) as well as industrial production processes.

(ii) Determine the measure for risk assessment, monitoring, evaluation and reduction in all operations involving GMOs or any other processes of biotechnology, including but not limited to the prescription of appropriate conditions for the use of biotechnology and its products.

(iii) Promote biosafety in the application and exploitation of innovative biotechnology products for the general wellbeing of humanity.

In general, the strategy seeks to facilitate the establishment and development of national capacities to assess and manage potential risks associated with Biotechnology. This would be specifically achieved by:

(a) Assessment and identification of priorities in human resources development and the implementation of national capacity building programmes for biosafety.

(b) Development and establishment of a comprehensive and up-to-date scientific database, infrastructure for information exchange upon which risk assessment and evaluation of products can be made and mechanisms for effecting AIAs;

(c) Strengthening research and development (R&D), industrial applications, commercialization and the risks associated with the application of GMOs. The strategy addresses human and environmental safety of all types of applications of biotechnological products containing or consisting of organisms with novel traits including but not limited to GMOs. It further recognizes and addresses the need for such products to comply with any specific product requirements such as food safety, efficacy and acceptable risks before their release into the environment.

(d) Intellectual property rights and traditional knowledge
(e) Biodiversity conservation and utilization
(f) Biosafety funding and mobilization of resources
(g) Promotion of public awareness on Biosafety through initiatives involving the community, policy makers, legislators, gender, partnership, the private sector and the industry.
(h) Gender considerations
(i) Linkages and partnerships
(j) Legal, institutional framework and enabling environment
(k) Regulations, guidelines and safety operating procedures for the research, manufacture, transportation, and handling, accident prevention, release, containment, and waste disposal and end-use of biotechnology products.

(l) Promotion and use of regular monitoring to verify the assumptions made in risk assessment and to evaluate whether the recommended risk management procedures are appropriate and effective.

(m) Bioethics and conduct

2.2.2. Guiding Principles

The fundamental principles guiding the formulation and implementation of the biosafety strategy is informed by the historical antecedents and a growing body of knowledge and experience at the global level. The principles are:

- *The precautionary principle:* It is a principle which was adopted at the Earth Summit of 1992 and holds that, when a biotechnological activity such as the transfer, handling and use of living modified organism, has the prospect of threat to the environment or human health, precautionary measures will be taken even if some cause and effect relationship is not yet fully established scientifically.

- *Ethical considerations*: Ethical issues are important when research touches the lives, welfare, interests, and privacy of people and their value systems. Therefore, implementation of this strategy will be sensitive to the ethical persuasions of the Rwandan society.

- *Alignment with the national development objectives:* This strategy aligns with the national development goals and is thus an integral component of the mechanisms towards attaining Rwanda's socio-economic development agenda and visions.

- *Access to information and inclusiveness*: A participatory approach to biosafety will guide decision-making in biotechnology development and application. Effective stakeholder engagement particularly women and youth in decision-making is essential and will be encouraged.

- *Institutional, regional and international collaboration*: Global innovation system for biotechnology development is essential to the effective implementation of this strategy. As such, linkages, collaboration and strategic partnerships with critical stakeholders including governments, scientific institutions and development partners to enhance the development of biotechnology and biosafety capacity in the country will be extensively explored.

- *Dynamism*: This strategy is a living document. Thus, it will be subject to review and update in light of national priorities and international trends in the development, application and management of biotechnology.

2.3. Benefits of the Strategy and Opportunities

This strategy will enable Rwanda to engage in, and safely use, modern biotechnology for national development. It also takes into account the implementation of international conventions and agreements including the Cartagena Protocol on Biosafety to which Rwanda is a signatory.

This strategy supports biotechnology development by establishing the institutional framework and regulatory mechanisms for sustainable socio-economic development. In providing the mechanisms for use of modern biotechnology, the Strategy emphasizes a strong focus on safety and sustainable use, freedom of choice for the individual and ethical acceptability. Overall, this strategy will create a good and enabling environment for the effective and sustainable utilization of bio-resources. These developments will ultimately lead to sustainable socio-economic development.

This strategy will have a positive impact on several sectors of the national economy in which biotechnology is applied. Biotechnology has applications in four major areas namely medical, agriculture, industrial and environmental.

2.3.1. Biotechnology in Health Care

The importance of biotechnology for health care is expected to increase due to the production of rapid diagnostics tools for the detection of diseases and possibly assist in gathering information on occurrence of hereditary diseases which may not have manifested yet. Beneficial impacts of biotechnology in the health sector ranges from new techniques in diagnostics, therapeutics, to development of new medicines and products, which include vaccines and plant medicines. More so, developments in the mapping of the human genome promises discovery of new cures that would have impacts on vector-dependent endemic diseases and other chronic ailments in the society.

2.3.2. Biotechnology in Agriculture

Rwanda is predominantly an agricultural country hence the economy, food and nutrition security are derived primarily from agricultural activities. The main farming activities are crop and livestock production.

Biotechnology applications can help to contribute in addressing increased food security needs and growth income in the country. These include plant tissue culture techniques to mass propagate the disease-free planting materials, generating disease diagnostic tools for economically important plant and animal diseases, accelerating plant and animal breeding through the use of molecular markers. In the field of plant improvement and cultivation (including forestry) this development in knowledge means that the genetic origin of valuable characteristics can be quickly identified. This knowledge can also be used in animal breeding for direct selection of desired genotypes for breeding animals.

2.3.3. Biotechnology in Industry

In industry, biotechnology is being used in production of various multi-purpose plants such as medicinal plant exploitation, production of different processed products such as beer, juice, yoghurt, etc. Biotechnology is also being used in production of bio-energy (biogas) and wastewater treatment. With the development of this enabling strategy, it is being anticipated that the national industry sector will benefit from the knowledge derived from biotechnology applications.

2.3.4. Biodiversity, Natural Resources, Environment and Climate Change

Rwanda is endowed with rich genetic resources (plants, animals and microorganisms). However, increasing pressure on these resources due to human activities has disrupted the balance between human consumption and natural regeneration, leading to loss of biodiversity and degradation of the environment.

Modern biotechnology can assist with genetic fingerprinting of plant and animal species to preserve endangered species through biochemical control of pests and diseases, cloning of the species, and harnessing plants to produce biofuel, a more environmentally friendly energy source. Modern biotechnology also brings new plant species which are water efficient and drought resistant. Those new species can be adopted for climate change adaptation programs.

There are various ways in which biotechnology can contribute to environmental sustainability. These include, but are not limited to,

biotechnology applications in waste management such as the enhanced decomposition of organic waste; and bioremediation to ensure the restoration of environmentally degraded ecosystems. Polluted water bodies can also be restored through the application of biotechnology. Biotechnology provides tools for characterization and aquaculture.

Consequently, the environment and climate change sector will benefit from the application of biotechnology.

2.3.5. Capacity Building, Research and Development

Genetic manipulation work including embryo transfer and plant breeding is increasingly being taught in institutions of higher learning in Rwanda with anticipated future applications of biotechnology in key national research institutions thus necessitating putting in place a biosafety implementation strategy.

Research generates technology and technology creates wealth, food security, good health and environmental protection. Research and development would be a critical component of biotechnology development in Rwanda. As mentioned previously, the status of biotechnology in Rwanda is still at embryonic stage, lagging behind in the EAC region, with dependency risk in the long term. However, the vision of the country is to embark in modern biotechnology, by undertaking research on third generation biotechnology and becoming a leader in the technology. Achieving that requires highly trained and specialized scientists, modern high-tech equipment, new infrastructure, substantial funding, and new regulations. It is thus clear that the development of this strategy creates an enabling framework for capacity development to have a critical mass of experts among the relevant stakeholders at the national level and beyond.

2.4. Linkages with national and global development agenda

2.4.1 Linkages with national strategic orientations

This strategy aligns with existing national development orientations to further enhance the achievement of the identified objectives. Specific areas of alignment are further highlighted as follows:

Constitution of the Republic of Rwanda of 2003 (revised in 2015)

The Constitution of the Republic of Rwanda of 2003 (revised in 2015) provides for the binding legal framework which guides this strategy. This strategy aligns with the articles 21, 22, 45, 53, 95 and 168.

Vision 2050 Aspirations

The Vision 2050 aims at ensuring a high-quality standard of living for all Rwandans. While targeting attainment of upper middle-income country status by 2035 and high-income status by 2050.

Vision 2020

The aim of Vision 2020 is to achieve transformation into a middle income nation in which Rwandans are healthier, educated, generally more prosperous and competitive both regionally and globally. To achieve this, Vision 2020 identifies six interwoven pillars, namely good governance and an efficient State, skilled human capital, vibrant private sector, world class physical infrastructure and modern agriculture and livestock, all geared towards prospering in national, regional and global markets. The Vision 2020 recognized modern agriculture, science and technology as critical areas of focus. Thus, modern biotechnology is one of such developmental tools to be safely harnessed to achieve the objectives of Vision 2020.

National Strategy for Transformation (NST1)

In the medium term, the National Strategy for Transformation, NST1/Seven Years Government Program (2017-2024) sets the priority for economic and social transformation among others. The Economic Transformation Pillar presents a strategy to accelerate private sector-led economic growth and increased productivity. Modern biotechnology as a tool would contribute to the achievement of identified priorities including creation of decent and productive jobs, acceleration of sustainable urbanization, establishment of Rwanda as a globally competitive knowledge-based economy, promotion of industrialization and attainment of a structural shift in the export base to high-value goods and services, modernization and increasing productivity of agriculture and livestock as well as promotion of sustainable management of the environment and natural resources. Some of the priorities for social transformation that would be met through the safe application of modern biotechnology include but not limited to eradication of malnutrition through improved nutrition and food security, access to income for improved livelihoods and to quality health.

Environment and Climate Change Policy

The policy objective two of the Environment and Climate Change Policy aims to "enhance functional natural ecosystems and manage biosafety".

It recognises that a key pillar in biosafety considerations is the Precautionary approach of the Cartagena Protocol, and this should be a vital guide in making decisions regarding biosafety and genetically modified organisms (GMOs).

Modern biotechnology that involves the use of genetic engineering techniques to transfer useful characteristics creates enormous opportunities for agriculture development, industrialization and environment protection. However, there is a need for the cautious adoption to contain negative impacts associated with its use.

The Environment and Climate Change Policy further notes that Rwanda, being a signatory to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, will need to put in place specific and adequate measures. This strategy therefore, aligns with the following policy actions:

- Establish and implement biosafety regulations
- Strictly regulate transboundary movement of genetically modified organisms and products and encourage the development of improved crop varieties and animal breeds under ethical research environments.
- Promote public awareness on biosafety through initiatives involving the community, policy makers, legislators, administrators and the private sector.

Biodiversity Policy

The target 12 of Biodiversity Policy specifically expects that by 2020, the potential risks resulting from modern biotechnology use and placement on the market of its products would have been minimized and/or eliminated. The establishment of a legal framework on biosafety is deemed critical for this target.

National Industrial Policy

National Industrial policy aims to increase domestic production for local consumption, improve Rwanda's export competitiveness and create an enabling environment for Rwanda's industrialization in order to achieve targeted competitive status. To this end, Rwanda must build and acquire appropriate science, technology, innovation, entrepreneurial, engineering, and technical/vocational capacity to produce more value-added goods and services.

Agriculture Policy

The agriculture policy seeks to promote new strategies that will stimulate productivity growth for a broadened base for nutritious food production, in order to secure further reductions in rural poverty, and transform the largely subsistence farming sector into a competitive and market-led agriculture sector. It also aims to develop and promote sustainable agricultural intensification and a resilient agricultural sector to counter environmental degradation and climate change in ways that maintain sustainable agricultural growth.

Science, Technology and Innovation Policy

It seeks to integrate science, technology, scientific research and innovation in a framework that shall include capability building, technical transfer initiatives, and the promotion of innovation, in the context of the issues facing Rwanda. Science, technology and scientific research shall therefore serve as a catalyst to underpin all public and private sector activities to enable Rwanda's Visions 2020 and 2050 to be realized.

Health Sector Policy which envisions having strong and vibrant research designed both to support evidence-based decision-making for an enhanced and sustainable national health system, and to inform and improve health outcomes in Rwanda and around the world.

2.4.2. Linkages with key global instruments

There are established linkages of this policy with regional and global commitments such as the Sustainable Development Goals (SDGs) 2030, Convention on Biological Diversities (CBD) and its protocols, African Union Agenda 2063 and EAC Vision 2050.

Sustainable Development Goals

In September 2015 world leaders agreed on 17 global goals for sustainable development. The 17 SDGs have built on the successes of the proceeding Millennium Development Goals and came into force on January 1, 2016. The goals with associated targets and indicators across a range of biotechnology-related socio-economic developmental aspects, include but not limited to, SDGs 1, 2, 3, 8, 9, 12, 13, 14, 15, 17.

Convention on Biological Diversities (CBD) and its protocols

Rwanda is a party to the Convention on the Biological Diversity (CBD), which was signed on June 6, 1992, and ratified on May 29, 1996 by Rwanda. Rwanda also signed the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity on May 24, 2000 and ratified the same on July 22, 2004. This strategy aligns with the provisions of the CBD and its protocols.

African Union Agenda 2063

The African Union Agenda 2063 and its First 10-Year Implementation Plan (2014-2023) seeks to build an integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the international arena. Specifically, this strategy aligns with aspiration 1 and goals 1, 2, 3, 4, 5 and 7.

EAC Vision 2050

The East African Community (EAC) Vision 2050 adopted in February 2016, is a regional vision for socio-economic transformation and development. The six pillars of the EAC Vision 2050 are infrastructure development; agriculture, food security and rural development; industrialization; natural resources and environment management; tourism, trade and services development; and human capital development. This strategy touches on all six pillars while having strong linkages with Pillars 2, 4, 5 and 6.

3.0. Scope And Coverage

3.1. General Coverage

This strategy shall cover all research and development activities related to field testing/ trials of genetically manipulated plants, animals and microorganisms. It should be noted that traditional biotechnology applications in Rwanda exist, even though not at the scale of developed countries, and these include such applications as bread making; yogurt; beer and wine brewing; hybrid maize, rice and potato breeding; banana tissue culture; artificial insemination and embryo transfer in animals; and use of hormones, among others. These biotechnology applications are not uncommon in Rwanda, and their regulation is handled by different institutions, such as RAB, Rwanda Standards Board (RSB), RBC, MINEDUC, MINAGRI, Rwanda FDA and others.

On the other hand, however, modern biotechnology which uses recombinant DNA or rDNA[1] is handled by a number of public and public institutions, at a limited scale (such as RAB), which operate without clear guidelines on safety standards. This has, in line with the relevant legislation and the Cartagena Protocol, raised the need for biosafety strategy in which relevant procedures are prescribed to ensure safety.

Specifically, this national Biosafety strategy will address the following aspects of R&D:

(a) Safety in genetic transformation of microorganisms, plants and animals.
(b) Safety in rDNA technology in different products development.
(c) Large scale production and deliberate or accidental release of GMOs and products derived there from.
(d) Appropriate measures to avoid adverse effects on human health, biodiversity and the environment, which might arise from the deliberate or accidental release of GMOs.
(e) Recommendations for regulatory measures to ensure safety for export, importation and use of GMOs and other biotechnology products.
(f) Liability and redress in the use, handling, transportation of GMOs.

The strategy shall deal essentially with the following issues:

1. Notification and Authorization: – covering procedures for the Advanced Informed Agreement, Acknowledgement, Decision making and Review of decisions.
2. Risk Assessment: – involve the identification of possible hazards and the projection or estimation of the combined consequences of the hazard and the likelihood of the actual occurrence of such hazard.
3. Risk Management – guided by the result of the risk assessment, it involves the application of adequate management strategies, procedures and methods to minimize the risks and their consequences or complete cancellation of the project.
4. Institutional framework, biosafety regime and Capacity Building: – essentially entails human resource development, adequate funding, provision and maintenance of appropriate infrastructure to implement the recommendations contained in the strategy.

[1] Where molecules developed outside living cells are joined to natural or synthetic DNA segments resulting in the replication of the new DNA.

3.2 Coverage of Fieldwork and Planned Release

As a requirement of the Rwandan Biosafety law, and as is the standard practice internationally, genetically manipulated organisms from laboratory work must be field tested before planned release into the environment or commercial application. The purpose of such genetic manipulation fieldwork embraces, among others, the following:

(i) to confirm the observations made during laboratory work, and the results from tests conducted at the laboratory level;

(ii) to gather accurate information / data on the stability, transmission/ heredity and expression of transgenes under field conditions;

(iii) to express the viability (e.g. survival, propagation, competitive ability) of genetically manipulated organisms under field conditions;

(iv) to assess the adaptability or evolutionary potential of genetically manipulated organisms under Rwandan field conditions.

Unless otherwise notified, all testing for purposes of biosafety risk assessment and certification, will be undertaken at designated and gazetted national biotechnology laboratories in Rwanda.

4.0. Notification And Decision Making Process

4.1. Notification

4.1.1. General

(a) Applications for the movement of GMOs into Rwanda shall be on Advance Informed Agreement (AIA). For the purpose of compliance with the provisions of the Guidelines, notification shall cover importation, exportation, research and development activities. In the case of importation, notification should be prior to the first intentional transboundary movement for all that fall within the scope of the strategy and should address the relevant information contained in Annex 1.

(b) Notification should be sent to the Registrar, who acts as the NBC Secretariat, using the appropriate form[2]. The Party of export shall ensure that legal requirements for the accuracy of information provided by the exporter are met.

4.1.2 Notification and Authorization of Transit

(a) Any person wishing to use Rwanda's borders for transit purposes in connection with the transboundary movement of GMOs shall notify the CNA in writing.
(b) A Written consent, stating the conditions under which transit is granted, must be obtained before the transit can take place.
(c) Failure to acknowledge receipt of the request for transit shall not be regarded as consent. The CNA shall, however, endeavour to acknowledge notification and any information received in writing, as promptly as possible.

4.1.3 Acknowledgement of Notification

(a) Acknowledgement of notification shall be made in accordance with the details as may be set out from time to time by the National Biosafety Committee (NBC) through the Competent National Authority (CNA).
(b) Failure by the CNA to acknowledge receipt of notification shall not imply its consent to an intentional release or transboundary movement of GMOs.

4.2. Decision Making Procedures

(a) The decision making procedures shall take into consideration risk assessment, which involves scientific, socioeconomic, cultural and ethical concerns. The decision to permit research and development in rDNA, import and release of GMOs for whatever purpose shall be on a case by case basis.

(b) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a GMO on the conservation and sustainable use of biological diversity and risk to human health, shall not prevent the relevant authorities from taking appropriate decisions, with regard to the release or importation of the GMO.

[2] This form shall be designed by the NBC depending on the particulars required from the applicant. The information requirements in Annex 1 should guide the design of such a form.

(c) As part of the requirements for taking decisions, the applicant is obliged to provide accurate information on the GMO in question.

(d) The decision making procedure shall cover field trials, releases for domestic use as food or feed, or for processing and placing in the market of a GMO including those that are subject to trans-boundary movement.

(e) A decision taken pursuant to these Guidelines by the relevant authorities shall not render it liable for any adverse impact directly or indirectly resulting from the use of GMOs and does not exclude the applicant from the requirements of other applicable regulatory instruments.

(f) Approval to import, export or carry out releases shall be given by the CNA based on advice of the NBC.

4.3 Review of Decisions

(a) A decision may be reviewed by the appropriate authority dealing with GMO based on new information on adverse effects on conservation and sustainable use of biological diversity, also taking into consideration the risks to human health.
(b) The CNA shall take steps, through the National Focal Point on CBD to inform applicants and the Biosafety Clearing House (BCH) of the Convention on Biological Diversity as appropriate.
(c) An applicant, notifier, exporter may request for review of a decision taken by the appropriate agency under the following conditions:

(i) a change in a piece of relevant information or
(ii) other circumstances have become available.

5.0 Unintentional Transboundary Release And Emergency

(a) All cases of unintentional transboundary release of GMO must be reported immediately to the NBC through the Registrar.

(b) Information accompanying such declaration should include, at the very minimum:
   i. Quantities and details provided for in Annex 1 of these guidelines;
   ii. Details of circumstances, estimated date of release, and the use in the country of origin.

iii. Possible harmful effects on conservation and sustainable use of biodiversity, taking also into consideration risks to human health as well as risk management measures;
iv. Any other relevant information and points of contact for further information.

6.0. Risk Assessment And Management Procedures

6.1. Overview

The Cartagena protocol advocates a precautionary principle. This implies that before any release is carried out, an evaluation of the impacts and risks posed to human health and the environment by the release, should be undertaken to identify if there are any hazards posed by the GMO to human health or the environment; the magnitude of harm; and what the risks are if the hazards are realized. Once the risks have been estimated, the assessment should identify whether or not any management procedures are required to control the risk and prevent or minimize damage to the environment or whether or not monitoring is required to determine that any risk control measure is effective.

6.2 Risk Assessment

The risk assessment shall take into consideration the following:

(a) The guiding principle of risk assessment i.e. the precautionary approach. Where the transboundary movement, use or handling of GMOs or products thereof may cause, or has a proven or theoretical potential to cause harm to biodiversity, ecosystems, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk shall not be interpreted as the lack of risk, or as acceptable risk.

(b) The risk assessment shall take into account, *inter alia*, all relevant scientific theory, evidence and experience, including previous risk assessments (see details in annex 3). This enables the risk assessment to evolve in the light of new evidence and knowledge. For example, a GMO or product thereof previously considered acceptable may no longer be acceptable, and vice versa.

(c) It should be acceptable as a principle underlying the risk assessment that every transgenic line is different because of random insertion, even if they are made with the same vector system, the same gene constructs, and the same variety, and that it has to be well characterized to be stable for at least

five generations under a reasonable range of environmental conditions that it may encounter. If the risk assessment at first shows that the level of risk of the intended use is not acceptable, additional risk management measures are to be taken and assessed until the risks have been minimized to an acceptable level. If the risk cannot be minimized in this way, it might be concluded that the intended operation should not proceed, or a risk / benefit analysis might be carried out to determine whether a higher level of risk is acceptable and whether the intended operation should proceed.

(d) Risk assessment shall be carried out by person(s) approved by the NBC.

(e) The cost of risk assessment and other administrative costs thereto shall be borne by the applicant.

6.3. Risk Management

6.3.1. Risk Management Procedure

Risk management refers to means by which a user applies certain control measures to an operation in order to eliminate, minimize or keep the risks to an acceptable level. Having identified and assessed the extent of risk, the next step is to consider how the risk can be minimized and best managed.

(a) Risk management is employed during the development and evaluation of an organism in a systematic manner, for example from the laboratory, through stages of field testing, to commercialization. The number and forms of these stages are not fixed but depend on the outcome of risk assessment at the different stages.

(b) The type of risk management procedure to be adopted will depend on the GMO and the particular application. For contained use, the degree of containment achieved depends primarily on the type of physical barriers and the application of appropriate work procedures. In the case of controlled release, different types of barriers, such as biological, chemical, physical or temporal barriers can be used to minimize or limit the dissemination and impacts of organisms with novel traits and/ or to provide genetic isolation as required. Different risk management practices may be applied, depending on the scale of the proposed release and its duration.

6.3.2. Measures for Controlled Releases

Appropriate risk management measures for releases will vary considerably from case to case. They will be determined by the risk assessment, the organisms involved and the method of release. In addition to general precautions to control release, risk management measures often focus on the control of the dissemination of the released organisms and control of the gene flow from the released organisms (See Annex 1 section 3). The type of risk management measures to be employed should be commensurate with the risk identified.

7.0. Handling, Packaging And Identification

(a) All GMOs should be handled, packaged and transported under conditions of safety taking into consideration national and international requirements.
(b) All GMOs and derivatives as well as products made from GMOs should, irrespective of their use, be properly identified and labeled.

8.0. Liability And Redress

Any person who carries out any activity in relation to GMOs or products thereof shall be strictly liable for any harm, injury or loss caused directly or indirectly by such GMOs or product thereof or any activity in relation to them. The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity. The characterization of liability and redress shall be determined based on the Cartagena Protocol and other relevant supplementary protocol(s).

9. Public Education, Awareness And Participation

In accordance with Article 23 of the Cartagena protocol on Biosafety and the Draft Biosafety law, the National Biosafety Committee (NBC), and the Competent National Authority have obligation to promote and facilitate public awareness, education and participation of the population in all decisions regarding the importation and use of GMOs. The NBC also has an obligation, through the Biosafety Clearing House and other channels, to ensure that the Rwandan public has access to information and are consulted on all decisions regarding GMOs.

9.1. Access to Information

The Biosafety Clearing House is the main means of accessing information on biosafety. The NBC will ensure that the general public is informed on how to access information in the Biosafety clearing house. Considering the level of general level of literacy among the Rwandan public; access to print, modern audio-visual, social media and telecommunication systems.

9.2. Public Education and Awareness

The CNA shall collaborate with the NBC to promote education and awareness among the Rwandan public on all issues regarding GMOs.

9.3. Public Participation in Decision Making

The Biosafety Law guarantees the right of the public to participate in the decision making process regarding GMOs.

10. Biosafety Regime

These relate to the coordination, authoritative guidance and implementation of the legal and regulatory framework for biotechnology – biosafety activities, as well as development and application of biotechnology in Rwanda to ensure optimal benefit to the Rwandese people.

10.1. National Biosafety Framework

In order to ensure the safe and responsible use and deployment of biotechnology, a National Biosafety Framework in line with the Cartagena Protocol on Biosafety is established in Rwanda. The key elements of the Rwandan National Biosafety Framework (NBF) are:

- the biosafety law,
- the biosafety framework implementation strategy,
- ministerial orders and guidelines,
- the biosafety competent national authority, which is the national decision-making body that makes decisions on proposed biotechnology activities and approves or rejects them on the basis of review recommendations,

- a biosafety administration office that receives and processes applications for biotechnology activities; carries out daily biosafety administration; and coordinates public input, risk assessment and decision-making activities of the NBF. This office is responsible for issuing biosafety communication (information about biosafety) and for coordinating consultation with stakeholders about biosafety processes.

A scientific advisory body that carries out, reviews or audits risk assessments on GM activities and recommends what, if any, terms and conditions (risk management measures) may be needed to protect the environment and human health. This body may also advise on general biosafety issues. This comprises a National Biosafety Committee and where necessary its ad-hoc sub-committee.

- An inspectorate that is responsible for inspections to ensure compliance with the regulations and which functions with, or in collaboration with, an enforcement authority.
- A mechanism for public participation, in decision-making.

The objective of the framework is to put in place a system that ensures an adequate level of protection in the field of the safe development, transfer, handling and use of Living Modified Organisms (LMOs) and their products on the basis of the precautionary principle to enhance conservation and sustainable use of Biological Diversity, taking also into account risks to human health. The framework focuses on movements of living modified organisms and their products within the country and/or transboundary movements. It identifies key stakeholders and their responsibilities.

10.2 Competent National Authority

The biosafety law recognises the Rwanda Environment Management Authority as the Competent National Authority for purposes of coordination of enforcement of the law and any regulations promulgated thereunder. Functions of the competent national authority are pursuant to the Cartagena Protocol on Biosafety and related technical matters and as stated in the ministerial order. The competent national authority shall also serve as the national focal point for the Cartagena Protocol and its Supplementary Protocol. It liaises with the Secretariat of the Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety.

However, other institutions, such as relevant regulatory agencies have responsibility for ensuring compliance with biosafety regulations in collaboration with the competent national authority. All such relevant institutions will retain their respective mandates while being bound by the common objective of enforcing and

preserving the integrity and purpose of the biosafety laws, regulations and guidelines. In the discharge of its duties, the CNA may co-opt additional members, form sub-committees and adopt other such measures which may facilitate its work.

10.3 National Biosafety Committee

The National Biosafety Committee (NBC) is the structure in charge of scientific operations of the law regarding biosafety issues in Rwanda.

The composition and functioning of the NBC is determined by the relevant Ministerial Order, and should reflect the direct interests of the following institutions:

- Ministry of Environment
- Rwanda Food and Drugs Authority
- Rwanda Agriculture and Animal Resources Board
- Rwanda Inspectorate and Consumer Protection Authority
- Rwanda Environment Management Authority
- National Industrial Research and Development Agency – Sanitary and Phytosanitary measures
- Rwanda Revenue Authority – Port and Frontiers Handling of LMOs in collaboration with other agencies
- Ministry of Local Government
- Rwanda Standards Board – International standards in biotechnology products and best practices in related issues
- Rwanda Development Board - Conservation
- Ministry responsible for Education, science, technology and scientific research
- National Council for Science and Technology
- Ministry of Health
- Ministry of Justice
- Representatives of relevant universities
- Representatives of relevant NGOs and civil society organizations

Where necessary, ad hoc committees should be formed.

10.4. Institutional Biosafety Committee

All institutions and organizations in Rwanda, both private and public, which plan to undertake biotechnology research and/ or development, are encouraged to establish an Institutional Biosafety Committee (IBC), which will be responsible to, and cooperate with the NBC. The composition, responsibilities and functioning modalities of the IBCs shall be determined by the relevant ministerial order.

11. Mechanism For The Strategy Implementation

Institutional coordination and collaboration are prerequisite for ensuring compliance and enforcement of this strategy. In this regard, the NBC and the IBC shall, under the auspices of the CNA, be responsible for ensuring the implementation of this strategy and regulations to be formulated hereunder.

11.1. Implementation Arrangements

Biosafety, as a cross-cutting and integrated issue, brings about convergence of sectors. It enables technologies developed in one sector to find direct application in other sectors. It is also a very sensitive issue due to the prevailing debate on its benefits and potential risks. Consequently, the Government will employ a multi-sectoral and coordinated approach to ensure effective implementation and to give a voice to all key stakeholders in decision making. In order to ensure effective development of biotechnology in Rwanda, it is imperative to put in place effective implementation mechanisms. This requires definition and assignment of clear roles and responsibilities of all relevant institutions.

Implementation of the biotechnology aspect of this strategy will be by all institutions involved in biotechnology research and development, and promotion. Such institutions are required to constitute and capacitate an Institutional Biosafety Committee (IBC). The IBCs are required to be certified by the competent national authority for biosafety. A person/institution wishing to carry out contained use and confined field trials shall operate under a certified institutional biosafety committee.

The competent national authority with the mandate to regulate the research, development, application and commercialization of biotechnology will be Rwanda Environment Management Authority (REMA). National Biosafety Committee should be constituted and capacitated to function as appropriate. The mandate of the committees is to be determined by the relevant Ministerial Order. The details of the implementation plan are provided in Annex 4.

11.2 Monitoring and Evaluation of the strategy

Monitoring and evaluation (M&E) will be done regularly to check effectiveness. The M&E framework will include specific objectives, indicators, source of data, baseline data, desired targets, key milestones, responsibility for implementation and timeframe.

Each stakeholder institution will designate a desk officer for biotechnology whose main responsibility will be to collect data on the status of biotechnology within the institution. Every year, institutions should submit information to the national competent authority in the manner provided by the Law.

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16. Rwanda Vision 2050
17. Sustainable Development Goals, 2015

ANNEX 1: INFORMATION REQUIRED FOR THE APPLICATION

I. General Information

A. Name and Address of applicant

B. Information on Personnel and Training

(a) Name of person(s) responsible for planning and carrying out the release, including those responsible for supervision, monitoring and safety, and qualification(s) of the responsible scientist(s)

II. Information relating the GMO(s) or products thereof

A. ***Characteristics of (a) the donor (b) the recipient (c) parental organism(s), where appropriate***

(a) Scientific name;
(b) Taxonomy;
(c) Other names (usual name, strain name, cultivar name, etc);
(d) Phenotypic and genetic markers;
(e) Degree of relatedness between donor and recipient or between parental organisms;
(f) Description of identification and detection techniques;
(g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
(h) Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts;
(i) Potential for genetic transfer and exchange with other organisms;
(j) Verification of the genetic stability of the organism and factors affecting it, taking into account the relevance of the laboratory experiments undertaken for the authentic ecological conditions under which the organisms live or are used;
(k) Pathological, ecological and physiological strains:

i. Classification of hazards according to existing national rules concerning the protection of human health and/ or environment;
ii. Generation time in natural ecosystems, sexual and asexual reproductive cycles;
iii. Information on survival, including seasonality and the ability to form survival structures e.g. seeds, spores or sclerotia;
iv. Pathogenicity: infectivity, toxicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including

non-target organisms, possible activation of latent viruses (proviruses) and ability to colonise other organisms;

v. Antibiotic resistance, and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy;

vi. Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

(l) Nature of indigenous vectors:

i. Sequence
ii. Frequency
iii. Specification
iv. Presence of genes which confer resistance

(m) History of previous genetic modifications.

B. ***Characteristics of the vector***

(a) Nature and source of the vector
(b) Genetic map if the vector(s), position of the gene(s) intended for transfer, other coding and non-coding sequences affecting the expression of the introduced gene(s), and maker(s);
(c) Frequency of mobilization of inserted vector and/ or genetic transfer capabilities and methods of determination;
(d) Information on the degree to which the vector is limited to the DNA required to perform the intended function;
(e) Factors (chemical, biological, climatic, etc) influencing the functional level of the promoter/ enhancer, and how the functional level is changed.

C. ***Characteristics of the GMO(s) or products thereof***

(a) Methods used for the modification
(b) Purpose of the modification and intended use in relation to need or benefit;
(c) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
(d) Description of the insert and/ or vector construction;
(e) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
(f) Number of intact and truncated vector inserts. Sequence, functional identity and location of the altered/ inserted/ deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence;

(g) Sequence and methylation pattern of the recipient DNA as far as 100kbp up and downstream from all DNA inserts.
(h) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
(i) Structure and amount of any vector and/ or donor nucleic acid remaining in the final construction of the GMO(s) or product thereof;
(j) Stability of the organism in terms if genetic traits;
(k) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
(l) Activity of the expressed protein(s);
(m) Expression levels for the recipient's genes situated as far as 100kbp up and downstream from all DNA inserts;
(n) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
(o) History of previous releases or uses of the GMO(s) or products thereof;
(p) Health consideration:
    1. Toxic or allergenic effects of the non-viable GMO(s) or products thereof and/ or their metabolic products;
    2. Product hazards;
    3. Comparison of the GMO(s) or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
    4. Capacity for colonization;
    5. If the organism is pathogenic or humans who are immuno-competent:
        - Diseases caused and mechanism of pathogenicity including invasiveness and virulence;
        - Communicability;
        - Infective dose;
        - Host range, possibility of alteration;
        - Possibility of survival outside of human;
        - Presence of vectors or means of dissemination;
        - Biological stability;
        - Antibiotics-resistance patterns;
        - Allergenicity;
        - Availability of appropriate therapies.

ANNEX 2: RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living 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. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

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

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 living modified organisms or products thereof, namely, processed materials that are of living modified organism 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 living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfill its objective, risk assessment entails, as appropriate, the following steps: (a) An identification of any novel genotypic and phenotypic characteristics associated with the living 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 realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism; (c) An evaluation of the consequences should these adverse effects be realized; (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized; (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 living modified organism in the receiving environment.

Points to consider

9. 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, centers of origin and centers 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;

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(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) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms; (f) Detection and identification of the living 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 living 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 centres of origin of the likely potential receiving environment.

ANNEX 3: IMPLEMENTATION PLAN

Strategic actions	Key deliverable indicators	Stakeholder institutions	Responsible institution (s)	Timeline	Budget estimate (Frw)
Strategic Objective 1: Assessment and identification of priorities in human resources development and the implementation of national capacity building programmes for biosafety.					
Promote focus on science-based subjects at all levels of education and review education curricula in basic sciences in order to promote scientific inquiry culture and generate a pool of science-oriented scholars with prospects in the field of biotechnology and biosafety,	- Education curricula reviewed to integrate biotechnology / Biosafety - Trainings of scholars conducted on biosafety / biotechnology - Sensitisation, awareness workshops/ campaigns conducted to promote biotechnology / biosafety - Curricula developed for emerging skills	MoE, REMA, RDB, MINEDUC, REB, HEC, Higher Learning Institutions, NCST, MINAGRI, RAB, Rwanda FDA, MIFOTRA	**REMA**, MOE, MINEDUC,	2021 – continuous	60,000,000
Support the development of a critical mass of technicians, technologists and middle level manpower to support biotechnology research, innovation and application,	- Trainings of technicians on biosafety/ biotechnology - Trainings of technologists - Trainings of researchers	REMA, MoE, MINICT, MINEDUC, NCST, FONERWA, MoE, UR, NIRDA, MINAGRI, RAB	**REMA**, MINEDUC, NCST	2021 – continuous	80,000,000
Provide incentive schemes/bursaries/scholarships for training of	- Incentives provided to local experts	MoE, MINEDUC, NIRDA,	MOE, REMA,	2021– 2030	170,000,000

human resource in biotechnology related disciplines in local and foreign institutions,	- Bursaries, scholarships provided - Medium term trainings on biotechnology	BRD, NCST, REB, REMA	**MINEDUC**		
Contribute significantly towards creating career opportunities and progression for well-trained and experienced individuals, this includes, provision of support for start-up funding that will lead to an expansion of the biotechnology industry, thereby better absorption of young scientists into career paths in biotechnology,	- Jobs, careers created in biotechnology / biosafety - Scientists and biotechnologists supported financially	NCST, REB, BRD, MINAGRI, MoE, MoH, MINICOM, PSF, MININFRA, REMA, RDB	**RDB**, REMA, MIFOTRA	2021 – 2022	180,000,000
Support collaboration among national scientists/institutions, and foreign public and private institutions/laboratories for the purpose of building/ strengthening national capacities, especially in areas where the country lacks sufficient expertise,	- Framework, MoUs for collaboration among scientist institutions (National and international) - Advocacy for collaboration	REMA, MoE, MINEDUC, RAB, NCST, NIRDA, MINICOM, MINAGRI, Development Partners	REMA, **MINEDUC**	2021 – continuous	50,000,000
Engage all stakeholders to prepare the detailed work plans assigning the roles	- Workshops for stakeholders' engagements in biosafety - Policy and strategic dialogs on biosafety	All biosafety stakeholders	REMA, **MOE**	2021	35,000,000

Strategic Objective 2: Development and establishment of a comprehensive and up-to-date scientific database, infrastructure for information exchange upon which risk assessment and evaluation of products can be made and mechanisms for effecting AIAs;					
Establish research centres of excellence and research innovation centres in specific fields of biotechnology e.g. plant biotechnology, animal biotechnology, genomics and medical biotechnology, and industrial biotechnology, among others,	- Centres of excellence on biotechnology research and application - Research innovation centres	RAB, MINAGRI, MoH, MINEDUC, NCST, RBC, Higher Learning Institutions, NIRDA, PSF, REMA	REMA, **MINEDUC**	2021 – continuous	180,000,000
Establish well-resourced biotechnology laboratories and refurbish existing ones in research and tertiary institutions in the country,	Biotechnology laboratories	RAB, FDA, MOE, REMA, NCST, MINEDUC, MINAGRI, MOH, RBC, PSF, RSB, NIRDA, Higher Learning Institutions	REMA, RAB, **UR**, MINDUC, NCST	2021 – continuous	90,000,000
Build containment facilities in every institution involved in biotechnology research,	Containment facilities	RAB, REMA, MOE, NCST, RBC, RSB, NIRDA, Higher Learning Institutions	REMA, RAB, +**Relevant institutions (Every concerned inst.)**	2022 – continuous	60,000,000
Support the development of efficient ICT network among institutions	ICT based equipment	RISA, RURA, MINICT,	REMA, **RISA**	2021 – continuous	50,000,000

involved in biotechnology research and the centres of excellence to enhance information exchange and communication,		REMA, MOE, RAB, Telecommunication companies			
Establish first class storage facilities at the country's entry points to handle sensitive biotechnology inputs (specimens, reagents, etc.) and products.	Facilities for storage of biotechnology related inputs and products at the entry points	REMA, MOE, RSB, RAB, RICA, RRA, RNP, MINICOM, NCST, RAB, MINAGRI, MININFRA	REMA, **RICA**	2022 - continuous	50,000,000
Strategic objective 3: Strengthening research and development (R&D), industrial applications, commercialization					
Institute linkages between the private sector and the Research Innovation Centres for commercialization of biotechnology spin-offs,	Guidelines produced to stimulate linkages between private sector and research innovation centres	RAB, REMA, MOE, MINICOM, RDB, PSF, MINEDUC, NCST, Higher Learning Institutions, RBC, RSB	REMA, **MINICOM**	2022 – continuous	40,000,000
Assist R&D institutions to collaborate with international research centres to conduct cutting-edge biotechnology research which are tailored to	Collaboration frameworks / MOUs between national R&D institutions and international research centres	REMA, MOE, RAB, RBC, RSB, NIRDA, Higher	REMA, MINEDUC, **NCST**	2022– continuous	30,000,000

address peculiar local problems,		Learning Institutions, Local and International NGOs			
Support public-private partnership in the establishment of local enterprises to manufacture reagents, components, and other requirements for biotechnology research,	Reagents, components, and other requirements for biotechnology research produced locally	RDB, REMA, MOE, PSF, Media, RAB, RBC, NIRDA, Civil Society, RCA	REMA, **PSF**,	2022 – continuous	40,000,000
Strategic objective 4: Intellectual property rights and traditional knowledge					
Increase access to foreign and local technology by local firms and research institutions,	Local firms and research institutions accessing technology	REMA, MOE, RDB, NIRDA, PSF, MINAGRI, RICA, RAB,	REMA, **NIRDA**	Ongoing – continuous	25,000,000
Enable access to IP-based technology and innovations,	IP-based technology and innovations	RDB, REMA, MOE, NIRDA, RICA, NCST, MINEDUC,	REMA, **NCST**	2022 – continuous	30,000,000
Establish schemes for acquisition of intellectual property rights on foreign innovations identified as essential for accelerating the beneficial application of biotechnology in Rwanda	Schemes established for acquisition of IPRs on essential foreign innovations	RDB, MINAFFET, MOE, NIRDA, NCST, RAB, REMA, MINEDUC	REMA, **NCST**, NIRDA	ongoing	15,000,000

Enhance traditional knowledge with elements of biotechnology and promote its integration with modern biotechnology,	- Initiatives on traditional knowledge with elements of biotechnology - Legal and regulatory system established	NIRDA, REMA, MOE, NCST, MINEDUC and institution, MINISANTE, MINISPOC, FDA, Higher Learning Institutions, PSF	**REMA**, MOE	Ongoing – continuous	50,000,000
Increase information access on traditional knowledge and biotechnology,	- Information access platforms and tools - Legal and regulatory system established	NIRDA, REMA, MOE, NCST, MINEDUC and institution, MINISANTE, MINISPOC, RFDA, Higher Learning Institutions, PSF	**REMA**, MOE	2021 – 2030	40,000,000
Maintain database of all biotechnology innovations in Rwanda and enable local and international protection of the proprietary rights of biotechnology innovators,	- Database of biotechnology innovations - Proprietary rights of biotechnology innovators enabled and protected	NCST, RAB, RDB, REMA, MOE, MINAFFET, MINAGRI,	**REMA**, MOE	2022 – continuous	20,000,000
Recognize and document biotechnology-related traditional knowledge and resources,	- Documentation on biotechnology-related traditional	REMA, MOE, NCST, CSOs.	**REMA**, MOE	2022 – continuous	60,000,000

	- knowledge and resources - Legal and regulatory system established	RDB, NIRDA, MINSPOC, MINISANTE, RAB, MINAGRI			
Ensure equitable benefit sharing and access to biotechnology related traditional knowledge,	- Equitable benefit, access and use of biotechnology related traditional knowledge - Legal and regulatory system established	REMA, MOE, MINAGRI, MINISANTE, MINISPOC, RAB, RDB	**REMA**, MOE	ongoing	50,000,000
Develop an effective proprietary system for indigenous knowledge that provides incentives for the generation and exploitation of indigenous knowledge.	- Proprietary system created for indigenous knowledge that provides incentives for the generation and exploitation of indigenous knowledge - Legal and regulatory system established	REMA, MOE, RDB, RAB, NCST, MINISPOC	**REMA**, MOE	ongoing	50,000,000
Strategic objective 5: Biodiversity conservation and utilization					
Standardize taxonomic databases,	Standardized taxonomic database	REMA, MOE, RSB, RAB, NIRDA, Higher learning institution	**REMA**, MOE, UR, CoEB	2022	25,000,000
Establish gene banks and genetic databases,	Gene banks and genetic database	RAB, REMA, MOE, RDB, MINEDU	REMA, UR, **RAB**	ongoing	60,000,000

		C, NCST, MINAGRI, RAB, NIRDA, FDA,			
Use biotechnology to characterize indigenous plants and animals so as to evaluate their economic potentials for biotechnological applications,	Indigenous plants and animals economic value evaluated by using biotechnological applications	REMA, MOE, RAB, RSB, RDB, NIRDA, RAB, MINAGRI, Higher learning institution, NCST,	REMA, RAB, UR, **RDB**	2022 – continuous	30,000,000
Promote sustainable exploration and exploitation of bio-resources.	Bio resources explored and evaluated sustainably	REMA, MOE, RAB, RDB, NST, NIRDA, RDB, MININFRA, MoE, MINICOM	REMA, **RDB**, NCST	2022 – continuous	25,000,000
Strategic objective 6: Biosafety funding and mobilization of resources					
Create a venture capital fund and extend its existing funding to the relevant national competent authority so as to include mandatory allocation to biotechnology,	- A venture capital fund created for biotechnology - Funds allocated for biotechnology applications	NCST, RAB, REMA, RSB, FDA, PSF, NIRDA, FONERWA, MINECOFIN, MINISANTE, MINAGRI, MoE, MINICOM	REMA, MOE, **MINECOFIN**, FONERWA	2 Years from adoption of the law	20,000,000

		, Dev Partners			
Set-up a competitive grant scheme that would ensure that the most urgent needs in biotechnology development are addressed along the whole spectrum from capacity building and skills development to biotechnology product innovation and commercialization.	A competitive grant scheme created to satisfy urgent needs in biotechnology	NCST, RAB, REMA,MOE, FONERWA, Rwanda-FDA, NIRDA, RBC, MINICOM, MINECOFIN, Dev Partners	REMA, MOE, MINECOFIN, **FONERWA**	1 Year after creation of the fund	24,000,000
Ensure that all the strategic actionable areas are given deserved attention, and that resource allocation is not determined on the basis of commercial needs alone, but also on the basis of social and developmental needs.	Financial resources allocated to biotechnology strategic areas on the basis of all inclusive needs	REMA, MOE, RAB, FDA, RBC, RSB, NIRDA, MINECOFIN, MINAGRI, RAB, MINISANTE, MINICOM, Dev Partners	REMA, MOE, **MINECOFIN**	Continuous	20,000,000
Provide side measures and incentive schemes that allow for risk-sharing to attract private capital into funding biotechnology innovations.	Incentive schemes allocated/ provided to attract private capital into funding biotechnology innovations	MINICOM, MINICOM, MINECOFIN, RDB, REMA, MOE, FONERWA, NCST,	REMA, MINECOFIN, **FONERWA**	Continuous	200,000,000

		RAB, NIRDA, Dev Partners			
Increase funding for biotechnology research, development and innovation through its annual budgetary allocation and also solicit more support from development partners,	Annual budget allocated by institutions for funding biotechnology research, development and innovations	MINECOFIN, REMA, MOE, RDB, PSF, NCST, BRD, FONERWA, NIRDA, NGOs, Development Partners	REMA, MOE, **MINECOFIN**	2022 – continuous	20,000,000
Strategic objective 7: Promotion of public awareness on Biosafety					
Develop a system or mechanism that ensures effective documentation, dissemination of information, access to information, public participation, engagement, education and dialogue in biotechnology development process,	- BCH website operationalized - Effective documentation, disseminated and accessed by the public	REMA, MoE, MINEDUC, MINALOC, NCST, MINICT, Higher learning institution and Research Agencies, MINAGRI, MINISANTE, MINIJUST, RSB, CSOs	**REMA**, MOE	Ongoing-Continuous	50,000,000
Include biotechnology and biosafety in the education curriculum at all levels of education,	Curricula which integrate biosafety/ biotechnology in all levels of education	MINEDUC and agencies, REMA,	REMA, **MINEDUC**, NCST, MOE	2021-Continuous	30,000,000

		MOE, NCST			
Build/strengthen capacity of communicators, media practitioners and scientists in biotechnology and biosafety communication,	Communicators, media houses and scientists receiving support to strengthen their capacity	MOE, MINICT, MINAGRI, REMA, NIRDA, RAB, Universities and Research center, Media High Council, RBA, Media, NCST	REMA, MOE, Media	ongoing	50,000,000
Encourage active participation of the general public, CSOs and NGOs in biotechnology and biosafety dialogue.	- General public, CSOs and NGOs participating in biotechnology and biosafety dialogue. - Events organized for dialogue with the public in biotechnology development process,	REMA, RAB, MoE, RGB, CSOs, NGPs, PSF, MINALOC, NCST, NIRDA	**REMA**, MOE	ongoing	40,000,000
Strategic objective 8: Gender considerations					
Improve gender balance in biotechnology and biosafety activities, including decision-making,	Disaggregated data on women and men participating in biotechnology and biosafety activities	REMA, MOE, MIGEPROF, MINECOFIN, GMO, MINECOFIN	**REMA**, MOE, GMO	Continuous	25,000,000
Promote participation of disadvantaged groups in the development and	Disadvantaged groups participating in biotechnology and biosafety programmes	REMA, MOE, MINECOF	**REMA**, MOE,	Continuous	20,000,000

application of biotechnology, and biosafety programmes.		IN, MIGEPROF, GMO, MINECOFIN, RAB, NCST	MINECOFIN		
Adopt affirmative action to address gender needs with respect to human capacity building/strengthening for biotechnology development and application,	Affirmative actions to address gender needs	REMA, MOE, GMO, MINECOFIN, MINEDUC, NIRDA, RAB, NCST	**REMA**, MOE, GMO	2022 – Continuous	20,000,000
Strategic objective 9: Linkages and partnerships					
Establish functional institutional collaboration frameworks in order to institute national, regional and international collaboration and networking in biotechnology development and biosafety matters,	Existence of institutional collaboration frameworks for national, regional and international collaboration and networking in biotechnology development and biosafety matters,	REMA, MOE, MINEDUC, NCST, MINAFFET, MOE, EAC, AU, UNEP	**REMA**, MOE	Continuous	30,000,000
Create mechanisms for functional linkages and partnerships between public and private sector, locally and internationally.	Existence of mechanisms for functional linkages and partnerships between public and private sector, locally and internationally.	REMA, MOE, MINECOFIN, PSF, MOE, EAC, AU, UNEP	**REMA**, MOE	**Continuous**	25,000,000
Strategic objective 10: Legal, institutional framework and enabling environment					
Institute a well-defined institutional and regulatory framework for effective promotion and coordination of biotechnological activities.	- Biosafety law - Biosafety implementation strategy - National biosafety framework established	MoE, REMA, MOE, MINECOFIN, MINAGRI, RAB,	**REMA**, MOE	2022	20,000,000

		MINICOM, MoH, RICA, RSB, NCST			
Establish effective mechanisms and procedures for obtaining approvals and clearances for biotechnology products developed within the country.	Existence of effective mechanisms and procedures for obtaining approvals and clearances for biotechnology products developed within the country.	REMA, MOE, MINECOFIN, RICA, RSB, RRA, RAB, MINAGRI, Rwanda FDA, MOH, MINICOM, NIRDA, RICA, NCST	**REMA**, MOE	2022-Continuous	25,000,000
Exempt biotechnology R&D inputs from import and related duties and establish mechanisms to fast track clearing of biotechnology inputs from the country's entry points in view of their very short shelf-life and fragile nature.	- Existence of exemption of biotechnology R&D inputs from import and related duties - Mechanisms to fast track clearing of biotechnology inputs from the country's entry points	MoE, REMA, MINICOM, MINAGRI, MINECOFIN, RICA, NIRDA, Rwanda FDA, MINAGRI, RAB, NCST	REMA, MOE, **RICA**	2022-Continuous	20,000,000
Support the establishment of enterprises to produce important biotechnology inputs, products and services.	Enterprises established to produce important biotechnology inputs, products and services.	MoE, REMA, MINECOFIN, RDB, RAB, MINAGRI, MINICOM, NGOs	REMA, MOE, **MINICOM**	2022-Continuous	25,000,000

		and UN agencies			
Review the existing Plant Breeders Law as well as the Seed and Plant Varieties Law with a view to including the use of DNA fingerprinting technology to help distinguish between different genotypes,	The existing Plant Breeders Law as well as the Seed and Plant Varieties Law reviewed to include the use of DNA	MoE, REMA, MINAGRI, RAB, RICA, NCST, MINICOM, MoH, MINECOFIN, MINIJUST	REMA, MOE, **MINAGRI**, RAB	**2023**	20,000,000
Consider the development of a law that will protect the rights of animal breeders- the equivalent of the Plant Breeders Rights. This will see to the protection and preservation of the local animal breeds from being lost to other parts of the world,	Existence of the law that will protect the rights of animal breeders	MoE, REMA, MINAGRI, RAB, RICA, NCST, MINICOM, MoH, MINECOFIN, MINIJUST	REMA, MOE, **MINAGRI,** RAB	2022-Continuous	20,000,000
Strategic objective 11: Regulations, guidelines and safety operating procedures					
Build on existing to prepare regulations, guidelines and safety (standards) operating procedures for good conduct of biotechnological applications	Regulations, guidelines and safety (standards) operating procedures for good conduct of biotechnological applications	REMA, MOE, NCST, RSB, MINAGRI, RAB, MINECOFIN, MINICOM, MINEDUC, MOH	REMA, MOE, **RSB**	2022 – continuous	25,000,000
Adopt biosecurity measures in laboratory and in use other sensitive	Biosecurity measures adopted in laboratory and in use other	REMA, MOE, NCST, RSB,	REMA, MOE, **RSB**,	2022 – continuous	20,000,000

infrastructure or equipment	sensitive infrastructure or equipment	MINAGRI, RAB, MINECOFIN, MINICOM, MINEDUC, MOH			
Strategic objective 12: Promotion and use of regular monitoring					
Enforce compliance with biosafety regulations by researchers, institutions and industry engaged in biotechnology research, development, and application and commercialization activities.	Enforcement / inspections and measures conducted	REMA, MOE, RICA, RSB, NCST, MINAGRI, RAB, RNP, RIB, MINIJUST, MOH, RBC, Rwanda FDA,	**REMA**, MOE, RNP	2021 – continuous	45,000,000
Strategic objective 13: Bioethics and conduct					
Establish mechanism for identifying gaps in existing ethical procedures and establish measures for addressing the identified gaps,	- Studies for identifying gaps in existing ethical procedures - Measures established for addressing the identified gaps,	REMA, MOE, RICA, RSB, NCST, MINAGRI, RAB, RNP, RIB, MINIJUST, MOH, RBC, Rwanda FDA, Higher learning institutions	**REMA**, MOE, NCST	Continuous	20,000,000
Establish acceptable national ethical standards for undertaking	National ethical standards for undertaking	NCST (Lead), RSB,	**NCST**, REMA, MOE	Within 2 years after	20,000,000

biotechnological research and applications.	biotechnological research and applications.	REMA, MOE, RAB		adoption of the law	
Ensure adherence to national and international regulations and ethical code of conduct,	Domestication mechanisms of national and international regulations and ethical code of conduct,	REMA (Lead), MOE, NCST, RAB, MINAGRI, MINIJUST, RSB, RAB	REMA, MOE, **NCST**	Continuous	25,000,000
Integrate bio-ethics in all training programmes on biotechnology so as to build a national culture of ethics in biotechnology applications.	- Training programmes on biotechnology integrating bio-ethics - Existence of national culture of ethics in biotechnology applications - No human cloning allowed	MINEDUC (Lead), HEC, REB, UR, REMA, MOE, RAB, MINALOC, MINAGRI	MINEDUC (Lead), **MIFOTRA**, REMA, MOE	Continuous	25,000,000
Establish mechanism for evidence-based decision making in biotechnology development and commercialization,	- Decision making system on biotechnology	REMA (Lead), MOE, NCST, MOH, MINAGRI, RAB, MoE	**REMA**, MOE	2 years after adoption of the law	25,000,000