REPUBLIC OF MOZAMBIQUE

MINISTRY OF AGRICULTURE

DRAFT NATIONAL BIOSAFETY FRAMEWORK OF MOZAMBIQUE

PREPARED BY

Grupo Inter-Institucional Sobre Bio-Segurança (GIIBS)

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PREFACE

Food and environmental security are on the top of the national agenda for fight against poverty and to ensure sustainable development of the country. In this context, the development and access to adequate novel technology for food and agricultural production is of crucial importance for achieving food security in the country. Biotechnology is a valuable novel technological tool with great potential to produce high yield, disease and pest resistant and high quality crops hence enhancing the agricultural and food production. This technology has also beneficial applications in key areas of animal production and health care. For this reason, the government of Mozambique recognise the contribution that modern biotechnology may have to meet critical needs for food, agriculture and human health care.

However, there are some legitimate public concerns about the potential adverse effects on the human health and environment posed by unregulated use of genetically modified organisms (GMOs). Equally, there are some socio-economic and ethical issues that need to be addressed properly when dealing with GMOs. Thus, the development of modern biotechnology must go hand in hand with appropriate regulation in order to maximise its benefits while minimizing its risks.

Biotechnology research and development in Mozambique is still at its infancy; However, the globalisation of trade, the vulnerability of the country to natural disasters (droughts, floods, cyclones) often leading to the need for food aid containing, in some cases, GMO food, and the fact that the Mozambique is used as transit country will not exclude the country from trading in GMOs. On another hand, due to its strategic importance, it is required to create an adequate environment that stimulate the development of biotechnology in the country in a safe and responsible manner. In this context, there is a need for the development and implementation of the national biosafety framework to address adequately and effectively biosafety and biotechnology issues in the country.

Mozambique ratified the CPB in December 2001 and has established the National Biosafety Working Group (GIIBS) tasked to co-ordinate biosafety activities in Mozambique. This is an inter-institutional and multi-disciplinary group with the task of co-ordinating the process of establishment of the National Biosafety Framework including the development of biosafety policy, regulatory regime and administrative system based on the CPB.

To fulfil these tasks, the National Biosafety Working Group with financial support from the UNEP-GEF Project on Development of NBFs coordinated work that led to development of this National Biosafety Framework

The National Biosafety Framework of Mozambique includes sectoral policies related to biosafety, regulatory regime, administrative system, monitoring and enforcement and mechanisms for public participation. It is expected that this NBF will contribute for protection of human health and environment from the risks of GMOs creating, at same time, an enabling environment for safe development and application of modern biotechnology in country. The NBF was developed taking into account the national legal framework and the national obligations under the Cartagena Protocol on Biosafety and other international agreements and treaties relevant biosafety that the country is signatory

I am quite confident that by developing NBF, Mozambique has made a remarkable step ahead toward safe and responsible application of modern biotechnology in the country. Now that the country has taken this important step, the challenge is to create an appropriate environment for the implementation of NBF. In this context, it is very important to mobilize resources for biosafety and biotechnology capacity building which is key factor for successful implementation of NBF.

The Minister of Agriculture
Dr Tomás Frederico Mandlate

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The Director General, IIAM

Dr Calisto Bias

LIST OF ACRONYMS

AIDS- Acquired Immune Deficiency Syndrome
BCH- Biosafety Clearing House
CBD- Convention on Biological Diversity
CBUEM- Centro de Biotecnologia da Universidade Eduardo Mondlane (Biotechnology Centre of the Eduardo Mondlane University)
COP- Conference of Parties of Convention on Biological Diversity
CPB- Cartagena Protocol on Biosafety
DINA- Direcção Nacional de Agriculture (National Directorate of Agriculture)
DINAP- Direcção Nacional de Pecuária (National Directorate for Livestocks)
DNA- Deoxyribonucleic acid
DNAIA- Direcção National de Avaliação do Impacto Ambiental (National Directorate for Environment Impact Assessment.
DNGA- Direcção Nacional de Gestão Ambiental (National Directorate for Environment Management)
DNS- Direcção Nacional de Saúde (National Directorate of Health)
DS- Departamento de Sementes (Department of Seeds)
EIA- Environment Impact Assessment
FAEF- Faculdade de Agronomia e Floresta- Faculty of Agronomy and Forestry
FAO- Food and Agriculture Organization of the United Nations
GEF- Global Environmental Facility
GIIBS- Grupo International Sobre Bio-Segurança (Biosafety Working Group)
GMO- Genetically modified organisms
HIV- Human Immunodeficiency Virus
IITPGRFA- International Treaty on Plant Genetic Resources for Food and Agriculture
MINAG - Ministério de Agricultura (Ministry of Agriculture)
MCT- Ministério de Ciência e Tecnologia (Ministry of Science and Technology)
MICOA- Ministério para Coordenação da Acção Ambiental (Ministry for Coordination of Environmental Affairs)
MOP- Meeting of Parties of the Cartagena Protocol on Biosafety
MP- Ministério das Pescas (Ministry of Fisheries)
PROAGRI- Programa de Investimento no Sector Agrário (Programme for Investment in Agriculture Public Sector)
SADC- Southern Africa Development Community
SARB- Southern Africa Biosafety Programme
TOR- Terms of Reference
UEM- Universidade Eduardo Mondlane (Eduardo Mondlane University)
UN- United Nations
UNIDO- Unted Nations Industrial Development Organisation
UNEP-United Nations Environment Programme
USAID- United States Agency for International Development
WHO- World Health Organisation
WTO- Word Trade Organisation

GLOSSARY

1. **Applicant**- any person or national or foreign entity that intends to import, export, develop or handle GMOs and their products for various purposes
2. **Biosafety** – measures to reduce the potential risks from GMOs and its products on environment particularly biodiversity and human health
3. **Biotechnology** – any technique that utilizes biologic systems, live organisms or their products, to produce or modify products or processes for specific purposes.
4. **Cartagena Protocol on Biosafety** – ratified by the Resolution 11/2001 of the Assembly of Republic, December 20th.
5. **Certificate of transit -** document issued by MINAG, certifying that the holder of the GMOs and their products is authorized to transport them through the national public roads.
6. **Country of origin –** country where GMO plants, animal and micro-organisms and their products were produced.
7. **Country of proceeding -** country from where GMO plants, animals and micro-organisms and their products as well as other material subjected to this regulation were exported regardless the country where they were produced.
8. **DINA –** National Directorate for Agriculture
9. **DINAP** – National Directorate for Animal Production
10. **Emergency** – anomalous situation that requires the need to take immediate and exceptional measures, on short-term, to save lives, protect assets, mitigate the adverse effects and restore the normality.
11. **Entry Points** – border entry to the country.
12. **Export authorisation of GMOs and its products** – A written authorization issued by MINAG, which gives permission to a person, or national or foreign entity to export GMO and their products, under specific conditions spelled out in it.
13. **Exporter** – any person or national or foreign entity that intends to export GMO and their products for various purposes.
14. **Genetically modified organism (GMO)** – any plant, animal or microbial organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
15. **IIAM –** Agriculture Research Institute of Mozambique.
16. **Importer** – any person or national or foreign entity that intends to import GMOs and their products for various purposes.
17. **Import authorisation of GMO and their products –** A written authorization issued by MINAG, which gives permission to a person, and national or foreign entity to import GMO and their products, under specific conditions spelled out in it.
18. **INGC** – National Institute for Disasters Management.

19. **Inspection –** Examination of plants, animals, foods, their products or any other related other material, with the aim to detect the presence of GMOs, performed by an official accredited by MINAG and tasked to ensure enforcement of the present Regulation.
20. **Lot -** specific quantity of a product identified by a number or a letter or a combination of both which is uniform for the information contained in the identification.
21. **MINAG –** Ministry of Agriculture, the entity responsible for the authorization of import, export, handling, development, utilization and transit of genetically modified organisms (GMO) and their products within the country, without prejudice to the competences of the Ministry of Industry and Trade related to external commerce operations to and from Mozambique.
22. **Modern Biotechnology** – application of technology of genetic manipulation, including genetic recombination, direct injection of DNA into cells or organelles, and fusion of cells besides the taxonomic family.
23. **National Biosafety Committee (NBC)**- multi-sectoral technical and scientific committee, with competence for analysis and advice in biosafety matters within the country.
24. **Organism** – any biologic entity capable of transferring or replicating genetic material.
25. **Package –** any container used to cover or protect the GMOs and their products.
26. **Products** – products of plant, animal or microbial origin containing GMOs.
27. **Risk Assessment** - evaluation of risks towards human health and to the environment that could originate from the deliberate release or display of GMO on the market, whether directly or indirectly, immediately or thereafter, preformed according to annexes II, III and IV of the Biosafety Regulation.
28. **Technical guidelines –** procedures for import, export, manipulation, handling, production, utilization and transit of genetically modified organisms and their products.
29. **Transit –** movement of GMO and their products, deriving from abroad, passing through Mozambique, with a third country as the destination

EXECUTIVE SUMMARY

1. While modern biotechnology may have potential role in contributing to meeting critical need for agriculture, food security and human health care there are some potential risks of GMOs to environment and human health and socio-economic and ethical issues that need to be addressed adequately. Thus, the development of modern biotechnology must go hand in hand with appropriate regulation in order to maximise its benefits while minimizing its risks.

2. It was within this context that Mozambique ratified the Cartagena Protocol on Biosafety in 2001 and created the National Biosafety Working Group tasked to coordinate the process of development the National Biosafety Framework in Mozambique

3 This document presents the National Biosafety Framework that is a result of 18-month work coordinated by GIIBS with financial assistance from the UNEP/GEF Project on Development of the National Biosafety Framework

4. In line with the national obligations under the Cartagena Protocol on Biosafety and other relevant international agreements and treaties that Mozambique is signatory, the National Biosafety Framework has the objective to establish an environment that ensures safe and responsible development and application of modern biotechnology, contributing, hence to the protection of human health and environment from potential risks posed by genetically modified organisms.

5. The present Draft National Biosafety Framework of Mozambique consists of a combination of sectoral policies related to biosafety, regulatory regime, an administrative system, systems for monitoring and enforcements and mechanisms for public participation and awareness

5.1. There is no stand-alone policy on biotechnology and biosafety in Mozambique but there are a number of current government policies that may have impact on the development of biotechnology and biosafety. The main elements of a guiding policy for development of environmentally sound and safe biotechnology activities are reflected either in Policy on Science and Technology (PST), the Strategy and Action Plan for Conservation and Sustainable Use of the Biological Diversity in Mozambique and the Public Investment for Agriculture Sector Development (PROAGRI). The PST indents to create an enabling environment for development of science and technology including new, innovative and emerging technologies such as biotechnology; The Strategy and Action Plan for Conservation and Sustainable Use of the Biological Diversity in Mozambique has a chapter that strategy focuses need for regulation and development of adequate infrastructure for the safe handling, use and transfer of genetically modified organisms and the framework PROAGRI provides an opportunity for technology development in country.

5.2. At present there is no approved law or regulation on biosafety and biotechnology in Mozambique. However, there are a number of regulations across different government sectors, namely agriculture, health, commerce and environment that are somehow related to biosafety and biotechnology. The existing national regulatory framework includes regulations on seeds, pesticides, quarantine and phyto-sanitary inspection, food importation and safety, animal health, environmental impact assessment and licensing of commercial activities.

5.3. Mozambique is either party or in the advanced stage of becoming part to some international agreements and treaties that may impact on the use of biotechnology. The most relevant of these international agreements and treaties include the International Plant Protection Convention Office International des Epizooties (OIE), *Codex Alimentarius*, General Agreement on Tariffs and Trade (GATT), Sanitary and Phyto-Sanitary (SPS) agreement and the SADC Protocol on Trade.

5.4. The proposed biosafety regulatory regime in Mozambique consists of a draft Decree of the Council of Ministers containing the biosafety regulation and 2 draft technical guidelines for risk evaluation as well as public awareness and participation in biosafety and biotechnology related issues.

5.5. The Draft Biosafety Regulation consists of a preamble, 27 articles organised in 9 chapters and 6 annexes. There is also a glossary of terms annexed to the biosafety regulation. The objective of the regulation is to establish rules for import, export, transit, deliberate release into environment, manipulation, handling and use of GMOs and their products as a means to contribute to the protection of the environment and human health from risks of GMOs. The scope of the regulation include all activities related to import, export, transit, deliberate release into environment, manipulation, management and use of GMOs and their products carried out by public and private entities in Mozambique.

5.6. The proposed administrative system for biosafety in Mozambique follows a single entry point scheme for application and it consists of 4 core bodies namely the National Biosafety Competent Authority (NBCA), the National Biosafety Committee (NBC), the Biosafety Technical Secretariat (BTS) and National Biosafety Focal Point (NBFP). The NBCA is the MINAG which shall exercise the powers and duties of national decision body and this will coordinate with relevant regulating agencies of MISAU (DNS) and MICOA (DNAIA); the National Biosafety Committee is composed of high ranked officials from biosafety related institutions including MINAG, MICOA, and MISAU. MCT, MIC, MP and Universities and it is tasked to provide policy advice and guidance to the NBCA; The Biosafety Technical Secretariat shall be responsible for the day to day administration of the framework and shall be housed under MINAG; the National Focal Point shall be charged to handle liaison activities related to the Cartagena Protocol on Biosafety on behalf of the Government of Mozambique.

5.7. It has not been proposed to create a new body specifically for monitoring and enforcement of GMOs and biosafety activities in Mozambique. The monitoring shall be carried out by the applicant responsible for the activities, whereas inspection and enforcement shall be done by the designated inspectorate of the existing regulating agencies for plants (DINA), animals (DINAP), health (DNS) and environment (DNAIA). The MINAG shall have an overall coordinating role for monitoring and enforcement of GMO and biosafety activities in the country.

5.8**.** The need for public awareness and participation in decision systems that may have potential adverse affect on environment or health has legal basis on the mandatory legal requirements emanating from the Constitution of the Republic, environmental impact assessment legislation and the land act. Indeed, the general public has the right to access information and comment on issues that have social, cultural, economic and political implications for their well-being. In this context, Mozambican has developed draft guidelines

on public participation in matters related to biotechnology and biosafety as a guidance document on good practices involving the development and deployment of GMOs. Mozambique proposes to use the radio, print and electronic media, television and the existing state administrative and local structures as avenues for sharing information. The NCA with the NBC shall also engage the public through public hearings, release of information on notifications and the development of brochures on biotechnology and biosafety activities in Mozambique.

5.9 A National Biosafety Database has been developed as a ready source of information for the public. The information for the database was captured as part of the information gathering and analysis of the national information through surveys.

5. It is strongly suggested that the NBF is further developed either to update the current national legal framework to enable the implementation of NBF or to keep it in line with fast growing field of biosafety and biotechnology.

6.1 Although some elements for biosafety and biotechnology policy are reflected in some existing sectoral policies, it would be recommended to develop a national biotechnology policy as guidance document for intervention of both public and private sectors in this field taking into account the strategic importance of biotechnology for sustainable development of the country.

6.2. With regards to the current legal framework, it is suggested that the article 33 of the regulation on seeds is amended to be in harmony with this draft NBF as it prohibits the import and use of GMO seeds. Yet concerning the legal regime, another area of intervention is the development of specific legislation on Intellectual Property Rights (IPR) particularly in the field of agriculture and health to create an adequate environment so that the country can benefit from the safe application of biotechnology.

6.2. The Draft Biosafety Regulation makes room for development of implementing regulations and technical guidelines, therefore, it is important that it taken as priority action the development of these regulations to help on the implementation of the National Biosafety Framework. In this context, priority should be given to the development of technical guidelines to govern the research in modern biotechnology (laboratories, greenhouses and field trials), identification, packaging and transport of GMOs, liability and redress, monitoring and inspection manuals as well as the rules of procedures of the proposed National Biosafety Committee.

6.3. Concerning the administrative system, a key gap identified is the need for continuous capacity building for the key institutional structures that will manage this framework. In that light Mozambique shall seek international cooperation through multilateral and bilateral arrangements and the provisions for capacity building as spelt out in Articles 14 and 22 of the Cartagena Protocol on Biosafety. Some of the envisaged training activities to make the administrative system of this framework functional include training on handling of notifications for the reviewers, the competent authority and the National Biosafety Committee, researchers and the regulatory agencies.

6.4. The NBF will utilise the existing human and infrastructure capacity in the fields of agriculture, health, environment and trade for enforcement of the proposed biosafety

regulatory regime. Thus, the future focus for monitoring and enforcement will involve training and certification of existing inspectors from the designated regulatory agencies, scientists and companies in public and private sector to handle issues relating to modern biotechnology. Inspection manuals shall be developed to assist inspectors in ensuring compliance with the regulatory regime. In addition, there is the need to equip, develop and certify molecular biology laboratories to act as referral laboratories for cases involving verification and detection of GMOs related in plant, animal and microbial related matters

6.5. The national biosafety database is to be improved and developed into the national node of the Biosafety Clearing House under the management of Secretariat of the CBD. Directories of institutions, expertise, equipment, legal instruments and other internal procedures and manuals related to the management of modern biotechnology shall be developed and made available to the public through the database or website and the print media. In addition, templates for regional agreements, national competent authorities, national focal points, and risk assessment procedures, the procedures for handling GMOs for food, feed and processing, capacity building initiatives among others shall be developed. All the survey reports, workshop reports and framework documents shall be placed in the national database. The next step is to develop a website into which the national biosafety database shall be incorporated

1. GENERAL INTRODUCTION

1.1. The nature and importance of biotechnology and biosafety

Biotechnology is any technique that uses biological systems, living organisms or derivates there-of to make or modify products or process for specific purposes (UNEP, 1992a).

The modern biotechnology related to recombinant DNA and genetic engineering techniques that produce genetically modified organisms (GMO's) is currently somewhat controversial because it involves adding new genes or altering existing genetic material to produce new traits or substances or perform new functions (Kitch *et al*., 2002). As in any new technology, there are concerns on the potential risks of GMOs to human health and environment, therefore, measures should be undertaken to ensure that GMOs are adequately tested for health and environment safety before they enter commercial chain.

Biosafety emerged as international priority issue in the Agenda 21 adopted by the Earth Summit on Environment and Sustainable Development held in Rio de Janeiro, Brazil, 1992 (UNEP, 1992b). This issue was further addressed in Article 19 (3) of the Convention on Biological Diversity which states "the parties shall consider the need for and the modalities of a Protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism (LMO) resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity'' (UNEP, 1992a). The mandate to start the negotiation of the biosafety Protocol under the Convention on Biological Diversity was given at COP 2 in Jakarta, in decision II/5 in 1995. After intense negotiations the Cartagena Protocol on Biosafety was adopted at an extra-ordinary COP held in Montreal in 2000 and it came into force in September 2003.

The Cartagena Protocol on Biosafety (CPB) establishes an international legally binding instrument to regulate the trans-boundary movement of GMOs. While the entry into force of the Protocol constitutes an important achievement of the international community, there is still a challenge for its implementation. Like other international agreements, the implementation of the Protocol will be on-going and iterative process where the primary step will be to translate the requirements of the Protocol into domestic legislation and other implementation measures (Zedan, 2003). Obviously, the effective implementation of this Protocol will depend heavily on the capacity of countries to develop the national legislation and to build institutional capacity towards its implementation.

Taking into account the need to build national capacity for the effective implementation of CPB, the UNEP/GEF decided to establish the Project on Development of National Biosafety Frameworks (NBF) in 2002. Ideally the NBF should consist of policy, regulatory regime, administrative system and mechanisms for public awareness and participation (UNEP/GEF 2003a; UNEP/GEF, 2003b; UNEP/GEF, 2003c).

1.2. Socio-economic context

Mozambique, located in the Southern African region, is a vast country with a total area of 799,390 km^2, lying in the latitude between 10° 27' S and 26º 52' S and in the longitude between 30° 12' E and 40° 51' E. The country has an extensive coastline on the east side of around 2,750 km^2 along the Indian Ocean, harbouring important seaports in the cities of Maputo, Beira, Nacala and Quelimane, mostly developed to connect the country with its neighbours, namely South Africa, Zimbabwe and Malawi. Data from the last census conducted in 1999-2000 (INE, 2003) indicates a figure of 18 million for the total population, 52% of who are women, the annual growth rate being estimated at 2.4% and with most populous provinces being Nampula (19.1%) and Zambezia (19%), while the least populated being Niassa (5%) and Maputo (6%) provinces respectively. Overall, the population density is around 20 people/km^2, with Maputo city presenting the highest density of around 3,500 people/km^2, contrasting with Niassa province, which presents a density of 6 people/km^2.

Mozambique has already achieved macroeconomic stability resulting from structural reforms that led to an increase in investments, significant reduction in inflation (9% in 2001) and increase in economic growth estimated at a rate of 7.7% from 2000 to 2003. However, the country is still poorly developed, sensitive to changes in the world market, depending on foreign assistance and vulnerable to natural disasters, such as floods and drought leading to food insecurity. Mozambique still faces the critical challenge of reverting to the current situation as one of the poorest country in the world, with one of the lowest per capita income of around US$ 220 per year and with high levels of adult illiteracy (60.5%), particularly for women, estimates indicating a level of around 84% (INE, 2003). The majority of Mozambican people (71%) still live below the absolute poverty line, with a significant number of people (65%) depending on less than US$ 0.5 per day for their subsistence. Poverty is widespread across the country, but it is higher in rural areas where a total of 71% (INE, 2003) of Mozambican population live and depending mostly in agriculture for their subsistence. Thus, poverty in rural areas is associated with factors that constraint agricultural production, some of the most important ones being attributed to the limited agricultural and market development and poor productivity levels. Associated with poverty is also the fact that investments are not yet sufficient to meet the basic needs of people, including access to basic goods, health and education. In addition, investments are also disproportionate across the country and, as result development is reduced in many geographical areas, with indicators of Human Development Index showing inequalities across the country, the central regions presenting higher levels of poverty.

1.3. The need for development of the National Biosafety Framework in Mozambique

Food and environmental security are on the top of the national agenda for fight against poverty and to ensure sustainable development of the country. In this context, the development and access to adequate novel technology for food and agricultural production is of crucial importance for achieving food security in the country. Biotechnology is a valuable novel technological tool with great potential to produce high yield, disease and pest resistant and high quality crops hence enhancing the agricultural and food production (FAO, 2004). This technology has also beneficial applications in key areas of animal production and health care. For this reason modern biotechnology is recognized as having great potential for promotion of human well-being, particularly in meeting critical needs for food, agriculture and human health care (FAO, 2004).

However, there are some legitimate concerns about the potential adverse effects of GMO products on the human health, biodiversity and environment, in general, posed by the unsafe use of genetically modified organisms (GMOs). There are also concerns on possible negative socio-economic impacts of GMOs on farmers from developing countries. Thus, the development of modern biotechnology must go hand in hand with appropriate regulation in order to maximise its benefits while minimizing its risks (Kitch *et al*., 2002)

Biotechnology research and development in Mozambique is still at its infancy; the country has just started developing its policy and strategy for intervention in this area. However, the globalisation of trade, the vulnerability of the country to natural disasters (droughts, floods, cyclones) often leading to the need for food aid containing, in some cases, GMO food, and the fact that the Mozambique is used as transit country will not exclude the country from trading in GMOs. There is, therefore, the need for the development and implementation of the national biosafety framework to address adequately and effectively biosafety and biotechnology issues in the country

1.4. The process of development of the National Biosafety Framework in Mozambique

Mozambique ratified the CPB in December 2001 and has established the National Biosafety Working Group (GIIBS) tasked to co-ordinate biosafety activities in Mozambique. This is an inter-institutional and multi-disciplinary group with the task of co-ordinating the process of establishment of the National Biosafety Framework including the development of biosafety policy, regulatory regime and administrative system based on the CPB.

To fulfil these tasks, the National Biosafety Working Group through the National Executing Agency and with financial support from the UNEP-GEF Project on Development of NBFs commissioned a consultancy to:

- Carry out a survey on the status of biotechnology and biosafety in Mozambique (application and use of biotechnology, research programmes, infrastructure and equipments, existing human resources (expertise) and training needs and opportunities);

- Conduct a survey and review the existing national and international legal instruments that may impact on use of modern biotechnology (e.g. phyto-sanitary regulation, regulations on pesticides, herbicides, import and export, food safety and others)

- Conduct survey and review of the existing National Biosafety Frameworks in Southern Region (South Africa, Zimbabwe, Namibia, Malawi and Zambia)

- Develop a national database of experts in Biotechnology and Biosafety

A drafting team in consultation with the National Biosafety Working Group was set to develop a draft National Biosafety Framework for Mozambique based on the results of surveys carried out.

1.5. Guiding principles

This NBF was developed to be consistent with the national regulatory framework, the Cartagena Protocol on Biosafety and other international regulatory frameworks relevant to biosafety. Therefore, it is harmony with following principles:

1.5.1. Precautionary Principle

The decision-making system of the NBF will be in accordance to the precautionary approach contained in article 15 of Rio Declaration on Environment and Development (Earth Summit, 1992) and the article 10.6 of the Cartagena Protocol on Biosafety (SCBD, 2000). Thus, scientific uncertainty due to insufficient relevant information and knowledge on extent of potential adverse effects of GMOs on environment and human health will not prevent that the competent authorities of the country take necessary measures, case by case, to prevent and minimise the potential adverse effects of GMOs.

1.5.2. Advanced Informed Agreement

Any entity that intends to be engaged in any activity related to GMOs must first notify and have approval from National Biosafety Competent Authority.

1.5.3. Balanced informed decision

The decision on activity on GMOs shall be on case-by-case based on risk assessment carried out in a scientific manner taking into account recognised risk assessment techniques. Both the potential benefits and risks of GMOs to human and the environment shall be taken into account in the decision making process.

1.5.4. Socio-economic considerations

Socio-economic aspects shall be taken into account in decisions on activity related GMOs.

1.5.5. Public awareness and participation

Decision making process shall be transparent and participatory where all relevant stakeholders shall have appropriate access to information and opportunity to participate in decision-making process.

2. OBJECTIVES

In line with the national obligations under the Cartagena Protocol on Biosafety and other relevant international agreements that Mozambique is signatory, the National Biosafety Framework has the objective to establish an environment that ensures safe and responsible development and application of modern biotechnology, contributing, hence to the protection of human health and environment from potential risks posed by genetically modified organisms.

3. INTRODUCTION TO DRAFT OF THE NATIONAL BIOSAFETY FRAMEWORK

The UNEP-GEF Project on the Development of the National Biosafety Framework of Mozambique was started October 2002 and ended in August 2004.

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The National Coordination Committee consisted of 39 being representatives from the institutions listed in table 1.

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4. DESCRIPTION OF THE NATIONAL BIOSAFETY FRAMEWORK

The Draft National Biosafety Framework is a combination of :

i. Sectoral policies related biosafety and biotechnology
ii. A regulatory regime for biosafety
iii. An administrative system to handle notifications and authorisations including Risk Assessment and Decision making
iv. Systems for "follow up" such as monitoring and enforcements
v. Mechanisms for Public Participation, Education and Public Awareness

4.1. National sectoral policies related to biotechnology and biosafety

There is no stand-alone policy on biotechnology and biosafety in Mozambique but there are a number of current government policies that may have impact on the development of biotechnology and biosafety namely:

(1) The Policy on Science and Technology (PST),
(2) Strategy and Action Plan for Conservation and Sustainable Use of the Biological Diversity in Mozambique,
(3) Public Investment for Agriculture Sector Development (PROAGRI),
(4) The National Environmental Management Plan
(5) The Agrarian Policy and Implementing Strategy

The main elements of a guiding policy for development of environmentally sound and safe biotechnology activities in Mozambique are reflected in the recently approved Policy on Science and Technology (PST) and Strategies for its Implementation. The Government of Mozambique approved the PST in 2003, with view to creating an enabling environment for development of science and technology including new, innovative and emerging technologies such as biotechnology. The objective of PST is to develop an integrated knowledge generation and management systems geared to the national needs and promotion of sustainable development in the country. The PST focuses on 4 main areas namely promotion of research and development, education, innovation in the private sector and information dissemination. The PST stresses the need for development of local capacity and technology transfer in key areas for national development. It aims at contributing to the reduction of absolute poverty, improvement of community livelihood and national development through creation of enabling environment that promotes research and scientific and technological competence**.** The strategic thrust of the policy is to allow for the integration of research activities into areas of the national development agenda that are not yet satisfactorily covered by the existing research initiatives such as energy, water, biotechnology, agro-processing, environment among others.

Mozambique ratified the Convention on Biological Diversity in 1994 (Resolution of the Assembly of Republic no. 34/94) and, bearing in mind the importance of conservation and

sustainable use of biodiversity and to meet its obligation under CBD, the government approved in July 2003, a Strategy and Action Plan for Conservation and Sustainable Use of the Biological Diversity. The ten year strategic plan sets out the guiding principles for the conservation and sustainable use of biological resources, through enhancement of control measures, change of attitudes and promotion of sustainable development and management practices related to use of biological resources. In the specific area of biosafety, the strategy focuses on regulation and development of adequate infrastructure for the safe handling, use and transfer of genetically modified organisms in order to reduce the potential risks that activities in modern biotechnology may pose to human health and biological diversity. It also aims at developing and implementing a National Biosafety Framework with additional emphasis on capacity building for management of GMOs and creation of accessible databases to promote access and sharing of information.

A new programme on public investment for agriculture sector development (PROAGR II) has been approved by the government. This programme is directed to address the main constraints, opportunities and needs of the family farming and private sectors and it is based on 6 themes namely infrastructure development, sustainable use of natural resources, development and access to technology, market and financial services. The framework of this programme provides an opportunity for technology development in which the safe application of biotechnology may play an important role.

Mozambique ratified the CPB in December 2001 and established in 2002 the National Biosafety Working Group (GIIBS). This is an inter-institutional and multi-disciplinary group that is charged with the responsibility of co-ordinating the process of establishing for National Biosafety Framework based on the Cartagena Protocol on Biosafety. The GIIBS is under the coordination of the Ministry of Agriculture and it is composed of institutions representing the public sector, civil society and private sector. The action plan developed by GIIBS to address the assigned responsibility includes priority areas such as the development of National Biosafety Framework, capacity building (infrastructure development and human resources), public awareness, development of national database on biosafety and biotechnology information, mechanism for information sharing, regional and international cooperation.

4.2. Biosafety regulatory regime

4.2.1. Draft regulatory regime

The proposed biosafety regulatory regime in Mozambique consists of a draft Decree of the Council of Ministers containing the biosafety regulation (Annex A) and 2 draft technical guidelines for risk assessment and public awareness and participation (Annex B).

The biosafety regulation will be enacted as a Decree of the Council of Ministers after consultation with relevant stakeholders is completed. This regulation consists of a preamble, 27 articles organised in 9 chapters and 6 annexes (Table 2). There is also a glossary of terms annexed to the biosafety regulation.

IX		**FINAL PROVISIONS**
	27	Doubts
ANNEXES		
1		General Application form for importation of GMOs and their products
2.		Risk assessment form for GMOs and their products destined food, feed or processing
3		Risk assessment form for GMOs and their productss destined for contained use: Model 1: Research in laboratories and greenhouses Model 2: Field trials
4		Risk assessment form for GMOs and their productss destined for deliberate release into the environment
5		Table of fees
6		Table of fines
		Glossary

The objective of the regulation is to establish rules for import, export, transit, deliberate release into the environment, manipulation, management and use of GMOs and their products as a means to contribute to protection of the environment with focuses on conservation of biological diversity and human health.

The scope of the regulation includes all activities related to import, export, transit, deliberate release into environment, manipulation, management and use of GMOs and their products developed by public and private entities in Mozambique. It is also clearly stated that the regulation does not intend to take over the responsibility of the Ministry of Industry and Trade, which is the government entity with the powers to regulate international trade with Mozambique.

Under the regulation, the Ministry of Agriculture (MINAG) will exercise its powers and duties as the designated National Biosafety Competent Authority through the National Directorates of Agriculture and Livestock.

The regulation makes provisions for creation of a National Biosafety Committee composed of representatives from Ministries of Agriculture, Health, Coordination of Environment Affairs, Industry and Trade, Higher Education, Science and Technology which will advise the government and MINAG in all matters related to biosafety. It will be also charged to produce the recommendations to be submitted to the National Biosafety Competent Authority for final decision.

The regulation has provisions that allow further development of implementing regulations and guidelines to facilitate the implementation of NBF. They also make room for development of legal instruments to address issues related to mandatory GMO labelling,

liability and redress and other emerging issues. Issues of appeal shall be handled by the current applicable civil law procedures which are handled by the administrative tribunal system of Mozambique.

4.2.2. Existing national legal instruments that may impact on biotechnology and biosafety.

At present there is no approved law or regulation on biosafety and biotechnology in Mozambique. However, currently there are a number of regulations across different government sectors, namely agriculture, health, commerce and environment that are somehow related to biosafety and biocenology. The existing national regulatory framework includes regulations on seeds, pesticides, quarantine and phyto-sanitary inspection, food importation and safety, animal health, environmental impact assessment and licensing of commercial activities. A detailed description of the existing regulatory framework is given in Table 3.1

4.2.2.1. Plant health inspection and quarantine regulation

This regulation was approved through *Diploma Ministerial no. 134/92* and is enforced by the Ministry of Agriculture through the National Directorate of Agriculture. This regulatory tool regulates import, export and transit of plants and plant products, in view to prevent introduction and dissemination of plant pests and diseases, in particular those organisms that are plant quarantine objects. A number of phyto-sanitary inspection posts and plant health inspectors are positioned at the main border posts, with back up support from central laboratories in Maputo. The regulation establishes that import and transit of plants and plant products is subject to a phyto-sanitary import permit, while for export of plants and plant products a phyto-sanitary certificate is required. Both imports and exports are subject to inspection by phyto-sanitary inspectors. The existing phyto-sanitary inspection framework should be used as a basis to establish a comprehensive system of enforcement of biosafety regulation, particularly in regard to application for imports, transit and inspection of GMOs.

4.2.2.2 Animal Health Regulation

This regulation was approved through *Decree no. 8/2004* and is enforced by the Ministry of Agriculture through the National Directorate of Livestock. This regulation set out the conditions for domestic movement, import, export and transit of animals and animal products, in view to prevent introduction and dissemination of animal diseases. This regulation can be used in combination with the proposed biosafety regulation when dealing with genetically modified animals or animal products. A number of veterinary inspection posts and inspectors are positioned at the main border posts, with back up support from central and provincial laboratories in Maputo. This capacity could be utilized for the enforcement of the proposed biosafety regulation.

4.2.2.3. Regulation on Seed Production, Marketing, Quality Control and Certification

This regulation was approved through Diploma Ministerial no. 184/2001 and is enforced by the Ministry of Agriculture through the National Directorate of Agriculture. This regulation set out rules for seed production, marketing, quality control and certification of import, transit and export seeds. In particular, the regulation establishes that:

- The introduction of new crop varieties is subject to approval by the Minister, under the proposition of the National Seeds Committee.
- The seed producers and processors must be registered
- Fields for seed production must be registered;
- Rules for seed quality control and certification;
- Sampling, sealing and labelling of seed lots;
- Seed imports must be accompanied with a Field Inspection Seed Certificate, Orange International Seed Lot Certificate, and an additional declaration stating that seed is not genetically modified; and a phyto-sanitary certificate.

The Article 33 of this regulation states that importation of GM seed is prohibited. Therefore, there is a need to harmonize the seed regulation with the proposed biosafety regulation, at least for those crop species when eventually GM varieties are allowed.

4.2.2.4. Environmental Law

This law is enforced by the Ministry for Co-ordination of Environmental Affairs and was approved through law 20/1997. It provides the legal basis for sustainable use and management of the environment and its components, in view to ensure sustainable development of the country. This law contains provisions directly related to the conservation of biological diversity by prohibiting all activities that may adversely affect conservation, reproduction, quality and quantity of biological resources, especially those at threat.

4.2.2.5. Regulation on Environmental Impact Assessment:

This regulation was approved through Decree 45/2004 and is enforced by the Ministry for Co-ordination of Environmental Affairs through the National Directorate of Environmental Impact Assessment. The regulation aims to protect the environment by ensuring compliance with the process for environmental impact assessment in both public and private activities that may influence the environment. The regulation defines three main categories of activities, namely:

- Category "A" activities, whose implementation require that an Environmental Impact Assessment to be conducted. For example, the introduction of new crops and exotic species (Annex 1, paragraph 3d) fall under this category. Eventually, the introduction of GM crops will fall under this category.
- Category "B" activities, which require a Simplified Environmental Study and

- Category “C” activities- require compliance with guidelines for sound environmental management.

The existing framework for environmental impact assessment can be seen as complementary to the proposed biosafety regulation, particularly in regard to the environment risk assessment associated with GM crops.

4.2.2.6. Law of Crime Against Public Health:

This law is enforced by the Ministry of Health and it establishes mechanisms to combat infringements against public health. The law is applicable for foods and foodstuffs including natural or artificial food derivates intended for human consumption, beverages, and spices. At present, the law is not translated into specific regulation. It is suggested that issues on genetically modified foods are addressed in the food safety regulation in preparation at the Ministry of Health. Furthermore, there is a need for implementing guidelines on this matter.

Table 3.1: List of national legal instruments that may have impact on Biotechnology in Mozambique

Title of legal instrument	Type/ status	Objective	Procedures/contents	Responsible institution	Remarks
Plant Health Inspection and Quarantine Regulation	Diploma Ministerial no. 134 (1992)	Regulates import, export and transit of plants and plant products, in view to prevent introduction and dissemination of plant pests and diseases	Import and transit of plants and plant products are subject to a phytosanitary import permit, while for export a phytosanitary certificate is required. Inspection is required in both imports and exports	MINAG (DINA)	
Animal Health Regulation	Decreto 08/2004	Regulates domestic movement, import, export and transit of animals and animal products, in view to prevent introduction and dissemination of animal diseases.	Import and export of animals or animal products is subject to an Import Permit and health certificate respectively. In both cases inspection is carried.	MINAG (DINAP)	
Regulation on Seed Production, Marketing, Quality Control and Certification	Diploma Ministerial no. 184 (2001)	Regulates seed production, marketing, quality control and certification of import, transit and export seeds.	Variety release and registration, seed certification, processing, treatment, marketing, export, penalties	MINAG (DINA)	This regulation need to be harmonized with the proposed biosafety regulation- currently GM seed not allowed (Article 33)
Regulation on Production and Marketing of Tobacco	Diploma Ministerial 176 (2001)	Regulates the relationship between big tobacco growers, small-scale tobacco growers and industry, in view to prevent conflicts amongst different stakeholders.	This regulation defines four categories of operators and establishes procedures for tobacco production, marketing, import and export	MINAG (DINA)	

Forestry and Wildlife Law	Law no. 10 (1999)	This law aims at protection, development and sustainable utilization of forest and wildlife resources for actual and future benefit of Mozambican people.	The law establishes the basic principles and rules governing the conservation and sustainable utilization of forestry and wildlife resources, within the framework of integrated management of resources for the country's economic and social development	MINAG (DNFFB)	
Forestry and Wildlife Regulation	Decreto no. 12 (2002)	Aims to protect forestry and wildlife resources thereby promoting their sustainable utilization.	The regulation is applicable to protection, conservation and utilization of forest and wildlife resources including their marketing, storage, transport, primary and industrial transformation as well as craftwork	MINAG (DNFFB)	
Regulation on Environment Impact Assessment	Decreto no. 45 (2004)	Aims to protect the environment by ensuring compliance with the process for environmental impact assessment in public and private activities that may influence the environment	The regulation defines three main categories of activities that require EIA. For example, introduction of new crops and exotic species (Annex 1, paragraph 3d).	MICOA (DNAIA)	Some aspects of risk assessment and management that are covered by the proposed biosafety regulation are also addressed in the EIA regulation.
Regulation on Licensing of Commercial Activities	Decreto no. 43 (1998)	This regulation establishes the conditions and procedures for licensing of commercial activities including sale, import	This regulation covers wholesale and retailer shops, general commerce, imports, exports and	MIC (DNC)	

		and export of products and services, in accordance with specific legal requirements of hygiene and safety	services		
Law of Crime Against Public Health	Law 8/82 (1982)	Defines mechanisms to combat infringements against human health.	The law is applicable for foods and foodstuffs including natural or artificial food derivates intended for human consumption, beverages, and spices.	MISAU (DNS)	
Environmental Law	Law no. 20 (1997)	This law provides the legal basis for sustainable use and management of the environment and its components, in view to ensure sustainable development of the country	This law contains provisions directly related to conservation of biological diversity by prohibiting all activities that may affect adversely conservation, reproduction quality and quantity of biological resources, especially those at threat.	MICOA	Precaution and accountability are amongst the basic principles of this law. These principles are also followed in the proposed biosafety regulation.

4.2.3. International agreements and treaties that may have impact on biosafety and biotechnology in Mozambique

The National Biosafety Framework of Mozambique shall be compliant with national obligations under international agreements and treaties related to biosafety and biotechnology that the country has ratified. Mozambique shall also follow the general principles of international agreements and treaties that the country is in the advanced stage of becoming party. The relevant international agreements and treaties that may impact on biotechnology and biosafety in Mozambique are listed in table 3.2.

4.2.3.1. Convention on Biological Diversity

This Convention is under the auspices of the United Nations and it aims to conserve and promote sustainable use of biological diversity as well as to promote fair and equitable sharing of benefits arising from the use of genetic resources. The Article 8(g), requires Parties to take domestic measures to regulate, manage or control risks associated with GMOs. This Convention was ratified by the Resolution no. 34/94 of the Assembly of Republic, 1994, BR no 34, Series 1). The implementation of the Convention is coordinated by MICOA through the National Directorate of Environment Management.

4.2.3.2. Cartagena Protocol on Biosafety

This Protocol is under the auspices of the CBD and it has the objective to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology. Mozambique was one of first countries to ratify the Protocol through the Resolution no. 11/2001 (BR no 5, Series 1) on 20th December 2001. The Institute of Agriculture Research of Mozambique constitutes the national focal point for this Protocol.

4.2.3.3. International Plant Protection Convention

This is an international treaty under the FAO and adopted in 1951 (amended in 1979 and revised 1997). Although not formally a party to IPPC, Mozambique is guided by its principles and expects to ratify this treaty during 2005. The objective of the treaty is to secure common and effective action to prevent introduction and spread of pests and diseases of plants and plant products. IPPC allows parties to take phyto-sanitary measures to prevent introduction and spread of pests and diseases based on pest risk analysis. GMOs that could constitute plant pests and diseases fall within the scope of the IPPC. The IPPC standards and technical guidelines are deemed to be consistent with the SPS Agreement under the WTO/GATT. The Plant Protection Services-National Directorate of Agriculture of the Ministry of Agriculture constitutes the entry point for the convention.

4.2.3.4. Office International des Epiz

and beneficial trade arrangements", and to "*establish a Free Trade Area in the SADC region*". The protocol establishes that member states shall base their sanitary and phyto-sanitary measures on international standards, guidelines and recommendations so as to harmonize sanitary and phyto-sanitary measures for agricultural and livestock production. The objective of free movement of goods in the region does not prevent parties from taking actions relating to conservation of exhaustible natural resources and the environment as well as actions necessary to ensure compliance with existing obligations under the international agreements.

Table 3.2. List of international agreements that may have impact on biotechnology and biosafety in Mozambique:

Title of legal instrument	Type/ status	Objective	Content/ main obligations of parties	National Focal Point	Remarks
Convention on Biological Diversity, SCBD, 1992	Legally binding, Ratified by Resolution no. 34/94 of the Assembly of Republic, 1994, BR no 34, Series 1.	To conserve and promote sustainable use of biological diversity and to promote fair and equitable sharing of benefit sharing arising from the use of genetic resources.	Article 8(g), requires Parties to take domestic measures to regulate, manage or control risks associated with GMOs	DNGA	
Cartagena Protocol on Biosafety, SCBD, 2000	Legal binding, Ratified by Resolution no. 11/2001 of the Assembly of Republic, 2001, BR no 5, Series I	To contribute to ensuring an adequate level of protection in field of safe transfer, handling and use of GMOs that may have adverse effects on conservation and sustainable use of biological diversity taking into accounts risks to human health	This protocol contains detailed obligations focusing in particular on the transboundary movements of GMOs. The Protocol requires Parties to ensure that the development, handling, transport, use, transfer and release of GMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account human health.	IIAM	
International Plant Protection Convention (IPPC), FAO, 1951 (amended in 1979 and revised 1997).	Legally binding, Mozambique expects to ratify this treaty during 2005	To secure common and effective action to prevent the introduction and spread of pests and diseases of plants and plant products (mainly in international trade).	IPPC allow parties to take phyto-sanitary measures to prevent introduction and spread of pests and diseases based on pest risk analysis. GMOs that could constitute plant pests and diseases fall within the scope of the IPPC.	DINA	IPPC standards and technical guidelines are consistent with the SPS Agreement under WTO/GATT
Office International des Epizooties (OIE), 1924	International treaty ratified by Mozambique in 1978.	OIE is an international treaty that which aims to prevent introduction and spread of animal diseases.	The OIE produces and assesses scientific evidence and operates by consensus to develop harmonized standards and technical guidelines and recommendations that govern the trade of animals and animal products.	DINAP	OIE standards and technical guidelines are deemed to be consistent with the SPS Agreement under WTO/GATT
Codex Alimentarius	Non-binding international code of conduct adhered to by	To elaborate standards, general principles, and guidelines and recommend codes of practice in	*Codex Alimentarius* will be an important instrument to GMOs as in future it may incorporate standards on safety of foods	DNS	

Mozambique	relation to food safety and related issues.	derived from

4.2.4. Further work on the regulatory regime

The Draft Biosafety Regulation makes room for further development of complementary regulations and technical guidelines therefore, it is important that it is taken as priority action the development of these technical guidelines to help on the implementation of the National Biosafety Framework. Among these, there is a need to develop the rules of procedures of the proposed National Biosafety Committee and technical guidelines for research in laboratories, greenhouse, field trials and monitoring and inspection. The draft technical guidelines on risk assessment and public awareness and participation should be further refined. Complementary regulations on identification,.00u2gring andtrainsporn of

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2. The National Biosafety Committee composed of high ranked officials from the Ministries of Agriculture, Health, and Coordination for Environment Affairs, Industry and Trade, Higher Education, Science and Technology and universities appointed by their respective Ministers or Rectors. This committee shall be charged for policy guidance and advice to Government, MINAG and other delegated competent institutions in matters related to biotechnology and biosafety. It will be also charged to produce the recommendations to be submitted to the national delegated competent institutions for final decision.

3. The Biosafety Technical Secretariat (BTS) shall be responsible for the day-to-day administration of the framework and it shall be housed under MINAG. Its functions will include processing applications for completeness, setting up *ad hoc* review committees with the advice from the National Biosafety Committee and liaison with the public and applicants, sending comments back to delegated national competent institutions for decisions. The Biosafety Secretariat in collaboration with the National Biosafety Focal Point will be responsible for development and maintenance of the national biosafety database as well as networking among national and international institutions involved in biotechnology and biosafety. It shall also be responsible in collaboration with the National Biosafety Committee and the delegated competent institutions for the promotion and facilitation of public awareness, education and public participation.

4. The National Biosafety Focal Point shall handle liaison activities related to the Cartagena Protocol on Biosafety on behalf of the Government of Mozambique and MINAG.

The proposed GMO application process is as summarised in figure 1

- The applicant submits the application documents to the Biosafety Secretariat which checks for completeness and conformity of the documents to the regulation.
- If the documents are satisfactory, the secretariat in consultation with the National Biosafety Committee will send the documents to the scientific review teams for risk assessment.
- At same time, relevant application documents which do not contain business confidential information are made available for comment and input from the public.
- The Biosafety Technical Secretariat receives the risk assessment and management report from the reviewers and input from the public. This report together with the summary of input from the public are forward by BTS to the National Biosafety Committee for further consideration and elaboration of recommendations.
-
- The National Biosafety Committee evaluates the risk assessment and management report and inputs from the public and produce recommendations to be sent together with the application to competent institutions for decision.

- The competent institutions shall communicate the decision taken to the applicant through the BST. They shall also issues copies of the authorisation with risk management plans for the inspectorate to initiate monitoring and enforcement activities.
-
- The final decision shall take into consideration

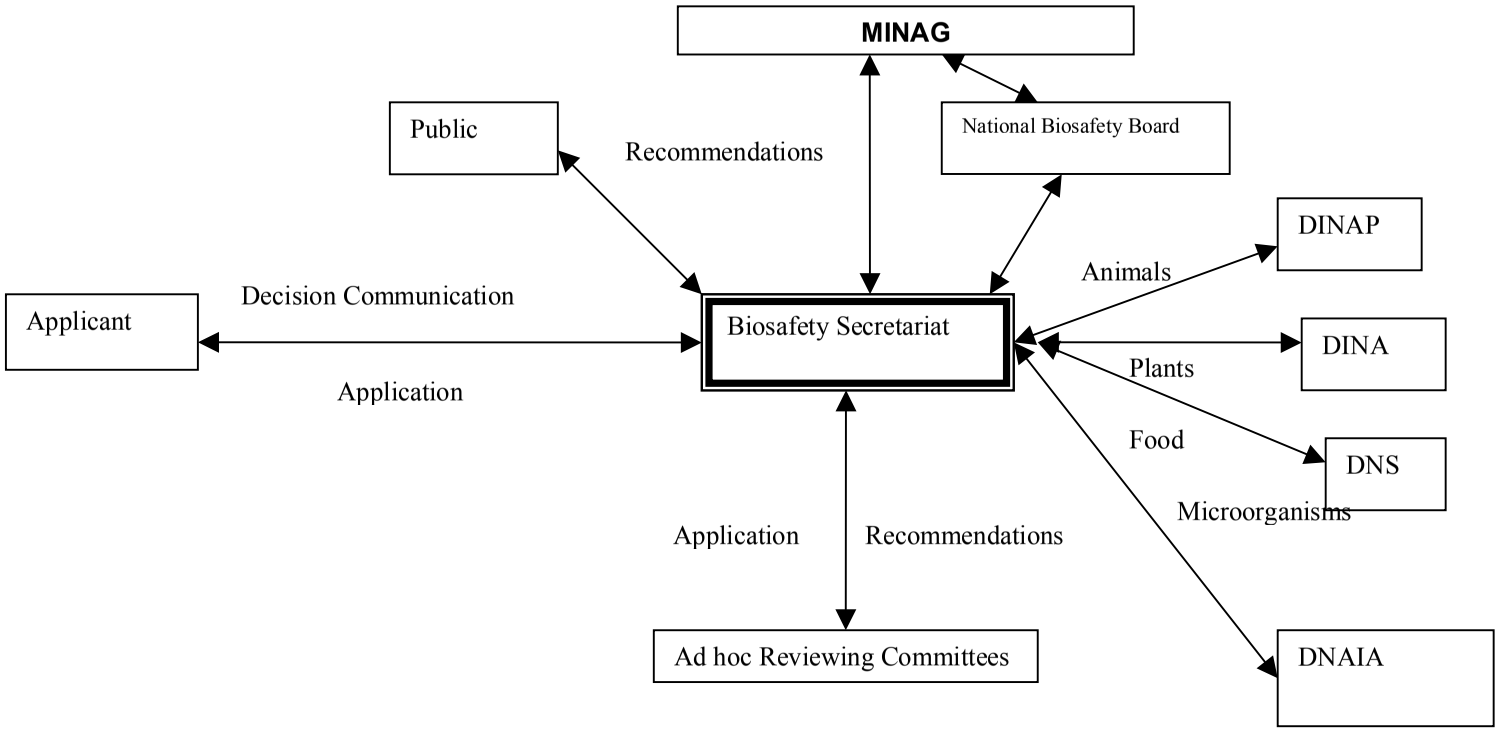
    i. Information submitted by the applicant
    ii. The risk assessment and management report
    iii. Inputs from the public
    iv. Socio-economic considerations

- The authorisation from the Competent authority shall

    a) clearly set out the specific conditions related to the approval.
    b) be specific and limited to the activity authorized as set out in the decision document.

Application forms for authorisation; risk assessment and a table of fees and fines have been developed to assist in the handling of notifications related to GMOs in Mozambique. These application formats have been annexed to the biosafety regulation.

Figure 1: Procedure for GMO application for import, export, manipulation and use in Mozambique



National Competent Institutions with delegated authority from MINAG (Regulating agencies responsible implementation, monitoring and enforcement)

4.3.2. Future plans related to the administrative system

The National Biosafety Competent Authority (MINAG) in collaboration with the proposed monitoring and enforcement agencies shall designate entry points for GMOs through the issuance of internal administrative procedures. Information on application forms including risk assessment and authorisations shall be made available to the public through the National Biosafety Database and the BST.

A key gap identified is the need for continuous capacity building for the key institutional structures that will manage this framework. In that light Mozambique shall seek international cooperation through multilateral and bilateral arrangements and the provisions for capacity building as spelt out in Articles 14 and 22 of the Cartagena Protocol on Biosafety. Some of the envisaged training activities to make the administrative system of this framework functional include training on handling of notifications for the reviewers, the competent authority and the National Biosafety Committee, researchers and the regulatory agencies.

The implementation of the NBF will be stepwise and iterative process. Thus, before embarking on dealing with general applications, Mozambique shall use test applications for contained activities to assess the functionality of its National Biosafety Framework. This will allow to identify eventual gaps and to make the necessary refinement of the administrative system.

4.4. Mechanism for monitoring and enforcement

The surveys conducted detected the absence of a monitoring and enforcement system specifically for GMOs and related biosafety matters in Mozambique and the draft NBF does not contemplate the establishment of a new body to this effect. Thus, in the proposed model, the monitoring will be carried out by the entity responsible for the activities and the inspection will be carried out by existing regulating agencies for plants, animals, health and environment.

4.4.1. Monitoring

In Mozambique, monitoring plans are usually part of the application process. Monitoring could be in the form of general surveillance and, depending on the results of the risk assessment, case specific monitoring. An applicant who places a product on the market or in the field should ensure the implementation of monitoring of the effects of the product and its use on the environment and human health in accordance with its programme and

regularly report to the MINAG on the results of monitoring. The applicant shall be held liable if emergency issues are not reported to the competent authority.

As already indicated, monitoring is usually carried out by the applicant responsible for the activities, whereas inspection and enforcement shall be done by the designate inspectorate of the National Biosafety Framework for Mozambique. The existing inspectorate agencies are mandated to handle these functions on behalf of MINAG.

A monitoring and enforcement mechanism for the Mozambican framework shall be conceptualised from the regulation listed in the conclusion and recommendation section. Identified institutions include the inspectorate services for plant, animal and human health and environment from MINAG, MISAU and MICOA.

4.4.2. Enforcement and the responsible institutions

The enforcement for compliance to legal instruments is usually undertaken by an inspectorate system. This is to ensure compliance with the regulatory regime. Inspectors are usually given powers to ensure compliance to the regulatory regime. The biosafety regulation spells out these functions in article 20 and 21. MINAG, which is National Competent Authority, shall serve as the executive body for the overall monitoring, risk management and commercial release of authorised GMOs and their products. In pursuit of its functions, MINAG shall designate the following regulatory institutions with specified mandate areas to assist in its enforcement functions after authorisations have been given to applicants. The monitoring and inspection functions shall handled as listed below

- DINA-MINAG – Plant production and protection and related safety matters;
- DINAP-MINAG – Animal production and health and related safety matters;
- DNS-MISAU -Human health matters particularly food safety and
- DINAI-MICOA -Environmental matters particularly environmental impact assessment.

The food safety inspectorate shall handle food safety issues whilst analysis will be done by the reference laboratory (LNAAHA) and issues of releases to the market place. Further activities in the area of monitoring and enforcement shall be elaborated through internal administrative procedures and periodic technical guidelines including the development of inspection manuals for the inspectorate.

4.4.3. Future plans for monitoring and enforcement systems

The future focus for monitoring and enforcement will involve training and certification of existing inspectors from the regulatory agencies listed in section 4.4.3, scientists and companies in public and private sector to handle issues relating to modern biotechnology. Inspection manuals shall be developed to assist inspectors in ensuring compliance with the regulatory regime. In addition, there is the need to equip, develop and certify molecular biology laboratories to act as referral laboratories for cases involving verification and detection of GMOs in matters related to either plants, animals and microbial. In this vein, in the area of food safety the national reference laboratory shall be strengthened and designated to assist in food safety analysis. Efforts shall also be made to equip the cross-sectoral and dispersed inspectors with rapid diagnostic methodologies (kits) to assist in their work.

4.5. Mechanisms for public awareness and participation

4.5.1. Proposed mechanisms for public awareness and participation

Public awareness of biotechnology and participation in decision systems that may have the potential to affect the environment, health or biodiversity have become critical in managing any development issue in Mozambique. This has been further addressed by the mandatory legal requirements emanating from the constitution, environmental impact assessment legislation and the land act.

Decision-making is no longer the right of the government but the wider civil society including NGOs and the private sector play a critical role. Indeed, the general public has the right to access information and comment on issues that have social, cultural, economic and political implications for their well being. This is further addressed by constitutional obligations on right to information.

Biotechnology and biosafety issues require the full awareness and participation of the public due to their persuasive nature and the fact these are new technologies in which Mozambique is now building the management systems. This is because, as useful as biotechnology is as a tool in agriculture and health-related research, among others, it must be emphasised that the deliberate release of GMOs into the environment and the possible accidental release of GMOs from certain types of contained use may have significant adverse effects on the environment, and pose risks to human health. This is enough justification for the need to ensure transparency and public participation in decision-making on GMOs. The ultimate objective hopefully will be to provide consumers with adequate information on products consisting of or containing GMOs to enable them to make

informed environmental and consumer choices and thus build public confidence in decision-making on the use of GMOs.

The important role of the public in the deployment of GMOs is spelt out in Article 23 of the Cartagena Protocol. Article 23 (2) requires that the public is consulted in the decision-making process regarding GMOs and the results of the decision are also made public while respecting confidential information. In the light of this, there is urgent need for innovative and practical methods for making information accessible to the public. Public education on genetic technologies and GMOs must also be intensified. The processes of educating the people must provide opportunities for the public to freely exchange information thus promoting active participation in decision-making.

It is against this background that Mozambican developed guidelines on public participation in matters related to GMOs as a guidance document on good practices in involving the development and deployment of GMOs. Mozambique proposes to use the media both print and electronic and the existing state an and local administrative structures as avenues for sharing information. The competent authority in collaboration with the National Biosafety Committee as already stated shall also engage the public through public hearings, release of information on notifications and the development of brochures on biotechnology and biosafety activities in Mozambique.

4.5.2. Examples of best practices and lessons learnt

In Mozambique, a notable example of best practice which could give guidance to the management of modern biotechnology is the case of public hearings under Environmental Impact Assessment Regulation and the Land Act. These legal instruments require the participation of the community in the hearing and decision on the issuance of environmental and land use permits. Similar public participation processes have been critical in the preparation of policy and other related legal instruments in most cases the public is given an opportunity to contribute in the processes. This has helped create a sense of national ownership of the development process in Mozambique.

4.6. The National Biosafety Database

A National Biosafety Database has been developed as a ready source of information for the public. The information for the database was captured as part of the information gathering and analysis of the national information through surveys. It includes information on a roster of experts at national level.

4.7. **Future plans for systems for public awareness, education and participation, in biosafety**

The national biosafety database is to be improved and developed into the national node of the Biosafety Clearing House under the management of Secretariat of the CBD. Directories of institutions, expertise, equipment, legal instruments and other internal procedures and manuals related to the management of modern biotechnology shall be developed and made available to the public through the database or website and the print media. In addition, templates for regional agreements, national competent authorities, national focal points, and risk assessment procedures, the procedures for handling GMOs for food, feed and processing, capacity building initiatives among others shall be developed. All the survey reports, workshop reports and framework documents shall be placed in the national database. The next step is to develop a website into which the national biosafety database shall be incorporated

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ANNEX A: DRAFT BIOSAFETY REGULATION

REPUBLIC OF MOZAMBIQUE

COUNCIL OF MINISTERS

DECREE Nº /2004

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The ever-increasing demand for food to meet the needs of the growing population, associated with high rates of absolute poverty challenge the country to increase the food production as well as agricultural production and productivity while conserving, at the same time, its environment particularly the biodiversity. At a global level, the resort to modern biotechnology has been claimed as one of the solutions to this challenge, due to its potential application in the production of crop varieties that are high yielding, resistant to pests and diseases, tolerant to adverse environmental factors such as drought and excess of salinity, and with enhanced nutritional value. The modern biotechnology has also potential applications in the field of animal production and pharmaceutical industry hence, it may make an important contribution for the improvement of health cares.

Like any emerging technology, the widespread adoption of modern biotechnology in the country may constitute a risk to the environment and to human health, if preventive measures and control rules are not established.

Thereby, as set forth in Article 2 of the Resolution of the Assembly of Republic no 11/2001, of December 20th and under sub-heading e) of the Article 153 of the Constitution of the Republic, the Council of Ministers decrees:

Article 1. The Biosafety Regulation, attached to the current decree in which it is integrated, is approved.

Passed by the Council of Ministers

Signed

The Prime-Minister , *Luísa Dias Diogo*

BIOSAFETY REGULATION

CHAPTER I
GENERAL PROVISIONS

Article 1
Objective

The Present Regulation has as its primary objective the establishment of rules for import, export, transit, production, manipulation, handling and utilization of genetically modified organisms (GMOs) and their products, resulting from modern biotechnology, thus contributing to ensuring the adequate protection of the environment with an emphasis on the conservation of the biological diversity and human health.

Article 2
Scope

1. The rules established by the present Regulation shall apply to all the public and private entities involved in import, export, transit, production, manipulation, handling and utilisation of GMO and its products, without prejudice to the regime set out by the Decree no 56/98, of November 11th that regulates the operations of international trade to and from Mozambique and other applicable legislation.

2. The present Regulation shall not apply to the transboundary movements of GMOs and its products, which are pharmaceuticals for humans that are subjected to other specific legislation emanating from other treaties and international agreements.

Article 3
National Biosafety Competent Authority

1. The Ministry of Agriculture (MINAG) shall exercise the powers and duties of the National Biosafety Authority and it shall have the competence to ensure the implementation, monitoring and enforcement of the present Regulation, through the National Directorates of Agriculture and Livestock in coordination with the entities relevant to the field of biosafety.

2. For the purposes of paragraph 1 of the present Article, the MINAG shall have the following competences:

    a) To confiscate, order the destruction or re-expedite GMOs and their products that do not comply with the present Regulation or other applicable norms;

b) To inspect and control the entry points of the country and the sites of experimentation, production, storage and sale of GMOs and their products, in order to verify the compliance to the provisions of the present Regulation;

c) To determine the plant. animal and microbial species resulting from modern biotechnology, whose import, export, transit, production, manipulation, handling and utilization are permitted under the terms of the present Regulation;

d) To grant permits stipulated under the present Regulation. based on risk assessment and management report, input from the public and any other socio-economic consideration.

3. The Ministries of Agriculture, Coordination of Environment Affairs, Health and Science and Technology shall have the competence to develop and enact complimentary norms required for the implementation of this Regulation

Article 4
National Biosafety Committee

1. The National Biosafety Committee (NBC) is hereby created, as a multi-sectoral technical and scientific advisory body on biosafety matters in the country, supported by the Biosafety Technical Secretariat (BTS).

2. The NBC shall have the competence:

a) To coordinate the development and updating of biosafety norms adequate to the national reality, based on the Cartagena Protocol on Biosafety, ratified by the Assembly of the Republic through the Resolution nº 11/2001, December 20th ;
b) To ensure in coordination with other competent institutions, the implementation of biosafety norms;
c) To produce periodical technical reports on the status of the biotechnology and biosafety in Mozambique;
d) To provide technical assistance to the Government and the National Competent Authority on the decision-making regarding transfer, development, handling, and safe use of GMOs in the country;
e) To evaluate the biosafety components in the projects proposals that involve GMOs;
f) To serve as vehicle for information exchange on biosafety at the national, regional international levels;
g) To promote public awareness and education programmes on biotechnology and biosafety issues at a national level.
h) Promote short-, medium- and long-term training programmes on biotechnology and biosafety.

3. The NBC is composed of representatives from the institutions listed below, appointed by their respective Ministers or Rectors:

a) Ministry of Agriculture
b) Ministry of Industry and Commerce
c) Ministry of Fishery
d) Ministry of Health
e) Ministry for Coordination of Environmental Affairs
f) Ministry of Science and Technology
g) Universities

4. The NBC shall meets on a quarterly basis and their meetings may be attended by participants representing public and private entities and experts.

CHAPTER II
IMPORT OF GMOs AND THEIR PRODUCTS

Article 5
Food, feed or processing

1. The import of GMOs and their products for direct use as food, feed or processing shall be subject to prior obtaining of authorization issued by the MINAG and to this end the interested entities should submit the following documents:

   a) Completed application form for import of GMOs and their products, according to Annex I of the present Regulation

   b) Risk assessment and management report that certifies the absence of risks to humans, animals, plants, micro-organisms and the environment and spells out the monitoring and controlling measures to be taken according to the Article 14 and Annex II of the present Regulation

2. The MINAG may request samples for testing purposes.
3. Once the requirements listed above are fulfilled, the MINAG shall issue an authorization within a time limit of 90 days.
4. The entry of GMOs and their products should be carried out under the conditions described in the authorization, on the dates and entry points indicated in it and it may contemplate several lots of the same consignment.
5. The validity of the authorization is one year at the end of which the applicant should request a new authorization.

Article 6
Contained use and field trials

1. The import and manipulation of GMOs and their products by any person or entity, whether public or private, for research purposes is subjected to obtaining of an authorization from MINAG with manipulation permitted only under containment conditions.

2. The execution of field trials is subject to a prior authorization from MINAG under the recommendation of the NBC and after presentation by the applicant of results of previous study carried out under containment conditions within the country, except in the cases where the applicant produces documents that certify that similar scientific experiments have been carried out in other countries by recognized scientists indicating the results obtained.

3. For the purposes of paragraphs 1 and 2 of the present Article, the applicant should observe the following requirements:

    a) Fill out the application form for import of GMOs and their products, according to Annex I of the present Regulation;

    b) Provide the risk assessment and management report that certifies the absence of risks to humans, animals, plants, micro-organisms and the environment and spells out the monitoring and controlling measures to be taken according to the Article 14 and variants of the Annex III of the present Regulation depending whether the experiments are carried in the laboratories, greenhouses or field.

4. The authorization for import and manipulation shall be issued by MINAG within a time limit of 90 days and it is valid for the import of one single lot, which should be carried out within a period of six months.

Article 7
Deliberate release to environment

1. The import of GMOs and their products for deliberate release to environment is only permitted for the species indicated in the Annex V of the current Regulation.

2. For the purposes of paragraph 1 of the present Article, the applicant should observe the following requirements:

    a) Submit the completed application form for import of GMOs and their products, according to the Annex I of the present Regulation;

b) Produce documents certifying that field studies of GMO or their products were conducted in other locations by recognized scientists and indicating the results obtained;

c) Submit the label for approval

d) Provide risk assessment and management report that certifies the absence of risks to humans, animals, plants, micro-organisms and the environment and spells out the monitoring and controlling measures to be taken according to the Article 14 and the Annex IV of the present Regulation

e) Declare in detail the source and the storage and transportation conditions of GMO and their products;

f) Describe the monitoring measures of the life cycle;

g) Submit the report of the pre-embarkation inspection performed at the point of origin or proceeding of the consignment, specifying the protection measures that the applicant shall take in order to avoid negative effects to human and animal health, plants, micro-organisms and the environment in general.

3. The authorization for production shall be issued by MINAG, within the maximum time limit of six months following the consideration and approval of monitoring and controlling measures contained in the risk assessment and management report.

4. The applicant shall produce the authorization for production issued under the terms of this Article, whenever it is requested.

Article 8
Food aid

1. The import of GMOs or their products for food aid shall be authorised after the competent body has officially decreed the emergency and it shall be only permitted for commodities destined for human consumption and in response to cases of extreme need as long as there are no alternative solutions to respond to such emergencies on a timely manner.

2. The genetically modified food in a grain form, imported under the terms of the present Regulation, should be processed prior to distribution to the final recipients of food aid, in order to avoid its utilisation as seed.

3. The request for import is done through a proposal from the National Institute for Disasters Management.

4. The import authorization is only valid for the period when the emergency is still in effect.

5. The reply to the import authorization request shall be given within a maximum time limit of 15 days.

6. In case where additional information is need, the period mentioned in the previous paragraph may be extended to additional fifteen days.

7. For the purposes of paragraph 1 of the present Article, the applicant should observe the following requirements

    a) Completed application form for import of food containing GMOs, according to Annex I of the present Regulation;

    b) Document describing the monitoring measures that the importing entity will take in the process of importation and transportation of food containing GMOs.

8. The entities that intend to carry out the same operation for the second time, they should submit copies of the documentation used for the first request plus documents referred to in the sub-headings a) and b) of the paragraph 7 of the present Article.

9. Following the consideration and approval of these documents, the MINAG will issue the authorization to import the consignment containing GMOs.

CHAPTER III
RESEARCH

Article 9
Development of modern biotechnology

1. Research on genetically modified organisms by public and private entities within the national territory shall be subject to prior authorization by MINAG

2. The research referred to in paragraph 1 of the present Article shall be only permitted under the containment conditions and after evaluation and approval of risk assessment and management report under the terms of the Article 14 and the Annex III of the present Regulation.

2. The MINAG shall develop and enact the technical guidelines to govern the research on GMOs referred to in paragraph 1 of the present Article.

CHAPTER IV
EXPORT OF GMOs AND THEIR PRODUCTS

Article 10
Requirements

The export of GMOs and their products shall be subjected to the requirements of the countries of destination.

Article 11
Inspection

1. The exporter or its representative shall be required to produce a request for inspection within 45 days prior to the exportation of consignment and to certify the compliance to the requirements of the country of destination.
2. The exporter or its representative shall facilitate the necessary means for carrying out adequate inspection, incurring the respective expenses.

CHAPTER V
TRANSIT

Article 12
Procedures

1. The transit operations of GMOs and their products through the national territory, destined to other countries in the Region, shall observe the following requirements:

    a) To submit to the MINAG the request for transit authorization ;
    b) To produce the import authorization issued by the country of destination with the expected dates for the transboundary movements of GMOs and their products;
    c) To produce the term of responsibility for reception issued by the country of destination or the country through which the products will move across.

2. Following the evaluation and approval of the documents referred to in the paragraph 1 of the present Article, the MINAG shall issue a certificate for transit though the national territory prior to the departure of the consignment from the country of origin and within a maximum time limit of forty-five days, starting from the date of the submission of the request.

3. All the shipments containing GMOs and their products should be properly sealed and packed.

4. The applicant shall present the transit certificate, whenever it is requested.

Article 13
Transit of food aid destined to countries in the Region

1. Any foreign entity intending to import food aid containing GMOs destined to the countries of the Region, that will move transit through the national territory shall request a transit authorization from MINAG and observe the following requirements:

   a) Import authorization by the country of destination;
   b) Contingency plan in the case of accident;
   c) Term of responsibility for reception issued by the Government of the country of destination;
   d) Expected dates of the transboundary movements and the respective entry point.

2. The documents referred to in paragraph 1 of the present Article must be submitted to the MINAG, fifteen working days prior to departure of the consignment from the exporting country.

3. All the consignments in transit should be transported in properly sealed containers

CHAPTER VI

COMMON PROVISIONS

Article 14
Risk assessment and risk management

1. The risk assessment of GMO and their products required for request for import, export, research, deliberate release to environment and transit shall be conducted according to the technical and scientific requirements described in Annexes II, III and IV of the present Regulation.

2. The risk assessment shall be coordinated by the NBC and it shall be conducted based on the information provided by the applicant, public and any other available scientific evidences, in order to identify and evaluate the possible adverse effects on environment particularly the biological diversity and human health.

3. The applicants shall specify, in their request, mechanisms, measures and strategies to be taken for monitoring, management and control of risks identified paragraphs 1 and 2 of present Article.

Article 15
Labelling

1. All the packages and/or containers containing GMOs and their products shall have a label or an informative booklet in accordance with the valid national or international rules regarding labelling, and in clear visible letters stating "CONTAINS GENETICALLY MODIFIED ORGANISMS."

2. With the exception of GMOs and their products in transit through the national territory, destined to countries in the Region, all other items destined for food, feed, processing, research, deliberate release to environment must present the information contained in the labels written in the Portuguese language and easily legible.

3. Any alteration of the information included in the label must be previously submitted to the MINAG for its approval.

Article 16
Packaging

1. The packages and/or containers containing GMOs and their products must be properly embossed and sealed from the point of origin.

2. The re-packaging of the GMOs and their products in the country shall require an authorization from the MINAG and it must ensure safety for the handler and the environment.

3. In case the GMOs and their products are re-packed for commercial purposes, the re-packaging site must be inspected and authorized by the MINAG.

4. The empty packages and the wastes of GMOs and their products must be duly treated according to the procedures described in the Annex II regarding the risk management.

Article 17
Confidential Information

1. All the information and the data related to the authorization process of import, export, research, deliberate release to environment or handling of GMOs and their products are of public domain, except those cases that require protection under the applicable legislation.

2. No third party should use the information or documents contained in the authorization process, unless a prior written authorization is granted by the applicant or its legal representative in conformity with the applicable legislation regarding the subject matter.

Article 18
Liability and redress

The applicant is legally responsible for the accuracy of the entire information contained in the documents submitted for analysis.

1. In cases where an accident involving products containing GMOs occurs, the responsible entity under their guard must ensure that the MINAG is notified on:

    a) The circumstances under which the accident occurred;
    b) The identity and quantity of the product released;
    c) The emergency measures taken to mitigate any adverse effects;
    d) The possible impact on the human health and the environment;

2. The applicant is entirely liable to meet the costs of redressing any damage resulting from its activities on GMOs and their products, as well as for the application process and analyses to be conducted.

Article 19
Public awareness, education and participation

The MINAG shall coordinate, in collaboration with the NBC, the activities on public awareness, education and participation in decision-making process on GMOs and their products and it shall ensure the access of public to information on decisions concerning GMOs without prejudice to the confidentiality granted under the applicable legislation.

CHAPTER VII
INSPECTION, MONITORING AND ENFORCEMENT

Article 20
General principles

1. All activities involving GMOs and their products carried out by public or private entities shall be subject to monitoring and inspection by MINAG in coordination with entities relevant to biosafety.

2. The content of paragraph 1 of the present Article does not exclude the competence for monitoring and inspection by the regulating authorities under the specific legislation**.**

Article 21
Inspection

1. Under the present Regulation, the GMOs and their products imported or in transit shall be subjected to an inspection to be conducted by the MINAG, at the designated entry point in the national territory

2. For the inspection, the applicant or its representative is required to submit the request for inspection to the MINAG within the deadline of fifteen days prior to the delivery of GMOs and their products, to produce the required accompanying documentation according to intended use and to meet the expenses related to inspection

3. The inspection may cover the entire consignment or part of it being the inspector allowed to take representative samples for laboratory analysis.

The inspectors shall check whether the consignments comply with requirements spelled out in the import authorisation.

Article 22
Inspections sites

The inspectors duly accredited shall have access to custom facilities and any other entry points, mailbags, storage facilities, laboratories, production sites for GMOs and their products as well as any other operation sites.

Article 23
Refusal of Entry

1. The omission of any document or information required for authorisation of entry of GMOs and their products under the present Regulation constitutes a reason for the refusal of its entry in the country.

2. If, as a result of the inspection, it is observed that the consignment does not comply with requirements stipulated under the present Regulation, the inspector may order its seizure or any other appropriate measure being the expenses covered by the applicant, without any right for compensation.

CHAPTER VIII
FEES AND PENALTIES

Article 24
Fees

1. Fees shall be charged for the handling of application requests required under the present Regulation based on the table contained in the Annex V.

2. The amounts paid by the applicant shall not be reimbursed even in case where there is refusal for entry or use of the consignment.

Article 24
Breaches and fines

1. Under the present Regulation and without prejudice to what is stipulated in specific legislation, the following acts constitute breaches:

a) The import and placing on the marketing of GMOs and their products destined for food, feed or processing without an authorization from the MINAG.
b) The handling, manipulation, production and possession of GMOs and their products without authorization from the MINAG;
c) The execution of field experiments with GMOs and its products without an authorisation from the MINAG;
d) To provide false declarations or biased information;
e) The obstruction of the work of the inspectors
f) The lack of labelling and correct identification of products containing GMOs;
g) The failure to report to the competent authority about any accident involving GMOs that have occurred;
h) The utilisation of GMOs for purposes different from what was indicated in the import authorization;
i) The introduction of GMOs and their products in the country through an entry point different from what was stipulated in the import authorization.

2. Any infringement under the paragraph 1 of present Article shall be punished through a fine and it shall imply the refusal of entry and subsequent returning of the imported products to the country of origin, or its seizure and subsequent reversion to the State.

3. The violator shall be liable for meeting the financial costs resulting from the measures taken to redress the infringement.

3. The fines charged under the present Regulation shall be calculated according to the table contained in the Annex VI.

4. The deadline for the payment of a fine is 15 days, starting from the date of notification of the violator

Article 25
Payment and application of the charged fees and fines

1. The amounts of fees and fine charged under the present Regulation shall be deposited at the Fiscal Section of the respective zone

2. The amount charged shall have the following destination:

   a) 40 % in favour of the General Government Budget;
   b) 60 % in favour of the Agricultural Promotion Fund;

3. The values charged for fees and fines shall be reviewed and updated by a joint Dispatch of the Ministers of Agriculture and Finance

CHAPTER VIII

FINAL PROVISIONS

Article 26
Doubts

Any doubts resulting from the application of the present Regulation shall be resolved through a joint Dispatch by the Ministers of Agriculture, Health, Science and Technology and for Coordination of Environmental Affairs.

GLOSSARY

1. Applicant- any person or national or foreign entity that intends to import, export, develop or handle GMOs and their products for various purposes

2. Biosafety – measures to reduce the potential risks from GMOs and its products on environment particularly the biodiversity and human health.

3. Biotechnology – any technique that utilizes biologic systems, live organisms or their products, to produce or modify products or processes for specific purposes.

4. Cartagena Protocol on Biosafety – ratified by the Resolution 11/2001 of the Assembly of Republic, December 20th.

5. Certificate of transit - document issued by MINAG, certifying that the holder of the GMOs and their products is authorized to transport them through the national public roads

6. Country of origin – country where GMO plants, animal and micro-organisms and their products were produced.

7. Country of proceeding - country from where GMO plants, animals and micro-organisms and their products as well as other material subjected to this regulation were exported regardless the country where they were produced.

8. DINA – National Directorate for Agriculture

9. DINAP – National Directorate for Animal Production

10. Emergency – anomalous situation that requires the need to take immediate and exceptional measures, on short-term, to save lives, protect assets, mitigate the adverse effects and restore the normality.

11. Entry Point – border entry to the country.

12. Export authorisation of GMOs and its products – A written authorization issued by MINAG, which gives permission to a person, or national or foreign entity to export GMO and their products, under specific conditions spelled out in it.

13. Exporter – any person or national or foreign entity that intends to export GMO and their products for various purposes.

14. Genetically modified organism (GMO) – any plant, animal or microbial organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

15. IIAM – Agriculture Research Institute of Mozambique.

16. Importer – any person or national or foreign entity that intends to import GMOs and their products for various purposes.

17. Import authorisation of GMO and their products – A written authorization issued by MINAG, which gives permission to a person, and national or foreign entity to import GMO and their products, under specific conditions spelled out in it.

18. INGC – National Institute for Disasters Management.

19. Inspection – Examination of plants, animals, foods, their products or any other related other material, with the aim to detect the presence of GMOs, performed by an official accredited by MINAG and tasked to ensure enforcement of the present Regulation.

20. Lot - specific quantity of a product identified by a number or a letter or a combination of both which is uniform for the information contained in the identification.

21. MINAG – Ministry of Agriculture, the entity responsible for the authorization of import, export, handling, development, utilization and transit of genetically modified organisms (GMO) and their products within the country, without prejudice to the competences of the Ministry of Industry and Trade related to external commerce operations to and from Mozambique.

22. Modern Biotechnology – application of technology of genetic manipulation, including genetic recombination, direct injection of DNA into cells or organelles, and fusion of cells besides the taxonomic family.

23. National Biosafety Committee (NBC)- multi-sectoral technical and scientific committee, with competence for analysis and advice in biosafety matters within the country.

24. Organism – any biologic entity capable of transferring or replicating genetic material.

25. Package – any container used to cover or protect the GMOs and their products.

26. Products – products of plant, animal or microbial origin containing GMOs.

27. Risk Assessment - evaluation of risks towards human health and to the environment that could originate from the deliberate release or display of GMO on the market, whether directly or indirectly, immediately or thereafter, preformed according to annexes II, III and IV of the Biosafety Regulation.

28. Technical guidelines – procedures for import, export, manipulation, handling, production, utilization and transit of genetically modified organisms and their products.

29. Transit – movement of GMO and their products, deriving from abroad, passing through Mozambique, with a third country as the destination

ANNEX I: GENERAL APPLICATION FORM FOR IMPORTATION OF GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS

Entry Date			
Registration # at MINAG			

(To be filled by competent authority)

1. Details of the importer

Name:	
Registration # at MIC	
Address	
City:	District:
Province:	Country:
Telephone:	Fax:
E-mail:	Web:

2. Brief description of the commodity to be imported

OGM	
Product	

(Mark with an X)

a) Name of the GMO

Common Scientific

b) Inserted genes (s)

c) Characteristics of the GMO or product

d) Intended use of the GMO or product

e) Site of origin or proceeding of the GMO or product

f) Regulatory status of the GMO or in the exporting country and/or country of origin

g) Is there any restriction imposed on the GMO or product in the exporting country?

Ye☐ N☐

If so, specify?

3.Quantity or volume of the GMO or product to be subject to transboundary movements.

4. Entry point

5. Expected importing date

_____/_____/_____

Signature of the Applicant

ANNEX II: RISK ASSESSMENT FORM OF GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS INTENDED FOR DIRECT USE AS FOR FOOD, FEED OR PROCESSING

Entry Date			
Registration # at MINAG			

(To be filled by competent authority)

1. Details of the importer

2. Address

City:	District:
Province:	Country:
Telephone:	Fax:
E-mail:	Web:

3. Brief description of the commodity to be imported

OGM	
Product	

(Mark with an X)

a) Name of the GMO

Common Scientific

b) Site of origin or proceeding

c) Intended use of the product

d) Inserted gene(s)

e) Level of gene(s) expression

f) Procedure used to induce the genetic modification

g) Detention techniques of the target or marker gene(s) and/or procedure to check /test the authenticity of the lots

h)Genotype and phenotype characteristics of the modified product

i) Nutritional value of the product, in case of food product

j) In case of a plant/crop:
j1.Reproduction type

j2.Pollination type

j3.Desirable and undesirable effects resulting from the use of the modified plant

j4. Is there any plant with weed characteristics that belongs to same genus of the modified plant?

Ye☐ N☐

If so, specify

j5. Phenotypic expression of transgene in wild relative species

j6. Probability that the inserted transgene can enter into the population of the pre-existing genes

j7. Specific plant/crop pollinators and measures to be taken in order to prevent the dissemination of pollen to the unmodified plants

l) Biosafety level of the product

m) Regulatory state of the modified product in the country of origin and/or export

n) Is there any restriction imposed on GMO or product in the country of origin and/or export?

Ye ☐ N ☐

If so, specify

4. Possible risks of the product to human and/or animal health

Effects	Yes/ No	Degree			
		Low	Medium	High	Very high
Allergenic					
Toxicity					
Digestibility					

In an affirmative case, describe in detail each one of them

5. Possible risks associated with the product to the environment

6. Possible risks to the genetic resources

7. Measures for safe handling of the product

8. Measures for management of the product residues

10. Possible socio-economic impact of the genetically modified product

Date

_____ / _____ / _____

Signature of the Applicant

ANNEX III – Model 1: RISK ASSESSMENT FORM FOR GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS DESTINED FOR RESEARCH CONDUCTED IN LABORATORIES AND GREENHOUSES

Entry Date			
Registration # at MINAG			

(To be filled by competent authority)

1. Name of the applicant

2.Address

City:	District:
Province:	Country:
Telephone:	Fax:
E-mail:	Web:

3. Research Goals

4. Research proposal

The Research proposal should include:

a) Background/ Justification
b) Objectives
c) Materials and methods
d) Expected results
e) Environmental, health, and- social-economic impacts

5. Brief description of the genetically modified organism to be studied

OGM	
Product	

(Mark with an X)

a) Name of the GMO

Common Taxonomic

b) Site of origin or proceeding

c) Inserted gene(s)

d) Level of gene(s) expression on the organism

e) Genotypic and phenotypic characteristics of the modified organism

f) In case of a plant/crop:
f1. Reproduction type

f2. Pollination type

f3.Desirable and undesirable effects resulting from the use of the modified plant

f4. Is there any plant with weed characteristics that belongs to same of the genus of the modified plant

Ye☐ N☐

If so, specify

f5. Phenotypic expression of the transgene in wild relative species

f6. Probability that the inserted transgene can enter into the population of the pre-existing genes

f7.Specific plant/crop pollinators and measures to be taken in order to prevent the dissemination of pollen to the unmodified plants

g) Biosafety level of the GMO (if applicable)

h) Regulatory status of the modified organism in the country of origin and/or export (if applicable)

6. Possible risks of the GMO to human and/or animal health

Effects	Yes/ No	Degree			
		Low	Medium	High	Very high
Allergenic					
Toxicity					
Digestibility					

In affirmative case, describe in detail each one of them

7. Possible risks associated with the GMO for the environment

8. Possible risks to the genetic resources

9. Measures for safe handling of the GMO (risk management)

10. Measures for management of the GMO residues

11. Benefits of the using in the trials compared to other traditional methods

12. Detailed description of the laboratory/greenhouse to be used in the study, with emphasis on the containment of the organism.

13. Description of the surrounding environment of the laboratory/greenhouse (villages, vegetation, fauna, water resources, etc.)

14. Supervision and monitoring of the experiment

15. Contingency plans (e.g. storms, floods, fires) during the course of the trial

16. Provisions to remove or eliminate the GMO from the testing location

Date

_____ / / _____

Signature of the Applicant

_____

ANNEX III – Model 2: RISK ASSESSMENT FORM FOR GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS DESTINED FOR FIELD TRIALS

Entry Date			
Registration # at MINAG			

(To be filled by competent authority)

1.Name of the applicant

2.Address

City:	District:
Province:	Country:
Telephone:	Fax:
E-mail:	Web:

3. Aim of the research

4. Research proposal

The Research proposal should include:

a) Background/ Justification
b) Objectives
c) Materials and methods
d) Expected results
e) Environmental, health, and- social-economic impacts

5. Brief description of the genetically modified organism to be studied

OGM	
Product	

(Mark with an X)

a) Name of the GMO

Common Scientific

b) Site of origin or proceeding

c) Inserted gene (s)

d) Level of gene(s) expression on the organism

e) Genotypic and phenotypic characteristics of the modified organism

f) In case of a plant/crop:
f1. Reproduction type

f2. Pollination type

f3.Desirable and undesirable effects resulting from the use of the modified plant

f4. Is there any plant with weed characteristics that belongs to same of the genus of the modified plant

Ye☐ N☐

If so, specify

f5. Phenotypic expression of the transgene in wild relative species

f6. Probability that the inserted transgene can enter into the population of pre-existing genes

f7. Specific plant/crop pollinators and measures to be taken in order to prevent the dissemination of pollen to the unmodified plants

g) Biosafety level of the GMO (if applicable)

h) Regulatory status of the modified organism in the country of origin and or/export (if applicable)

6.Possible risks of the GMO to human and/or animal health

Effects	Yes/ No	Degree			
		Low	Medium	High	Very high
Allergenic					
Toxicity					
Digestibility					

7. In affirmative case, describe in detail each one of them

8. Possible risks associated with the GMO to the environment

9. Possible risks to the genetic resources

10. Measures for safe handling of the GMO (risk management)

11. Measures for management of the GMO residues

12. Benefits of the using GMO trials compared to other traditional methods

13. Detailed description of the trial site.

14. Detailed description of the site where the trial will be conducted, with emphasis on the containment of the organism.

13. Distance between the trial site and the closest village(s)

14. Distance between the trial site and surface waters

15. Distance between the trial site and the protected areas

16. Description of the environment surrounding the trial site

17. Barriers planned to isolate the trial site

18. Supervision and monitoring of the trial

19. Contingency plans (e.g. storms, floods, fires) during the course of the trial

20. Provision to remove or eliminate the GMO from the testing location

21. Process of GMO release.

Date

_____/_____/_____

Signature of the Applicant

_____

ANNEX IV: RISK ASSESSMENT FORM FOR GENETICALLY-MODIFIED ORGANISMS AND THEIR PRODUCTS DESTINED THE DELIBERATE RELEASE TO ENVIRONMENT

Entry Date			
Registration # at MINAG			

(To be filled by competent authority)

1.Name of the applicant

2. Address

City:	District:
Province:	Country:
Telephone:	Fax:
E-mail:	Web:

3. Brief description of the characteristics of the genetically modified organism

OGM	
Product	

(Mark with an X)

a) Name of the GMO

Common Scientific

b) Inserted gene(s)

c) Level of gene(s) expression on the organism

d) Procedures used to induce the genetic modification

e) Detection technique of target and marker(s) gene(s) and/or procedure to test the authenticity of the lots.

f) Characteristics of the modified organism or product

g) In case of a plant/crop:
g1.Reproduction type

g2. Pollination type

g3.Desirable and undesirable effects resulting from the use of the modified plant

g4. Is there any plant with weed characteristics belonging to the same genus of the modified plant?

Ye☐ N☐

If so, specify?

g5. Phenotypic expression level of the transgene in the wild relative species

g6.Probability that transgene can enter into the population of the pre-existing genes

g7. Specific plant/crop pollinators and measures to be taken in order to prevent the dissemination of pollen to unmodified plants

h) Nutritional value of the product, in case of food product

i) Biosafety level of the product (if applicable)

j) Site of origin or proceeding of the GMO

l) Regulatory status of the modified organism in the country of origin or export (if applicable)

4. Possible risks of the product to human and/or animal health

Effects	Yes/ No	Degree			
		Low	Medium	High	Very high
Allergenic					
Toxicity					
Digestibility					

In an affirmative case, describe in detail each one of them

5. Possible risks associated with the GMO to the environment

6. Possible risks to the genetic resources

7. Expected socio-economic impact of the GMO

8. Measures for safe handling the GMO (risk management)

9. Measures for management of the GMO residues

10. Aim of the commercialisation

12. Benefits of the commercial use of the GMO, compared to other traditional products

13. Detailed description of the site of commercial production (province, district, locality and area)

14. Distance between the production field site and the closest village(s)

15. Distance between the production field site and surface waters

16. Distance between the production field site and the protected areas

17. Description of the environment surrounding the site of the commercial production field

18. Barriers planed to isolate the commercial production site

19. Supervision and monitoring of the commercial production

20. Contingency plans (e.g. storms, floods, fires) during the course of the production

21. Measures to remove or eliminate the GMO from the production site

Date

_____/_____/_____

Signature of the Applicant

_____

ANEX V: TABLE OF FEES

	Service	**Fee (MZM)**
1.	Handling of general application form for importation of genetically modified organisms and their products	**120,000, 00**
2.	Handling of risk assessment form of genetically modified organisms and their products intended for direct use as for food, feed or processing	**3.000.000, 00**
3.	Handling of risk assessment form for genetically modified organisms and their products destined for research conducted in laboratories and greenhouses	**500.000, 00**
4.	Handling of risk assessment form for genetically modified organisms and their products destined for field trials	**500.000, 00**
5.	Handling of risk assessment form for genetically modified organisms and their products destined the deliberate release into environment	**5.000.000, 00**
6.	Issuing of certificate of transit	**100.000, 00**
7.	Permit for field trials	**100.000, 00**
8.	Request for inspection at the entry points and storage and/or re-packaging sites of genetically modified organisms and their products within the country	**100.000, 00**
9.	Request for authorisation of re-packaging of genetically modified organisms within country.	**100.000, 00**

ANEX VI: TABLE OF FINES

Article 24, Paragraph 1	**Breach**	**Fine (MZM)**
Sub-heading	The importation and placing on the marketing of GMOs and their products destined for food, feed or processing without an authorization from the MINAG.	**25.000.000, 00 to 100.000.000, 00**
Sub-heading b)	The handling, manipulation, production and possession of GMOs and their products without authorization from the MINAG;	**100.000.000, 00 to 500.000.000, 00**
Sub-heading c)	The execution of field experiments with GMOs and its products without an authorisation from the MINAG	**25.000.000, 00 to 100.000.000, 00**
Sub-heading d)	To provide false declarations or biased information	**100.000.000, 00**
Sub-heading e)	The obstruction of the work of the inspectors	**50.000.000, 00**
Sub-heading f)	The lack of labelling and correct identification of products containing GMOs	**50.000.000, 00**
Sub-heading g)	The failure to report to the competent authority about any accident involving GMOs that have occurred	**25.000.000, 00 to 100.000.000, 00**
Sub-heading h)	The utilisation of GMOs for purposes different from what was indicated in the import authorization	**200.000.000, 00**
Sub-heading i)	The introduction of GMOs and their products in the country through an entry point different from what was stipulated in the import authorization	**200.000.000, 00**

ANNEX B: DRAFT GUIDELINES FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS IN MOZAMBIQUE

1. INTRODUCTION

This guideline is a guidance document to assist reviewers and scientists in handling notifications related to GMOs. The National Biosafety Authority shall periodically release revised versions. The document gives the scope, the general principles, methodology of risk assessment and the format for reporting on risk assessment. Application forms on requirements related to risk assessments are annexed to the Draft Biosafety Regulation (annexes I, II, III and IV).

2. SCOPE

These guidelines shall apply to the contained use, deliberate release into the environment or placing in the market of all types of genetically modified organisms (micro-organisms, plants, animals), within the sovereign territory of Mozambique

3. OBJECTIVE OF RISK ASSESSMENT

The objective of risk assessment 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. Risk assessment should be conducted with a view to identifying if there is the need for risk management and if so, the most appropriate method to be used.

4. USE OF TERMS

Adverse effects of GMOs can be direct, indirect, immediate or delayed, where:

a. 'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a casual chain of events;
b. 'indirect effects' refers to effects on human health or the environment occurring through a casual chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Such effects are likely to be delayed;
c. 'Immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;
d. 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO,

but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

Risk assessment underpins the decision making process for *granting* permits for the contained use, release and/or marketing of GMOs.

5. GENERAL PRINCIPLES OF RISK ASSESSMEN

In accordance with the precautionary principle, the under mentioned general principles should be followed when performing risk assessment of GMOs:

- The risk assessment should be carried out in a scientifically sound and transparent manner based on latest available scientific and technical data;
- Identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;
- The risk assessment should be carried out on a case-by-case basis. This implies that the required information may vary depending on the type of GMO concerned, their intended use and the potential receiving environment, taking into account, among other things, GMOs already in the environment;
- If new information on the GMO and its effects on human health and the environment becomes available, the risk assessment should be re-examined.
- The information required in the notification must include possible impacts of the specific techniques used for the management of the GMO where these are different from those used for Non-GMOs.
- Where the GMO is a crop, it is important to place the assessment in the context of existing agricultural practices and also evaluate the effect of the management of the GMO.
- The risk assessment should document the uncertainties, the assumptions made and the effect of these on the final risk estimate.
- Both qualitative and quantitative risk assessment methods are valid.

6. INFORMATION REQUIRED FOR A SCIENTIFICALLY SOUND RISK ASSESSMENT

1. Characteristics of host organism

- Name and identity;
- Pathogenicity, toxicity and allergenicity;
- Natural habitat, geographic origin, distribution and role in the environment;
- Mechanisms by which the organism survives, multiplies and disseminates in the environment and
- Means for transfer of genetic material to other organisms.

2. Characteristics of the organism(s) from which nucleic acids are obtained (the donor)

- Name and identity
- The relevant characteristics include, pathogenicity, toxicity and allergenicity;
- Natural habitat, geographic origin, distribution and role in the environment;
- Mechanisms by which the organism survives, multiplies and disseminates in the environment and
- Means of transfer of genetic material to other organisms.

3. Characteristics of the vector

- Identity, origin, natural habitat and the relevant safety characteristics;
- The frequency at which the vector can transfer itself to other organisms and
- Factors which will affect the ability of the vector to become established in other hosts.

4. Characteristics of the inserted nucleic acid (the insert)

- Functions coded by the inserted nucleic acid including any residual vector and
- Information on the expression of the inserted nucleic acid and the activity of the gene product.

5. Characteristics of the organisms with novel traits (GMO)

The GMO should be compared with the organism from which it is derived, examining where appropriate the following points:

- Pathogenicity, toxicity and allergenicity to humans and other organisms;
- Survival, persistence, competitive abilities and dissemination in the environment;
- Capacity to transfer genetic material and the way this might happen;
- Methods for detecting the organisms in the environment and for detecting the transfer of the donated nucleic acid;
- Functions which might affect its ecological range and
- Characterization of the product(s) of the inserted gene(s) and, where appropriate, the stability of the modification.

6. Information relating to the intended use

The amount of information required will vary with the characteristics of the organisms and use, frequency and the scale of the intended use.

<u>For contained uses, this can include:</u>

- Number or volume of organisms to be used;
- Scale of the operation;
- Proposed containment measures, including verification of their functioning;
- Training and supervision of personnel carrying out the operation;
- Plans of waste management;
- Plans for safety of the health of personnel;

- Plans for handling accidents and unexpected events and
- Relevant information from previous uses.

For deliberate use, this can include:

- Purpose and scale of the release;
- Geographical description and location of the release;
- Proximity to residences and human activities;
- Method and frequency of release;
- Time and duration of release;
- Expected environmental conditions during the release;
- Proposed risk management measures including verification of their functioning;
- Subsequent treatment of the site and plans for waste management;
- Plans for handling accidents and unexpected events/disasters;
- Relevant information from any previous releases;
- Likelihood of Transboundary Movements.

7. Characteristics of the potential receiving environment

The potential of an organism to cause harm is related to the environments into which it may be released and its interaction with other organisms.

Relevant information can include:

- The geographical location of the site and any special features of the environments that expose them to damage;
- The proximity of the site to human settlement and to other significant biota;
- Any flora, fauna and ecosystems that could be affected by the release, including rare, endangered, potential competitive species and non-target organisms;
- The potential of any organisms in the potential receiving environment to receive genes from the released organism;

7. METHODOLOGY OF RISK ASSESSMENT

To fulfill its objectives, RA should entail as appropriate the following steps:

1. An identification of characteristics of GMO that may cause adverse effects on human health or the environment.

Comparing the characteristics of a GMO with those of the non modified organism will help the assessor identify any potential adverse effects that may arise due to the genetic modification.

2. **An evaluation of the potential consequence of each adverse effect should it occur.**

   The magnitude of the consequences of each potential adverse effect is evaluated on the assumption that such an adverse effect will occur bearing in mind that such magnitude is likely to be influenced by the environment into which the GMO is intended to be released at the manner of the release.

3. **Evaluation of the likely of the occurrence of identified potential adverse effects.**

   A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO is intended to be released and the manner of the release.

4. **Estimation of the risk posed by each identified characteristic of the GMO that can be a cause of adverse effect.**

   This is done by combining the likelihood of the adverse effect occurring and the magnitude of the consequence if it occurs.

5. **Identification of management strategies**

   Risks that require management are identified and appropriate strategies to manage them proposed.

6. **Determination of the overall risk of the GMO**

   This should be made taking into account any risk management strategies which are proposed.

8. STRUCTURE OF ASSESSMENT REPORT

The assessment report should include in particular the following.

1. Identification of the Characteristics of the recipient organisms which are relevant to the assessment of the GMO(s) in question.
2. Identification of any known risks to human health and the environment resulting from the release in the environment of the recipient non – modified organism.
3. Description of the result of the genetic modification in the modified organism.
4. Assessment of whether the genetic modification has been characterized sufficiently for the purpose of evaluating any risks to human health and the environment.

5. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question, as compared to the release of the corresponding non-modified organism(s)
6. A conclusion as to whether the GMO(s)in question should
   I. be placed in the market and under which conditions
   II. not be placed in the market, in which case reasons should be given.
   III. be used under containment

ANNEX C: DRAFT GUIDELINES ON PUBLIC AWARENESS AND PARTICIPATION IN MATTERS RELATED TO BIOSAFETY AND BIOTECHNOLOGY

1. INTRODUCTION

Public awareness and participation in issues that have the potential to affect society in one way or the other have become an integral part of the democratic process. Decision-making is no longer the prerogative of the Government alone but the wider civil society also has a critical role to play. Indeed, the general public has the right to know, access information and comment on issues that have social, cultural, economic and political implications for the well being of the populace. These requirements are further addressed in the rights to information emanating from the Constitution.

The important role of the public in the deployment of GMOs is spelt out in Article 23 of the Cartagena Protocol. Article 23 (2) requires that the public is consulted in the decision-making process regarding GMOs and the results of the decision are also made public while respecting confidential information. In the light of this, there is urgent need to innovative and practical methods for making information accessible to the public. Public education on genetic technologies and GMOs must also be intensified. The processes of educating the people must provide opportunities for the public to freely exchange information thus promoting active participation in decision-making. It is against this background that the following guidelines have been provided as guidance document for best practices in development and deployment of GMOs.

2. OBJECTIVE

The objective of these Guidelines is to:

(a) Facilitate and give guidance to the practical application of the provisions of the Cartagena Protocol on Biosafety and the National Biosafety Framework for Mozambique relevant to GMOs;

(b) Encourage the development of procedures to facilitate access to information, and public participation with respect to GMOs;

(c) Stimulate open, transparent, efficient and accountable decision-making on activities with GMOs, thereby fostering good practices for public participation in decision-making that may go beyond the scope of these guidelines; and

(d) Promote and facilitate public awareness, education and participation in decision-making on activities involving GMOs.

3. PUBLIC PARTICIPATION IN DECISION-MAKING ON SPECIFIC ACTIVITIES WITH GMOs

3.1. SCOPE

In principle, public participation should be provided for in decision-making procedures in all three areas of GMO applications, and adapted to the specific requirements of these decision-making procedures and uses:

a. Deliberate release;
b. Placing on the market and
c. Contained use.

This does not mean that public participation processes should be applied to all decision-making procedures in these areas. The following two paragraphs aim to give guidance on which decision-making procedures should generally be subject to public participation.

Public participation as described in paragraphs 1 to 6 of section 3.2 and 1 to 8 of section 3.3 should be provided for as appropriate in the following GMO-related decision-making procedures:

(a) First-time deliberate release into the environment of GMOs in any new location;
(b) First-time placing on the market of GMOs not exclusively intended for research;

(c) Procedures for determining whether sufficient experience has been obtained with respect to deliberate releases of certain GMOs in certain ecosystems and simplified procedures could therefore be followed;

(d) The contained use of GMOs in a specific installation where in the event of an accident there would be a risk of serious damage to the environment and/or human health and therefore suitable contingency/emergency plans are foreseen.
The following general criteria should be considered when deciding if a specific case should be subject to public participation or not:

(a) The type of GMO (host organism, genetic modification, unique identification code and transformation event);
(b) The intended use;
(c) The characteristics of the potentially affected environment;
(d) The level of experience obtained with the GMO and intended use in question with respect to risks to the environment and/or human health;
(e) Any proposal for simplified procedures in the decision-making procedure on the basis of experience;
(f) For genetically modified micro-organisms, the risk category (if any);
(g) First-time or subsequent application;
(h) The scale of use, if applicable;

(i) Any planned containment or other risk management measure, if applicable;
(j) The significance of any adverse affects on the environment and/or human health that could result from the unintended release of the GMO or from a lack of appropriate risk management measures;

3.2. PUBLIC NOTICE AND ACCESS TO INFORMATION RELEVANT TO PUBLIC PARTICIPATION

Providing adequate public notice of a specific planned activity with GMOs within the scope of this section of the Guidelines should be the first step in the public participation process. The nature and contents of the public notice will vary, depending *inter alia* on the type of the planned activity (e.g. contained use, deliberate release, placing on the market). The following paragraphs provide examples of good practice and should be applied in a flexible manner.

1. The public concerned should be informed, either by public notice in the radio, print media, television or individually as appropriate, early in the decision-making procedure, and in adequate, timely and effective manner of the aspects described in Annex II.

2. The National Competent Authority in collaboration with the National Biosafety Committee should find effective means to inform the public concerned about the proposed activity with GMOs, for example through notices;

   (a) In the official government gazette;
   (b) In appropriate national, regional or local newspapers; radio & TV stations
   (c) Through notices to state administrative structures and local government in the proximity of the facility or site where the proposed activity (contained use or deliberate release) with GMOs is intended to take place and other traditional modes of communication including ;
   (d) On their website; and/or
   (e) On any existing national or regional biosafety clearing-house.

3. In addition to notifying the public concerned according to paragraphs 1 and 2 above, the National Competent Authority in collaboration with the National Biosafety Committee shall provide opportunities for members of the public concerned to seek and obtain information relevant to the decision-making procedure so that they can participate in an informed manner.

4. Without prejudice to their right to refuse to disclose certain confidential information as spelt out in the biosafety regulation, the information which should be publicly accessible includes, where appropriate, the elements described in Annex III. In this context, Annexes I, II and III to the Cartagena Protocol on Biosafety may also be useful sources of information. The National Competent Authority in collaboration with the National Biosafety Committee shall give the

public access to the information that they possess and that is available at the time of the public participation.

5. The National Competent Authority may give the public access to the relevant information for examination by publicly disclosing this information:
   (a) At national, regional and, where applicable, state administrative structures and local governmental or public premises, such as libraries, in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place; and/or
   (b) On their website/or the National Biosafety Clearing House

6. The National Competent Authority shall provide public access to information for examination free of charge and endeavour to supply copies of information free of charge in response to requests from the public. However, a reasonable charge for supplying the information requested may be made through internal procedures. The National Competent Authority shall make available a schedule of charges which may be levied, indicating the circumstances in which they may be levied or waived and when the supply of information is condition on the advance payment of such a charge.

3.3. PROCESS FOR PUBLIC PARTICIPATION AND DECISION-MAKING

The public participation processes should provide for early participation, when all options are open and effective public participation can take place. The following paragraphs provide examples of good practice on processes for public participation and should be applied in a flexible manner.

1. The public participation processes should include reasonable time frames for the different phases, taking into account any legally binding time frames as spelt out in the National Biosafety Framework. Sufficient time should be allowed for informing the public and also for the public to prepare and participate effectively during the decision-making on certain specific activities with GMOs.

2. The National Competent Authority in collaboration with the National Biosafety Committee shall ensure that potential notifiers or applicants identify the public concerned, enter into discussions and provide information regarding the objectives of their application before notifying or applying for authorisation for certain specific activities with GMOs.
3. Public participation processes should allow the public to submit, in writing or, as appropriate, at a public hearing or inquiry (with the notifier or applicant), any comments, information, analysis or opinions in relation to the proposed activity with GMOs

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4. The National Competent Authority shall ensure that in its decision making process , due account is taken of the outcome of the public participation. This should, where

appropriate and feasible, include an analysis of the comments and a description of the reasons for taking or not taking them into account in the (draft) decision.

5. When the National Competent Authority has taken a decision on a proposed specific activity with GMOs, the public should be promptly informed of the decision, e.g. through notices:

   (a) In the official government gazette;
   (b) In national, regional and, where applicable, local newspapers, radio and television in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place;
   (c) On the National Competent Authority's website (e.g. in cases of placing on the market); and/or
   (d) On any existing national, regional or international biosafety clearing-house.

6. The National Competent Authority in collaboration should make publicly accessible the text of the decision and the reasons and considerations on which the decision is based, together with, where appropriate, a description indicating how due account has been taken of the outcome of the public participation. This can be done by making the information available, for example:
   (a) At national, regional and where appropriate, local governmental or public premises, such as libraries, offices of state administrative structure or community centres in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place;
   (b) On their website.

7. The National Competent Authority shall consider, when deciding on whether to renew authorisation after it has expired, if paragraphs 1 to 6 of this section should be applied *mutatis mutandis* and where appropriate. In a similar way this could be done when the National Competent Authority considers and updates the operating conditions for a specific activity with GMOs on the basis of new information on the potential significant effects on the environment and/or human health.

8. In order to improve public knowledge, public participation and awareness of activities involving GMOs, the National Competent Authority in collaboration with the National Biosafety Committee shall explore mechanisms and measures such as consensus conferences, public hearings, round-table discussions, stakeholder dialogues, citizens' juries and community meetings facilitated by traditional leaders and local opinion leaders on issues relating to, for example, the risk assessment and risk management of GMOs.

4. ACCESS TO ENVIRONMENTAL INFORMATION ON GMOS, COLLECTION AND DISSEMINATION OF INFORMATION ON ACTIVITIES WITH GMOS

4.1. SCOPE

This section of the Guidelines deals with the broader and more general access to information for the public in the context of activities with GMOs. The Guidelines cover information on -

(a) Deliberate releases of GMOs;
(b) Placing on the market of GMOs as or in products;
(c) Contained uses of GMOs and
(d) Transboundary movement

recognizing that the need for the provision of information on products from GMOs, which do not necessarily contain the GMO as such, should be addressed through additional regulations when the need arises.

4.2. COLLECTION AND DISSEMINATION OF INFORMATION ON GMOS BY THE NATIONAL COMPETENT AUTHORITY

In addition to the information requirements for notification of the public in the context of public participation in decision-making, the National Competent Authority in collaboration with the National Biosafety Committee may collect and disseminate further information on GMO activities which can be made accessible to the public.

1. The National Competent Authority shall :
   (a) Maintain and update information on activities with GMOs, e.g. via registers and databases through the Biosafety Clearing House;
   (b) Establish mandatory systems to facilitate adequate flow of information about proposed and existing activities with GMOs;
   (c) In the event of any imminent threat to the environment and/or human health of activities with GMOs, disseminate immediately and without delay to members of the public who may be affected, all information they hold, and which could enable the public to take measures to mitigate harm arising from the threat.

2. The National Competent Authority should have transparent ways of making information on activities with GMOs available to the public and effectively accessible, *inter alia,* by the ways described in Annex IV.

3. The publicly accessible lists, registers or files established and maintained by the National Competent Authority as described in paragraph 16 above and Annex IV should contain, *inter alia,* the information on activities with GMOs listed in Annex V.

4. The National Competent Authority shall establish and maintain an up-to-date list of web sites which are considered to be examples of good practice in this area.

5. At regular intervals not exceeding in principle three years, the National Competent Authority in collaboration with the National Biosafety Committee shall publish and disseminate reports on the experience gained with activities with GMOs, including any results of monitoring their effects on the environment and/or human health, such reports should also include possible implications for the risk assessment and risk management of further activities with GMOs. Information on deregulated products based on current information should be made available to the public.

6. The National Competent Authority in collaboration with the National Biosafety Committee shall develop mechanisms to ensure that sufficient information on products consisting of GMOs or containing GMOs is made available to the public in a manner which enables consumers to make informed environmental and consumer choices about such products. Activities and progress in other forums, such as the Cartagena Protocol, the *Codex Alimentarius* and WTO, should be taken into account.

7. One such mechanism is the labeling of products consisting of or containing GMOs or the provision of relevant accompanying documentation in particular for bulk quantities at any stage of the production and distribution chain.

8. The notifiers or applicants for activities with GMOs having a significant impact on the environment are encouraged to inform the public regularly of the environmental impact of such activities.

5. ACCESS TO JUSTICE

The implementation of the provisions of these Guidelines shall be effected through the Biosafety Regulation, which provides for access to justice as required, including, where appropriate appeals against decisions of the NCA, through the administrative tribunals with respect to GMO activities that fall within the scope of these Guidelines.

6. IMPLEMENTATION OF THE GUIDELINES

1. The National Competent Authority, to the extent possible and where appropriate, shall seek assistance to build capacity for the practical implementation of these Guidelines.

2. The National Competent Authority in collaboration with the National Biosafety Committee shall monitor and keep under review the implementation of these Guidelines after every three years.

3. The need for and the possible substance of proposals for further refinement and amendment of the Guidelines, as may be necessary, as well as proposals for complementing the Guidelines with more detailed guidance (such as detailed handbooks) shall be further assessed and, if need be, acted upon by the National Competent Authority.

4. The Regulatory Agencies listed in Annex VI shall, through their mandates. assist the National Competent Authority in collaboration with the National Biosafety Committee in the implementation of these Guidelines.

ANNEX I: USE OF TERMS

1. Unless otherwise stated, the terms 'National Biosafety Competent Authority', 'environmental information', 'public' and 'public concerned' shall have the meanings given to them in the Cartagena Protocol on Biosafety and the Biosafety Regulation.

2. For the purpose of these Guidelines, the following terms based on existing international and regional documents, such as the Cartagena Protocol on Biosafety are employed:

   (a) "Accident" shall mean any incident involving a significant and unintended release of GMOs in the course of their contained use which could present an immediate or delayed hazard to the environment and/or human health.

   '(b) "Contained use" means any activity, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment

   (c) "Deliberate release' is defined as any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment

   (d) "Genetically modified organism" (GMO) means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

   (e) "Modern biotechnology" means the application of:
   In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or fusion of cells beyond the taxonomic family;

   (f) "Organism" means any entity capable of replication or of transferring genetic material;

   (g) "Placing of GMOs on the market" is defined as making GMOs available in the market whether in return for payment or free of charge;

   Where reference is made to human health, this refers to aspects of human health which are linked to the use of a GMO and its intended or unintended release into the environment.

ANNEX II. RECOMMENDED CONTENTS OF THE PUBLIC NOTICE DESCRIBED IN PARAGRAPH 1

The following information shall be actively notified to the public concerned in the context of the decision-making procedures referred to in section 3:

(a) The proposed activity and the application on which a decision will be taken;

(b) The type of decision which is being taken (e.g. a decision on whether to grant a permit for the import of a GMO, a deliberate release, etc.);

(c) The National Competent Authority responsible for making the decision;

(d) The envisaged process, including, as and when this information can be provided:

  (i) The commencement of the process;

  (ii) The opportunities for the public to participate (these can vary depending on the case: e.g. examination of the dossier and/or draft decision, possibility for written comments, participation in any public hearing);

  (iii) The time and venue of any planned public hearing;

  (iv) The National Competent Authority or any other official body from which relevant information can be obtained and where the relevant information has been deposited for examination by the public;

  (v) The National Competent Authority or any other official body to which comments or questions can be submitted and the time schedule for the transmittal of comments or questions; and

  (vi) An indication of what environmental information relevant to the proposed activity with the GMOs is available, e.g. a notification dossier; and

(e) Any other information that the National Competent Authority considers appropriate.

ANNEX III: INFORMATION RECOMMENDED TO BE AVAILABLE WITHIN A PUBLIC PARTICIPATION PROCESS

In addition to the information items listed in annex II, the following information should be available to the public in the context of the decision-making procedures referred to in chapter III:

(a) A general description of the GMOs; including the common, scientific, and technical name, the unique identification code and transformation event;
(b) The name and address of the notifier or applicant;
(c) The purpose of the proposed activity with the GMOs;
(d) Experience obtained with deliberate releases into the environment of certain GMOs;
(e) In the case of a proposal for simplified procedures for deliberate releases of certain GMOs into the environment, experience obtained with deliberate releases into the environment of those GMOs;
(f) The location of the site where the proposed deliberate release of the GMOs into the environment will take place (depending on the legal and administrative practice in a country this can vary between the description of the exact plot, the land register or the local community); the intended uses of the GMOs; an environmental risk assessment including a description of the potential effects on the environment and/or human health; a description of the measures, if any, to limit potentially adverse effects on the environment and/or human health; a description of the plan for monitoring the effects on the environment and/or human health; a description of the measures, if any, to treat waste arising from the deliberate release of the GMOs; a description of any emergency response plan;
(g) The location of the facility where the contained use of GMOs under the scope of this chapter of the Guidelines will take place, and a description of the specific containment measures; a description of the expected waste of the GMOs and its treatment; a description of any emergency response plan and the possibility for its implementation
(h) A non-technical summary of the above; and
(i) The main reports and advice issued by expert committees or advisory bodies to the National Biosafety Authority, in accordance with national legislation.

ANNEX IV: POSSIBLE WAYS FOR THE NATIONAL COMPETENT AUTHORITY TO MAKE INFORMATION ON GMOs AVAILABLE TO THE PUBLIC

(a) Providing sufficient information to the public about the type and scope of information on activities with GMOs that they hold, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained. This can be done through their websites or regular publications;

(b) Establishing and maintaining practical arrangements, such as: (i) publicly accessible lists, registers or files; (ii) requiring officials to support the public in seeking access to information; and (iii) the identification of points of contact;

(c) Providing access to the information on activities with GMOs contained in publicly accessible lists, registers or files free of charge; and

(d) The lists, registers or files with publicly accessible information on activities with GMOs may be available at national, regional and/or local governmental or public premises, as appropriate, and progressively on their Internet sites.

ANNEX V: POSSIBLE CONTENTS OF PUBLICLY ACCESSIBLE LISTS, REGISTERS OR FILES ON ACTIVITIES WITH GMOs ESTABLISHED AND MAINTAINED BY THE NATIONAL COMPETENT AUTHORITY

The contents of this annex are not meant to duplicate existing national obligations or any obligations under other international organizations and instruments, such as the Biosafety Clearing House or other international and regional databases. It is meant as a checklist, which should be applied in a flexible manner according to the specific activity with the GMO. If parts or all of these aspects are dealt with in an existing national or regional register/database/web site, no new mechanism needs to be established. Parts of this paragraph are already listed in Annex III (containing the possible information according to paragraph 4) and are not meant as duplication but have to be seen as complementary to each other. Please observe the different scopes of chapters III and IV of these Guidelines and therefore of Annexes III and IV. The National Competent Authority should take measures within the framework of their legislation for the purpose of disseminating, *inter alia,* the information items listed in subparagraphs (a) to (d).

(a) Legislation and policy documents on activities with GMOs prepared at various levels (local, national, regional and international). This may include a description and, where applicable, the actual texts of legal and policy frameworks related to GMOs and contact point(s) for further information;

(b) Legislation and policy documents on public information and public participation in decision-making at various levels (national, regional or international);

(c) International treaties, conventions and agreements relevant to activities with GMOs, such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety;

(d) Other significant international documents on regulatory approaches and the risk assessment of GMOs by international organizations, such as the Food and Agriculture Organization of the United Nations, the World Health Organization and their *Codex Alimentarius Commission*, the United Nations Industrial Development Organization, International Plant Protection Convention, *Office Internationale des Epizooties* and the Organization for Economic Co-operation and Development;

(e) A non-technical explanation of the types of activities with GMOs regulated by national, regional and international legislation

(f) A list of GMOs which have gained approval for placing on the market within the country including contact points and links to Internet sites for further information on the risk assessments of these GMOs; this may include a list of GMOs which have been approved for food use, feed use or any other use within the country, and the requirements for product information;

(g) (i) Notifications of and/or applications for certain contained uses of GMOs; (ii) a (summary of the) risk assessment; and (iii) any decisions on such applications made by the National Biosafety Authority;

(h) (i) Notifications of and/or applications for deliberate releases of GMOs into the environment; (ii) a (summary of the) risk assessment; and (iii) decisions

made by the National Competent Authority;

(i) Non-technical summaries of applications for deliberate releases of GMOs into the environment and decisions made by the National Biosafety Authority;

(j) Experience obtained with deliberate releases into the environment of certain GMOs, in particular those for which simplified authorization procedures are proposed;

(k) Information on methods of protection if any risk arises for the environment and/or human health;

(l) New information relevant to the risk assessment that may become available whilst the notification of or application for a specific activity with GMOs is under consideration by the National Competent Authority;

(m) The advice on a notification or application for a specific activity with GMOs of any expert committee or advisory body to the National Competent Authority;

(n) Decisions to grant or refuse consent or permit for a proposed specific activity with GMOs;

(o) Any limitations and/or conditions attached to any consent or permit granted, including the reasons of the National Competent Authority for attaching limitations and/or conditions;

(p) Significant new information on a specific activity with GMOs for which a consent or permit has previously been granted subsequently notified to the National Competent Authority and which may have an influence on the risk assessment;

(q) Information on the effects of deliberate releases of GMOs into the environment, including information on the results of the monitoring of their effects on the environment and/or human health, and its implications for any further deliberate releases; information on the monitoring of products containing or consisting of GMOs which have been placed on the market;

(r) Decisions taken by the National Competent Authority to revoke or to vary limitations and conditions attached to a consent or permit granted;

(s) Information on the advance informed agreements on GMOs imported into the country as foreseen by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (reference should be made to the Biosafety Clearing House of the Cartagena Protocol);

(t) Information shared by the National Competent Authority with different countries, if a deliberate release of GMOs into the environment will take place in more than one country;

(u) Information on sites of deliberate releases of GMOs and, where appropriate, places where GMOs are grown commercially. This may be information specifying the actual plot, the land register or the local community; and

(v) Contact points to obtain further information from the National Competent Authority.

ANNEX VI: BIOSAFETY REGULATORY AGENCIES

- DINA-MINAG–Plant Production and protection and related safety matters
- DINAP-MINAG – Animal production and health and related safety matters
- DNS-MISAU- Human health matters in particular food safety
- DNAIA- MICOA -Environment matters in particular Environmental impact assessments