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**National Institute for Environment and
Nature Conservation**

NATIONAL BIOSAFETY FRAMEWORK IN BURUNDI

Draft Document

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ABBREVIATIONS AND ACRONYMS

DNA: Deoxyribonucleic Acid

AAB : African Agency de Biotechnology

AATF: African Agricultural Technology Foundation

AFRICABIO: African Biotechnology Association for Food, Feed and Fibbers

AGROBIOTEC: Agro biotechnologies

CNA : Competent National Authority

AIA : Advanced Informed Agreement

ASARECA: Association for Strengthening Agriculture Research in Eastern and Central Africa

BCH : Biosafety Clearing House

BIO-EARN: East Africa Regional Programme and Research Network for Biotechnology, Biosafety, and Biotechnology policy development

CBD: Convention on Biological Diversity

CEPGL : Economic Community of Great Lakes Countries

IBC : Institutional Biosafety Committees

NBCC : National Biosafety Consultative Committee

NBEC : National Biosafety Experts Committee

NCCP : National Correspondent of the Cartagena Protocol

CNT A : National Centre for Food Technology

PBC : Public Biosafety Committee

EIA : Environmental Impact Assessment

ELISA: Enzyme Linked Immuno Sorbent Assay

FACAGRO : Faculty of Agronomy

FAO : Food and Agriculture Organisation

GEF : Global Environment Facility

GBDI : Global Biosciences Development Institute

ICGEB: International Centre for Genetic Engineering and Biotechnology

HDI : Human Development Index

IIRSDA : International Scientific Research Institute for for Development for Africa

INECN: National Institute for the Environment & Nature Conservation

INSP : National Institute of Public Health

IPGRI: International Plant Genetic Resources Institute

IRAZ : Agronomic and Zootechnical Research Institute

ISA: Higher Institute of Agriculture

ISAAA : The International Service for the Acquisition of Agri-Biotech Applications

ISABU : Institute of Agronomic Sciences in Burundi

MINATTE : Ministry of Urban Planning, Tourism and Environment

GMO: Genetically Modified Organism

WHO : World Health Organization

NGO : Non-Governmental Organization

LMO : Living Modified Organism

FP/BCH : Focal Point Focal of the Biosafety Clearing House

GDP : Gross Domestic Product

UNEP : United Nations Environment Programme

SLB : ISNAR Biotechnology Liaison Service

SNEB : National Strategy for the Environment

SNPA-DB : National Strategy and Action Plan relating to Biological Diversity

UNESCO : United Nations Educational, Scientific and Cultural Organization

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INTRODUCTION

This National Biosafety Framework is the fruit of a process conducted in Burundi in the framework of the Project “Development of a National Biosafety Framework”

This project financed by the GEF and supervised by UNEP has been carried out by the Ministry of Urban Planning, Tourism and Environment through the National Institute of Environment and Nature Conservation. This National Biosafety Framework document is a product of a clear political will to take advantage of the benefits that Burundi can draw from biotechnologies while preserving the environment and the health of the population.

Thus, the set-up of such a framework must allow the decision-making regarding the transfer, the handling and the safe use of living modified organisms. It is in the end about a guiding strategy that paves the way for a rational and safe use of GMOs in Burundi.

According to the provisions of the Cartagena Protocol, the National Biosafety Framework provides that Burundi can:

- have the choice on the possibility of importing or using or not the living modified organisms;
- ensure the safety by estimating, assessing and managing a potential adverse effect linked to the transboundary movements, transit, handling and use of living modified organisms;
- allow all actors and national decision centres to express themselves during decision-making relating to the use of GMOs;
- develop and or build its capacities on risk assessment, notification and participation to informed decision-making;
- ensure the operation durability of the national Biosafety mechanism.

The draft Biosafety law that accompanies this framework is a tool that will allow Burundi to legislate on the products derived from new biotechnologies. The adoption of this draft Biosafety law will constitute once more the proof, in the eyes of the international opinion, that Burundi makes every effort to regulate the import, the production and the release of GMOs.

The preparation process of this document has mainly been participatory, associating the various technical ministries, the private sector, research institutes and centres and the civil society. The activities took place in the following manner:

- Organization of an information workshop of the members of the National Coordinating Committee of the project;
- Spreading of general information to target audiences, through technical workshops on the Cartagena Protocol so as to prepare the public on the various surveys to be conducted on the whole territory.
- Inventory studies on the following subjects:
 - the knowledge and practices on Biotechnology and Biosafety;
 - the Programmes and Projects relating to Biotechnology and Biosafety;
 - the Legal and regulatory framework in relation to Biotechnology and Biosafety
- Assessment, enrichment and adoption of the study reports by the National Coordinating Committee;

- Holding of a national workshop to examine the conclusions of surveys, to identify the shortfalls, the needs and the priorities;
- Preparation and organisation of training workshops on risk assessment and management;
- Preparation and organisation of consultation workshops of parties to the development of the National Biosafety Framework;
- Development of the National Biosafety Framework.

This document that has just been pre-ratified by the National Coordinating Committee should also be subject to analyses through the following steps:

- Submission of the National Biosafety Framework document to UNEP for comments;
- Organisation of a National Workshop for the ratification of the National Biosafety Framework.

This document is centred on the following seven parts:

The first part presents the general context through two important points these are the physical, biotic and socioeconomic situation and the current status Biotechnology and Biosafety in Burundi. The second part is about the Biosafety policy and presents the national Biosafety issues, the implementation objectives and strategy of this policy. The third part gives the legal and regulatory regime and the fourth part presents the decision-making mechanisms. The fifth part develops the risk assessment and management mechanisms while the sixth part presents the awareness mechanisms, education and public involvement in the decision process. And finally, the last part proposes accompanying measures in the implementation of National Biosafety Framework.

CHAPTER I: GENERAL CONTEXT

I.1. PHYSICAL, BIOTIC AND SOCIO-ECONOMIC SITUATION

I.1.1. Physical Situation in Burundi

I.1.1.1. Geographical situation

Burundi is one of the countries of the Great Lakes Region of Africa. It spreads 27,834 km² of which 25,200 km² are terrestrial and it extends between the meridians 29°00' and 30°54' East and the parallels 2°20' and 4°28' South. Without access to the sea, it borders however the Lake Tanganyika that covers 32,600 km² of which 2,634 km² for Burundi. The neighbouring countries are the Democratic Republic of Congo to the West, the Republic of Rwanda to the North and the United Republic of Tanzania to East and South.

I.1.1.2. Relief

The relief of Burundi is typical of that of the area of the great rift of Eastern Africa which gave place to the formation of Lake Tanganyika in a rift valley in the West and a set of plateau with the relief strongly cut out in the East. The set of this relief forms a complex of 5 geomorphological zones quite differentiated including the Western plain located between 775 and 1000 m of altitude, the Western highlands forming the Congo-Nile watershed and located between 1000 and 2600 m of altitude, the central plateau covering most of the countries and located between 1400 and 2000 m of altitude, the Kumoso depression located at the East between 1200 and 1400 m of altitude and the Bugesera depression located in the North-East of Burundi and between 1200 and 1500 m of altitude.

I.1.1.3. Climate

The climate of Burundi is of tropical type but moderate in high altitude. Precipitations vary from 800 mm/year, in the Rusizi plain, to 2000 mm on the peak. The temperature varies according to altitudes. It reaches an average of 24°C in the Imbo plain, and 15.6°C at around 2000 m of altitude. There are two types of seasons which are the rainy season and the dry season.

I.1.1.4. Hydrology

The country is divided into two main hydrographical basins: the Nile basin and the Congo basin. The Nile basin includes on one hand the Ruvubu River and its tributaries and on the other hand the Kanyaru River, tributary of Kagera River. Le Congo basin consists of two sub-basins: the sub-basin located at the West of the Congo-Nile crest formed by Rusizi and its tributaries and the Lake Tanganyika and the Kumoso sub-basin located in the East of the country and including the Malagarazi River and its tributaries.

I.1.1.5. Soil context

According to material of origin, the main soil groups recognized in Burundi are the following:

- Recent material: recent tropical soils, tropical black cotton soils, tropical brown soils, recent textural soils, rough mineral soils, organic soils.

- Highly altered Material: iron soils, inter-grade iron soils towards recent tropical soils, inter-grade iron soils towards the tropical brown soils, iron soils slightly ironic soils, orthotypical feral soils.

These various soil features play an important part in the distribution of the vegetation at the national level. In altitude, the soils are not very fertile and generally ironic soils or iron soils. On the slopes and the peaks, one finds tropical brown soils and lithosoils. Organic, mineral and peat soils characterize the depths of marshy valleys. The Rusizi plain is characterized by saline *regogleys*.

I.1.2. Biodiversity in Burundi

The ecosystems of Burundi are divided into two main groups: terrestrial ecosystems and aquatic and semi-aquatic ecosystems.

The terrestrial ecosystems include the ombrophilous mountain forests on the highlands of Burundi located between 1600 and 2600 m of altitude, the forests of average altitude appear in the form of clear forests and of gallery forests located between 1000 and 1600 m of altitude and the forests of low altitude made up of Kigwena periguinean dense forest and Rukoko *Hyphaene* forest located between 775 and 800 m of altitude. There are also savannas primarily occupying a good part of the East of Burundi and groves found in the North of Burundi in Bugesera and in the Rusizi plain. The lawns and steppes are types of vegetation forming mainly the Bututsi pastures and a part of Mugamba and Kirimiro.

The aquatic and semi-aquatic ecosystems include marsh lands, lakes (Lake Tanganyika and Northern lakes), ponds as well as rivers.

The vascular flora of Burundi is estimated at 2950 species divided into 1046 kinds and 195 families. The endemism of the wild flora with more than 70 species of higher plants is very pronounced in high altitude. The fauna of Burundi is represented by the vertebrate ones known relatively well and invertebrates rarely studied. For the vertebrate ones, the stock-take counts 163 species, 716 species of birds, 52 species of reptiles, 56 species of Amphibians and 215 fish species. The endemism is very pronounced in high altitude in the mountain forests for the mammals with 17 species and the birds with 22 species. It is also in Lake Tanganyika for fish with 200 species and molluscs with almost the whole of the counted species.

The main forest ecosystems constitute primarily protected areas which occupy a surface of approximately 127 662 ha.

I.1.3. Socioeconomic situation

I.1.3.1. Population

Burundi is a very populated country with a total population estimated at 7.02 million inhabitants, in 2003, with an annual growth rate of 3.4%. The average density of the population is about 250 inhabitants/ Km². The urban population nears 105. The total fertility rate is about 6.8 children per woman. Typically, the Burundian population is young. That of less than 15 years is estimated at 46.5%, while that of more than 65 years is about 2.3%.

I.1.3.2. Economic situation

Burundi is characterized by a generalised poverty that further worsened since 1993. Around 90% of the population lives off the agricultural sector. The dry lands represent about 50% of the total area. The average agricultural area per family holding is about 1 ha, it reduces in areas of high density (about 0.5 ha). In the long run, these trends of occupying soils by agriculture, pasture, etc exert pressure on the natural ecosystems.

According to the World Report on Human Development (2005), Burundi is ranked in 169th out of 177 countries with the following indicators:

- Human Development Index (HDI) is equal to 0.378;
- Life expectancy at birth of 43.6 years;
- Adult Literacy Rate (% of 15 years and more) is equal 58.9%;
- Rate of schooling (combined from primary education to university): 35%.

The GDP remarkably fell since the civil war: whereas it was of USD 180 per capita in 1992 (before the war), it is currently estimated at USD 83. The economy relies mainly on the primary sector. The exported agricultural produces are coffee and tea and cotton. The foreign trade is blocked economically and politically by being geographically landlocked and by refunding the foreign debt.

I.1.3.3. Socio-political situation

The recent progress of the political situation materialized by the installation of democratically elected institutions can constitute a springboard to install sustainable good political governance and to make it possible for Burundi to effectively start poverty reduction activities and the promotion of sustainable development on the basis of a well reasoned biotechnology.

Burundi has naturally subscribed to the Millennium Development Goals. Currently, this country prepares itself to adopt a Poverty Reduction and Economic Growth Strategy Paper (Republic of Burundi, 2005).

Within this framework, Burundi recognizes that the consolidation of the bond between the safeguard of the environment and the development will pass by the promotion of natural resource management and public awareness and education about the safeguard of environment, the rational and sustainable exploitation of natural resources through the conservation of biodiversity, by protecting and restoring of plant cover, the clean-up of the human environment, the strengthening of the institutions and the generalization of impact studies.

I.2. STATUS OF BIOTECHNOLOGY AND BIOSAFETY

According to the Cartagena Protocol, the modern biotechnology extends as modern biological techniques of genetic modification and new methods of cell and tissue culture for particular ends. Biotechnology constitutes a economic sector that has considerably developed since early 1960's and that, actually, bears various applications especially in agriculture and food security, industries, human and animal health, medicine and environment protection.

The assessment of the situation of the development of biotechnologies in Africa reveals that biotechnological products are available on the continent. As this continent possesses a rich biodiversity, raw material of biotechnologies, the development of production activities would enjoy a big boom if the technological transfer mechanisms were developed, applied and encouraged.

In Burundi the modern biotechnology, especially the use of genetic transformation experiences few applications. However, Burundi has understood the interest of conducting biotechnological researches to improve the traditional technologies but also adapt the modern biotechnologies to national realities and to the needs of the rural population.

I.2.1. Current status of biotechnologies

I.2.1.1. Use of biotechnologies

According to the stock-taking surveys conducted in this country, the national institutions put more and more efforts in the sectors of training, research, production and use in the field of biotechnologies.

- At the level of plant and animal biotechnologies

In the area of training, the programmes on biotechnological matter are identified through some courses given in university education. These courses constitute the foundation of modern biotechnologies. Thus, there are no courses or education programmes appropriate to biotechnology. The concerned university institutions are especially the Faculty of Agronomic Sciences (FACAGRO), the Faculty of Science, the Higher Institute of Agriculture (ISA).

The research in the area of biotechnologies is done at the University of Burundi, at the Institute of Agronomic Sciences in Burundi (ISABU), at the Agronomic and Zootechnical Research Institute (IRAZ) and at the National Centre for Food Technology (CNTA).

The Faculty of Sciences conducts diversified researches on the in vitro tissue culture for the rapid multiplication of plant material. The research concerns cereals, root and tuberous plants, ornamental plants, medicinal plants and micro-organisms. The Faculty of Agronomic Sciences (FACAGRO) conducts researches in biotechnologies in the areas of phytopathology, plant breeding, biofertilizer, Proteins of Unicellular Organisms (PUO), culture of mushrooms "Mycoculture", etc. The researches in biotechnology at the Higher Institute of Agriculture concern the production of vitroplants, the conservation of germoplasma and the transformation of food products.

ISABU has an in vitro culture laboratory which has enabled it to carry out several programmes in Burundi within the biotechnology framework:

- Tubers and Roots programme through the Irish potato and sweet potato component and the Potato Components and the Cassava Component;
- Leguminous plants programme through the Bean Component and the Rhizobium/ Soya Beans Component.

CNTA is a technological centre having as objective of making technological innovation and transfer of technology in rural areas, more specifically in the agro-alimentary sector. The main practised biotechnological activity is the biotransformation by fermentation.

IRAZ is interested in the culture of various root plants and has obtained equipment thanks to the assistance of the European Community and FAO. IRAZ also maintains an *ex-situ* collection of various plant species. The institute makes the conservation of genetic material by in vitro culture with the assistance of the International Plant Genetic Resources Institute, IPGRI. IRAZ programmes relate to the plant biotechnologies begun since 1987 on the tropical plants especially the banana tree, the potato, the cassava, the sweet potato and the taro.

Animal biotechnology is developed at ISABU and relates to bovine genetic improvement with absorption crossbreeding of the Ankole race by the Sahiwal one or another exotic breed. Biotechnology intervenes in the conservation of the seed and embryos of the domestic animals of which genetic variability is in regression.

The Veterinary Laboratory of the Ministry of Agriculture and Animal Husbandry is a care and communication centre for domestic animals and carries out few research activities. The biotechnological activities of the veterinary laboratory are the transfer of bovine embryos and the prevention of cattle diseases.

In the area of human health, biotechnology is less exploited in medicine in Burundi because of moral brakes and ethical requirements, as well as insufficient human resources. Following the AIDS pandemic, the Elisa (Enzyme-Linked Immunosorbent Assay) tests and Westernblot are practised there.

- At level of industrial Biotechnologies

The Burundian industrial sector is less developed, less diversified and highly dependent on the outside. The main food and drinks industries are those which transform cash crops, the breweries and import-substitution industries.

I.2.1.2. Consumption of modern biotechnology products

No known genetically modified products are currently being used in Burundi. The biotechnological product users in Burundi are: Research Institutes like ISABU and IRAZ, dairy companies, bakeries, breweries, the Veterinary Centre, the health centres (vaccines), the Enviro-pure Company and other centres. The biotechnological products used in the research centres, the production centres and the industrial transformation companies (leavens and yeasts) are imported from countries where the regulations on the standards of quality of food and phytosanitary products are respected.

It is suited to point out that the training level of the Burundian population as a consumer does not enable it to correctly apprehend the biosafety issue given its highly scientific character. However, the Burundian Consumer Association (ABUCO) is against the illegal import of any is transgenic product however, it does not have any means of control.

I.2.1.3. National capacities in Biotechnologies

- Human resources

Burundi, while not having enough trained human resources in all the biotechnological fields, has sufficient expertise all over to carry out some traditional biotechnology activities. This country counts 149 officers who work in the biotechnology sector.

In the education sector, there exists few of degree programmes for the main sectors of biotechnologies. The existing training programmes are not even specific and consequently are unfit. Currently, Burundi does not have laboratory researchers and technicians or biotechnological industries, in a sufficient number.

With regards to research, much of the research is carried out in the area of plant biotechnologies. One records an increased shortage of the high level scientific personnel. For example, the ISABU laboratory at Gisozi, specialized in plant biotechnology, counts only 6 technicians of whom only one high-level technician while the IRAZ in vitro culture laboratory, of regional class, counts 6 officers including 4 engineers.

Concerning the production and use, small and medium-sized enterprises, although absorbing a large quantity of manpower, display a shortage of qualified staff, be it at the level of executives or specialized technicians.

Despite of this remarkable shortage of personnel, the expertise available, once structured around a well guided and equipped biotechnology, with continuous training, would be capable of fulfilling the important development activities.

- Infrastructures and equipments

Burundi has 10 biotechnology laboratories distributed in 8 institutions including the University of Burundi, the Institute of Agronomic Sciences in Burundi (ISABU), the Agronomic and Zootechnical Research Institute (IRAZ), the National Institute of Public Health (INSP), the Veterinary Laboratory of Bujumbura, the National Centre for Food Technology as well as the two private institutions: AGROBIOTECH and PHYTOLAB. It is the area of the plant biotechnology that is most affluent.

The University of Burundi has alone four laboratories: the In Vitro Culture Laboratory of the Faculty of Science, Biology laboratories (mycoculture) and plant Biotechnologies of Facagro as well as the biological analysis laboratory of the Faculty of Medicine. The laboratories of Facagro and the Faculty of Medicine are modestly equipped but are functional, one regrets however obsolescent condition of the laboratory of the faculty of Sciences. ISABU has three laboratories which are responsible for biotechnology: The laboratory of, the laboratory of microbiology and that of Phytopathology. The laboratory of Gisozi is a laboratory endowed with the sterilization installations of in vitro environments and cultures. This laboratory of modest size is equipped and its potential production capacity is not reached. It is however regretted that the culture environments are not produced there, but always ordered from outside of pays. IRAZ has a very efficient in vitro culture laboratory. This sub-regional institution has a very efficient gene bank for the collection and the conservation of germoplasma. It can keep the capacity to germinate of a usual seed for more than one hundred years. The two private laboratories of plant biotechnology to namely AGROBIOTECH and PHYTOLAB are ill-equipped and use modest infrastructures

In the human and animal health sector, on top of the Faculty of Medicine of the University of Burundi, the INSP of the Ministry of Public Health has a laboratory of biological analysis and environment control. The latter is well equipped and operational. The Veterinary Laboratory of the Ministry of Agriculture and Animal Husbandry carries out biotechnological activities limiting itself to bovine insemination and the prevention of cattle diseases.

I.2.2. Current status of Biosafety

I.2.2.1. Absence of a Biosafety policy

The ratification of Convention on Biological Diversity is a concretization of the political will of the Republic of Burundi to preserve the national biodiversity and manage it in a sustainable way. However, the definition of the overall and sector-specific policies related to biotechnology is not yet operational in Burundi. Admittedly, according to the National Strategy and Action Plan on Biological Diversity (SNPA-DB), Burundi is neither equipped with clear biotechnology and biosafety policy nor with specific biosafety regulation. This policy document regarding biological diversity, around its objective 8 "*Promotion of biotechnologies which support the improvement and the maintenance of biodiversity*", recognizes that Burundi may find it beneficial to make its research in biotechnology. This country must not only improve traditional technologies but also adapt modern biotechnologies to national realities and to the needs of a mainly agricultural population.

While taking as guideline "*To encourage the industrial research in biotechnology*" and in complete agreement with Convention to Biological Diversity (Articles 15, 16, 19), the SNPA-DB retains already the following actions:

- To develop the microbial processes of degradation of pollutants and restoration of environments;
- To begin research aiming at the recovery of waste of any kinds;
- To reinforce safety measures in the use of the biotechnological products in research centres and other production services;
- To encourage research on bio-pesticides, bio-fertilisers and on mycoculture;
- To support the transfer of technologies between the research centres and industry;
- To guide training relating to biotechnologies in industrial production programmes;
- To set up a biotechnology research policy.

I.2.2.2. Legal and regulatory regime

- **Existing regulatory instruments**

The Burundian legal framework is composed of legal and regulatory texts concerned with the national law and the International Conventions ratified by Burundi. The legal texts contain provisions at times very insufficient on the key issues of biosafety. However, some provisions of existing texts in various sectors could apply to some aspects of GMOs. These are in particular texts relating to the introduction of plants to Burundi, the protection of the species or plant varieties, the conservation of biological diversity, etc.

- ***Import and export of Genetically Modified Organisms (GMO)***

The term of GMO does not appear in any legal nor regulatory text in application in Burundi. However, the concerns of safeguarding the genetic identity of the seeds, the plants and the crop products clearly appear in various laws. Thus, the law n°1/ 010 of June 30, 2000 on the Environment

Code in the Republic of Burundi specifies that the introduction of a new animal or plant species is subjected to the joint analysis of the Minister in charge of the Environment and the Minister in charge of Agriculture and Animal Husbandry, to make sure that the proliferation of the considered species do not harm the population of the indigenous species and natural balances.

The law n° 1/02 of March 25, 1985 on the Forestry Code requires that the forest reproduction materials have to meet standards suitable to guarantee genetic and external qualities of these materials. The decree n° 1/033 of June 30 1993 on plant protection establishes that the Minister in charge of Agriculture will have to draw up a list of all the bans and restrictions which are subject to import and export. This decree finds its application in the ministerial order n° 710/754/98 of December 29 1998 on application measures of the Decree law n° 1/033 of June 30 1993 on plant protection.

The decree law n° 1/032 of June 30 1993 on the production and the marketing of the plant seeds indicates that the agricultural varieties exploited in Burundi, whether local or imported, must be approved following comparison tests in cultures relating to the genetic composition, the stability, the homogeneity and the farming value.

- Food Security

Food security seems to be a great concern for the legislator at the national level, but also in the community framework in the Great Lakes Countries sub-region. In fact, the decree law on the plant protection, that relating to seed production and marketing, the zoosanitary convention and the convention on plant protection of the member countries of CEPGEL, have no other purposes than to create conditions of a good agricultural production and animal husbandry, so as to maintain or attain some food security at the national level and at the sub-regional level.

- Setting in quarantine of plants and animals

Setting in quarantine has been one of the main strategies adopted by the countries of the Economic Community of Great Lakes Countries, to which Burundi belongs. This strategy was taken in order to fight against the propagation of plant enemies and animal diseases especially their introduction within the borders of the community.

This commitment was included in the national legislation. Indeed, the decree on the plant protection provides for quarantine measures (provisional consignment, seizure, disinfection or disinfestations, destruction) in the event where it is noticed that the plants, crop products, or plants intended for the multiplication are contaminated by foes of the plants or present suspicious signs of contamination.

- Use of pesticides and herbicides

The use of pesticides is well regulated following the fact that Burundi has noticed very fast that a reckless use of these products could have adverse effects on human health and on the environment.

The decree law n°1/ 033 contains provisions on the general management of pesticides. The government orders n° 710/837 and n° 710/838 of 29/10/2001 respectively fix the pesticides approved for agricultural use as well as the pesticides prohibited for agricultural use in Burundi. The government order n° 770/406 du March 24 2003 set up a National Code of conduct for the management of

pesticides and many government orders approve or prohibit the use of some specific pesticides according to information held by the National Commission in charge of approving and controlling pesticides.

However, the risks related to the use of these pesticides do not miss, following the fact that this law, written in a language not understood by the main users (farmers and cattle keepers) is not well spread among the latter. Some aspects like the destruction of pesticide wastes and expired pesticides are not regulated. On top of that Burundi does not have infrastructures for this purpose. Some risks such as those linked to the handling of the pesticides or their wastes in food, are not well apprehended.

- *Introduction of new species*

The introduction new species is repeated in many texts of laws especially: the environment code, the forest code, the decree law on plant protection and the decree law seed on production and marketing.

- *Invading species*

The concern that the proliferation of some new species could harm the populations of indigenous species and natural balances is taken into account by the environment code in its article 92.

- *Threatened species*

Regarding threatened species, the environment code states a general provision that stipulates that the reconstruction of damaged ecosystems and the regeneration of animal and plant species threatened or disappearing constitute a requirement that is incumbent on the State, the local authorities and the private, physical or moral entity.

- *Intellectual property rights*

The intellectual property rights are regulated the decree law n° 1/9 of 04 May 1978 relating to copyrights and intellectual property in Burundi, prior to the Convention on Biological Diversity and the Cartagena Protocol. They thus don't cover all aspects of intellectual property especially the rights on traditional knowledge presenting an interest for phylogenetic resources for food, agriculture, medicine and others.

- *Impact assessment*

In principle, the EIA (Environmental Impact Assessment) is a requirement of the law. It is management tool aiming at ensuring that the environmental issues are taken into accounts at the beginning of the planning process of the project. From the point of view of the EIA legal and institutional situation in Burundi, the institution responsible for the EIA is the Ministry of Urban Planning, Tourism and Environment. The law on the environment code promulgated on June 30, 2000 is most important for managing the environment. Chapter 3 of this law especially in its articles (21, 22, 24, 25, 26 and 27) talks about the environmental impact assessment procedures. The biotechnology field being recent in Burundi, no environmental impact assessment was geared towards the biotechnological aspects.

- **Agreements and international instruments having an impact on the use of Genetically Modified Organisms**

- ***Agenda 21***

Adopted by 178 States, including Burundi, in June 1992 in Rio de Janeiro, the Agenda 21 is an action plan including all the areas where an interaction occurs between the human activity and the environment. The Agenda 21 thus provides a model, without binding legal force, for the governmental actions in the promotion of sustainable development. The Chapter 16 of Agenda 21 considers biotechnology as an important tool for the 21st century and invites the States to define mechanisms that will allow the development of biotechnologies and their safe application for the environment.

- ***Convention on Biological Diversity***

The Convention of Biological Diversity was one of the key agreements adopted at the Earth Summit in Rio de Janeiro in 1992. It aims at the conservation of the biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits deriving from the exploitation of genetic resources. Burundi ratified it in 1996. Two articles contain specific references to modern biotechnology. These are Article 8 that deals with the *in-situ* conservation. As well as the Paragraph 8(g) provides that *“Each Contracting Party shall, as far as possible and as appropriate: Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health”*

The Article 19 requires that the parties take measures to implement research programmes, which would allow the efficient use of biotechnology, especially in the case of developing countries.

It is this instrument that is at the origin of the Cartagena Protocol, such as stipulated in its article 19(3) that recommends that *“The Parties shall consider the need for and 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 resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.”*

- ***Cartagena Protocol on Biosafety***

The Cartagena Protocol on Biosafety was adopted as an annex agreement to the Convention of Biological Diversity, on January 29, 2000. Burundi has already started procedures of its ratification. The Cartagena Protocol deals essentially with the issues of transboundary movement of living modified organisms that could have harmful effects on the biological diversity.

The article 1 concerning the objective of the Protocol says that *“In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological*

diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”

The Protocol talks of the risk assessment and risk management at the level of articles 15 and 16 and in the Annex III. Risk assessment should be carried out in a scientifically sound and transparent manner (Annex III (3)). According to Article 16, *“Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.”*

The precautionary approach is taken into account in Article 11(8) that stipulates that: *“Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.”*

The Protocol also talks about the Biosafety Clearing House which is a crucial mechanism for its application. The role of the Clearing House is, among others, “to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms”

. It “assists Parties to implement the Protocol , taking into account the special needs of developing country Parties , in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.”(Article 20)

- Other relevant international instruments

The other international agreements and instruments having an impact on the exploitation of Living Modified Organisms are:

- the International Technical Guidelines of the United Nations Environment Programme about Biosafety;
- the Agreement instituting the World Trade Organization (WTO);
- the World Animal Health Organization;
- the International Plant Protection Convention;
- the Convention on plant protection among the member States of Economic Community of Great Lakes Countries;
- the Zoosanitary Convention among the member States of Economic Community of Great Lakes Countries;
- the Phytosanitary Convention for Africa.
- the International Treaty on the Phytosanitary Resources for Food and Agriculture.

Most of all of these conventions have not been integrated in the national legislation and thus they remain rarely applied.

I.2.3. Lessons learnt

I.2.3.1. Training in Biotechnology and Biosafety

On training matters, the teaching of applications of some disciplines regarding biotechnologies is made only at the university education level or post university. Currently, there is no course in biotechnology or a whole training specialized in biotechnology. All the main disciplines of modern biotechnology are not taught in Burundi. However, the risk assessment and management must be based on the scientific knowledge regularly updated with high level scientific equipment.

I.2.3.2. Research and production in Biotechnology

The research institutions experience constraints such as the inexistence of a clear policy regarding biotechnological research, the striking lack of human resources for the biotechnological risk assessment and management, the weakness of the bonds between research and development and popularization, the weak spreading of information on the results of biotechnology at the national and international level.

There is also a lack of coordination of the activities of research and development and popularization. The institutions and the private sector involved in biotechnology work separately. The legal diagram of the seed sector is not followed by all the actors. It results from the introduction of the undesired organisms capable being harmful not only to the environment but also to human health.

The technological capabilities are limited to a biotechnology relatively less sophisticated such as the tissue culture or fermentation. Several interesting areas of biotechnology are not explored.

Several crop plants of undeniable interest and the wild biological resources are not developed. In animal biotechnology, research remains silent especially on the sheep, goats and fowls.

In spite of their number, few of existing biotechnology laboratories are currently functional, some for lack of equipments, others for lack of human resources. Burundi records also non-involvement of the private sector in the biotechnological systems for lack of training and information. The population, the institutions, the decision makers and other actors are not informed on safety related on the use or transfer of GMOs.

While not having the desired human resources in all the biotechnological disciplines, Burundi has enough expertise to undertake some traditional biotechnology activities. These institutions and this expertise are the fruit of the efforts of the country but also of bilateral as well as multilateral co-operation. An inter-institutional collaboration has also favoured research in some institutions.

I.2.3.3. Biosafety Practices

As regards to Biosafety practices, there are neither laboratories & equipments to produce GMOs in Burundi, nor expertise to produce them. However, the presence of GMOs on the Burundian territory is not excluded.

The biotechnological products used in the research centres, production centres and industrial transformation companies are imported from countries where regulations on the standards of the

quality of food and phytosanitary products are respected. However, none of the general safety measures (appropriate information and training, analysis equipment, control mechanism) on GMOs of taken. The commission of experts in charge of GMO risk assessment is not yet set-up in Burundi.

Although a democratic participation of the public in debate and in possible decisions concerning new technologies is recommended in the Rio declaration, it is noted that the level of scientific knowledge of the Burundian population is rather poor to understand and apprehend the universe of biotechnologies and especially the genetic transformation.

I.2.3.4. Legal and regulatory texts

Burundi does not have specific legislation relating biotechnology and biosafety which would make it possible to better control the transfer, the handling and the safe use of the living modified organisms.

The various laws relating to the movement aspects of reproduction materials within Burundi or through its boundaries were formulated a long time before the ratification of Convention on Biological Diversity and the Cartagena Protocol, therefore before the current issues in connection with biotechnology and biosafety.

However, even if these laws and conventions make provisions which would make it possible to limit the introduction to Burundi or export from our country of the plant or animal materials whose genetic identity would not be known, many constraints limiting their application and their effectiveness still exists.

CHAPITRE II: BIOSAFETY POLICY

Modern biotechnology has already shown its utility. It has allowed progress in medicine and promises improvements on the level of the agricultural produce and industrial processes. However, there are concerns as for the potential risks posed by the genetically modified organisms to biodiversity and to human health. The community as a whole can benefit in an optimal way of biotechnology only if it is known and applied in a rational way. This is why, it is advisable to ensure the safety in the development, the application, the exchanges and the transfer of the biotechnological products.

It is thus essential for the Republic of Burundi to lay down a very clear biotechnology and biosafety policy based on the fundamental axes of the Cartagena Protocol. This protocol stresses the transboundary movements. It thus constitutes an important means of organizing and securing international exchanges concerning the living modified organisms. The national biosafety policy must thus aim at ensuring an adequate level of safety in the application of modern biotechnology.

II.1. NATIONAL BIOSAFETY ISSUES

Burundi is not isolated from the external world which, currently, uses the GMO. It is forced to use plant and animal seeds from foreign countries to improve her own. It can in this way introduce on its territory of the undesirable organisms having harmful effects on the human organism and the environment. On the other hand, the genetic recombination can help improve the species by introducing genes responsible for the resistance to diseases, with the deficiency in nutritive elements, as well as genes responsible for increased productivity. In Burundi, the public is more and more aware of these problems. It massively takes part in debates with the specific aim of fully benefiting from these safe technological advances. Accordingly, the national Biosafety policy is articulated around the following major issues:

- Protecting the population health;
- Safeguarding the environment and the biodiversity;
- Food Security.

- Protecting the population health

Food and food additives developed thanks to the DNA recombining technology are already available on the market. The new organisms created from new biotechnologies to improve agriculture can endanger the consumers' health since they enter in the diet. But also of many drugs are produced using the GMO and the "humanized" antibodies are part of the great hopes of this century.

- Safeguarding the environment and the biodiversity

With biotechnology, environmental advantages that can be expected from insect-resistant and herbicidal-tolerant plants, as well as the cultures that will resist to hard climatic conditions are especially the reduction of the insecticidal and herbicidal treatments, the saving of water for soil irrigation, etc.

However, the use of GMOs also presents environmental risks especially: uncontrolled gene transmission through pollination and inter varietal crossbreeding; appearance of insects resistant to transgenic plants, risks of biodiversity reduction, modifications of agricultural practices, etc.

- Food safety

Biotechnologies, sources of scientific progress, present prospects for important economic spin-offs in the production of seeds for the communities. From now up to 2020, the world population would reach 8 billion inhabitants, of which 6.7 billion in the developing countries. Thus, according to the United Nations Food and Agriculture Organisation (FAO), "the increase in absolute value of the number of people to feed risks, with the current methods, to quickly reach the maximum capacity of arable lands". Considering that it is necessary to increase the agricultural productivity on the same places of consumption, the transgenic cultures are regarded as an adequate response to the problem of the hunger.

In conclusion, Burundi is called to make a right choice in the development of a biosafety policy which must take into account of the health of a large population and provide it with enough food in a well preserved environment.

II.2. OBJECTIVES

II.2.1. Global objective

The use of the GMOs requires taking precautions which impose the respect of a code of conduct to reduce the risks on human health and the environment. Thus, the policy of Burundi in the Biosafety area must be in conformity with the requirements of the precautionary principle contained in the Rio declaration. The global objective will be stated as follows "*promoting the development of modern biotechnology around a participative Biosafety system*".

II.2.2. Specific objectives

The specific objectives are the following:

- Capacity building of actors in biotechnology and Biosafety;
- Adaptation of the national legal framework;
- Promotion of the prevention modern biotechnology risks;
- Development of regional and international partnership in the area of biotechnology and Biosafety.

1st Specific objective: Capacity building in Biotechnology and in Biosafety

In Burundi, research in biotechnology is still at an embryonic stage. The majority of users do not have sufficient knowledge and experiences in the various disciplines concerning biotechnologies. Currently, Burundi cannot produce biotechnological laboratory or industrial researchers in a sufficient number. This country still records a lack of infrastructures and equipment adapted to modern biotechnology. Several interesting areas of biotechnology are not explored and the coordination of research and development activities leaves a lot to be desired. One also notes a low spreading of information on the results of biotechnology at the national and international level.

The Government of Burundi should promote training in order to cover all the useful areas of biotechnology for this country. It will have to obtain a research policy on biotechnologies and adequate means to quickly access scientific information. It will be necessary to set up infrastructures and avail the necessary equipments. A coordination structure of the research and development activities in biotechnology is greatly needed. Burundi will have to also involve itself in the regional and international networks of exchanges of experiences and information in biotechnology.

1st Guideline: Human resource capacity building

- To ensure the training of the trainers in biotechnologies and biosafety;
- To organize advanced training courses and training of the scientific staff of research and production institutions;
- To train the lawyers in environmental regulation for the development of national biosafety guidelines;
- To train the personnel of quality control and standards' laboratories;
- To organize advanced training courses of the executives on the monitoring system;
- To set up one or more certificate courses specific to biotechnology, especially to animal, plant and microbial biotechnologies and the valorisation of biodiversity;
- To introduce general modules in relation to biotechnology into secondary and higher education.

2nd Guideline: Institutional capacity building

- To lay down a clear policy relating to research in biotechnologies;
- To set up a laboratory and a genetic engineering equipment
- To equip the existing laboratories with suitable biotechnology Biosafety equipments;
- To equip the supervising authorities with adequate means for the achievement of their missions with regards to biosafety;
- To set up a Biosafety Clearing House;

3rd Guideline: Biosafety promotion in the fight against hunger for poverty reduction

- To encourage and support the participation of the actors in the area of biotechnology and biosafety;
- To popularize tested biotechnological products not having harmful effects on the environment.

2nd Specific objective: Adaptation to the national legal framework

The Burundian legal framework relating to the biotechnology and the biotechnological risk management appears very incomplete, and, even the few provisions which exist as well as conventions to which Burundi is Party cannot be applied. Burundi is thus exposed to the risks which would be related to the uncontrolled introduction into its agricultural and livestock system of the genetically modified reproduction materials whose impacts cannot be determined in advance. Burundi should obtain a more specific law on biosafety. Let us note that there is a Biosafety bill in Burundi which should be obliged to adopt. On top of creating a new national Biosafety regulation, it can also be important to modify, amend the existing laws whose contents could partly or completely be applicable to the exchanges of GMO products or product deriving from GMOs.

Burundi should also obtain an adequate framework for the protection of the genetic resources and traditional knowledge, like any other innovation in the area of biotechnology and biosafety.

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1st Guideline: Elaboration of legal texts specific to Biotechnology and Biosafety

- To organize communication campaigns on legal texts relating to Biosafety;
- To develop a regulation on biotechnology and biosafety;
- To encourage the application of the existing legal and regulatory tools relating to biotechnology and biosafety;
- To translate the new legal texts in the various languages used in Burundi (Kirundi, French and Swahili);
- To organize popularization campaigns of the legal texts relating to biosafety;

2nd Guideline: Protection of knowledge and inventions in Biotechnology

- To protect genetic resources and traditional knowledge in the areas of biotechnology, biodiversity and biosafety;
- To give training on the intellectual property for the award of certificates on any knowledge or invention;
- To create a framework for consultation among researchers to indicate the origin of the genetic resources used in order to protect the rights of the holders.

3rd Specific objective: Promotion of Biosafety within institutions and users

Burundi like all the other countries of the world needs laboratories equipped for the analysis of the genetic material of organisms in order to well control the movement of the genetically modified organisms. There is also the need for national structures for Biosafety management having for mission to look further into a reflection on biotechnologies and biosafety and proposing development strategy and programmes vis-à-vis the crucial problems of the country.

The participation principle must be reinforced to allow the involvement of all the actors in the Biosafety activities. The fulfilment of the objectives of safety requires the precondition of taking measures which make it possible to classify the risks that biotechnology generates, to know in real time their level of execution and to take measures anticipated to face the various crises which could occur. Thus, the organization of safety within the establishments and institutions require the implementation of a control mechanism by the authorities on the use of modern biotechnology and the reinforcement of measures specific to the safeguard of biological diversity.

1st Guideline: Coordination of interventions relating to biotechnology and biosafety

- To set up national structures for biosafety management;
- To coordinate modern biotechnology development programmes at the level of all the sectors involved;
- To develop an information flow mechanism involving all sectors, including the grassroots communities to have information in real time on the operations in progress while observing the requirements for confidentiality;
- To harmonize work protocols while taking care of spreading the best practices with regards to safety considerations;
- To set up a concerted safety plan this will be activated in the event of biotechnological incidents.

2nd Guideline: Population involvement in the biotechnological risk prevention and management

- To inform and sensitize the various Parties, including the grassroots communities for their participation in the development, the implementation and the monitoring of biotechnology and biosafety policies;
- To sensitize the ministries concerned on the urgency to combine their efforts to work out a national strategy on biotechnologies and biosafety and a national biosafety legislation;
- To involve and train the media on the various issues related to biosafety and to set-up a collaboration framework for specialized public information and awareness programmes;
- To use newspapers in national languages and set-up other tools (Posters, flyers and billboards) to broadcast messages relating to biosafety.

- To involve cultural centres to disseminate information by drama companies, debates in the public places, sketches, etc.

3rd Guideline: Public education and training on biotechnological risks

- To organize training workshops and debates for the actors groups concerned about biosafety;
- To ensure the journalists specialized in the environmental issues training in the area of the biotechnological risk prevention and management;
- To organize a national workshop on the role and the running of the Biosafety Clearing House;
- To create and keep going a Biosafety liaison bulletin.
- To involve cultural centres to disseminate information by drama companies, debates in the public places, sketches, etc.

4th Guideline: Setting up of control measures by the authorities on the use of modern biotechnology

- To set up a system aiming at subjecting the use of modern biotechnologies to authorization by taking into account the various alternatives in particular the use in confined environment and the intentional release for purposes of research or market for human or animal consumption;
- To establish a risk assessment system as a prerequisite to the authorization decision-making by the authorities, but also to define risk management measures;
- To set-up a control after obtaining the authorization awarded by the authorities in order to make sure that the use of the GMO is in conformity with the regulations contained in the act of authorization;
- To create a bio-vigilance network to ensure that the use of GMO products does not cause damage to human health and the environment;
- To create an operational detection system of illegal introduction of GMOs.

5th Guideline: Stepping up of specific measures for safeguarding the biological diversity

- To plan the occupation of the territory in order to proscribe any experimentation of an organism in a zone where the risks of transmission of a character to a related species are high;
- To spread quarantine measures for LMOs intended for field experiments;
- To improve the conservation ex situ of genetic resources;
- To regulate the access to local genetic resources;
- To set-up fair share methods among the stakeholders (local firms and population) of the benefits drawn from the development of the genetic resources and traditional knowledge.

4th Specific objective: Development of regional and international partnership in the area of Biotechnology and Biosafety

A certain number of private, governmental, nongovernmental and inter-state organizations take part, at times in a multidimensional way, in capacity building the programmes in the area of biotechnology. The guiding axes of these activities are the assistance in the development of policies, research, technological transfer, Biosafety measures and the regulatory monitoring which accompanies it, the development of relevant legislative texts and public awareness.

1st Guideline: Building of sub-regional and regional cooperation

- To create and develop contacts between the National Biosafety Committee and the other similar national structures at the sub-regional and African levels;

- To promote and develop the relations between the National Biosafety Clearing House and all its counterparts as much African countries as in the whole world;
- To build the capacities of IRAZ by CEPGL countries by equipping it with a laboratory that can identify the nature of the products which circulate within the community and a multidisciplinary scientific body in charge of analyzing the risks of GMO use of the on health and the environment;
- To work out and adopt rules and guidelines which would be transposed in law which regulates the authorization and the GMO use at the level of each Member State of the CEPGL.

2nd Guideline: Development of international cooperation

- To take part in the spreading of information on biotechnology and biosafety through the national Biosafety clearing house;
- To cause and encourage collaboration between the local and international structures on the exchange data and of information on GMOs;
- To take part in the sub-regional, regional and international meetings relating to the activities of exchange of information on biotechnology and the biosafety;

II.3. IMPLEMENTATION STRATEGY OF THE BIOSAFETY POLICY

For the implementation of the biosafety policy, Burundi intends to make all the provisions so as to fulfil its obligations towards the Cartagena Protocol. The implementation of the objectives and guidelines of the biosafety policy are articulated around the following priority axes:

- Implementation of the legal framework;
- Adoption of a participative approach in the decision-making;
- Implementation of a risk management system;
- Public Education and training on biotechnological risks.

- Application of a legal framework

The development and the adoption of a specific Biosafety law, the harmonization of the existing texts with the contents of the Convention on Biological Diversity, and more especially, of the Cartagena Protocol will make it possible Burundi to fulfil its obligations towards the Protocol.

- Adoption of a participative approach in the decision-making

The methods of decision-making in relation to the requests aiming at importing or developing products resulting from modern biotechnology on the territory constitute a key element in the risk management mechanism. This mechanism must involve at the same time the authorities with regard to the management of notifications or requests, the risk assessment, as well as the private sector and the civil society with regard to the process of final decision-making.

- Risk Management System

The risk management system means the limitation of potential negative impacts linked to the use of biotechnologies. In the framework of the implementation of the Biosafety policy, there should

be the building of human capacities and the set-up of appropriate institutional structures with the clarification of missions and responsibilities of each structure. It is crucial set up a National Biosafety Committee, to define the risk assessment principles and methods first then enact strict procedures that will allow the monitoring and evaluation of impacts. It will take part in the coordination of the development programmes of modern biotechnology and supports the central authority in charge of following on the Biosafety policy, to articulate its strategies of risk management.

- Public education and training on biotechnological risks

About education and training, article 23 of the protocol specifies the main requirements to fulfil, especially : (a) “*public awareness, education and participation concerning the safe transfer, handling and use of LMOs*” (b) “*public awareness and education encompass access to information on LMOs that may be imported*” (c) “*inform its public about the means of public access to the BCH.*” Admittedly, the development of modern biotechnology and the implementation of health safety measures, imply the help of the population which must be informed beforehand of what is undertaken.

CHAPTER III: LEGAL AND REGULATORY REGIME

The Cartagena Protocol avails the Parties, some legal requirements must necessarily be taken into account at the national level, so as to ensure the transfer, the handling and the use in all safety of any genetically modified organism (GMO) deriving from biotechnologies and likely to have harmful effects on the conservation and sustainable use of biological diversity as well as human health.

The national legislation must match the provisions of the Protocol, however, while respecting the objective fixed in article 1, it can, as article 2 authorises it, be more rigorous than some of these provisions.

The Burundian draft Biosafety law on includes thirteen chapters and five annexes. It sets the fundamental rules meant to guarantee the safety of the population and the environment against the risks that could be present the genetically modified organisms and their derived products resulting from modern biotechnology.

III.1. LEGAL REQUIREMENTS UNDER THE CARTAGENA PROTOCOL

The legal requirements from the Protocol were repeated in different articles of Protocol text. To the number of requirements of the Cartagena Protocol, some must constitute the legal regime of every Party member. These are especially about, the implementation of the institutional framework of Biosafety management as well as the definition of procedures especially the notification and acknowledgement of receipt procedures, advance informed agreement procedures, risk management procedures, LMO handling, transport, packaging and identification procedures.

III.2. IMPLEMENTATION OF THE REQUIREMENTS OF THE CARTAGENA PROTOCOL

The stock-taking and analysis of the existing legal texts and their relevant provisions relating to the Biosafety issues have revealed that these texts are not completely adapted to answer to the requirements of the Protocol. That is why Burundi has chosen to set up a new system that allows

fulfilling its role towards the requirements relating to the GMO regulation by elaborating a draft law specific to Biosafety issues. This draft law comprises the following main elements:

- General provisions;
- Institutional framework;
- Notification and authorization;
- The decision procedure and review;
- Risk assessment and management;
- Unintentional release and emergency measures
- Identification and labelling;
- Confidential information of commercial nature;
- Export of genetically modified organisms or products derived of genetically modified organisms;
- Liability;
- Penal provisions;
- Various provisions;
- Final provisions;

In the aim of harmonizing the whole of the Burundian regulations to the new Biosafety policy, Burundi will amend and adapt the existing closely related legislations

III.3. APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

According to article 7 paragraph 1 of the Cartagena Protocol, *“Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.”*

The Advance Informed Agreement (AIA) procedure guarantees the possibility of assessing the potential adverse effects of a GMO before accepting its import. The Protocol adds that this AIA procedure does not apply to GMOs in transit in a country, to GMOs intended to be used in a contained environment (in a scientific laboratory, for example) or to GMOs intended to be directly used as food or feed, or for processing. However, a country can, according to its national regulatory framework and in cases where it is compatible with the objective of the Protocol, decide to submit such GMOs to a risk assessment or to other requirements.

Burundi will ensure that the AIA procedure occurs before the first transboundary movement of the GMO, it will ensure to include that AIA is required for all the activities touching GMOs and the various forms of GMO use.

The Competent Authority should receive the notification of the intended transboundary movement, information on the GMO and its use before taking any decision (additional information, refusal or consent). It should give a prior consent before any LMO first transboundary movement.

1. Notification

The notification is the first step in the advance informed agreement. About the notification, the article (8.1) of the Protocol say this : *“The Party of export shall notify, or require the exporter to*

ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.”

The notification should be done according to the provisions of article 8 and will be required for any GMO transboundary movement. It should be addressed in French in writing to the Competent National Authority.

The notification should contain at least the information contained in the Annex I of the Protocol as well as the additional information required by the Minister in charge of the Environment:

- 1) Name, address and contact details of the exporter.
- 2) Name, address and contact details of the importer.
- 3) Name and identity of the living modified organism, as well as the domestic classification, if any, of the Biosafety level of the living modified organism in the State of export.
- 4) Intended date or dates of the transboundary movement, if known.
- 5) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to Biosafety.
- 6) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- 7) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to Biosafety.
- 8) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- 9) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- 10) Quantity or volume of the living modified organism to be transferred.
- 11) A previous and existing risk assessment report consistent with Annex III.
- 12) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- 13) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

- 14) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
- 15) Information relating to a previous or a present transfer of GMO or products thereof in the country or any other country.
- 16) Information relating to the authorization already granted or denied in any other country.
- 17) Place and purpose for which the GMO or product thereof must be used, conserved, released or placed on the market as well as the conditions of use and a labelling and packaging procedure, according to the provisions of the draft law.
- 18) Sworn declaration testifying the accuracy of the information supplied, signed by the notifier, including depending on cases a commitment from the supplier of this information guaranteeing that it is exact and complete.

The Minister of Urban Planning, Tourism and Environment should ensure that the country of export has enacted in its legislation the requirement of notification. According to article 21 of the draft law, the notifier should supply to the Minister in charge of the Environment, the proof that he/she has the means to fulfil its obligations.

2. Acknowledgement of receipt of the notification

The Cartagena Protocol in its article gives guidelines regarding the acknowledgement of receipt “*The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.*” The paragraph 2 lists the data that the acknowledgement of receipt must contain. It indicates:

- a) The date of receipt of the notification;*
- b) Whether the notification, prima facie, contains the information referred to in Article 8;*
- c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.*

The Minister in charge of the Environment should address to the notifier in writing, the acknowledgement of receipt within the 90 days following the reception of the notification. The acknowledgement of receipt should contain the date of reception, the assessment on the information supplied as well as legal procedure applicable to the subject of notification.

The fact, for the Minister in charge of the Environment, of not acknowledging the notification, should not be interpreted by the Party of export, as consent.

3. Decision procedure

The decision procedure is mentioned in article 10 of the Protocol. The Competent National Authority will address in writing to the author of the notification and within 270 days after reception of the notification the decision on the transboundary movement. It will also inform the national and international clearing houses on the decision taken.

Article 15 of the draft law stipulates that: “ *The import on the Burundian territory of a genetically modified organism is subject to a written authorization from the Minister in charge of the environment*”.

The Minister of Urban Planning, Tourism and Environment will base himself/herself on various elements to pass his/her decisions:

- The information contained in the notification;
- The results of the risk assessment;
- The interest of the GMO for the sustainable development of the country;
- The respect of ethical values and concerns of the communities;
- The results of public consultations;
- The information available at the clearing house.

After the assessment of these elements, the Minister in charge of the Environment can decide:

- to request the notifier for additional information and in this case, the 270 days time limit can be prolonged;
- to authorize the import with or without conditions;
- to reject the request.

The Minister of Urban Planning, Tourism and Environment should specify its decision in writing and indicate the reasons that have justified his/her decision to the notifier, to the national clearing house, as well as to the public.

III.4. RISK ASSESSMENT AND MANAGEMENT PROCEDURES

1. Risk assessment

The Protocol authorized the governments to subject a GMO, whatever it is, to a risk assessment before taking a decision regarding its import, so as to establish and assess the potent adverse effects of these GMOs on the conservation and sustainable use of the biological diversity in the receiving environment. This assessment will be conducted in scientifically sound manner and taking into account recognized risk assessment techniques. Article 15 provides that “*Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.*”

The Minister in charge of the Environment should require a risk assessment before giving the authorization or the first time entry to a GMO on the national territory. The assessors will be recruited within the Biosafety Scientific Experts’ Committee and short of that at the level of the Clearing House

when necessary. We can in fact proceed to the recruitment of experts at the regional level and even at the international one, when there are no competent national experts.

The Minister of Urban Planning, Tourism and Environment should ensure that no one be authorized to participate in the risk assessment relating to a subject where he/she has direct or indirect interests or whose participation in the assessment process could cause a conflict of interest.

It is up to the notifier to proceed with or let proceed to a risk assessment linked to a genetically modified organism for which he/she introduced a request.

2. Risk management

The provisions relating to risk management are included in article 16 of the Cartagena Protocol. The Protocol requests the Parties to manage and contain the risks defined during the risk assessment and to take measures and strategies to regulate, manage and contain the risks linked to LMOs. Among the key elements of an efficient risk management are the monitoring systems, research programmes, technical training and an improved national coordination among the governmental services.

The Protocol also requests each Party to consult and notify the States actually affected or likely to be affected, of any incident that falls within its competence and likely to lead to an unintentional LMO transboundary movement for reasons of trade or illicit release occurring under its jurisdiction, once it becomes aware of it. The governments must however establish the official contact points for emergencies so as to improve the international coordination.

In application of this article, Burundi must take all the necessary measures to reduce or avoid the risks of GMOs or their derived products on the human health, the biological diversity and the environment.

The Minister in charge of the environment must:

- develop, maintain and use if necessary, a strategy aiming to contain the accidents from genetic engineering or deriving from GMO;
- impose any necessary measures to the implementation of the Annex III of the Cartagena Protocol and to the softening of negative effects of GMOs;
- stop any use made in contravention to the provisions and decisions provided by the law of GMO or derived product renown for its adverse effects on the health, the environment and the economy;
- order the seizure or the destruction on the territory, of a GMO or its derived products;
- request the notifier to submit its GMO to an observation period.

III.5. LMO HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION PROCEDURES

The handling, transport, packaging and identification procedures are part of legal requirements of each State, they are elaborated in the provisions of article 18 of the Cartagena Protocol. Point 2 of article 18 specifies the indications that must appear in the export documents, these are according to GMOs. In application of this article, the Minister in charge of the environment must:

- Take the necessary measures to require that the LMOs that are subject to an unintentional transboundary movement falling under the Protocol be handled, packaged and transported in safe conditions taking into accounts the relevant international rules and standards.

- Take measures to require that the documentation accompanying the products going to be used for food and feed:

- clearly indicate that they “may contain” LMOs and they are not intended to be intentional introduced in the environment;

- indicate the name and addresses of persons or services to contact for any additional information.

- Take measures to require that the documentation accompanying the LMOs intended to be used in contained environment:

- clearly indicate that they are GMOs;

- specifies the safety rules to observe for the handling, warehousing, transport and use of these organisms;

- indicate the names and addresses of the person or service to contact for any additional information;

- indicate the names and addresses of persons or institutions to which these organisms are sent.

- Take measures to require documentation accompanying the LMOs intended to be intentionally introduced in the environment as well as any LMO targeted by the Protocol:

- clearly indicates that it is a LMO;

- specifies their identity and the relevant traits and characteristics;

- mentions any safety rule to observe for the handling, warehousing, transport and safe use of these organisms;

- indicates the names and addresses of the person to contact for any additional information;

- mentions, if need be, the name and address of the importer and the exporter;

- contains a declaration certifying that the movement conforms to the prescriptions of the Protocol.

CHAPTER IV: DECISION-MAKING MECHANISMS

Burundi has judged it necessary to bring some modifications to the existing systems by adding them to new organs, to fulfil its obligations towards the Protocol, its objectives mentioned in the second chapter of this National Biosafety Framework, as far as regulation of GMOs and derived products by means of genetic modification and activities involving GMOs. In fact, this country has been led to favour an institutional mechanism which will ensure the implementation of a decision-making process that allows collecting and reflecting the whole of points of views of interested parties. It was guided by the following principles:

- The concern to implement a communication and collaboration framework among all the partners;
- The need to ensure the risk assessment linked to GMOs, to ensure the monitoring and control of their introduction;
- The concern to ensure public information, the awareness and participation.

IV.1. BIOSAFETY MANAGEMENT INSTITUTIONS

The institutions responsible of the Biosafety framework include especially:

- The Ministries;
- The Competent national Authority which is the decision-making organ in charge of the requirements of the Protocol;
- The National Biosafety Consultative Committee (NBCC);
- The National Biosafety Experts Committee (NBEC);
- The Public Biosafety Committee (PBC);
- Two correspondents: the National Focal of the Biosafety Clearing House (BCH), the National Correspondent of the Cartagena Protocol.

IV.1.1. Ministries

The Ministries, at various levels, will intervene in the running of the National Biosafety Framework. These are the following ministries: Ministries of Agriculture and Animal Husbandry, Public Health, Urban Planning, Tourism and Environment, Commerce and Industry, National Education and Culture, Finance, External Relations and International Cooperation.

In case of diverging views between the technical ministry and Ministry in charge of the Environment, the decision is taken after deliberation in the Cabinet. The decisions relating to the authorization requests are taken, after advice of the Ministry in charge of the environment on the basis of the technical case file instructed by the NBCC and results of public consultations.

IV.1.2. Competent National Authority (CNA)

In accordance with the provisions of article 19 of the Cartagena Protocol, Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

The Competent National Authority is the Ministry of Urban Planning, Tourism and Environment. Its competence covers all the requests regarding the uses of all GMOs, should they be intended for food or feed or for release in the environment.

The Competent National Authority has for mission:

- to take or allow to take at the national and international level the required legal measures for protecting the health and the environment against the risks linked to the use of modern biotechnology;
- to see to the application and the respect of the Protocol and legal and regulatory prescriptions regarding the intentional and unintentional transboundary movements;
- to develop and make operational a permanent mechanism allowing access of public information from a database of GMOs and their derived products;
- to follow global trends of modern biotechnology issues;
- to identify national needs in human and institutional resource capacity building and development in the area of Biosafety;
- to identify national needs in financial resources, access to technology and know-how, and transfer of technology;
- to establish contacts and to maintain the link with the control organisms of other countries and with relevant international organizations;

The effectiveness of Competent Authority will be ensured by the National Institute for the Environment and Nature Conservation (INECN) which will play the role of biosafety administration office with the mandate of:

- Administering Biosafety on a day to day;
- Receiving and dealing with the authorization requests concerning the activities involving genetic modifications and communicating the decision taken to the notifier and to the Biosafety Clearing House (BCH);
- Coordinating activities of collecting public opinions, activities linked to the risk assessment and activities of decision-making;
- Proceeding if need be, to the consultations with the notifier, on handling confidential information;
- The INECN will also be responsible for the communication on Biosafety (Biosafety information) and for the consultation on the process with the stakeholders

IV.1.3. National Biosafety Consultative Committee (NBCC)

The National Biosafety Consultative Committee is created to assist the Minister in charge of the Environment in his/her mission of preparing and implementing the national policy on Biosafety.

The National Biosafety Consultative Committee will be composed of representatives from ministries, public and private institutions, non governmental organizations and associative movements,

trade union organizations whose mission or scope or competence has some relation to the use of modern biotechnology and Biosafety management.

The concerned ministries and institutions will especially be the Ministries of Urban Planning, Tourism and Environment, Agriculture and Animal Husbandry, Commerce and Industry, Finance, the Institute of Agronomic Sciences of Burundi, the Agronomic and Zootechnological Research Institute, the National Institute of Public Health, the town technical services, the National Centre for Food Technology and the National Institute for the Environment and Nature Conservation.

The National Biosafety Consultative Committee could with some revision be the present Coordinating Committee of the Biosafety Project. The National Biosafety Consultative Committee will be the national permanent dialogue framework. Instituted by the Government, it must enjoy autonomy in running.

The National Biosafety Consultative Committee will have among others the missions of:

- Contributing to the periodic definition and revision of the main guidelines of the national Biosafety policy;
- Assessing all the Biosafety issues that have been submitted by the Competent National Authority and report back within the prescribed deadlines;
- Receiving and analyzing any notice issued by the public on the introduction, handling, use and release of GMOs or their derived products.
- Periodically analysing and validating activity reports of the National Biosafety Experts Committee;
- Defining priorities on research and capacity building matters;
- Monitoring and evaluating the national policy, legislation and public participation according to the Cartagena Protocol on Biosafety;
- Making recommendations and if necessary advising the Competent National Authority.

The NBCC will have a secretariat whose mission is to manage daily the Administrative tasks needed for its running. It is carried out by the INECN. The Permanent Secretary will be the National Coordinator of the Biosafety Project.

IV.1.4. National Biosafety Experts Committee (NBEC)

The National Biosafety Experts Committee is in charge of carrying out the risk assessment linked the activities involving genetic modifications and making recommendations, if need be, on the risk management measures that can be required for protecting the environment and health.

The NBEC is first and foremost a scientific and technical organ on Biosafety issues. It will be composed of specialist coming from scientific and technological institutions as much public as private, as well as other resource people having competences and/or experience in disciplines relating to Biosafety as mentioned in the UNEP guidelines on Biosafety.

The mission of the NBEC will be to:

- Give a scientific advice on their acceptability;
- Examine the ethical aspects of requests;
- Take note and assess the potential damages subsequent to the intentional or otherwise GMO release;

- Assess or evaluate the risk assessment reports of genetically modified organisms and derived products before any import, contained use, voluntary release and placing on the market;
- Define and revise, according to the development of scientific knowledge, the risk assessment and management procedures of genetically modified organisms and derived products;
- Propose the norms, indications and rules required for the application of the legislation on Biosafety.
- Assess all technical issues relating to the application of the national and international legislation on Biosafety
- Elaborate and participate in the revision of guidelines relating to the contained use of GMOs and applicable control procedures according to the estimated level of risk linked to the GMO research, development and release activities;
- Assess research and development projects and recommend the conditions in which these projects will be carried out;
- Assist the CNA in the organization and running of public consultations;
- Give its opinion on requests for import, contained use, release and placing to market of a GMO or a derived product and give its approval to the competent authority to take the decision;
- Follow up on the effective application of its technical recommendation on the ground.

IV.1.5. Public Biosafety Committee (PBC)

The Public Biosafety Committee is non governmental structure, exclusively composed of members from the Civil Society and having in their mission the protection of the environment, the protection of health, the protection of consumers, the sustainable development, the promotion of biotechnologies, the protection of culture, rights of local and indigenous communities and traditional knowledge. The PBC will have within itself a president elected by his/her peers and will have as mission to:

- Participate in the public information and awareness;
- Ensure transparency in the monitoring and evaluation of files relating to GMOs;
- Arouse the enlightened public participation in decision-making.

IV.1.6. National Correspondents of the Cartagena Protocol (NCCP)

National Correspondent (or Focal Point) of the Cartagena Protocol (NCCP) makes the connection between the country and the Secretariat of the Protocol. He is assisted in his/her mission by the Assistant Focal Point. He receives the notifications relating to the meetings of the Protocol as well as the requests for nomination of delegates. In the same way, he/she is invited to comment on issues being debated in the framework of international negotiations. The Focal Point assumes his/her mission in close collaboration with the Competent National Authority.

The National Correspondents of the Cartagena Protocol (NCCP):

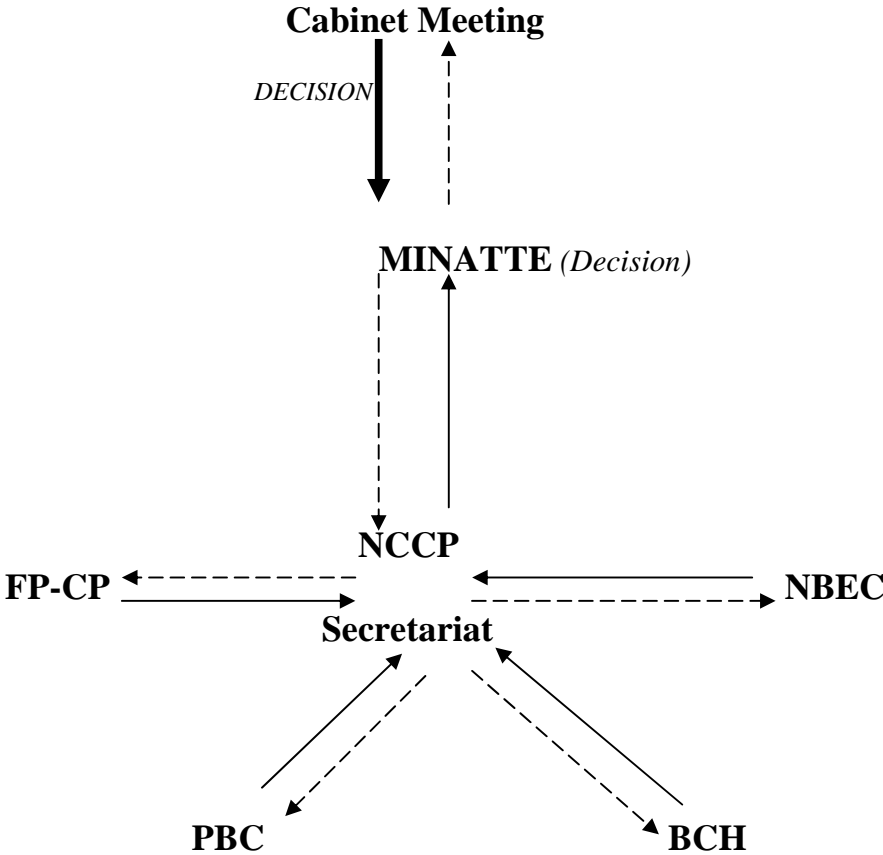
- Advise on the training needs and opportunities of managers, technicians, researchers, of the civil society on Biosafety;
- Gather and disseminate information on GMOs (proven patents, tests, impacts, etc.) in the country and throughout the World and ensure the implementation of public awareness and education programmes relating to Biosafety and the Protocol;
- Collect analyses and observations of the public and draw reports from them;
- Make a regular stock-take of laboratories, staff, GMOs and other products created on the territory or imported;

- Coordinate the activities of drawing up reports (national and specialized reports) and account for the status of Biosafety at the national level;
- Participate in the drawing up of national strategies and action plans for Biosafety;
- Establish partnerships with the international institutions and the developed countries for human resource, technical and institutional capacity building in the area of Biosafety.
- Participate in international meetings and conferences relating to Biosafety.

IV.1.7. National Correspondents of the Biosafety Clearing House (FP/BCH)

He/she establishes the contacts with the Biosafety Clearing House (BCH) set up at the international level in the framework of the implementation the Cartagena Protocol. He/she is responsible for the communication all the required information according to article 20(3) of the Protocol. The nomination of the National Focal Point of the BCH falls under the Ministry in charge of the Environment. The FP/BCH is in charge of:

- Communicating to the international Biosafety clearing house about all the laws, regulations and guidelines in force especially those governing the approval of GMOs and products intended for food and feed; as well as any bilateral, regional or multilateral agreement or arrangement;
- Indicating to the Biosafety clearing house whether the national regulation applies to some determined imports;
- Communicating to the international Biosafety clearing house about the import of GMOs exempted from the advance informed agreement procedure;
- Communicating to the international Biosafety clearing house the name and address of the person entitled to receive the information communicated by other States on the unintentional transboundary movements, according to article 17.
- Informing the Secretariat in the event of non-access to the international Biosafety Clearing House and providing copies of the notifications addressed to the international Biosafety clearing house;
- Communicating to the Biosafety clearing house, a summary of risk assessments and environmental surveys relating to GMOs carried out for the implementation of the regulation in force and according to article 15;
- Announcing the final decisions on the import or the release of GMO as well as the reports submitted according to article 33 of the Protocol;
- Availing to the international Biosafety clearing house the information relating to cases of the illicit transboundary movements;
- Informing the international Biosafety Clearing House of any relevant modification to the previously communicated information;
- Transmitting in writing to the international Biosafety Clearing House the decision communicated to the author of the notification.



- > : Information
- - - - -> : Consultation and advice
- > : Decision

Illustration 1: Structure of the Biosafety institutional framework in Burundi

IV.2. MANAGEMENT SYSTEM OF AUTHORIZATION REQUESTS AND DECISION-MAKING

When requests concerning GMOs arrive in a country, they must follow well specified steps deadlines (table 1 and illustration 2). Clear instructions should also be given on the type of data and information required, for each type of activity.

Burundi has chosen a system that centralizes all authorization requests on the territory. Whatever the type of use of GMOs, the request will be addressed and dealt with at the Ministry of Urban Planning, Tourism and Environment (MINATTE), that constitutes the Competent National Authority.

IV.2.1. Request procedure

- Notification

Given that the notification will be required before an intentional transboundary movement of GMO aimed at in paragraph 1 of article 7 of the Cartagena protocol on the Burundian territory, any person wishing to engage in the import, release, contained use, placing to market of a genetically modified organism or a product of a genetically modified organism should notify it in writing and in French, to the Minister in charge of the Environment. Concerning GMOs intended to be directly used as food or feed or for processing, the notification will be required before the first transboundary movement.

- Acknowledgement of receipt

After the reception of the file and its recording, the Minister in charge of the Environment acknowledges reception of the request, records it and gives it an identification number. Once the request is recorded, an acknowledgement of receipt is sent to the applicant.

- File Verification

The file is then transmitted to the NBCC secretariat that verifies its conformity (verification of the information that must be legally contained in the request, as mentioned in Annex I of the draft law on Biosafety and verification of allowed deadlines for the procedure)

- Public Participation

The NBCC informs all the various partners by issuing a public acknowledgement of receipt. It also launches the public consultation such as described in Chapter VI of this National Biosafety Framework.

As far as public participation and information is concerned, the focal points or national correspondents of the Cartagena Protocol also have an important role to play. They gather and disseminate information on GMOs in the country and ensure the setting up of public education and awareness programmes on Biosafety and the Protocol. They also collect public analyses and observations and draw reports from them.

- Risk assessment

The NBCC then organizes a study of risk assessment reports and provides for the carrying out such assessments. This carrying out is entrusted to the National Biosafety Experts Committee (NBEC). If it required, the NBCC would organize meetings between the applicant and the NBEC. The NBEC can request additional studies to be carried out in approved laboratories locally or abroad. In all these cases, the costs will be charged to the applicant.

- Decision-making

The NBCC receives the recommendations of the NBEC as well as those issues from the public consultation and from the technical ministry or ministries and forwards them to the Minister in charge of the Environment. After reception, the Minister organizes a consultative meeting with the NBCC. The NBCC develops a decision document, which should be discussed in the Cabinet for approval. The final decision will be pronounced by the Cabinet.

- Transmission of decisions

Once the decision on the authorization request is taken by the Cabinet, the Minister in charge of the Environment will take care of transmitting the decision to the applicant to the Focal Point of the Cartagena Protocol and at the disposal of the public through the PBC. This task will be entrusted to the NBCC Secretariat. The BCH Focal Point will be in charge of transmitting the decision to the National Biosafety Clearing-House.

The applicant will be informed of in writing and in French by a refusal or consent letter of his/her request. The Cartagena Protocol requires the importing parties to specify the reasons that justify any decision, except in case of an authorization or of unconditional consent (Article 10.4). In accordance with this article, in case of an authorization, the decision document should list the conditions on the risk management, while in case of refusal; the document should contain explanations on the reasons that have justified the refusal.

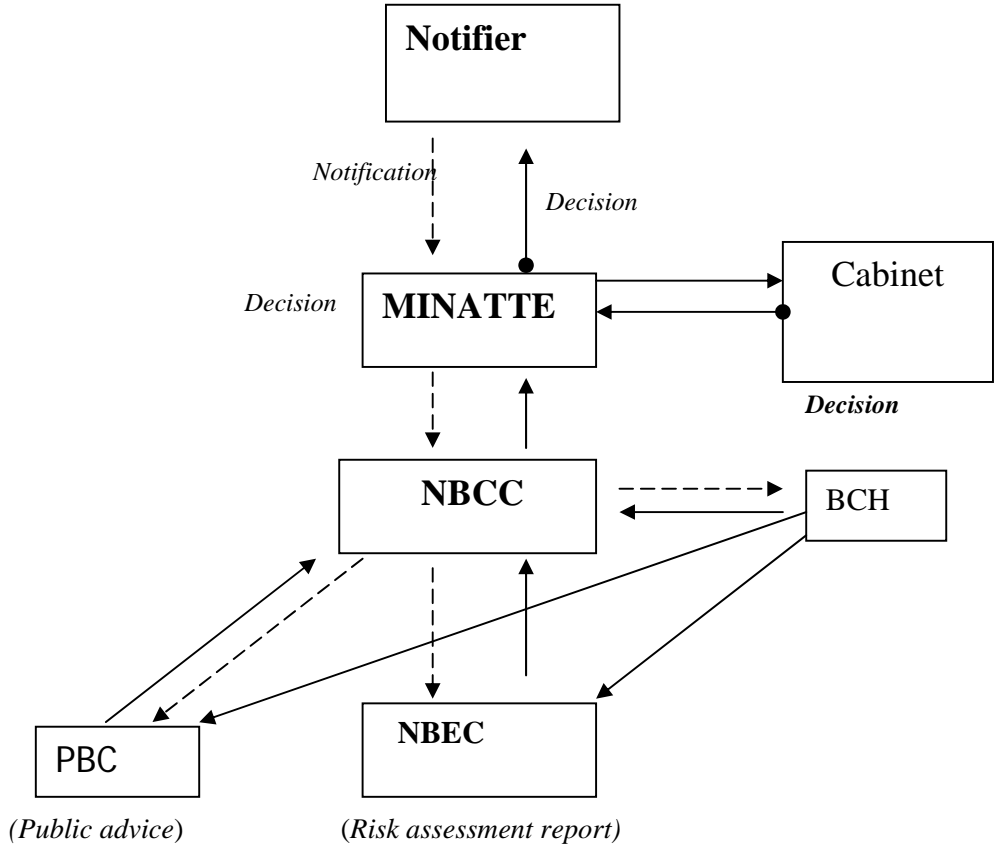
IV.2.2. Decision documents and deadlines

The content of decision documents, the format should be specified. The files of authorization requests are public documents, as well as the risk assessment report. The Cartagena Protocol, in the provisions of articles 9(1), 10(3), 11(1), 11(6), 12(1), 12(3) and 17(1) give specific deadlines for each decision. The proposed deadlines in the draft law are in accordance with those of the protocol and are mentioned in Table 1.

Table 1: Required Deadlines

Task	Deadline
Acknowledgement of receipt	within the ninety days,
Decision making	two hundred seventy days following the reception date of the authorisation
Decision prior for the first import of a Living Modified Organisms intended for direct use as food or feed or for processing	within a predictable deadline not exceeding two hundred seventy days.
To inform, by indicating the reasons of its decision, in case of modification of the decision.	thirty day deadline,

The Party of import replies in writing to this request of the applicant to reconsider the decision	within the ninety days
To notify, any unintentional transboundary movement of a LMO likely to have adverse effects	from the time, the concerned Party is aware of this situation



- ▶ : **Information**
- ▶ : **Consultation and advice**
- ▶ : **Decision**

Illustration 2: Decision-making procedure

CHAPTER V: RISK ASSESSMENT AND MANAGEMENT MECHANISMS

Articles 15, 16 and Annex III incorporate into the Protocol the notions of risk assessment and management. Risk assessment represents an important first step in any effort aiming at reducing or preventing the potential adverse effects to the environment. It allows taking decisions on transboundary movements of LMOs with full knowledge of the facts. Risk management answers to the question of knowing how to manage appropriately and efficiently to any risk identified during the assessment procedure.

V.1. RISK ASSESSMENT

The objective of risk assessment in the Protocol consists of identifying and assessing the potential adverse effects of LMOs for the conservation and sustainable use of biological diversity, also taking into account the risks to human health. Article 15 establishes the basic conditions for risk assessment; it refers to Annex III for more information.

The Protocol authorizes States to subject a GMO, whatever it is, to a risk assessment prior to taking a decision about its import, so as to determine and assess the potential adverse effects of these GMOs on the conservation and sustainable use of the biological diversity in the receiving environment. This assessment will be conducted in scientifically sound manner and taking into account recognized risk assessment techniques. Though the potential importer of a GMO is responsible ensuring that a risk assessment is performed, he/she has the right of requiring the exporter to be in charge of or meet the costs.

The Cartagena Protocol on Biosafety provide for any decision “of unintentional introduction of LMO in the environment” or “use in the country, including the placing on the market, of LMOs that could be subject to transboundary movements intended for direct use as food or feed or for processing” must be based on a risk assessment according to Annex III. The Protocol specifies, in particular, that the importing Party must ensure that the risk assessment is performed for decisions of unintentional introduction of LMOs in the environment and that, for LMOs intended for direct use as food or feed or for processing, it must be submitted to the Biosafety Clearing House by the Party taking the final decision on the LMO.

V.1.1. Basic principles

Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques.

Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10.

V.1.2. Elements of a risk assessment procedure

At a minimum, risk assessment for LMOs subject to the AIA procedure is to be based on information provided in accordance with Article 8 including Annex I, and other available scientific evidence (Art.15.1). Relevant scientific evidence to be taken into account will include scientific data (including statistical data, if available), scientific theories, models, and other sources of scientific knowledge, that assist in the identification of possible adverse effects, and evaluation of the probability of adverse effects occurring, and of their consequences. Evidence that might not be regarded as scientific – for example, indigenous and traditional knowledge and information, as well as anecdotal information – might also be considered where relevant.

The user must proceed to an assessment before the use and the release of genetically modified organisms or products of such organisms, assessment relating to risks to human and animal health, to the biological diversity, to the environment and to the socioeconomic well-being of the societies in question. This assessment should take in consideration the following criteria as well as any other criterion judged relevant:

- Risks on human and animal health

Toxicity, allergenic pathogenicity, resistance to antibiotics, digestibility, nutritional side-effects, unintentional side-effects, persistence in the organism, others....

- Environmental risks

Unintentional release, persistence in soil and in water, effects on the sustainability of agriculture, effects on related species, effects on insects, effects on soil microflora and microfauna, invading effect (resistance to herbicides), biodiversity disturbance and phytosanitary risks. The assessment should however take into account Considerations of the socio-economic, commercial, ethical, cultural and religious nature as well as Considerations linked to the sustainability of the use of the GMO.

V.1.3. Mechanisms

The mechanisms used by Parties for carrying out or evaluating risk assessment may vary from one country to another. In some countries, national authorities perform a risk assessment, on the basis of information provided by the applicant/ notifier. In other countries, the authority responsible for decisions acts as an auditor of the risk assessment provided by the applicant.

In the case of Burundi, NBCC will request for a risk assessment that will be performed by the NBEC on the basis information supplied by the author of the notification in addition to information on the GMO and its history, information contained in the BCH or other databases on Biosafety.

In addition to the information required for the notification, it will be required for the applicant to give information on proposed risk management measures. Risk assessment strategies related to GMOs adopted by international and national systems are very similar. They are predominantly based

on familiarity (i.e. knowledge and experience) with the unmodified donor and recipient and the likely impact due to the changed characteristics of the organism; with the intended application; and with the potential receiving environment.

V.2. RISK MANAGEMENT

The purpose of risk management as provided in Article 16 is to regulate, manage and control risks identified in risk assessments carried out under the Protocol. The provisions 1 to 5 are particularly important concerning the obligations of parties on risk assessment issues, including the issue of cooperation.

The Protocol request every Party to consult and notify the States effectively affected or likely to be, of any incident comes within its remit and likely to lead to an unintentional transboundary movement of a GMO for purpose of illegal trade or release happening under its jurisdiction, once it becomes aware of it. That will allow the Parties to determine the necessary interventions including emergency measures.

The governments must however establish official points of contacts for emergencies so as to improve the international coordination.

The important elements to take into consideration are the following:

- An assessment of potential risks linked to a biotechnological product must be carried out in a scientifically sound manner and recognized by the whole international community.
- An appropriate management of these risks is defined in terms of an appropriate strategy allowing either to reduce to a strict minimum the risk and its consequences or if that is not possible, to give up the biotechnological product.
- An optimal management of risks linked to the GMO character of the material used taking into accounts the biological characteristics of the donor organism, of the type of vector used, of the insert or introduced gene. It must also take into consideration the preferred type of application whether it is about an adaptive research in a laboratory in contained use or about a deliberate release or a commercial release of a biotechnological product already subjected to Biosafety controls.
- The potential receiving environment is also a key element that intervenes in the assessment and management of the biotechnological risk.
- The classification of biotechnological risk levels is important given the fact that the development, the production and the use of GMOs and derived products expose the environment and human and animal health, the socioeconomic fabrics and cultural values to variable levels of risks:

- **risk level I**: the modern biotechnology projects acknowledged as not presenting risks to human and/or animal health, the biological diversity, the socioeconomic fabrics and/or cultural values;
- **risk level II**: the modern biotechnology projects acknowledged as presenting minor risks to human and/or animal health, the biological diversity, the socioeconomic fabrics and/or cultural values;
- **risk level III**: the modern biotechnology projects acknowledged as presenting slight risks to human and/or animal health, the biological diversity, the socioeconomic fabrics and/or cultural values;
- **risk level IV**: the modern biotechnology projects acknowledged as presenting sure or high probability risks to human and/or animal health, the biological diversity, the socioeconomic fabrics and/or cultural values;

For the introduction of genetically modified plants, the risk management measures to apply will especially be the following:

- taking into account the separating distance or “buffer zone” (up to the following plot for the same culture and up to other hybridising partners so as to reduce the transmission of pollen);
- taking into account the borders of non transgenic plants (so as to capture the pollen);
- performing treatments after introduction: inactivation of plants and remaining seeds, specific treatments of soils after harvest (for example, measures of premature germination so as to destroy the eventual regrowths);
- conducting controls after the introduction (destruction of regrowths years after);
- establish total or partial restrictions of planting in specific areas (to prevent horizontal flow, for example);
- Ensure that every GMO is subjected to an appropriate observation period before being used a planned,
 - Ensure this observation period happens in other countries having the same environmental conditions. If the observation period happens in an environmental different from that of the receiving one, another observation period should occur, this time in the receiving environment and to equal to:
 - A generation for organisms with long life cycle (the big trees and animals)
 - A period longer than the life cycle for organisms with a short life cycle (insects, bacteria, plants with short life cycle).
- ensure the set-up and the application of concerted strategies with the countries so as to fight against adverse effects of GMOs.

The NBCC will set up a monitoring committee which will propose a monitoring plan and develop specific monitoring measures. The finalization of a monitoring plan should:

- be made case by case;
- take into account the characteristics of the GMO, the type and the magnitude of the activity as well as conditions present on the release site;
- incorporate specific monitoring measures centred on the adverse effects identified by the risk assessment and a global monitoring aiming at detecting the unforeseen adverse effects;
- be monitored long enough to detect the immediate and delayed effects that have been identified by the risk assessment;
- use proven routine monitoring practices, if possible;
- identified the people (applicant, users) who will carry out the different monitoring tasks and will be responsible for carrying out the monitoring plan;
- ensure that the data are analysed and used to define management strategies of future risks;
- making sure that there is a channel for informing the applicant and the competent authority of the eventually observed adverse effects;
- for appropriate arbitration measures to use in case where significant adverse effects would be detected;
- provide for mechanisms of data analysis data aiming at determining whether they are useful or if, on the contrary, it is necessary to adapt the methodology so as to obtain more useful information.

V.3. GMO CONTROL AND MONITORING

It is important to follow in the short, medium and long term the effect of the introduction of a GMO on the environment, the human and animal health but also to be able to control the execution of the decisions of the competent authority.

Monitoring measures following the release of GMOs in the environment are envisaged and safety measures specified in the Draft law. It is about cases where an assessment of risks established subsequent to the authorization demonstrates the existence of a risk to human and animal health or for the environment.

The Competent National Authority can, at the expenses of the holder of the authorization or GMO owners:

- suspend the authorization while waiting for additional and, if possible, order the of products from the market and ban its use;
- impose modifications to the conditions of deliberate release;
- withdraw the authorization;

- order the destruction of Genetically Modified Organisms and, in case of inadequacies of the authorization holders or owners, to immediately proceed to it.

The search and observation of breaches can be carried out, in collaboration with the Biosafety Competent National Authority, by duly authorised officers. In the framework of provisions of the Biosafety Draft law, the breach searches will be carried out in collaboration with the Biosafety Competent National Authority. The Biosafety inspectors and controllers do not exist, the control and monitoring could be carried out by officers on oath (customs, environment police, police force, phytosanitary inspection, environment inspectors empowered to make arrests and act as policeman, etc.) It would however be interesting to offer them training on movements of GMOs.

V.4. RISK ASSESSMENT AND MANAGEMENT STRUCTURES

V.4.1. Scientists

The NBCC calls upon the NBEC to perform the risk assessment. The scientists will have to respect the confidentiality of the information, contained in the files. The experts used for the risk assessment will be paid. Where necessary, Burundi can call upon a foreign expertise, in particular through the experts' file. The people in charge of the risk assessment must combine competence and integrity at the highest level and fulfil the necessary criteria in order to make public any real or potential conflict of interest. It is also important that these people be independent and free from any potential conflict of interests.

V.4.2. Inspectors

The inspectors will be composed of inspectors of the existing regulatory agencies by giving them training to carry out the biosafety inspections. The regulatory agencies, customs, Burundi bureau of Standards, the ministries of agriculture, health and environment often already have inspectors at their service. Their inspectors already received a legal training which gives them the right to inspect, but should also benefit from further training before being given mission for the inspection of Biosafety activities.

V.4.3. Monitoring committee

The monitoring can be performed by the user of GMOs (or products of GMOs), government services of the ministries involved in the management of GMOs or by other independent institutions such Non Governmental Organizations and associative movements. The monitoring can also be performed by a qualified agency identified by the NBCC.

V.4.4. Laboratories

The risk assessment and management could be performed by an authorized structure held and controlled by the Biosafety Competent National Authority. This structure considered as a reference laboratory will be the only entity entitled to carry out tests and risk assessment; this reference laboratory should be endowed with a consequent budget allowing it to perform in all independence the analyses required for the assessment.

There are research structures at University of Burundi (plant biotechnology laboratory of the Faculty of Sciences and the Faculty of Agricultural Sciences). The two laboratories could be used

initially with the help of some equipment. As far as the Institute of Agronomic Sciences in Burundi (ISABU), it has space for field tests, which could take care of the field experiment and observation. These research structures could be solicited in short term while waiting for the installation of national reference laboratory and thereafter in a specific way.

V.4.5. National warning system of biotechnological catastrophes

This national warning system could be based on the existing structure: the food security warning system. It could also include representative from the ministry of health, WHO, environment inspectors as well as the National Biotechnology Experts Committee as well as the Focal Point of the Biosafety Clearing House.

V.4.6. Running of risk assessment and management structures

The notifier introduces a request, the Competent National Authority sponsors a risk assessment according to article 15.2 (Illustration 3). The file is transmitted to the Secretariat of the National Biosafety Consultative Committee that recruits experts at the level of the National Biosafety Experts Committee and also chooses one or more work laboratories. The NBEC draws up a risk assessment report and transmits it to the NBCC. It also takes inventory of the risks that must be subject to management. The Government in the final analysis receives the assessment report as well as the risks that must be subject to management; it defines mechanisms, measures and strategies to manage these risks according to article 16(1). The implementation of these strategies will be carried out by the responsible actors who are among others agriculturists and GMO distributors. While defining strategies, it would be necessary to take into consideration the opinions of all the stakeholders affected by the introduction in the environment of LMOs.

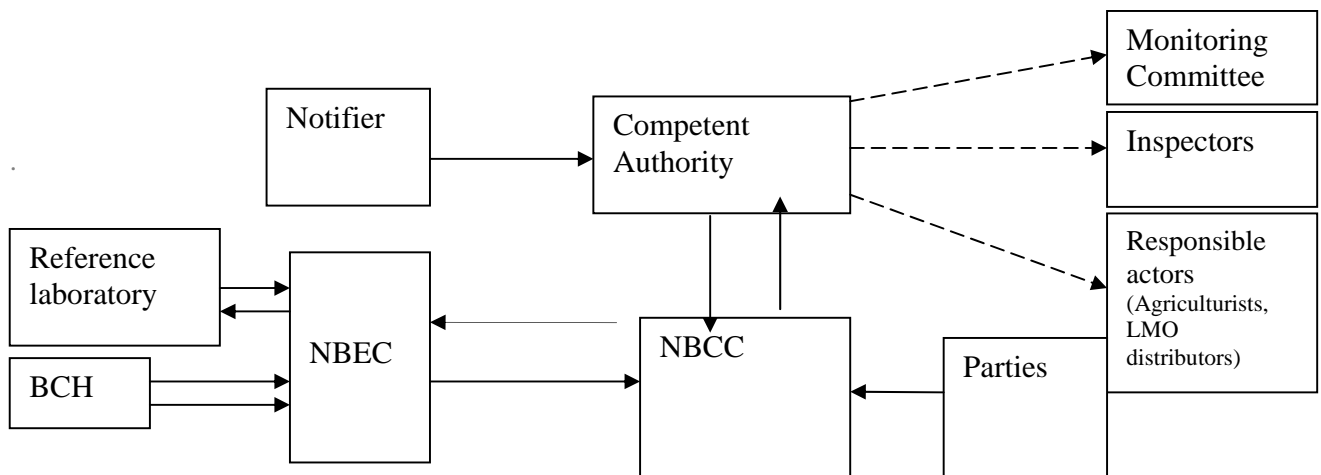


Illustration 3: Running of the risk assessment and management structures

CHAPTER VI: AWARENESS MECHANISM, EDUCATION AND PUBLIC INVOLVEMENT IN THE DECISION PROCESS

VI.1. THE EXITING SITUATION

VI.1.1. Awareness and education relating to the environment

VI.1.1.1. National policy on the environmental awareness and education

Environmental awareness and education constitutes one of the strategies of the Ministry of Urban Planning, Tourism and Environment for safeguarding the environment in Burundi. Thus, the National Strategy for the Environment in Burundi (SNEB) and the National Strategy and Action Plan on Biological Diversity (SNPA-DB) have concluded with the need for building information and communication strategies to reach the general public. Objective 10 of the SNPA-DB is "*Awareness on the importance of the conservation of biological diversity and the sustainable use of the biological resources as well as their taking into account in the education programmes*". This objective thus tends to support awareness at all the levels on the behaviour to adopt towards biodiversity. It also puts forward the education which is the only means of modifying long-term mentalities. Thus, the SNPA-DB gives three following guidelines:

- *To avail to the public data relating to the constituting elements of the biodiversity;*
- *To incite the public and other sectors of production to be involved in the biodiversity protection activities and the sustainable use of the genetic resources;*
- *To support accompanying measures that consists of public sensitization, education and awareness on the texts of laws.*

With an aim of making the SNPA-DB operational, Burundi has just worked out the National Strategy and Action Plan in Capacity Building with regards to Biological Diversity. The document of capacity building policy puts forward the following guidelines:

- Continuous training in human resources with regards to biodiversity and education & awareness techniques.
- Integration of the concepts in connection with the education and extra curricular education.
- Setting-up of a framework of sharing experience in education - awareness.
- Reinforcement of the education & awareness tools.
- Creation of a coordination body
- Involvement of the local communities in the management of biodiversity and in the formulation of the priority themes of education - awareness.

VI.1.1.2. Interventions relating to the environmental awareness and education for the management of biological diversity

Generally, education and awareness actions are carried out by the various sectors. At the Ministry of Urban Planning, Tourism and Environment, many actions are constantly being carried out. These are the broadcasting of radio and televised programmes. The same Ministry annually runs special days dedicated to the environment and trains and supervises environment clubs in schools, awareness meetings are regularly carried out around the protected areas. Seminars, workshops, round tables, symposiums and exhibitions are organized during special days dedicated to the environment. A project of integration of the environmental themes in the programs of primary education and secondary education is in hand. The National Institute for the Environment and the Nature conservation includes a Department having for mission the environmental education at the national level.

Within the Ministry of Communication, the Information, Education and Communication Centre Project on population development (CIEP) comprises in its activities the environment aspect.

Within the Ministry of Agriculture and Animal Husbandry, priority themes of awareness and communication are identified with the population. Messages are prepared and broadcasted by the multimedia centre of the Agricultural Extension Services.

In the sector of the media, the radios broadcast environmental programmes. The newspapers are relatively not very present in the area of public awareness. Some newspapers sporadically publish in their columns environmental articles.

For a decade, Burundi has known a multiplication of NGOs which are concerned with the public awareness and education about the environmental protection. The Press House of Burundi started in September 2002 a series of training of the journalists on the environment. A national NGO "Global Biodiversity Institute Burundi" which is a Burundian Branch of Global Biodiversity Institute has for mission to train, inform and sensitize on Biotechnology, Biodiversity, Biosafety and on intellectual property right with regards to biodiversity and biotechnology.

VI.1.2. Public involvement in the decision-making process

The policy of community involvement in the environmental actions has been recognized by Burundi. The SNPA-DB presents its objective 7 enacted as follows: "*Introduction of an integral policy and a framework for dialogue where the responsibilities of all contributors in the conservation and the sustainable use of biodiversity are clearly defined*". Burundi is thus aware of the urgency of adopting an integral policy of all the actors and of defining the roles of everyone. Moreover, in order to allow the population to access the resources, some facilities must be taken into account for their needs expressed in a participative way.

VI.2. SPECIFIC MEASURES TO BE TAKEN FOR BIOSAFETY

VI.2.1. Public information, awareness and education

The Burundian population is not very informed about risks arising from modern biotechnology. However, discussions held in the framework of the project show an ambivalent situation. The debates on Biosafety would be heated in some government institutions and practically absent in the private sector and at the level of local communities.

The public information, awareness and education must thus be registered among the main activities to be conducted on biotechnological matters so as to allow people to choose with full knowledge of the facts, indicating their preferences during the decision-making process and to take charge of interventions.

VI.2.2. Public participation

The promotion of all stakeholders' participation in the biotechnological risk prevention and management is the primary objective in the Biosafety policy. Burundi must use of the formula of partnership with all the people using of biotechnologies. It must be based on the institutions coordinating biotechnological initiatives, local and international NGO, religious congregations, as well as organisational structures of the local communities.

The participative process of the public must allow decision-making of all the Parties, including the local communities, in the development of policies and their execution.

The information of all actors, decision makers at the local communities, could be done in two stages:

- It is of utmost importance that all the actors are beforehand informed on GMOs and the Biosafety Protocol. The existing tools and strategies (departments of environmental awareness and education, media, etc.) are adapted to carry out this task. Consultative Workshops according to target groups also constitute a strategy to reach the public.
- Information in connection with the instruction of the files of notification must be also disseminated. An organisational system of spreading information as of the reception of a notification or a request for application of modern biotechnology must be set up. It will be a system which will allow the public to have access to information on technical dossier and the results of the risk assessment analysis. And the biotechnological risk management prevention policy must aim at all the Parties to take responsibilities. The formal and informal education system is to be privileged.

Participation t the decision-making must be articulated around two processes:

- Process descending from responsible institutions to the grassroots communities. It is a way of informing the population on the various actions to be carried out with regards to biotechnology.
- Process ascending from grassroots communities to the deciding authority. Through consultations and dialogues, the communities are brought to give their opinion.

This public participation must be based on a regulation which reminds its the mandatory character. Indeed, the public participation constitutes an obligation of the Parties as the Cartagena Protocol stipulates it; moreover, in conformity with its global objective which is "the promotion of modern biotechnology around a participative Biosafety system", Burundi registered "the public involvement in the prevention and the biotechnological risk management in its guidelines" (2nd guideline of 3rd objective.) It would also be necessary to develop a mechanism of evaluating the taking into account of the public opinions in the final decision.

VI.2.2. Public access to the Biosafety Clearing House

The Biosafety Clearing House has been established by the organs of the Protocol to facilitate the effective implementation of provisions of the said international instrument so as to facilitate the exchange of information and help the Party Countries apply the provisions of the Protocol. The Parties to the Biosafety Protocol are invited to facilitate the population access to said clearing house. This mechanism is a precious tool for informing, sensitizing and educating the stakeholders.

CHAPTER VII: ACCOMPANYING MEASURES IN THE IMPLEMENTATION OF THE NATIONAL BIOSAFETY FRAMEWORK

Burundi currently does not have all the human, technical and financial resources required for the implementation of the Protocol, especially as far as risk assessment, risk management of GMOs and the continuous monitoring of LMOs introduced in the environment. Thus, the National Biosafety Framework should include accompanying measures for its effective implementation especially the capacity building and resource mobilization.

VII.1. CAPACITY BUILDING

The capacity building is a crucial strategy for the effective steering of the proposed policy and strategic guidelines. The concerned priority areas are especially the building of human capacities in risk assessment and management and the development of legal (legislative and regulatory) and administrative capacities, the development of institutional (scientific, technical and telecommunication infrastructures) capacities. The capacity building should also allow the active participation of Burundi in the Biosafety Clearing House and the involvement of the public in Biosafety activities.

VII.2. RESOURCE MOBILIZATION

The Modern biotechnologies require much financial means. The main current sources of financing of research in Burundi are poor and are constituted of State subsidies, revenues from activities of these institutions, the project and programme support by development partners. The implementation of efficient research & development programmes are faced with the insufficiency in financial means. The implementation of the National Biosafety Framework will require sizeable funds. These financial resources will be especially used for the elaboration of rules and guidelines and the establishment of recommended structures, the training of human resources and the purchase of equipments. It is essential to mobilize internal resources, but also from the international community for the implementation of an Operational National Biosafety Framework.

- *Internal resources*

The internal resources will come from:

- the ordinary budget;
- the monetary benefits drawn from the exploitation of genetic resources;
- the indemnities and damages in case of damage caused to human, animal health and to the environment.
- the partnership contracts with companies, non governmental organizations and associative movements.

- *International community resources*

- The Global Environment Facility

The Global Environmental Fund (GEF) is a financing mechanism of the Convention on Biological Diversity. It has already materialized this commitment by the financing, the development project of the National Biosafety Framework. It remains to translate the said framework into facts.

- The international intergovernmental organisations

The role of international intergovernmental organizations is important in the measure that these organizations contribute to supplying consultative services to governments so as to formulate policies and national programmes in biotechnology; to implement concerted research projects or joint enterprises between developing countries and industrialized countries, to favour the participation of researchers and technicians from all countries, the enterprises and to build national capacities in research and training. That is how, for many years, UNESCO, FAO and World Health Organization (WHO) programmes tend to develop and enlarge the international cooperation in applied microbiology in their respective areas of competence.

- The regional and international cooperation

The regional and international cooperation is without any doubt one of the means of encouraging the transfer of biotechnologies and the realization of their promises in developing countries. The terms of regional and sub-regional cooperation can be decided on to study the common problems, to conduct concerted research and obtain results applicable in many countries in the same region or sub-region.

This cooperation has also the advantage of making industrialized countries participate in the framework of bilateral agreements, as well as private sector institutions, including the multinational corporations.

Burundi could thus initiate or strengthen the cooperation with the following regional and international networks

- Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA)
- African Agency of Biotechnology (AAB);
- East Africa Regional Programme and Research Network for Biotechnology, Biosafety, and Biotechnology policy development (Bio-earn);

- International Centre for Genetic Engineering and Biotechnology (ICGEB);
- International Scientific Research Institute for Development for Africa (IIRSDA)
- ISNAR Biotechnology Liaison Service (SLB);
- African Agricultural Technology Foundation (AATF);
- Global Biosciences Development Institute (GBDI).
- The International Service for the Acquisition of Agri-Biotech Applications (ISAAA)
- African Biotechnology Association for Food, Feed and Fibbers (AFRICABIO)

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