



Ministry of Natural Resources and Environment
Directorate General of Environment

NATIONAL BIOSAFETY FRAMEWORK OF S. TOMÉ AND PRÍNCIPE

ELABORATED BY:

National Biosafety Coordination Committee (NCC)

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PREFACE

S. Tome e Príncipe is a vulnerable, fragile and small island developing country therefore, all measures should be taken in order to minimise negative impacts arising from socio-economic development initiatives that the country wish to embark on.

The development and access to new technologies is a basic requirement for achieving the sustainable development. Biotechnology is an integration of both new techniques emerging from modern biotechnology as well as the well established techniques of traditional biotechnology, enabling the introduction of specific changes in the DNA, i.e. genetic material of plants, animals and microbial systems aiming to obtain useful products and technologies. This technology may provide a great contribution for sustainable development of the country in several fields namely health, agriculture, industry, thus enhancing food security.

However, despite all benefits that may accrue from the development of biotechnology, the national authorities, in particular, and the population, in general, are concerned on the adverse effects that the unregulated utilisation of genetically modified organisms may cause in different social, economic and ethic sectors.

Although the appraisal carried out on the use of biotechnology within S. Tome e Príncipe did not find out worrying situations, as the country is still in early stages of development, the national authorities have decided to take preventive measures to know how to best accrue benefits from modern biotechnology and to manage potential adverse effects.

It is foreseen that the development and application of modern biotechnology in S. Tome e Príncipe will be carried out closely linked with the process of development of a legal framework for these activities so that the benefits are maximised and risks are minimised.

I am quite confident that the National Biosafety Framework proposed for S.Tome e Príncipe, will establish a policy, legal, administrative and technical structure that may ensure safe development and application of modern biotechnology, contributing to the conservation and sustainable use of biological diversity as well as the protection of human health.

The participation of general public in decision making process and, in particular, the involvement of bilateral and multilateral partners of S.Tome e Príncipe in this matter has great importance, above all, in mobilisation of resources for both technical and institutional capacity building activities which are considered fundamental factors for the implementation of the policy in this field within S.Tome e Príncipe

The Minister of Natural Resources and Environment

Manuel de Deus Lima

AKNOWLEDGEMENT

Thanks to this financial support of GEF and technical and administrative assistance from the United Nations Environment Programme, the country was able to develop its first National Biosafety Framework. This is a policy instrument that enables the country to be prepared to deal with eventual consequences of the introduction of GMOs in the country whose consequences on health and environment are not yet fully predictable.

Therefore, our thanks go first to the UNEP/GEF due to this precious contribution as well as to the promptness shown by their advisers in assisting the country in the development of the document. Our thanks are extended to the international consultants who were able to provide the technical assistance to the country through their technical knowledge and work carried out so that today the NBF of STP becomes a policy instrument that will assist the Government to take necessary measures to protect the populations and their biodiversity.

We would like to take this opportunity to thank also national consultants, technical experts from different institutions who provide their contribution for the enrichment of the document. This has created a true national ownership to the document.

Lastly, our thanks go to all those who directly and indirectly contributed to the successful implementation of the Project and, as a result, for the development of the National Biosafety Framework of S. Tome e Príncipe.

Thank very much for all of you.

The Commission

LIST OF ABBREVIATIONS

AIDS- Acquired Immune Deficiency Syndrome
ADB - African Development Bank
CCNBIO- National Biosafety Coordination Committee (Comité de Coordenação Nacional da biossegurança)
CENAREST -National Centre of Scientific and Technological Research (Centro Nacional de Pesquisa Científica e Tecnológica)
CIAT – Centre for Agriculture and Technological Research (Centro de Investigação Agronómica e Tecnológica)
CTNBIO- National Technical Commission on Biosafety (Comissão Técnica Nacional de biossegurança)
DC- Directorate of Trade (Direcção do Comércio)
DGAER – Directorate of Agriculture and Rural Extension (Direcção Geral de Agricultura e Extensão Rural)
DGA- Directorate General of Environment (Direcção Geral do Ambiente)
DF- Directorate of Forestry (Direcção das Florestas)
DP- Directorate of Fisheries (Direcção de Pescas)
DTH- Directorate of Tourism and Hotel Industry (Direcção do Turismo e Hotelaria)
ECOFAC- Programme on Conservation and Utilisation of Forest Ecosystem in Africa
EU – European Union
FAO- Food and Agriculture Organisation of the United Nations
GEF- Global Environment Facility
GRDSTP- Government of the Democratic Republic of S. Tomé and Príncipe (Governo da República Democrática de São Tomé e Príncipe)
GDP -Gross Domestic Product
IFAD - International Fund for Agriculture Development
IRAF - Agriculture and Forestry Research Institute
IRET- Tropical Ecology Research Institute
IRSH- Human Sciences Research Institute
IUCN- World Nature Conservation Union
ME- Ministry of Economy (Ministério da Economia)
MPF- Ministry of Planning and Finances (Minsitério do Plano e Finanças)
MNEC- Ministry of Foreign Affairs and Cooperation (Ministério dos Negócios Estrangeiros e Cooperação)
MDOI – Ministry of Defence and Homeland Affairs (Ministério da Defesa e Ordem Interna)
MOPIOT- Ministry of Public Works, Infra-Structures and Land Planning (Ministério das Obras Públicas, Infra-estruturas e Ordenamento do Território)
NBF- National Biosafety Framework
NMA- Ministry of Natural Resources and Environment (Ministério dos Recursos Naturais e Meio Ambiente)
NWFP- Non-wood forest products
PNADD- National Environment Plan for Sustainable Development (Plano Nacional do Ambiente para o Desenvolvimento Durável)
RDSTP - Democratic Republic of S. Tomé e Príncipe
TRIPS – Trade Related Intellectual Property Right Agreements
UEMOA- West Africa Economic and Monetary Union
UN- United Nations
UNDP- United Nations Development Programme
UNEP- United Nations Environment Programme
UNESCO- United Nations Educational, Scientific and Cultural Organisation

USAID- United States International Development Agency
WB- World Bank
WWF- World Wildlife Fund

GLOSSARY

ORGANIC AGRICULTURE	Food production practise without use of synthetic inputs and which follows the natural cycles
DNA	Abbreviation for DeoxyriboNucleic Acid. A long chain polymer of deoxyribonucleotides that constitutes the genetic material of most organisms and organelles
RECOMBINANT DNA	Made from recombination of DNA fragment from different sources.
TRANSGENIC ANIMALS	New breeds of animals obtained through modern biotechnology.
BIODIVERSITY	Term used to designed the richness and diversity of living organism in the earth
BIOETHICS	Study of human conduct in the field of biology and health sciences. The code of conduct is developed based on moral, legal, religious, cultural and humanitarian. They seek to govern and guide the implications arising from the use of new technology and procedures in living organisms.
BIOSAFETY	Rules and mechanisms for controlling the impact of possible negative effects of new species or products arising from genetically modified organisms.
BIOTECHNOLOGY	All techniques that utilizes biologic systems, live organisms or their products, to produce or modify products or processes for specific purposes.
BSE	Bovine Spongiform Encephalopathy also known as Mad Cow Disease
CLONE	A set of genetically identical cells or individuals derived from a common ancestor.
COMPOSTING	The decomposition process of prior separated waste without yielding toxic residuals or eventual environmental hazards.
EX-SITU CONSERVATION	The components of biological diversity are conserved outside their natural habitats.
IN SITU CONSERVATION	Conservation of biodiversity and genetic resources that it contains in the original ecosystems.
CULTIVAR	Plant variety used in agriculture; cultivated, improved and more uniform variety; these traits are obtained through human selection
SPECIES DIVERSITY	The number and distribution of species in one location
GENETIC DIVERSITY	Diversity of genes of plants, animals and micro-organisms living in the earth. Species consists of individuals with different heritable traits.
ECOSYSTEM	Dynamic complex consisting of plants, animals and micro-organisms communities and their non living environment which forms a functional unity through interaction.
GENETIC ENGINEERING	Set of molecular biology techniques using genetic material. These techniques may identify and isolate the DNA as well as to modify and/or transfer it from one organism to another.
SPECIES	Group of individual that may naturally cross and reproduce among themselves and produce fertile progeny. There are cases where it may occur crossing among individuals of related species. A species may be subdivided into differentiated populations such as varieties, breeds or strains
THREATENED SPECIES	Species that are potentially endangered in its territory.
STERILIZATION	Elimination of pathogenic germs.
PHENOTYPE	Set of observable [(physical)] traits of an individual [genotype].
GENE	Portion of DNA that contains the information required for performance of specific genetic trait. Biological unit that determine specific traits of an organisms.
GENOME	Set of genetic information contained in the DNA of living organisms.

GENÓTYPE	Genetic information of each living organism that determines its heredity. This, together with environmental factors, determines the observable traits of each individual.
GERMOPLASM	Set of genes in a population or set of populations; they may be used for selection in a species.
HYBRID	Individual resulting from crossing between genetically different organisms but belonging to the same genus. Hybrids are normally fertile.
INCIDENCE	Ratio that indicates the number of new cases of diseased animals of certain species over the known total population during certain time interval.
ARTIFICIAL INSEMINATION	Artificial fertilisation of the ovule; the act of insemination through non natural means.
GENETIC MATERIAL	Plant, animal, microbial material or other that contains functional units of heredity.
MONITORING	Follow up; term related to planning and management.
TRANSBOUNDARY MOVIMENT	Understood as movement of goods and services from one country to another.
GMO (GENETICALLY MODIFIED ORGANISM)	A living organism that has genetic material modified by other than natural multiplication and recombination.
PRIONS	Abnormal proteins responsible for the Mad Cow Disease or the Creutzfeldt-Jakob disease in humans.
GENETIC RESOURCES	Genetic material with actual or potential value.
RESISTENCE	Capacity of a living organism to resist against attack by other pathogenic living organisms (disease causing agents), predators, or unfavourable environment conditions. Currently, 65% of transgenic plants are herbicide or pesticide resistant.
TRACEABILITY	Principle that includes the need for a sanitary safety assessment, on case-by-case basis, of all that is placed on the market, under the framework of the <i>Codex Alimentarius</i> .
TRANSGENE	X fragment, normally with a complete gene sequence, that is artificially introduced into the genome of other organism.
TRANSGENICS	See GMO
NATIONAL COMPETENT AUTHORITY	National entity responsible for monitoring, control, and supervision of the implementation of legal regime on biotechnology and biosafety within the country.
RISK EVALUATION	The evaluation of the direct and indirect, short, medium and long term risk to human health, biological diversity and the environment, in general
DELIBERATE RELEASE	Any intentional introduction of genetically modified organisms or their products into environment
BCH FOCAL POINT	Entity designated to liaise with the Biosafety Clearing-House
NATIONAL BIOSAFETY FOCAL POINT	National entity designated by the Government to be responsible, on its own behalf, for liaison with Secretary of the Secretariat of the Cartagena Protocol on Biosafety.

EXECUTIVE SUMMARY

Biotechnology is any technique that uses biological systems, living organisms or their derivatives to make or modify products or processes for specific purposes (UNEP, 1992). Modern biotechnology has an enormous potential in the fields of agriculture, livestock, food and health care and it may contribute to human welfare if it is used in a safe and responsible manner. However, modern biotechnology tools that lead to genetic modification which produces genetically modified organisms causes great controversies due to a lot of scientific uncertainties still existing in this matter. In deed, there are still uncertainties regarding the potential risks of genetically modified organisms on human health and environment. Furthermore, there are socio-economic and ethical issues that need to be considered before embarking on mass utilisation of genetically modified organisms in food and production chains

Thus, it turns out to be extremely important to adopt scientific, technical, legal and institutional measures to maximize the benefits of modern biotechnology while minimizing its adverse effect on human health and environment and taking due account the need to address adequately the socio-economic and ethical issues.

It was in this context of maximising the potential applications of modern biotechnology whilst at the same time being cognizant of the existence of scientific uncertainties on potential risks to human health and environment, that the issue of biosafety emerged as international priority issue during the Earth Summit on Environment and Development which adopted, among other instruments, the Convention on Biological Diversity. In fact, the Article 19.3 of the Convention on Biological Diversity (CBD) states that *“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, 1992).

After several years of negotiations, the Cartagena Protocol on Biosafety was adopted in Montreal Canada on the 29th January of 2000 at the Extraordinary Conference of Parties of the Convention on Biological Diversity

The Cartagena Protocol on Biosafety is an international legally binding instrument aimed at the regulation of the transboundary movement of GMOs in order to contribute to protection of human health and safeguard environment from the potential risks resulting from the transfer, handling and use of genetically modified organisms. This Protocol entered into force on 11th September of 2003.

The Protocol is extremely important as it facilitates the strengthening of instruments and mechanisms for controlling the introduction and use of living modified organisms that may have adverse impacts on human, animal and plant health as well as on fragile ecosystems such as the case of STP.

The STP has not yet built human and technical capacity for domestic production of GMOs. Even though, the country can not exempt itself from developing mechanisms to control the genetically modified organisms since the country is vulnerable to the introduction of GMO through the importation of products containing GMOs

It is therefore necessary to develop and implement the National Biosafety Framework in order to regulate the transfer, handling and utilisation of GMOs aiming at protection of national public health and environment particularly the rich biological diversity of STP from the risks of biotechnology and their products

STP is not a Party of the Cartagena Protocol on Biosafety, but, in 2006, the country benefited from funding provided by the Global Environment Facility for the development of the National Biosafety Framework. The UNEP/GEF Project known as UNEP/GEF Project on Development of National Biosafety Frameworks was started in July 2006 scheduled to last for 18 months. The objective of this project was to develop the National Biosafety Framework according to the Article 2.1 of the Cartagena Protocol that stipulates “each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this.

To this effect, a multi sectoral and representative National Coordination Committee was created is to ensure the execution and supervision of all aspect related to the development of the NBF.

The National Biosafety Framework has the objective to establish a policy, legal and administrative framework to ensure safe development and application of modern biotechnology, contributing to the conservation and sustainable use of biological diversity and the protection of human health

Broadly speaking, biotechnology and biosafety are in very early stages of development in STP. There is a weak technical and institutional capacity both for research and development in the field of biotechnology and for management of biosafety issues within the country. Specific biosafety and biotechnology policy and legislation are still absent. It is expected that the current process will facilitate the development of policy and legal instruments as well as institutional mechanisms for addressing properly the biotechnology and biosafety issues within the country

However, there are several sectoral policy instruments that may have indirect impact on the development of biotechnology and biosafety namely: National Environmental Plan for Sustainable Development, National Strategies and Action Plan for Conservation of Biodiversity of S.Tome e Príncipe, Strategy for Poverty Reduction and Agriculture development.

STP does not have any legislation developed or approved to address specifically biotechnology and biosafety issues. However, there are sectoral regulations that reflect biotechnology and biosafety issues. The country need to produce an appropriate legislation to this effect that will set out rules and procedures in order to minimise the adverse effects or risks resulting from utilisation of modern biotechnology tools in agriculture, livestock, forestry, fisheries and environment.

With regards to biosafety, STP does not have structures to deal with technical issues related to the management of genetically modified organisms. However, within the implementation of UNEP/GEF Project on Development of National Biosafety Framework, the National Coordination Committee which is responsible for execution and supervision of all project activities will address this issue. This multi-sectoral and multi-disciplinary committee consists of 7 members representing different Government institutions (environment, forestry, livestock, agriculture, nature conservation) and it has a main function to develop the national biosafety framework. This committee will play an

important role in promoting biosafety issues until a definitive structure for managing biosafety is adopted and it is extremely important to build its capacity in order to fulfil its role in this field.

Taking into account the prevailing situation in the country regarding biosafety, the NBF of STP comprise a set of components which will seek to meet obligations under the Biosafety Protocol and national priorities in the field of biosafety such as: a Government policy on biosafety issues; legislative and regulatory biosafety regime, the administrative and institutional system for the management of biosafety and biotechnology including notification and request for authorisation, the monitoring and enforcement system and the mechanism for public awareness, participation and education

For the implementation of the proposed objectives, the country need to develop a legal framework that enables the country to establish rules for the importation, exportation, transit, production, manipulation, handling and utilisation of genetically modified organisms and their products arising from modern biotechnology.

In this context, the conditions are being created for the development of the legislation on biosafety that will constitute one of the main pillars of legislative and regulatory framework towards the effective implementation of the Protocol.

The draft regulation developed will be subjected to public consultation and participation process taking into account the nature and complexity of issues on environmental and human health issues which are of public concern

The Ministry of Agriculture and Rural Development is entrusted the competence (MADPR) for implementation, monitoring and enforcement of the proposed regulation through the National Directorates of Agriculture and Livestock, in collaboration other relevant institutions related to biosafety issues.

The administrative and institutional system for management of biosafety in STP consists of 5 bodies, namely, National Competent Authority (NCA), National Biosafety Commission (NBC), Biosafety Technical Secretariat (BTS), Biosafety Focal Point (BFP) and Biosafety Clearing-House Focal Point (BCHFP).

Since the country does not have a body responsible for monitoring and control of GMO and biosafety, it is proposed that the monitoring activities will be carried out by the Centre for Agriculture and Technological Research and the enforcement will be under the responsibility of a commission coordinated by Directorate General of Environment. This commission will include services responsible for phyto-sanitary, veterinary, sanitary, economic and environmental inspection.

In absence of specific legislation applicable to biosafety and biotechnology matters, the institutions will continue to base their activities on existing rules and ministerial decisions according to the nature and relevance of each case.

I. General Introduction

I.1 Physical-geographic and socio-economic context

The Democratic Republic of S. Tomé and Príncipe consists of 2 islands: With a land area of 1001 km², S. Tomé and Príncipe lies in the Western coast of the African continent, between 1° 44'N and 0° 01'S Latitude and 7° 28'E and 6° 28'W longitude. The country has an Exclusive Economic Zone of 160.000 Km².

The climate is tropical wet with abundant rains almost all over the year except in the months from June to September which correspond to the dry season. The rainfall varies between 1000 mm in lower lands to 7000mm in the high mountains.

Data from the population census carried out in 2001 (INE, 2001) indicated that the country had a total of 137,599 inhabitants with an annual growth rate of 1.6%. In 2001, the distribution of population by sex has shown a balance trend, with a male population of 49.5% and a female population of 50.5%.

Overall, the population density is about 137 inhabitants/km². The smallest District of Água-Grande, where the capital city is located, has the highest population density with 3085 inhabitants/km² in contrast with the District of Caué, the largest in terms of land area, which has a population density of 20 inhabitants/km².

The economy of the country is based on agriculture which covers 54% of the population and contributes about 30% of the Gross Domestic Product. The agriculture and fisheries are the main economic activities of the country and the cocoa is the main export product accounting for about 95% of the country product export.

The poverty rate has increased from 36% in 1987 to 54% in 2001. Fifty percent of the population live with less than a dollar per day. The poverty affects 53.8% of the population with the largest incidence in rural areas whose main activity is the subsistence agriculture. The most vulnerable social groups are women, small holder farmers, public servants with lower wages, fisheries, *palaiês*, etc.

Meanwhile according to the data from the National Institute of Statistics (2006), some of the macro-economic indicators of the country have shown some improvement as the case of GDP per capital which recorded an actual growth of 4% in 2001 and 8% in 2006 having increased from 555.70 US\$ (2001) to 764.10 US\$ (2006) (INESTP, 2006).

1.2 Biodiversity in STP

Despite its small size, the country hosts diversified ecosystems with a large number of species that are found in different conservation status. According to the report on the 'Current Status of Biodiversity in S. Tomé and Príncipe' (2007), the existing 148 taxa endemic to the islands were assigned the following IUCN categories adapted to the archipelago: It is estimated that 14.9% of STP endemic species are extinct (EX), 12.8% are critically endangered (CR), 10.8% endangered (EN), 41.9% vulnerable(VUD2), 12.2% nearly threatened (NT) and 7.4% have a wide distribution area (LC, least concerned).

The plant biodiversity of both islands consists of 139 families. For the S. Tomé Island, the species diversity is great in the following families: Rubiaceae (41%), Orquidaceae

(24%), Euphorbiaceae (19%), Melastomataceae (50%), and Bigoniaceae (50%). The ferns contribute with 13 endemic species.

The animal biodiversity consists of small mammals (10 species), 49 bird species, 14 reptiles, 5 batrachia as well as other animals with considerable representation in S. Tomé and Príncipe. Regarding the insect fauna, there are 89 butterfly species: S. Tomé (47 species) and Príncipe (42 species), making up an endemism rate/index of 38% and 21%, respectively.

1.3 Nature and importance of biotechnology and biosafety

Broadly speaking, biotechnology is any technique that uses biological systems, living organisms or their derivatives to make or modify products or processes for specific purposes (UNEP, 1992). Thus, biotechnology uses both technical-scientific knowledge and living organisms to produce goods and services. Taking into account the complexity of level of knowledge, biotechnology may be classified into classical biotechnology (eg. fermentation), conventional biotechnology (eg. tissue culture) and modern biotechnology (eg. genomics and genetic engineering).

According to Article 3 of the Cartagena Protocol on Biosafety, modern biotechnology means the application of *in-vitro* nucleic acid techniques including the recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles or fusion of cell beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Biosafety is a set of procedures aiming at the prevention of risks in biological activities (Fonte, 1998). It is understood that both classical biology and recombinant DNA biology are included in this concept. In context of the Cartagena Protocol on Biosafety, biosafety means efforts meant to reduce or to eliminate the potential risks on human health and environment (particularly the biological diversity) resulting from biotechnology and its products.

Modern biotechnology has enormous potential applications in the fields of agriculture, livestock, food and health care and it may contribute to human welfare if it is used in safe and responsible manner. However, the part of modern biotechnology related to the genetic modification that produces genetically modified organisms causes great controversies due to a lot of scientific uncertainties still existing in this matter. In deed, there are still uncertainties regarding the potential risks of genetically modified organisms on human health and environment. Furthermore, there are socio-economic and ethical issues that need to be considered before embarking on mass utilisation of genetically modified organisms in food and production chains.

Thus, it turns out to be extremely important to adopt scientific, technical, legal and institutional measures to maximize the benefits of modern biotechnology while minimizing its adverse effect on human health and environment and taking due account the need to address adequately the socio-economic and ethical issues.

It was in this context and, on one hand, aware of the potential application of modern biotechnology and, on other hand, the existence of scientific uncertainties on potential risks to human health and environment, that the issue of biosafety emerged as

international priority issue during the Earth Summit on Environment and Development which adopted, among other instruments, the Convention on Biological Diversity. In fact, the Article 19.3 of the Convention on Biological Diversity (CBD) states that “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, 1992).

Thus, after several years of negotiations, the Cartagena Protocol on Biosafety was adopted in Montreal, on the 29th January of 2000 at the Extraordinary Conference of Parties of the Convention on Biological Diversity.

I. 4. The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is an international legally binding instrument aimed at regulation of the transboundary movement of GMOs in order to contribute to protection of human health and safeguard of environment from the risks resulting from transfer, handling and use of genetically modified organisms. This Protocol was adopted by the Conference of Parties of the Convention on Biological Diversity on the 29th January of 2000, in Montreal and it has entered into force on 11th September of 2003. Currently, 147 countries are parties of this Protocol.

The Cartagena Protocol on Biosafety is the first Protocol signed under the Convention on Biological Diversity. This Protocol aims to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity taking into account risk to human health and specifically focusing on transboundary movements (SCBD, 2000).

The preamble of the Protocol recognises that biotechnology has great potential for human welfare as long as it is developed and applied with adequate safety measures to human health and environment. At the same time, it reaffirms the precautional approach contained in the Principle 15 of the Rio Declaration on Environment and Development and it states that the parties are aware of growing public concern over the adverse effect that transgenic may pose to human health and environment.

In order to prevent the risks of biotechnology, the Cartagena Protocol on Biosafety is supported by the precautional approach contained in the Principle 15 of the Rio Declaration on Environment and Development.

Thus, we are dealing with an international legally binding instrument which intends to protect fundamental human rights such as human health, biodiversity and ecological equilibrium of the environment without which there would be caused harm to the right to the dignity, life quality and the life itself. These rights are protected under the National Constitution and they granted by the 1948 United Nations Universal Declaration on Human Rights.

The Protocol is extremely important as it facilitates the strengthening of instruments and mechanisms for controlling the introduction and use of living modified organisms that

may cause implications on human, animal and plant health as well as on fragile economies such as the case of STP.

I. 5. Need for development of the National Biosafety Framework of S.Tomé e Príncipe.

Modern biotechnology comprises plant, animal and genetic manipulation techniques carried out intentionally to modify the traits that are inherited from one generation to another. Biotechnological innovation includes techniques of genetic modification that enable the increase in size and speed as well the precision in genetic change

The use of biotechnology may result in negative and positive impact on agriculture and livestock production whether in developed countries or in developing countries such as STP.

The experts on the subject claim that biotechnological research techniques in agriculture may be developed in the laboratory with derived advantages concerning the speed and precision of the experiment as well the economy of the space.

The modern biotechnology is growing rapidly and it creates a growing concern of the society on its adverse effects on biological diversity. However, it also has a considerable potential for human welfare when it is used with safety measures to human health and environment.

However, what is happening is that the STP has limited resources to address the nature and magnitude of known and potential risks associated with living modified organisms.

Biotechnology makes it possible to achieve fast progresses in livestock, as a result of its successful application in vaccines and antibiotic production as well as in reproduction techniques. The bovine growth hormones increase the yield which enables to save grazing land. This is also applies to aquaculture and pisciculture.

There are uncertainties on potential adverse effects of genetically modified organisms on human health:

Regarding the human health, it may be cited as potential adverse risks, the introduction of new toxins and allergens into food chain as well the boosting of the antibiotic resistance.

Ecological risks are several and they result from the fact that the genetically manipulated material may be transferred into similar plants that live in their natural and semi-natural habitats which lead to changes with unpredictable consequences. Once they released into environment, the modified genes may have terrible and unpredictable effects and it will not be possible to control them. The most cited environmental risks include the dissemination of herbicides tolerant weeds and pesticides resistant pests as well as the genetic erosion.

Furthermore, there are socio-economic impact and ethical issues that need to be addressed adequately when dealing with genetically modified organisms.

The STP has not yet built human and technical capacity for domestic production of GMOs. Even though, the country can not exempt itself from developing mechanisms to

control the genetically modified organisms since the country is vulnerable to the introduction of GMO through the importation of products containing GMOs.

Thus, it turns out to be necessary to develop and implement the National Biosafety Framework in order to regulate the transfer, handling and utilisation of GMOs aiming at protection of national public health and environment particularly the rich biological diversity of STP from the risks of biotechnology and their products.

I. 6. The Process of Development of the National Biosafety Framework in STP

STP is not a Party to the Cartagena Protocol on Biosafety, but, in 2006, the country benefited from funding provided by the Global Environment Facility for the development of the National Biosafety Framework. The UNEP/GEF Project known as UNEP/GEF on Development of National Biosafety Framework was established in July 2006 scheduled to last for 18 months. The objective of this project was to develop the National Biosafety Framework according to the Article 2.1 of the Cartagena Protocol that stipulates “each part shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this.

To this effect, it created a National Coordination Committee with multisectoral representation whose objective is to ensure the execution and supervision of all aspect related to the development of the NBF.

The activities consisted of the following:

- Development of the list of potential GMOs existing in STP;
- Survey on the status of biotechnology and biosafety in STP including the uses of biotechnology and existing human resources, infrastructure, training needs and opportunities and research programmes in STP;
- Survey and review of the existing national and international legal instruments that may impact on use of modern biotechnology;
- Survey and review of the existing national biosafety frameworks in the Sub-Region;
- Survey of the existing mechanisms for harmonisation of risk assessment and control and the causes that may hinder their application.
- Identification and building of synergies between national and international institutions responsible for biosafety in order to foster coherent intervention in GMOs related matters.
- Development of a proposal of concrete and urgent measures to deal with biosafety issues in accordance with the Convention on Biological Diversity and the Cartagena Protocol on Biosafety;
- Development of a proposal of alternatives measures to the use of genetically modified organisms;
- Development of a database containing information on biotechnology and biosafety in STP consistent with BCH.

A drafting team was set up subsequently to develop a draft National Biosafety Framework for STP based on analysis of surveys and thematic reports undertaken.

With the development of this document, it is expected that STP will have an instrument that enables the country:

- To be aware of the current status of biosafety and biotechnology and biosafety;
- To create a legal and institutional framework relating to biosafety matters; and
- To produce an action plan for the implementation of the NBF.

This document that presents the Draft National Biosafety Framework of STP is a result of activities coordinated by the Directorate General of Environment with financial support from UNEP/GEF-NBF Project.

National Executing Agency:

The National Executing Agency was the Directorate General of Environment (DGE).

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National Coordination Committee (NCC):

The National Coordination Committee was responsible for the execution and supervision of project matters. Consisting of 7 members representing different Government institutions (environment, forestry, livestock, livestock and nature conservation), the NCC had as the main duty to develop the National Biosafety Framework according to NBF format provided by UNEP/GEF Project on Development of National Biosafety Framework.

Table 1. List of the members of the National Coordination Committee

Name	Title	Institution
Arlindo de Ceita Carvalho	Chair	DGEnvironment
Victor Manuel do Sacramento Bonfim	Director, CN	DGEnvironment
Juvêncio Amado d'Oliveira	Director, AIA	DGEnvironment
Lourenço Monteiro de Jesus	Director, EEA	DGEnvironment
Severino Espírito Santo	Scientific Director	CIAT
Aurélio Sousa de Jesus Rita	Technician, DF	Directorate of Forests
Idalécio Barreto	Director, Livestocks	Directorate of Livestock
Manuel Fernandes de Ceita Vaz do Rosário	Technician de DGA	DGEnvironment

I. 7. Objectives of the NBF

The National Biosafety Framework has the objective to establish a policy, legal and administrative framework to ensure safe development and application of modern biotechnology, contributing, hence to the conservation and sustainable use of biological diversity and the protection of human health.

II. The state of biotechnology and biosafety in STP

Broadly speaking, biotechnology and biosafety are in early stages of development in STP. There is a weak technical and institutional capacity both for research and development in the field of biotechnology and management of biosafety issues within the country. Specific biosafety and biotechnology policy and legislation are still absent. It is expected that the current process will facilitate the development of policy and legal instruments as well as institutional mechanisms for addressing properly the biotechnology and biosafety issues within the country.

II.1. Government policy on biosafety matters

STP still does not have a specific biotechnology and biosafety policy. However, there are several sectoral policy instruments that may have indirect impact on the development of biotechnology and biosafety namely: National Environmental Plan for Sustainable Development, National Strategies and Action Plan for Conservation, Strategy for Poverty Reduction and Agriculture Policy (Table 2).

Table 2 – Sectoral documents with relevance for biotechnology

Type of the instrument	Date of publication	Objective/Relationship with biosafety or biotechnology or articles/paragraph related to biotechnology/biosafety
PNADD	1998	This a general document for the establishment of policies in the field of environmental; The objective of PNADD is to strengthen the national policies for the integration of the concept of sustainability in national development process. The same document constitutes a strategic multidisciplinary document for active participation and involvement of all sectors and national stakeholders in environmental, economic, social and policy issues. However, it does not any specific paragraph on biosafety.
ENPAB	2004	Establishment of appropriate legal and administrative rules for production, importation, and utilisation of genetically modified organisms and their products, ENPAB – Part 3, Annex A-5 – Draft Legal Regime no 2 – Development of a National Legal Regime on Biosafety and Promotion of Scientific Research in the Field of Biotechnology.
National Plan for the Stockholm Convention on POPs	2006	Although there are no specific chapters in text of the Stockholm Convention on POPs addressing directly biosafety, in meantime, the strengthening of technical and human capacities in field of laboratory analysis via CIAT is proposed as one of common points between the 2 structures: biosafety/biotechnology and POPs
NAPA	2007	Chapter IV – Assessment of Vulnerabilities and Adaptation Needs, under the sub-chapter related

		to Agriculture and Forest Sectors, paragraph related to establishment of mechanisms of agriculture and livestock development and the chapter related to the selection and genetic improvement as measure to fight against inbreeding and genetic erosion.
Strategies for Poverty Reduction	2005	Objective: - To halve the percentage of the population (53.8%) living under poverty line by 2010 and reduce it to less than one third by 2015. - To ensure that the whole population has access to basic social services in 2015 and to promote enhancement of living conditions.
Agriculture Policy Document	2006/2007	Objective: - To assess the opportunities and constraints for sustainable development of the agriculture, rural development and fisheries sector in the RDSTP; To draw recommendations for policies, strategies and priority programmes, sub-programmes and projects that promote sustainable development on a short, medium and long term in line with the Millennium Development Goals, priority pillars of the National Strategy for Poverty Reduction and other RDSTP official Government documents.
Reports on Millennium Development Goals	In 2004, it was developed the first report on MDGs and the second one, in 2008 which enables the evaluation of progresses under way.	Objective: - The MDGs represent a global partnership that has grown from the commitments and targets established at the world summits of the 1990s. Responding to the world's main development challenges and to the calls of civil society, the MDGs promote poverty reduction, education, maternal health, gender equality, and aim at combating child mortality, AIDS and other diseases. - The eight goals and 21 targets include: <ul style="list-style-type: none"> • Eradicate extreme poverty and hunger • Achieve universal primary education • Promote gender equality and empower women Reduce child mortality • Improve maternal health • Combat HIV/AIDS, malaria, and other diseases Ensure environmental sustainability • Develop a global partnership for development.
NLTPS	September, 1998	The NLTPS Document, as merely strategic vision exercise, does not objectively address the biosafety issues, although it addresses environmental issues under the Strategy no. 5- To

		ensure the environmental preservation for sustainable development- its option no 2- Preservation and protection- contains some actions aimed to ensure food sustainability for the populations, promotion of conservation of biological diversity,etc.
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II.1. National Plans and Strategies

II.1.1. National Environmental Plan for Sustainable Development (PNADD)

One of the environment policy instruments is the National Environmental Plan for Sustainable Development which was developed within the framework of Capacity 21 Programme. This policy instrument was approved by the Government in 1999 and the objective of the Plan is to strengthen the national capacities for mainstreaming the concept of sustainability into the national development process. The same plan constitutes a strategic multidisciplinary document prepared with the active participation and involvement of all sectors and stakeholders involved in environmental issues as well as those from economic, social and policy sectors.

The implementation of PNADD has enabled the country to produce an operational strategic framework capable of ensuring socio-economic development consistent with preservation of environment and biological resources of the country. This plan has 8 programmes one among which addressing particularly biological diversity and fragile ecosystems. The Plan aims:

- ✓ To promote exhaustive and in-depth knowledge of characteristics of genetic resources (animal and plant) and phenomenon of soil erosion in the country;
- ✓ To implement the National System for Protected Areas (SNAP);
- ✓ To promote and adopt adequate cultural practices in agricultural lands which are consistent with protection of flora, fauna and soil conservation.
- ✓ To implement measures for preservation of threatened animal [and plant] species.

II.1.2. National Strategies and Action Plan for Conservation of Biological Diversity

Apart from the PNADD, STP validated its National Strategies and Action Plan for Conservation of Biological Diversity in 2004. In its Part III, Annex A5, Project no 2, the strategy establishes the guiding principles for conservation and sustainable use of biological resources. Regarding biosafety, the strategy proposes the development of the national biosafety framework and the promotion of scientific research in the field of biotechnology through the development of appropriate legal and administrative procedures for production, importation and utilisation of genetically modified organisms as well as their derivatives.

The proposed strategies and actions refer to the 4 major ecosystems namely forest, inland waters, marine and coastal, agriculture and livestock ecosystems including measures that shall be implemented at short, medium and long terms with participation of the international community.

II.1.3 Strategy for Poverty Reduction

The Strategy for Poverty Reduction approved by the Government in December 2002 and promulgated by the President of the Republic in January 2003, does not take into consideration specific programmes and strategies related to biosafety. However, this document recognises the need for protection of environment, human health as well the promotion of sustainable development.

II.1.4. Document on Agriculture Policy

With the exception of National Strategies and Action Plan for Conservation of Biological Diversity that address this issue, there are policy gaps in relation to obligations under the Cartagena Protocol on Biosafety. It is expected that this situation as well other institutional weaknesses will be overcome under the implementation of the NBF.

In this context, it is recommended that a future national biosafety policy should be aligned to existing sectoral policies in different fields of environment, agriculture, livestock, and fisheries.

It is worth mentioning that the preparation of the NBF constitutes a sign of strong Government involvement and political will for the implementation of the Cartagena Protocol on Biosafety through the creation of a national structure for biosafety issues.

II. 2. Legislative and Regulatory Framework

STP does not have any legislation developed or approved to address specifically the issues of biotechnology and biosafety. However, there are sectoral regulations that reflect biotechnology and biosafety issues (Table 3)

Table 3 – National Legislation related to biosafety issues

Title of the Instrument	Type of the Instrument	Date of publication	Objective	Responsible entity
Framework Law on Environment	Law no 10/99	15/04/99	It establishes the basis for the national development policy	Ministry of Natural Resources and Environment
Regulation on Environmental Impact Assessment	Law by Decree no. 37/99	31/11/99	It establishes the processes for environmental impact assessment	Ministry of Natural Resources and Environment
Phyto-Sanitary Control	Decree no. 40/99	30/11/99	It establishes the competences for phyto-sanitary control	Ministry of Agriculture and Fisheries
Livestocks Code	Law no. 13/2005	30/12/2005	It assembles all provisions related to animals and their derivatives, and, in general, veterinary	Ministry responsible for Livestock

			public health	
Code on Public Health	Law by Decree	18/12/90	Environmental sanitation, food and nutritional security and fight against epidemics	Ministry of Health
Regulation on rules and procedures of the health inspection services	Decree no 5/2002	26/07/02	It creates the norms for the regulation and pursuing of on activities to the sanitation of the way.	Ministry of Health
Law on Conservation of Flora, Wildlife and Protected Areas	Law no 11/99	31/12/99	It aims to conserve the existing ecosystems, wildlife and flora.	Ministry of Agriculture and Fisheries

From the list above, the country needs to produce an appropriate legislation which would set out rules and procedures in order to minimise the adverse effects or risks resulting from utilisation of modern biotechnology in agriculture, livestock, forestry, fisheries and environment.

II.2.1. National legal instruments with impact on biotechnology and biosafety

Despite the lack of specific legislation on biosafety, there are some legal instruments that may contribute for assurance of biosafety namely:

II.2.1.1. Framework Law on Environment

The Framework Law on Environment n° 10/99, of April 15th, establishes the environmental legal framework in STP and, under its Article 2, it states that « *All citizens have the right to an ecologically balanced human environment and the obligation to protect it* » which therefore also calls for the raising of awareness of citizens of STP to environment issues. This law set out the framework for the policy on sustainable development according to the Constitution and the Rio Declaration on Environment and Sustainable Development.

II.2.1.2. Regulation on Environment Impact Assessment

This regulation was approved by the Decree no. 37/99, of November 31st, published in Government Gazette no. 12 of 1999. The regulation aims to protect the environment and to ensure the process of environmental impact assessment both in public and private activities that may have impact on the environment.

There are other instruments that would be adapted in order to regulate genetically modified organisms resulting from biotechnology such as:

- Law by Decree no 40/99 – Competence for Phyto-sanitary Control of Plant Products and Materials entrusted to CIAT. Government Gazette no. 12, 30th November of 1999.

- Code on Livestock – Law no 13/2005 has as objective to assemble all provisions related to animals, their derivatives, and, in general, veterinary public health. It revokes the Law by Decree no 26/85 (dealing with the export of living organisms, importation of animal, food safety...). Government Gazette no 12, Supplement no. 38.
- Code on Public Health (Environmental sanitation, food safety and nutrition, fight against epidemics). Government Gazette no. 56 of 18th /12/1990.
- Decree no. 5/2002- It regulates the functioning of sanitary services, Government Gazette no 4/26, July 2002.
- Decree no. 6/2002- It set out the parameters related to fisheries which must be complied with. Government Gazette no. 4/26, July 2002.
- Law by Decree no. 12/2000 - It approves the sanitary rules for the export of fishery products to the European market. Government Gazette no. 9, 28th December of 2000.
- Decree by Law no. 52/93- It approves the provisional regulation for the use of forests. Government Gazette no 13, 1st September of 1993.
- Law on Conservation of Wildlife, Flora and Protected Areas- Law no. 11/99 published on Supplement 5 of the Government Gazette no. 15 on the 31st December of 1999. This legal instrument aims to promote the conservation of plant and animal species and biological diversity, in general. It must be understood as a set of technical and legal measures to enable the natural development of genetic status of animal and plant communities and the biotic community as national human heritage as well their sustainable social and economic utilisation.

II.3. International agreements and treaties that may have impact on the use of biotechnology

The table 4 presents the summary list of international agreements and treaties that may have impact on biotechnology to which STP has adhered to. The list includes also those agreements/treaties that are in process of ratification or adherence to by the STP. The list contains the most relevant agreements/treaties to biosafety in the field of environment, in particular, biological diversity, human health, food safety, trade and plant and animal health.

Table 4 - International agreements that may have impact on the use of biotechnology

Title of the instrument	Date adherence or ratification	Objectives	Main obligations	Focal Point or entity responsible for the implementation
Convention on Biological Diversity	30 th May of 1998	To conserve and promote sustainable use	Article 8(g), requires Parties to take domestic	Aurélio Rita – (Ministry of Agriculture and

		of biological diversity and to promote fair and equitable sharing of benefit sharing arising from the use of biological resources	measures to regulate, manage or Control risks associated with GMOs	Fisheries)
<i>Codex Alimentarius</i>	The country is not a Party but it is recommended to do so	To develop standards, general principles, and guidelines and recommend codes of practice in relation to food safety and related issues.	Provides guidelines on food safety and related issues	Ministry of Agriculture and Fisheries
Cartagena Protocol on Biosafety	S. Tomé e Príncipe expected to ratify this Protocol in 2008	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.	Ministry of Natural Resources and Environment
International Plant Protection Convention (IPPC),	2006	To secure common and effective action to prevent the introduction and spread of pests and diseases of plants and plant products	IPPC allow parties to take phyto-sanitary measures to prevent introduction and spread of pests and diseases of plants and plant products	Ministry of Agriculture and Fisheries

II.3.1. Convention on Biological Diversity (CBD)

The STP ratified this Convention on the 30th December of 1998, and its implementation is under the coordination of the MRNA, through the Directorate General of Environment. This Convention, under the auspices of the United Nations, aims to conserve and promote sustainable use of the biological diversity as well to promote fair and equitable sharing of benefits arising from the utilisation of genetic resources. Article 8(g) requires parties to take domestic measures to regulate, manage and control the risks associated with GMOs.

II.3.2. Cartagena Protocol on Biosafety

The STP has not ratified this Protocol. It is expected that the country will ratify it in 2008. This Protocol is under the auspices of the CBD and it has objective to ensure an adequate level of protection in field of transfer, handling and use of GMOs arising from modern biotechnology.

II.4. Regional agreements and treaties that may have impact on biotechnology and biosafety

S. Tome e Príncipe is not a Party to many economically important regional treaties and agreements that may have impact on biosafety. A survey carried out under the implementation has found out that only some sub-regional agreements may have some impact on transaction of products at local level. The Table 5 makes reference to these important agreements and treaties.

Table 5 – Regional agreements and treaties with impact on biotechnology and biosafety

Title of the instrument	Date adherence or ratification	Objectives	Main obligations	Focal Point or entity responsible for the implementation
COMIFAC Treaty	2005	To manage the forest resources of the Central Africa in a sustainable and harmonised manner for the welfare of the Sub-Region; To establish a network of representative biodiversity and ecosystems protected areas for the welfare	Implementation of the Convergence Plan of that intends: Harmonisation of forestry and control policies; Knowledge on resources; Ecosystems planning and re-forestation; Conservation of biological diversity, sustainable valuation of forest resources;	Ministry of Agriculture and Rural development/Ministry of Natural Resources and Environment

		of the population and ecological equilibrium of the planet.	undertaking of alternative activities and poverty reduction; Strengthening of capacities, stakeholders participation, Information and training; Research and development; Development of mechanisms for funding, cooperation and partnership.	
Bamako Convention on transboundary movement of toxic and dangerous substances				Directorate General of Environment
Abidjan Convention for cooperation in matters regarding the protection and development of marine and coastal zones of West and Central Africa and the 1981 Protocol	5 th August of 1984	To establish bilateral and multi-lateral agreements including regional and sub-regional agreements for the protection of marine and coastal zones of West and Central Africa Region provided that these agreements are compatible with the Convention and they comply with the international law	To adopt adequate measures, on case-by-case basis, either individually or collectively, in accordance with the provisions of the existing Convention and its Protocols, aiming to combat pollution in the area under the implementation of Convention and to ensure environmentally sound management of natural using, for this purpose, all available means according to the capacities.	Directorate General of Environment

COMIFAC Treaty is declaration on sub-regional policies signed by the Heads of States and Governments of Central Africa related to the conservation and sustainable management of forest ecosystems of Central Africa and it creates the Central Africa Forest Commission (COMIFAC). This Treaty was signed by 10 Heads of States of Central Africa in February 5th, in Brazzaville – Congo. The Treaty is implemented through its COMIFAC Contingence Plan that consists of 10 strategic intervention areas. The strategic intervention area no 4 refers explicitly to the Convention on Biological Diversity stressing the need for strengthening of national protected areas, integrated management of transfrontier protected areas and genetic resources.

The Abidjan Convention for cooperation in matters regarding the protection and development of marine environment and coastal zones of West and Central Africa and the 1981 Protocol on Co-operation to Combat Pollution in cases of emergencies are a sub-regional agreement that covers marine environment, coastal zones and inland waters under the jurisdiction of the states of the West and Central Africa Region. Although they are no specific agreement on biosafety issues, they enable the contracting parties to recognise the threat that the pollution and the lack of integration of environmental aspects into development processes represents to the marine and coastal environment, its ecologic equilibrium, its resources and its legitimate utilisation and the need for implementation of a duly planned research, surveillance and assessment programme as well as to agree on the need for cooperation to ensure sustainable and environmentally sound development through a coordinated and global approach.

The Bamako Convention on the ban on the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa is a treaty of African nations prohibiting the import of any hazardous (including radioactive) waste. Only States which are members of the Organization of African Unity (OAU) are a Party to the Bamako Convention.

The objectives of the Bamako Convention are to protect human health and the environment from dangers posed by hazardous wastes by reducing their generation to a minimum in terms of quantity and/or hazard potential.

The Convention was negotiated by twelve nations of the Organization of African Unity at Bamako, Mali in January, 1991. It came into force in 1996 (although some sources cite other dates), and as of late 2005 has 20 parties.

Impetus for the Bamako Convention arose from the failure of the Basel Convention to prohibit trade of hazardous waste to less developed countries (LDCs), and from the realization that many developed nations were exporting toxic wastes to Africa. This impression was strengthened by several prominent cases.

The Bamako Convention uses a format and language similar to that of the Basel Convention, but is much stronger in prohibiting all imports of hazardous waste. Additionally, it does not make exceptions on certain hazardous wastes (like those for radioactive materials) made by the Basel Convention.

II.5. Administrative and institutional framework

With regards to biosafety, STP does not have structures to deal with genetically modified organisms. However, within the implementation of UNEP/GEF Project on Development

of National Biosafety Framework, the National Coordination Committee has been created through a decree and is responsible for execution and supervision of all project activities. This multi-sectoral and multi-disciplinary committee consists of 7 members representing different Government institutions (environment, forestry, livestock, agriculture, nature conservation) and it has a main function to develop the national biosafety framework. This committee will play an important role in promoting the biosafety issues until the definitive structure for managing biosafety is adopted and it is extremely important to build its capacity in order to fulfil its role in this field.

The surveys carried out indicated the existence of several public institutions that may play an active role in management of biosafety and biotechnology within the country as long as their mandates are reviewed and the necessary training and institutional strengthening are provided. These institutions include the following:

- The Ministry of Economy with its different directorates (Agriculture, Industry Livestocks, Fisheries Trade, Hotel Industry
- Ministry of Health and the different directorates;
- Ministry of Natural Resources and Environment;
- Ministry of Administrative Reforms and Homeland Affairs;
- Ministry of Planning and Finances;
- Directorate General of Environment; and
- Research Laboratories and Centres

Other development partners mentioned in the following chapters will take part in the comprehensive structure that will be created under the framework of biosafety and GMOs.

The common denominator of all these institutions is the weak technical and human capacity as well the lack of adequate facilities and equipment required for their full functioning in order to fulfil their role in national biosafety framework, hence, the urgent need for investing in institutional strengthening including the development of competences, infra-structures, adequate equipments in order to enable successful implementation of the national biosafety framework within the country.

III. Components of the National Biosafety Framework

The main elements of NBF that will enable STP to meet its obligations under the Biosafety Protocol and national priorities in the field of biosafety are the following:

- ✓ A Government policy on biosafety issues;
- ✓ Legislative and regulatory biosafety regime
- ✓ The administrative and institutional system for the management of biosafety and biotechnology including notification and request for authorisation;
- ✓ The monitoring and enforcement system;
- ✓ The mechanism for public awareness, participation and education

III.1. Biotechnology and biosafety policy

STP does not have a specific policy on biotechnology and biosafety. However there are several sectoral policies that may have indirect in the development of biotechnology and biosafety namely: The National Environment Policy for Sustainable Development, the National Strategy and Action Plan for Conservation of Biological Diversity in STP, the National Strategy for Poverty Reduction and the Document on Agriculture Policy.

Thus, there is an urgent need to develop a **national biotechnology and biosafety policy** which would create an enabling environment that contributes to the protection of human health and environment particularly biological diversity from risks of genetically modified organisms and to minimise the socio-economic risks as well to ensure the required ethics in activities with genetically modified organisms within the country.

This policy should be based on the precautional approach contained in Principle 15 of Rio Declaration on Environment and Development and meet the national demands for protection of environment and human health as well for the promotion of sustainable development of the country.

III.2. Legislative and regulatory framework

There is no specific legislation on biotechnology and biosafety in STP. However, there are sectoral laws and/regulations that regulate several issues related to biotechnology and biosafety namely the issues related to agriculture, industry, trade and food safety. The enforcement of this sectoral legislation may constitute an indispensable element for the effective implementation of the NBF. Nevertheless, there is need to develop a specific legislation to address adequately the specificities of biotechnology and biosafety issues.

As mentioned before, the country is not a Party of the Cartagena Protocol on Biosafety and it does not even have a specific legislation on biotechnology and biosafety. However, with the current process of globalisation, STP can not fall apart; at contrary, the country need to be prepared in order to prevent the serious consequences on environment and human that may from the introduction of GMOs.

Hence, it is urgent and imperative to develop a draft law that shall set out rules for importation, exportation, transit, production, manipulation and handling and use of genetically modified organisms and their products arising from modern biotechnology.

In this context, the conditions are being created for the development of the legislation on biosafety that will constitute one of the main pillars of legislative and regulatory framework towards the effective implementation of the Protocol.

The draft law to be developed shall be subjected to public consultation and participation process taking into account the nature and complexity of issues on environmental and human health issues which are of public concern.

The draft decree on biosafety of S. Tome e Príncipe contains a regulation on biosafety aimed to set up rules for importation, exportation, transit, manipulation, handling and utilisation of genetically modified organisms and their products resulting from modern biotechnology, contributing to the protection of environment with focus on conservation of biodiversity and public health.

The regulation set out a set of rules that apply to all public and private entities involved in importation, exportation, transit, production, manipulation, handling and utilisation of GMOs and their products; It also applies to transboundary movements of pharmaceuticals for humans that are GMO and their products subject to specific regulation emanating from international treaties and agreements.

The Regulation entrust the Agriculture, Rural Development and Fisheries the competence for its implementation, monitoring and enforcement through the National Directorates of Agriculture and Livestock in coordination with other institutions relevant for biosafety issues.

The Regulation consists of 27 articles organised into 9 chapters and 6 annexes as indicated in the table 6.

Table 6 - Structure of draft Biosafety Regulation

Chapter	Articles	Content
I		GENERAL PROVISIONS
	1	Objective
	2	Scope
	3	Competence on biosafety matters
	4	Biosafety Advisory Body
II		IMPORTATION OF GMOS AND THEIR PRODUCTS
	5	Food, feed or processing
	6	Contained use and field trials
	7	Production
	8	Food aid
III		RESEARCH
	9	Development of modern biotechnology
IV		EXPORTATION OF GMOS AND THEIR PRODUCT
	10	Requirements
	11	Inspection

V		TRANSIT
	12	Procedures
	13	Transit to neighbouring countries in case of food aid
VI		COMMON PROVISIONS
	14	Risk assessment and management
	15	Labelling
	16	Packaging
	17	Confidential Business Information
	18	Liability and redress
	19	Public awareness and participation
VII		MONITORING AND ENFORCEMENT
	20	General principle
	21	Inspection
	22	Inspection sites
	23	Refusal to entry
VIII		FEES AND FINES
	24	Fees
	25	Breaches and fines
	26	Payment and application of the collected fees and fines
IX		FINAL PROVISIONS
	27	Doubts

III.3. Administrative and institutional system for management of biotechnology and biosafety issues

III.3.1. Proposal for institutional framework for the management of biotechnology and biosafety issues.

As it may be seen in the figure 1, it is proposed that the administrative and institutional system for management of biotechnology and biosafety issues in STP shall consist of 5 bodies, namely:

1. National Biosafety Competent Authority (NBCA);
2. National Biosafety Commission (NBC);
3. Biosafety Technical Secretariat (BTS);
4. National Biosafety Focal Pointy (NBFP); and
5. National Biosafety Clearing House Focal Point (NBCHFP).

III.3.1.1. National Biosafety Competent Authority (NBCA)

The National Biosafety Competent Authority is the decision making body and the coordinator of all and any activities relating to biosafety. This shall be the Ministry responsible for Environment and shall perform its functions in coordination with entities responsible for Agriculture, Livestocks, Trade and Health.

III.3.1.2. National Biosafety Commission (NBC)

The National Biosafety Commission (NBC) shall be an extended body consisting of representatives from the institutions related to biosafety including:

- Centre for Agriculture and Technological Research (CIAT);
- Central Laboratory for Veterinary Diagnosis and the Border Inspection Unit of the Directorate of Livestock;
- Fishery Laboratory and Inspection Services of the Directorate General of Fisheries;
- Directorate General of Environment (DGE);
- Directorate of Livestock;
- Directorate General of Trade, Industry and Tourisms;
- Directorate for the Inspection of Economic Activities;
- Directorate of Health Care;
- Representatives from public and private sectors; and
- Environmental protection Non-Governmental organisations,

This commission shall be charged to establish guiding policies and provide advice to the Government and the National Biosafety Competent Authority in matters related to biosafety. This commission shall be also responsible for drawing recommendations to be submitted to Ministry of Natural Resources and Environment or to the delegated competent authority for a final decision.

III.3.1.3. Biosafety Technical Secretariat (BTS)

This body shall be under the Ministry responsible for agriculture through the CIAT in coordination with Directorate of Livestock and it shall be responsible for day-to-day management of biosafety related issues.

Its duties shall include the handling of applications, setting up *ad hoc* applications reviewing committees with advice from the NBC, liaison with public and applicant, as well as the compilation and submission of public inputs to the competent authority. The BST shall collaborate with National Biosafety Focal Point and the National BCH Focal point in development and maintenance of data base as well as the establishment of a national network among national and international institutions involved in biotechnology and biosafety. This body shall, in coordination with NBC and the NBCA, be responsible for promoting and facilitating public awareness, education, and participation.

III.3.1.4. National Biosafety Focal Point (NBFP) shall be responsible for liaison with the Cartagena Protocol on Biosafety, on behalf of the Government of STP.

III.3.1.5. National Biosafety Clearing Housing Focal Point (NBCHFP) shall be responsible for facilitating the exchange of scientific, technical, environmental and legal information and experience relating to genetically modified organisms.

III.3.2. Proposal of the system for management of notifications and requests for authorisations

All activities with GMOs or their products whether importation, propagation, commercialisation or direct use as food are subjected to obtaining authorisation from the National Biosafety Competent Authority. To this effect, the notifications and request for authorisations shall be submitted to the National Biosafety Competent Authority through the Biosafety Technical Secretariat following the application process described in III.3.3.

III.3.3. Application process

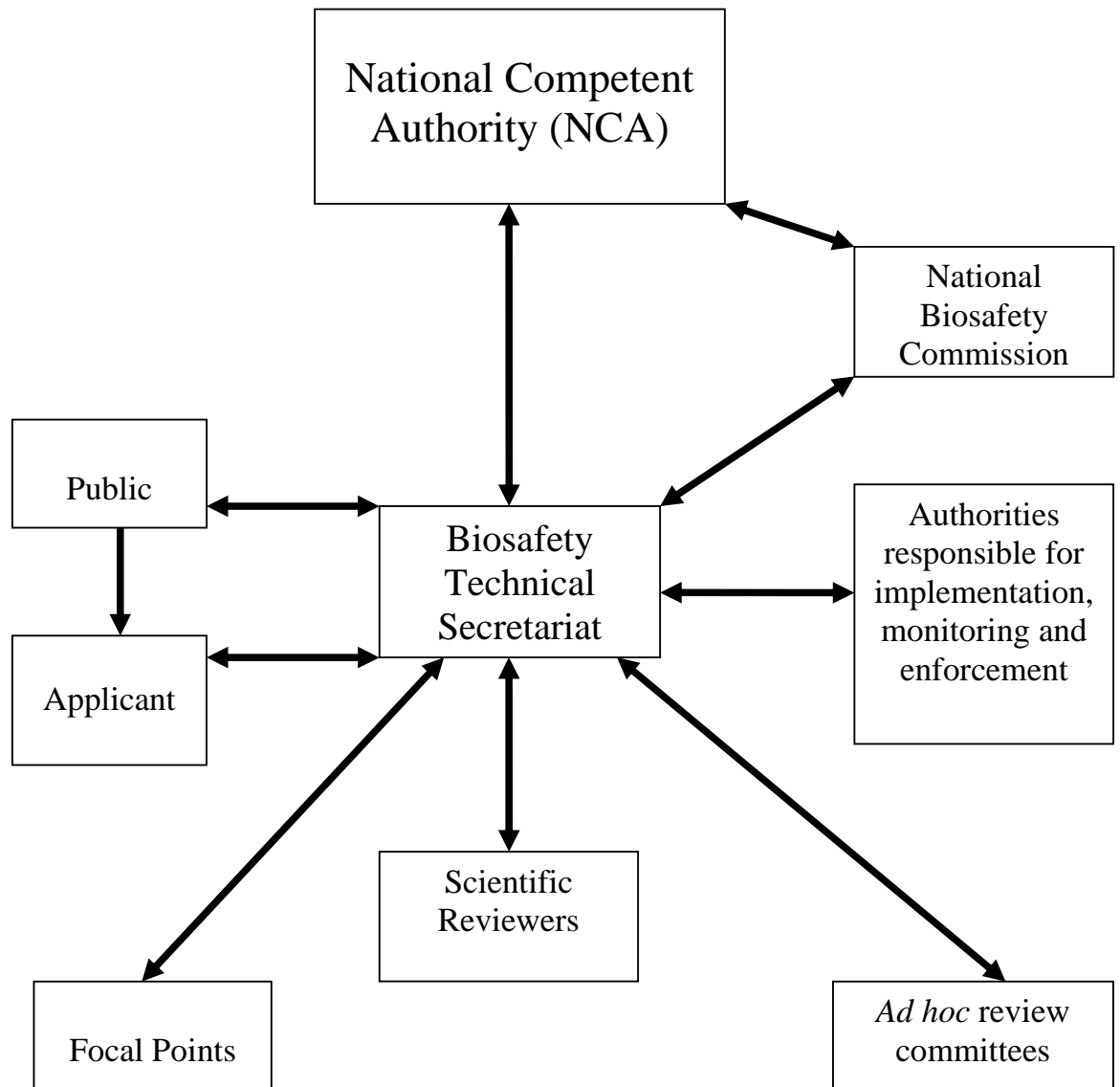
- The applicant submits the request for authorisation to the National Biosafety Competent Authority through the Biosafety Technical Secretariat which shall check its completeness and conformity to the biosafety legislation and notify receipt of the application to applicant.
- If the documents are satisfactory, the BTS shall send them to the National Biosafety Commission for review and recommendations taking into account public inputs and analysis from scientific reviewers. In absence of risk assessment experts in the country, the roster of experts set up shall be consulted for a possible international technical assistance in reviewing of documents.
- The NBC reviews the assessment carried out by the scientific reviewers and public inputs and it draw recommendations to be submitted together with application to the National Biosafety Competent Authority for final decision.
- The National Biosafety Competent Authority make the decision on the application which is further communicated to the applicant through the Biosafety Technical Secretariat. Copies of authorisation with risk management shall be issued to enable the inspectorate to carry out the monitoring and enforcement activities.
- The Biosafety Technical Secretariat receives the risk assessment and management report from scientific reviewers and public inputs. This report is sent to the NBC, together with the summary of public inputs, for further consideration and drawing of recommendations.

The final decision should take into consideration the following aspects:

- Information submitted by the applicant;
- Risk assessment and management reports;
- Public inputs;
- Socio-economic aspects;
 - a) To clearly define the specific conditions relating to the authorisation; and
 - b) To be specific and limited to the activity set out in the decision document.

The application and risk assessment forms as well as the fees and fines schedule shall be developed to assist the application process related GMOs in STP.

Figure 1. Application procedures for importation, exportation, manipulation and use of GMOs in S. Tomé e Príncipe.



III.4. Mechanisms for monitoring and enforcement

Since the country does not have any structure to carry out monitoring and control of GMOs and biosafety, it is proposed that the monitoring activities shall be carried out by the Centre for Agriculture and Technological Research (CIAT) and the inspection by a commission coordinated by the Directorate General of Environment. This commission should also include the services responsible for phyto-sanitary, veterinary, health, economic and environmental inspection.

The monitoring shall be done through visits where risk evaluation on both environment and human health will be carried out. For each visit, a report shall be written and copy of it submitted to the bodies responsible for inspection process.

The core objective of inspection shall be to check compliance to legal instruments that regulates GMOs and biosafety within the country.

For smooth functioning of these structures, a legal and regulatory framework will be developed.

III.5 Mechanism for public awareness and participation

III. 5.1. Mechanism for public awareness and participation

The preamble of the Decree no. 37/1999 that institutes the Regulation on Environmental Impact Assessment states the following: *“The planet earth, as it is known to date, has limited natural resources. The pressure we are putting on the utilisation of these natural resources at the expense of economic growth and better life quality, should also focus on progressive loss and irreversible degradation of natural resources”*

The decree proposes that the public and concerned communities including the non-Government organisations, companies and other single and collective entities should be involved and consulted in assessment of projects and development policies. In the same preamble, it states that environmental licensing procedures for development projects should be transparent, fast and efficient.

Besides some advantages, the introduction of GMOs in STP may have significant adverse effects in the environment and constitute risks to human health.

These risks constitute a sufficient ground to promote public participation in order to ensure the transparency in decision making process.

This participation will enable the consumers, once informed, to be able to provide adequate and credible information on the products they will use and whether these products contain or GMOs so that they may better decide on their choices.

A regulatory framework shall be developed to regulate the public and participation process.

A process for public information, education and communication shall be established. To this effect, the media such as the radio, television, newspapers shall be used to inform, educate and communicate with public on GMOs.

Thus, taking into consideration, the already mentioned Decree 37/99 that regulates environmental impact assessment process setting out mechanisms for public participation, the same example should be used and adjusted to public participation process in issues related to biosafety.

For having the public access to information on biosafety, a mechanism will be established through Internet for facilitating the scientific, technical, environmental and legal

informations exchange on living modified organisms and experiences under them. Despite the country has not yet created the national Biosafety Clearing House (BCH), the Focal Point on the Cartagena Protocol and Focal Point on BCH have already been appointed with the following data:

Name	Institution	Contacts
Severino Neto do Espírito Santo (Cartagena Protocol Focal Point)	Direcção Científica Centro de Investigação Agronómica e Tecnológica (CIAT)	Tel. +239 903963/223342 Fax: +239 223343 Email: santosev@yahoo.fr / santosev@cstome.net
Lourenço Monteiro de Jesus (BCH Focal Piont)	Direcção Geral do Ambiente	Tel. +239 904445/225271 Fax: +239 227156 Email: lomoje@yahoo.com.br / bureau_ozono@cstome.net

III.5.2. Examples of good practices

One of the examples that may serve as model for issues related to biosafety is the case of participatory methodology used during the development of National Environmental Plan for Sustainable Development that enabled the Saotomense civil society to actively participate in the activities identifying problems and putting forward proposals for the solution of several problems identified.

Similear good practices shall be implemented on the basis of recommendations and existing regulations contained in approved and published different legal instruments in field of environment namely, the framework law on environment and the decree that regulates the environmental impact assessment.

Article 3 of the framework law on environment entitled “the Right to Development” states that all citizens have the right to participate, contribute and benefit from economic, social, cultural and political development in which all fundamental human rights and liberties may realised.

IV. Priority intervention area

To address the constraints of policy, legal, institutional, technical and human nature identified in the course of the development of the draft National Biosafety Framework, priority intervention areas have been identified in the field of policy, legislative and regulatory framework, administrative system, capacity building, institutional strengthening and database.

IV. 1. Development of the national biotechnology and biosafety policy

To fill in the gap resulting from the absence of a coherent and specific policy for this sector, there is an urgent need to develop a national biotechnology and biosafety policy within the country. This policy should be based on the precautional approach contained in the Principle 15 of the Rio Declaration on Environment and Development taking into account the existing institutional and human weakness for controlling GMOs in the country. The same policy should be developed aiming to protect human health and environment, in particular, the biological diversity, from the risks of GMOs, to minimize the socio-economic risks as well to promote ethics in activities with GMOs within the country.

IV. 2. Legislative and regulatory framework

IV.2.1. Development of specific law on biotechnology and biosafety

Taking into consideration that the existing legislative and regulatory framework in the country is not adequate to regulate biotechnology and biosafety issues, there is a need to develop a new legislation that shall enable the country to address properly the specific nature of biotechnology and biosafety issues.

In this context, it is imperative to develop a law that establishes rules for carrying out activities with genetically modified organism including the importation, exportation, transit, production, manipulation, handling and utilisation of genetically modified organisms and their products.

Inspired by the Cartagena Protocol on Biosafety, this law should be based on the draft presented in the annex I of this document. The draft law should be subjected to public consultation and participation process taking into account the nature and complexities of issues on environmental safety and public health to be addressed by the same law.

IV.2.2. Development of complementary legislation

The draft law will only regulates general issues on biotechnology and biosafety. There are specific issues such as the rules and procedures of bodies set out under the administrative system (National Biosafety Commission), identification, labelling, handling and transport of GMOs, risk assessment and management, public consultation and participation that should be regulated by specific regulations to be further developed. Further more, as biotechnology and biosafety are dynamic fields, there will be the need to develop complementary norms to accommodate changes required by the advances in knowledge related biotechnology and biosafety over time.

IV.2.3. Transitional provisions

In absence, of the applicable specific legislation, the institutions will continue to carry out their activities based on existing rules and ministerial decision according to the nature and relevance of the cases.

IV.3. Administrative system

The management of biosafety and biotechnology issues shall follow the model presented in Figure 1. This draft model shall be subjected to public consultation in order to reach consensus on its nature and functionality. Regardless, the model that will adopted, it will indispensable to provide the administrative and institutional framework with human resources, equipment, facilities for its full operation, then, there will be a need for investment in capacity building/institutional strengthening.

There will be the need to develop the rules and procedures of several bodies involved in the system in order to establish their nature, composition, relationship among bodies as well the rights and obligations of several stakeholders of the systems.

Rules for documentation pathway procedures shall be developed (procedures for risk assessment and management) to guide and facilitate the decision making process. These rules should be published and available in hardcopy and in the official website of the National Biosafety Competent Authority.

The structure responsible for management of biotechnology and biosafety shall be provided with training in order to enable it to make informed and responsible decision.

IV. 4. Monitoring and enforcement

With regards to monitoring and enforcement, there is a need for:

- Institutional strengthening of laboratories;
- Accreditation of national laboratories related to biosafety (quarantine, biotechnology, plant and animal health and food safety);
- Training and accreditation of biosafety inspectors;
- Training of researchers and entities involved in activities with GMOs; and
- Development of the regulation on biosafety inspection.

IV.5. Public awareness and participation

With regards to public awareness the following activity need to be carried out:

- Training and workshops for public awareness targeting different categories of stakeholders (National Biosafety Competent Authority, National Biosafety Commission and other institutions involved in administrative and institutional framework, public and private institutions related to biotechnology and biosafety and
- Awareness creation on the National Biosafety Framework (all components) and training material related to biotechnology and biosafety (through workshops, radio, newspapers and internet; and

Regarding the public participation, there will be developed the rules for public participation based on the existing good practices under the framework law on environment and the regulation on environmental impact assessment.

IV. 6. Capacity Building/Institutional strengthening

Although it is a positive step to have designed structures for management of biosafety, there will be the need for investment on capacity building/institutional strengthening in order to ensure the effective implementation of National Biosafety Framework. Part of support will be requested within the framework of funding mechanisms established under the Cartagena Protocol on Biosafety as well bilateral cooperation. National commitment will be indispensable to attract these funds.

The main areas requiring investment include:

- Institutional strengthening of laboratories (infrastructure and equipment) related to biotechnology and biosafety (quarantine, biotechnology, plant and animal health and food safety); and
- Training of personnel (National Biosafety Competent Authority, National Biosafety Commission, institutions involved in administrative and institutional framework, public and private sectors related to biotechnology and biosafety.

IV. 7. Development and maintenance of the data base

A National Database on Biosafety and Biotechnology has been developed based on surveys carried out during the development of NBF. This database shall be updated and made available to the national portal linked to the Biosafety Clearing House (BCH) where the information related to the Cartagena Protocol on Biosafety is accessible via the internet.

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Annex A: Draft Biosafety Law

Law by Decree no /08

Considering that the ever-increasing demand for food to meet the needs of the growing population, associated with high rates of absolute poverty put the country under 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.

Considering that, at global level, recourse 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 and resistant to pests and diseases.

Considering that modern biotechnology has also potential applications in the field of animal production and pharmaceutical industry and it may make an important contribution for the improvement of health cares of the population.

Yet taking into account that, like any emerging technology, the widespread dissemination of modern biotechnology in the country may constitute a risk to the environment and human health, if rules and regulations are not put in place to regulate its application.

Article 1

It is herewith approved The Biosafety Regulation, attached to the current Law by Decree which is an integral part of it

Article 2

This Law by Decree enters into force immediately.

Checked and passed by the Council of Ministers

The Primer Minister and Head of Government

The Minister of Natural Resources and Environment

The Minister of Agriculture, Fishery and Rural Development

The Minister of Health

Promulgated on/...../.....

Assented for publication

The President of the Republic

BIOSAFETY REGULATION

CHAPTER I GENERAL PROVISIONS

Article 1 Objective

The objective of the regulation is 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 safeguard of public health

Article 2 Scope

1. The rules under this 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 other applicable
2. This 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 Competence on biosafety matters

1. The Ministry of Agriculture, Rural Development and Fisheries (MARDP) is entrusted the competence to ensure the implementation, monitoring and enforcement of this Regulation, through the National Directorates of Agriculture and Livestock. Agriculture and Livestock Research Centre in coordination with other entities relevant to the field of biosafety.
2. For the purposes of paragraph 1 of this Article, the MARDP shall have the following competence:
 - a) To confiscate, order the destruction or withdrawal GMOs and their products that do not comply with the this Regulation or other applicable norms;
 - b) To inspect and control the entry points of the country and sites of experiments, production, storage and sales of GMOs and their products, in order to check the compliance to the provisions of this Regulation;
 - c) To determine which plant, animal and microbial species resulting from modern biotechnology, whose import, export, transit, production, manipulation, handling and utilization are allowed under this Regulation;
 - d) To grant authorisations under this Regulation based on risk assessment report, public inputs and any other socio-economic considerations.
3. The Ministries of Agriculture, Rural Development and Fisheries, Environment, Health, Health and related and Ministries are entrusted the competence to develop and enact complementary norms required for the implementation of this Regulation

Article 4

Biosafety Advisory Body

1. The National Biosafety Commission is hereby created, as a multi-sectoral technical and scientific advisory body on biosafety matters within the country, supported by a Technical Secretariat
2. The NBC is entrusted the following competences:
 - a) To develop biosafety rules suitable to the national reality, based on the Cartagena Protocol on Biosafety;
 - 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 S. Tome e Príncipe;
 - d) To provide technical assistance to the Government 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 hub/resource centre for biosafety information sharing at national level,
 - 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 consists of representatives from the institutions listed next, appointed by their respective Ministers or Rectors:
 - a) Ministry of Agriculture, Rural Development and Fisheries;
 - b) Ministry of Industry and Trade;
 - c) Ministry of Health;
 - d) Ministry of Natural Resources and Environment;
 - e) Universities;
 - f) Autonomous Region of Príncipe;
 - g) Ministry of Planning and Finance;
4. The NBC shall meet on a quarterly basis and their meetings may be attended by participants representing public and private entities and experts.

Article 5

National Biosafety Competent Authority

National Biosafety Authority is the national decision body and coordinator of all and any activities related to biosafety. This body shall be the Ministry responsible for Environment and it shall perform its duties in coordination with the entities responsible for Agriculture, Livestock, Trade and Health.

Article 6
National Biosafety Commission

The National Biosafety Commission shall be an extended body consisting of representative from biosafety related institutes including:

- Centre for Agriculture and Technological Research,
- Central Laboratory for Veterinary Diagnosis and Border Inspectorate of the Livestocks Directorate,
- Fisheries Laboratory and Inspection Services, Directorate General of Fisheries,
- Directorate General of Environment,
- Directorate of Livestocks,
- Directorate General of Trade, Industry, and Tourism,
- Directorate General for Inspection of Economic Activities,
- Directorate of Health Cares,
- Representatives from public and private sectors,
- Environmental Protection Non-Governmental Organisations,

This Committee shall be responsible for developing guidelines policies and advising the Government and the National Competent Authority on matters related to biosafety and biotechnology. This Commission shall be also responsible to draw recommendations to be submitted to Ministry of Environment or delegated competent authority for final decision

CHAPTER II
IMPORT OF GMOs AND THEIR PRODUCTS

Article 7
Food, feed or processing

1. The import of GMOs and their products intended for direct use as food, feed or processing shall be subject to prior granting of an authorization issued by the MADRP and, for this purpose, the applicant should submit the following documents:
 - a) Completed application form for import of GMOs and their products, according to Annex I of the this Regulation;
 - b) Documents that certify the absence of risks to humans, animals, plants, micro-organisms and the environment and specify the monitoring measures to be taken according to the Article 14 and Annex II of this Regulation
2. The MADRP may request biological samples for testing purposes.
3. Once the requirements listed above are fulfilled, the MADRP 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 specified in it and it may include several lots of the same consignment.
5. The validity of the authorization is one year after which the authorisation will be void and applicant should request a new authorization

Article 8
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 granting of an authorization from MADRP and manipulation permitted only under containment conditions.
2. The conducting of field trials is subject to a prior authorization from MADRP 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 this Article, the applicant should meet the following requirements:
 - a) Fill out the application form for import of GMOs and their products, according to Annex I of the this Regulation;
 - b) To provide documents that certify the absence of risks to humans, animals, plants, micro-organisms and the environment and specify monitoring measures according to the Article 14 and variants of the Annex III of the this Regulation depending whether the experiments are carried in the laboratories, greenhouses or field.
4. The authorization for import and manipulation shall be issued by MADRP 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 9
Production

1. The import of GMOs and their products for production shall be only permitted for the species indicated in the Annex V of this Regulation.
2. For the purposes of paragraph 1 of this Article, the applicant should meet the following requirements:
 - a) To submit the completed application form for import of GMOs and their products, according to the Annex I of the this Regulation;
 - b) To produce documents certifying that field studies of GMO or their products in question were conducted in other locations by recognized scientists and indicating the results obtained;
 - c) To submit the label for approval
 - d) To provide documents that certify the absence of risks to humans, animals, plants, micro-organisms and the environment and specify monitoring measures to be taken according to the Article 14 and the Annex IV of the present Regulation

- e) To declare in detail the source and the storage and transportation conditions of GMO and their products;
 - f) To describe the monitoring measures of the life cycle;
 - g) To 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 MADRP, within the maximum time limit of six months following the evaluation 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 this Article, whenever it is requested.

Article 10 **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 intended for human consumption and in response to cases of extreme need as long as there are no alternative solutions to respond to the emergency on a timely manner.
2. The genetically modified food consisting of grains, imported under paragraph 1 of this Article, should be processed prior to the distribution to the final recipients of food aid, in order to avoid its utilisation as seed.
3. The request for import shall be submitted by the responsible entity under the recommendation of Directorate General of Environment.
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 30 working days.
6. In case where additional information is required, the time limit specified 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 meet the following requirements:
 - a) Completed application form for import of food containing GMOs, according to Annex I of this Regulation;
 - b) Document describing the monitoring measures that the importing entity shall 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 this Article.

Following the evaluation and approval of these documents, MADRP will issue the authorization for the import of the consignment containing GMOs

CHAPTER III RESEARCH

Article 11 Development of modern biotechnology

1. The development of genetically modified organisms by public and private entities within the national territory shall be subject to prior authorization by MADRP.
2. The development referred to in paragraph 1 of this Article shall be only permitted under the containment conditions and it shall preceded by assessment risk under the Article 14 and the Annex III of the this Regulation.
3. The MADRP shall develop and enact the technical guidelines to govern the development of GMOs referred to in paragraph 1 of this Article.

CHAPTER IV EXPORT OF GMOs AND THEIR PRODUCTS

Article 12 Requirements

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

Article 13 Inspection

1. The exporter or its representative shall be required to submit a request for inspection not late than 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 14
Procedures**

1. The transit operations of GMOs and their products through the national territory, destined to other countries in the Region, shall be required to meet the following requirements:
 - a) To submit to the request for transit authorization;
 - b) To produce the import authorization issued by the country of destination specifying the expected dates for the transboundary movements of GMOs and their products;
 - c) To produce the term of liability for reception issued by the country of destination or the country in which the products will pass through;
2. Following the evaluation and approval of the documents referred to in the paragraph 1 of the present Article, the MARDP shall issue a transit certificate prior to the shipment of consignment in the country of origin and within a maximum time limit of 60 days, 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 produce the transit certificate, whenever it is requested.

**Article 15
Transit of food aid with destination to countries in the Region**

1. Any foreign entity intending to import food aid containing GMOs with destination to the countries of the Region, that will move through the national territory, shall request a transit authorization from MARDP and meet the following requirements:
 - a) Import authorization by the country of destination;
 - b) Contingency plan in the case of accident;
 - c) Term of liability 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 this Article must be submitted to the MARDP, thirty working days prior to the shipment 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 16

Risk assessment and risk management

1. The risk assessment of GMO and their products required for request for import, export, research, production and transit shall be conducted according to the technical and scientific requirements described in Annexes II, III and IV of the this Regulation.
2. The risk assessment shall be coordinated by the NBC 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, appropriate mechanisms, measures and strategies to be taken for monitoring, management and control of risks identified paragraphs 1 and 2 of this Article.

Article 17

Labelling

1. All the packages and/or containers containing GMOs and their products shall have a label or an information booklet in accordance with the existing national or international rules regarding labelling, and clear visible letters stating “CONTAINS GENETICALLY MODIFIED ORGANISMS.”
2. With the exception of GMOs and their products in transit through the national territory, with destination to countries in the Region, all other GMOs and their products intended for food, feed, processing, research and production must have the information contained in the labels written in the Portuguese language and easily legible.
3. Any change of the information included in the label must be previously submitted to the MARDP for its approval.

Article 18

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 within the country shall require an authorization from the MARDP 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 shall be inspected and authorized by the MARDP.
4. The empty packages and the residuals of GMOs and their products must be duly treated according to the procedures described in the Annex II regarding the risk management.

Article 19
Confidential Information

1. All the information and the data related to the authorization process of import, export, development, production or handling of GMOs and their products are in 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 matter.

Article 20
Liability and redress

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

1. In cases where an accident involving products containing GMOs occurs, entity responsible for their guard must ensure that the MARDP 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 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 21
Public awareness, education and participation

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

CHAPTER VII
ENFORCEMENT

Article 22
General principles

1. All activities involving GMOs and their products carried out by public or private entities shall be subject to control by MARDP in coordination with entities relevant to biosafety.
2. The control stipulated under paragraph 1 of this Article does not exclude the competence for control by the authorities under the specific legislation.

Article 23

Inspection

1. Under of this Regulation, the GMOs and their products imported or in transit shall be subjected to an inspection to be conducted by the MARDP, at the entry point into the national territory
2. For the inspection, the applicant or its representative is required to submit the request for inspection to the MARDP not later than 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 and the inspector is allowed to take representative samples for laboratory analysis.
4. The inspectors shall check whether the consignments comply with requirements spelled out in the import authorisation.

Article 24 Inspection 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 25 Refusal of Entry

1. The omission of any document or information required for authorisation of entry of GMOs and their products under this Regulation constitutes a ground for the refusal of its entry into country.
2. If, as a result of the inspection, it is found that the consignment does not comply with requirements stipulated under this Regulation, the inspector may order its seizure or any other appropriate measures and the expenses shall be borne by the applicant, without the right for compensation.

CHAPTER VIII FEES AND PENALTIES

Article 26 Fees

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

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 27
Breaches and fines

1. Under this 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 intended for food, feed or processing without an authorization from the MARDP.
 - b) The handling, manipulation and possession of GMOs and their products without authorization from the MARDP;
 - c) The conducting of field experiments with GMOs and its products without an authorisation from the MARDP;
 - 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 regarding 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 into the country through an entry point different from what was stipulated in the import authorization;
2. Any breach 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 appropriation by the State.
3. The violator shall be liable for meeting the financial costs resulting from the measures taken to redress the breach.
4. The fines charged under this Regulation shall be calculated according to the fine schedule contained in the Annex VI.
5. The deadline for the payment of a fine is 15 days, starting from the date of notification of the violator.

Article 28
Payment and application of the charged fees and fines

1. The amounts of fees and fine charged under the this Regulation shall be deposited at the Directorate of Finances
2. The amount charged shall have the following application:
 - a) 40 % for General Government Budget;
 - b) 60 % for the Centre for Agriculture and Technological Research
 - c) 20% for National Competent Authority;
3. The amount charged for fees and fines shall be updated by a joint Decision of Ministers of Agriculture, Rural Development and Fisheries and Finance.

CHAPTER VIII

FINAL PROVISIONS

Article 29

Doubts

Any doubts resulting from the application of the present Regulation shall be resolved through a joint Decision of the Ministers of Agriculture, Rural Development and Fisheries, Health and Natural Resources and Environment.

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.
- 5. Certificate of transit** - document issued by MARDP, certifying that the holder of the GMOs and their products is authorized to transport them through the national public roads.
- 6. CIAT** – Centre for Agriculture and Technological Research
- 7. Country of origin** – country where GMO plants, animal and micro-organisms and their products were produced.
- 8. 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 have been produced.
- 9. DA** – Directorate of Agriculture of the MADRP
- 10. DP** – Directorate of Livestock of MADRP
- 11. 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.
- 12. Entry Point** – border entry to the country.
- 13. Export authorisation of GMOs and its products** – A written authorization issued by MARDP, which gives permission to a person, or national or foreign entity to export GMO and their products, under specific conditions spelled out in it.
- 14. Exporter** – any person or national or foreign entity that intends to export GMO and their products for various purposes.
- 15. 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.
- 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 MARDP, 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. 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 MARDP and tasked to ensure the enforcement of the this Regulation.

19. 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.

20. MARDP – Ministry of Agriculture, Rural Development and Fisheries, 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 trade operations to and from S. Tome e Príncipe.

21. 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.

22. Inter-Institutional Group on Biosafety (NBC) - multi-sectoral technical and scientific group, with competence for review and advice on biosafety matters within the country.

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

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

25. Products of genetically modified organisms – products of plant, animal or microbial origin containing GMOs.

26. 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, performed according to annexes II, III and IV of the Biosafety Regulation.

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

28. Transit – movement of GMO and their products from abroad through Mozambique, with destination to a third country

**ANNEX I: REGISTRATION FORM FOR IMPORTATION OF GENETICALLY
MODIFIED ORGANISMS AND THEIR PRODUCTS**

Entry Date

Registration Number at the MADRP

(To be filled by competent authority)

1. Details of the importer

Name:

Registration at the MIC

Address:

City, District: Province: Country:

Telephone: Fax:

E-mail:

Web:

2. Brief description of the commodity to be imported

GMO

Product

(Mark with an X)

a) Name of the GMO

Common name:

Scientific name:

b) Inserted genes (s)

c) Characteristics of the GMO or product

d) Intended use of the GMO or product

e) Place 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?

Yes

No

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 Number at MADRP

(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

GMO

Product

(Mark with an X)

a) Name of the GMO

Common name:

Scientific name:

b) Place 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) Detection 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 method

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?

Yes

No

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?

Yes

No

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 –Variant 1: RISK ASSESSMENT FORM FOR GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS INTENDED FOR RESEARCH CONDUCTED IN LABORATORIES AND GREENHOUSES

Entry Date

Registration Number at MADRP

(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

GMO

Product

(Mark with an X)

a) Name of the GMO

Common name:

Taxonomic name:

b) Place 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

Yes

No

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 – Variant 2: RISK ASSESSMENT FORM FOR GENETICALLY MODIFIED ORGANISMS AND THEIR PRODUCTS INTENDED FOR FIELD TRIALS

Entry Date

Registration at the MADRP

(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

GMO

Product

(Mark with an X)

a) Name of the GMO

Common name:

Scientific name:

b) Place 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 Method

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

Yes

No

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 nearest 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 INTENDED FOR PRODUCTION

Entry Date

Registration Number at the MADRP

(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

GMO

Product

(Mark with an X)

a) Name of the GMO

Common name

Scientific name

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 method

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?

Yes

No

If so, specify?

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

G6.Probability that transgenic 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 planned 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

ANNEX V: FEES SCHEDULE

Service/Amount of fees charged

1. Handling of registration form for importation of genetically modified organisms and their products: **STD 37,500,000.00 (Thirty seven millions, five hundreds thousands dobras).**
2. Handling of risk assessment form of genetically modified organisms and their products intended for direct use as for food, feed or processing: **STD 37,500,000.00 (Thirty seven millions, five hundreds thousands dobras).**
3. Handling of risk assessment form for genetically modified organisms and their products intended for research conducted in laboratories and greenhouses **STD 156,250,000.00 (One hundred and fifty millions, two hundreds and fifty thousands dobras).**
4. Handling of risk assessment form for genetically modified organisms and their products intended for field trials **STD 156,250,000.00 (One hundred and fifty millions, two hundreds and fifty thousands dobras).**
5. Handling of risk assessment form for genetically modified organisms and their products intended for production: **STD 1,562,500,000.00.**
6. Issuing of certificate of transit: **STD 31,250,000.00 (Thirty one millions, two hundreds and fifty thousands dobras)**
7. Permit for field trials: **STD 31,250,000.00 (Thirty one millions, two hundreds and fifty thousands dobras)**
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: **STD 31,250,000.00 (Thirty one millions, two hundreds and fifty thousands dobras)**
9. Request for authorisation of re-packaging of genetically modified organisms within country: **STD 31,250,000.00 (Thirty one millions, two hundreds and fifty thousands dobras)**

ANEXE VI: FINES SCHEDULE

Article 24, Paragraph 1

Breach /Fine (STD)

Sub-heading a) The importation and placing on the marketing of GMOs and their products intended for food, feed or processing without an authorization from the MADRP: **From STD 78,125,000.00 (Seventy eight millions, one hundred and twenty five thousands) to 312,500,000.00 (Three hundreds and twelve millions, five hundreds thousands dobras).**

Sub-heading b) The handling, manipulation, production and possession of GMOs and their products without authorization from the MADRP: **From STD 31.250.000.00 (Thirty one millions, two hundreds and fifty thousands dobras) to a STD 156,250,000.00 (one hundred and fifty six millions, two hundreds and fifty thousands dobras)**

Sub-heading c) The conducting of field trials involving GMOs and its products without an authorisation from the MADRP: **From STD 7,812,500,000.00 (Seven billions, eight hundreds and twelve millions and five hundreds thousands) to STD 15,625,000.00 (fifteen millions, six hundreds and twenty five thousands dobras).**

Sub-heading d) To provide false declarations or biased information: **STD 31,250,000,000.00 (Thirty one billions, two hundreds and fifty dobras).**

Sub-heading e) The obstruction of the work of the inspectors: **STD 15,625,000.00 (Fifteen millions, six hundreds and twenty five thousands dobras).**

Sub-heading f) The lack of labelling and correct identification of products containing GMOs: **STD 15,625,000,.00 (Fifteen millions, six hundreds and twenty five thousands dobras).**

Sub-heading g) The failure to report to the competent authority on any accident involving GMOs that have occurred: **From STD 15,625,000.00 (Fifteen millions, six hundreds and twenty five thousands dobras) to STD 31,250,000,000.00 (Thirty one billions, two hundreds and fifty millions dobras).**

Sub-heading h) The utilisation of GMOs for purposes different from what was specified in the import authorization: **STD 62,500,000,000.00 (Six two billions, five millions dobras).**

Sub-heading i) The introduction of GMOs and their products in the country through an entry point different from what was specified in the import authorization **STD. 62,500,000,000.00 (Six two billions and five millions dobras).**

ANNEX B: DRAFT GUIDELINES FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS IN S. Tome e Príncipe

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 S. Tome e Príncipe

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, and then 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.

For contained uses, this can include:

- 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 fulfil 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 and the manner of 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 S. Tome e Príncipe 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 the 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 effects 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
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 labelling 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.

6. 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.

7. 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.

End