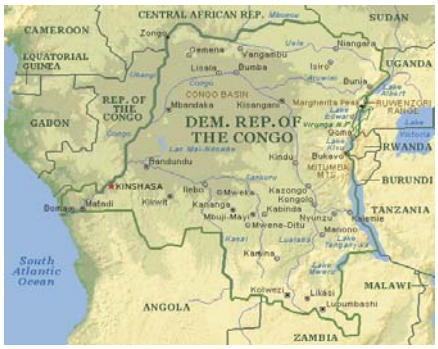

UNEP-GEF Project
"Development of a National Biosafety Framework"

National Biosafety Framework in Democratic Republic of Congo

Final draft

Kinshasa – December 2007

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ACRONYMS AND ABREVIATIONS

DNA : Deoxyribonucleic Acid
TRIPS : Trade-Related Aspects of Intellectual Property Rights
CNA : Competent National Authority
AIA : Advance Informed Agreement
BUNASEM : National Seed Office
CBD : Convention on Biological Diversity
CITES : Convention on International Trade in Endangered Species of Wild Fauna and Flora
COMIFAC : Central African Forest Commission
CRAA : Agri-food Research Centre
CRM : Maize Research Centre;
DRC : Democratic Republic of Congo
PRSP : Poverty Reduction Strategy Paper
EIA : Environmental Impact Assessment
FAO : Food and Agriculture Organisation
GEF : Global Environment Fund
ICCN : Congolese Institute for Nature Conservation**;**
INERA : National Institute for Agronomic Study and Research
INRB : National Biomedical Research Institute
OCC : Congolese Authority of Control
OFIDA : Customs and Excise Authority
GMO : Genetically Modified Organism
WTO : World Trade Organisation
ONDE : National Livestock Authority
NGO : Non Governmental Organisation
LMO : Living Modified Organism
GDP : Gross Domestic Product
PCR : Polymerase Chain Reaction
PMURR : Multisector Emergency Programme for Rehabilitation and Rebuilding
PMPTR : Minimal Partnership Programme for the Transition and the Revival in the DRC
PNAE : National Programme of Environmental Action
TBT : Technical Barriers to Trade Agreement
UNEP : United Nations Environment Programme

FOREWORD

1- Context of the Project implementation

Since the 1970's, biotechnologies have registered an evolution characterised especially by the use of genetic engineering so as to obtain genetically modified organisms (LMOs). During the last ten years of its discovery, modern biotechnology has only occurred mainly in contained use and field. Moving from contained use/limited field trials to open field and especially the release of LMOs in the food chains, has given rise today to a great debate on the safety in modern biotechnology.

The use of modern biotechnology and the low level of control of GMO impact on health and environment justify a cautious approach to the use of genetic engineering referred to as modern biotechnology. That is among others translated by the adoption of national regulations and international legal instruments.

Already, in 1992 the Convention on Biological Diversity (CBD) required according to paragraphs 3 and 4 of article 19, from the Parties the adoption of an international legal instrument dealing with measures to ensure the safety of modern biotechnology.

In fact, despite knowledge and experiences acquired concerning some forms and uses of modern biotechnology, the Parties have found it necessary to adopt an international Protocol on Biosafety. The negotiation and the adoption in January 2000 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity translate the concerns raised about modern biotechnology. The Protocol entered into force on September 11, 2003.

The protocol aimed at above has thus for objective of "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".

DRC is Party to the Convention on Biological Diversity and has adhered to the Cartagena Protocol on February 8, 2005.

In the view of preparing the Countries to the entry into force of the Cartagena Protocol on Biosafety relating to the CBD and to set up National Biosafety Frameworks, the Global Environment Facility has approved the UNEP/GEF Project on the Development of a National Biosafety Framework.

It is in this framework that the DRC benefited from the financing mechanism of the Global Environment Facility (GEF) administered by the United Nations Environment Programme (UNEP) for the setting up of its National Biosafety Framework so as to progressively create the preventive measures to manage the potential risks associated with the use of modern biotechnology. *By definition the National Biosafety Framework is a set of institutional arrangements, legal and regulatory provisions, including technical guidelines and laboratory activities that help in the prevention of biotechnological risks*. The project of

developing a national biosafety framework started in March 2005. The phase had been dedicated to the carrying out surveys and development of national inventories on the policies, programmes and legislations likely to have an impact on the use of modern biotechnology in the DRC. *The inventories were carried out at two levels: (i) the national survey aiming at gathering data on the national activities, infrastructure, capacities concerning biosafety and biotechnology; (ii) surveys to identify the national actors in area of biosafety and biotechnology; (iii) the surveys were also guided towards determining the actual national policies programmes and legislations likely to have an impact on the use of biotechnology and on the sustainable management of modern biotechnology products in the DRC.*

2- Issues relating to the development of the UNEP-GEF Project of the National Biosafety Framework

LMOs constitute an important issue. Also, we very often observe a certain reluctance of the political class on this question. Although it is not very well known by the public in the DRC, the modern biotechnology is used elsewhere in the World in different sectors such as food processing, energy, chemical industry, the environment, agricultural sector, medical sector and pharmaceutical sector. The most common applications are the following:

- *Food processing:* to improve the production, the nutritional and visual quality, the taste, the composition, the toxicity exemption…..
- *Chemical Industry:* making of oils derived from colza, linen, sunflower, Soya, specific chemical products (cosmetic, dye) …
- *Medical and pharmaceutical industry:* making of vaccines, antibiotics, insulin, vitamins, proteins of medical interest, genetic therapy, etc.
- Environment: to reduce pollution
- *Agriculture:* to improve agricultural farming and practices, animal health and nutrition, productivity and fertility…

For the DRC, some agricultural issues could be mentioned:

- ✓ Improvement of agricultural performances (production rates, increase in yield, access to varied genetics resources)
- ✓ Change in farming practices (reduce resorting to slash-and-burn cultivation)
- ✓ Production of modified plants (species resistant or tolerant to diseases/insects leading to reduction in insecticide use, reduction in use of irrigated water (drought resistant plants)
- ✓ Reduction of post-harvest losses or treatment of viral diseases in modern medicine.

However, the transfer of a gene of an organism to another is not without risk for the environment and for human health. This activity can have unpredictable and irreversible consequences. The following table shows the different types of potential risks likely to result in the use of LMOs.

Risk type	Consequences
Health	- Risk of allergy; - Risk of transfer of resistance to antibiotics.
Environmental	- Genetic pollution; - Modification of ecological balances by a pressure of an abnormally important selection; - Creation of invasive alien species.
Geopolitical	- Growth of North-South inequalities, the countries of the south becoming slowly by slowly excluded from the global economic development.
Socioeconomic & cultural	- Some big groups becoming exclusive suppliers of the planet.
Ethical	- Dependence on the agriculture in the south towards the transgenic varieties of the north.

So that the GMO is used advisedly, without risk and in an appropriate manner for a secured sustainable development, there should be a biosafety structure capable of assessing and managing the risks. This National Biosafety Framework will allow the development of guidelines for a biosafety programme for the DRC.

3- Objectives of the UNEP-GEF Project of the National Biosafety Framework

The UNEP/GEF Project on the "Development of National Biosafety Framework" aims at helping more than a hundred developing countries, including the DRC, to set up their own national structure for the management of living modified organisms, so that they meet the requirements of the Cartagena Protocol on Biosafety.

To meet these obligations, the project has targeted a certain number of priority actions, especially:

- The national capacity building in order to develop a national biosafety framework (structure, law, rules, standards) ;
- The national capacity building for efficient decision making concerning the notifications and the requests relating to Living Modified Organisms, including the set up of an institutional framework;
- The application of other initiated or adopted measures and meeting the requirements of the implementation of the Cartagena Protocol on Biosafety taking into account the works and recommendations of the Intergovernmental Committee for the Cartagena Protocol ;
- The promotion of regional and sub-regional cooperation including the harmonization of national legislations and regulations ;
- Public awareness on questions relating to handling of living modified organisms, so as to promote rich debates and to ensure the transparency while respecting the legislation and the regulation on the Living Modified Organisms ;
- The participation of decision centres to the conception and the implementation of National Biosafety Framework.

4- Purpose of the "National Biosafety Framework" document

The development of the "National Biosafety Framework" document aims at defining guidelines for:

- A National Biosafety Policy;
- A Legal Framework (legislative and regulatory) ;
- An Administrative System ;
- A Risk assessment and Management System ;
- Public Participation and Information-sharing Mechanisms.

5- Methodology

Under the direction of the National Coordination Committee for the Development of a National Biosafety Framework placed under the trusteeship of the Ministry of the Environment, Nature Conservation, Waters and Forests, the development process of a National Biosafety Framework has taken the following steps:

- The set up of a National Coordination Committee;
- The recruitment of consultants in charge of conducting the basic surveys and studies (inventories) ;
- The identification of all stakeholders: administration in charge of Agriculture, the Environment, Health, Trade, Scientific and Technological Research, as well as private and public organizations dealing in the concerned sector (such as Congolese Control Authority, the University of Lubumbashi, the National Institute for Agronomic Studies and Research, the Maize Research Centre, the National Institute of Biomedical Research, the Agri-Food Research Centre, the civil society, the universities and research centres, the media, etc.)
- The analysis of basic survey reports by the National Coordinating Committee;
- The organization of awareness activities with stakeholders ;
- The development of a summary document of basic survey and study reports carried out by the consultants ;
- The analysis of the summary basic study reports carried out by the Project Coordinating Committee and then by the stakeholders ;
- The production of the first version of the document "National biosafety Framework in the DRC"

The process was further pursued with submission of this document to national and international second expert opinion before its final review and its validation respectively by the Project Steering Committee and by the participants during a national stakeholder workshop. The process should end with the development and the adoption of a draft Law on Biosafety in the Democratic Republic of Congo.

6- Difficulties encountered

Among the main difficulties encountered in the completion of this first version of the "National Biosafety framework in the DRC" document especially depict:

- The absence of awareness activities on the use modern biotechnology and LMOs ;

- The lack of convergence of stakeholders on the use of modern biotechnology and LMOs ;
- The absence of documents/literature and policies on the use of biotechnologies in general and modern biotechnology and the absence of national debates on the risks relating to it,
- the absence of specific studies dedicated to the use of biotechnologies, etc.

7- Some Advantages

To facilitate the production of document, the Project Coordination has been able to benefit from some of the following:

- The commitment of the Government to the ratification process of the Cartagena Protocol on Biosafety;
- the financial and technical support of UNEP/GEF;
- the availability of stakeholders;
- the willingness of the Ministry in charge of the Environment to facilitate the steering of the implementation process of the National Biosafety Framework in the DRC ;
- the existence of a team of resolutely committed consultants.

SUMMARY

The Democratic Republic of Congo is Party to the Convention on the Biological Diversity and ratified , on February 8 2005, to the Cartagena Protocol on Biosafety.

It is in this framework that the DRC benefits from a financing from the Global Environment Fund (GEF) administered by the United Nations Environment Programme (UNEP) for the set up its National Biosafety Framework so as to progressively create regulatory conditions for biosafety. This project started in March 2005 with the carrying out of the first phase dedicated to the surveys of inventories on the policies, programmes and legislation likely to have an impact on the use of modern biotechnology in the DRC. The main objective of this project is to help the DRC to put in place its own national structure for the management of living modified organisms, so as it meets the requirements of the Cartagena Protocol on Biosafety.

GENERAL INTRODUCTION

1. General remarks on the physical and socioeconomic characteristics of the Democratic Republic of Congo

The DRC is located on both sides of Equator on a surface of approximately 2.345.000 km². The climate of the DRC is of tropical type, characterized by annual precipitations going from 810 mm at the coasts up to more than 2000 mm in the central basin. The DRC has a relief made up of a central Basin surrounded of plates and mountains and of a dense hydrographic network (lakes, river, coastal reach and Atlantic coast).

The variety of its climate translates in a great diversity on the level of the flora and fauna. The DRC is one of the first ten countries in the World concerning the importance of its biological diversity. The DRC has many listed species: nearly 480 species of mammals, 1,117 species of birds, 1,069 fish species, 350 species of reptiles, 20 species of chameleons, 15 species of terrestrial and fresh-water tortoises, 105 water mollusc species, 167 species of chironomidae and more than 10,000 species of angiosperms of which approximately 3,000 would be endemic. A relative protection of biological diversity is ensured in the context of the protected areas (approximately 9.7 % of area of the territory). The forest resources of the DRC are estimated at approximately 135.207 million hectares on the 235 million hectares of the national territory.

The land above the sea level of the DRC represent 226.705 million hectares, i.e. 97% of the national territory. They are grouped in six main types of lands: andosols (0.5% of the whole of the soils), vertisols (1%), hydromorphic soils (5%), nitosols (ferrisols) (14%), feral soils (53.5%) and arenoferrals (26%). The truly fertile soils (andosols) are of restricted surface. Nevertheless, 80 million hectares are considered to be relatively suited for agriculture of which only 10 million is devoted to cultures and pastures.

The population of the DRC was estimated at 58 million inhabitants in 2003 including nearly 70% in rural area. The population is projected to 92.20 million inhabitants in 2020. Between 2000 and 2005, the annual variation rate of the population was 2.8 % per annum. The density, estimated at 22 inhabitants per km² in 2000 is projected to 39 inhabitants per km² by 2020.

Like some other African countries, the DRC does not escape from the phenomenon of poverty. The agricultural sector occupies a dominating place in the Congolese economy. Agriculture rests primarily on:

- food production including especially cereals, roots, tubers, oilseeds, vegetables and leguminous plants;
- modern farm estate related to revenue or export cultures, with as main products coffee, cotton, tea, rubber, palm oils, cocoa, hevea, quinquina, onion, sugar cane, fruits and vegetables;
- the breeding of cattle, sheep, pigs, goats and poultry;
- forest productions, etc.

The contribution of agriculture to the GDP is on average 38.33% and this sector ranked second after the mining sector. In 2003, the value added of the branch "Agriculture, Sylviculture, Animal Husbandry, Fishery and Hunting" which increased by 1.2% in 2003 is

estimated at 0.6% in 2004. Brought back to their levels of 2003, the activity indices of the food production and the agricultural production for export have stagnated in 2004, settling respectively at 103.6 points and 60.5 items compared to 103.8 and 60.8 points one year earlier. Despite of this increase, the DRC never reached food self-sufficiency and the Congolese State is obliged to resort so far to importing foodstuffs to make up the deficit.

Agriculture rests on the following main food crops: cereals (maize, rice paddy, millet and sorghum, wheat and barley), roots and tubers (cassava tubers, sweet potato, taro, potato, onion, garlics, yam), vegetables and leguminous plants (beans, vandzou, cassava leaves, chilli and peppers, cabbage, other vegetables), oilseeds (groundnuts, soya, palm nut, other oilseeds), fruits (soft bananas, plantains, other fruits) etc.

In the DRC, the main imported foodstuffs are especially: maize, rice, salted and smoked fish, meat and offal, wheat. Some of these foodstuffs of import are likely to contain GMO. It is the case in especially for maize, rice, meat and offal, wheat and wheat flour, salad oil, fruits and juices, etc.

It is important to emphasize that many economic operators are completely unaware of whether the imported products contain or not GMOs/LMOs. They are also unaware of the existence of the Cartagena Protocol on Biosafety.

Lastly, the analysis of sector policies relating to the environment, agriculture, livestock, industry, scientific research, health and food shows that the latter do not lay down any guideline with regards to the use of the GMO and derived products nor the prevention of biotechnological risks.

1.1. General context and use of biotechnologies

The aim pursued by modern biotechnology in the area of plant kingdom, among others, is no doubt the production of more performing varieties. In total, the production process of LMOs includes several stages in the field of agri-food whether they are genetic engineering processes carried out on the plants, the animals and yeasts. The agri-food sector remains in all the cases more concerned than that of the seeds and that of agrochemicals.

1.2. Use of biotechnologies in the DRC

No doubt, the use of LMOs presents advantages in some sectors like agriculture, livestock and agri-food industry:

- In the agriculture and livestock sector, it contributes to the increase in the animal resistance to some diseases and to the improvement of the nutritional quality of the plants used in the animal feeds;
- In the area of agri-food industry, it contributes to the improvement of food conservation;
- In the area of human health, we noted for example the production of insulin, the vaccines, etc

However, the use of LMOs can also have negative impacts in other sectors like human health (risks of toxicity and allergenicity), the environment and biodiversity (risks of the release of transgenic genes by the wind or insects, risks of impoverishment of the biodiversity, risks of advent and proliferation of mutants resistant to pesticides, etc).

In the DRC, the use of biotechnologies limits itself to traditional biotechnologies in the following three areas:

- production of beers and soft drinks with mainly imported raw materials;
- the transformation and the conditioning of the dairy products whose production rests mainly on imported raw materials;
- the traditional production of fermented food (traditional cheese and other products), of local drinks (yoghourt, curdled milk, palm wine, etc).

1.3. Status of biosafety management in the DRC

The DRC has neither a framework law on environmental protection nor a specific legal framework on biosafety meeting the requirements of the Cartagena Protocol.

In addition to the Principles of the Agenda 21, whose chapter 16 deals, among others, in the establishment of mechanisms for the development of biotechnologies and the their application in the respect of the environment, the DRC adheres to certain multilateral agreements on the environment concerning biosafety. It is the case of the CBD whose article 19 lays the principle of adopting a protocol on the mechanisms enabling to ensure the safety in biotechnology.

However, the DRC has legal and regulatory texts on phytosanitary protection, animal health (especially the pushing back and the setting in quarantine) and the protection of the patent and intellectual rights. There is not however provisions which take into account the requirements of implementing of the Cartagena Protocol.

However, there exists in the DRC ministries and organizations whose responsibilities are likely to relate to the area of biosafety. They are especially the Ministries in charge respectively of agriculture, livestock, the environment, health, external trade, industry, scientific research, etc. There is however no national structure specialized in ensuring the coordination of activities regarding biosafety.

The DRC also has some various competences and expertise in the area of research and biotechnologies and whose areas of specialization concern in particular: biology, biotechnology, botany, biochemistry, chemistry, ecology, entomology, forestry, genetics, environmental management, microbiology, nutrition, parasitology, pedology, phytopathology, plant production, plant protection, sylviculture, environmental sciences, zoology, animal husbandry, etc. A human capacity building programme will have to be set up under accompanying measures of the implementation of the National Biosafety Framework in the DRC.

Lastly, the research, risk assessment and management infrastructure available to the institutes and research centres do not meet the requirements for the management of biotechnological risk.

2. Components of the National Biosafety Framework

The National Biosafety Framework gathers a certain number of guidelines in relation to its various components.

2.1 National biosafety policy

The national biosafety policy will have to be based on guiding principles of environment management, especially the precautionary principle and the preventive principle, in conformity with the provisions of the Cartagena Protocol. This policy takes into account of the concern of assessing the advantages and disadvantages related to the use of LMOs and products thereof.

The National Biosafety Framework aims at developing a system for the safe management of modern biotechnology based on the advanced informed agreement procedure

If the national biosafety framework intends to organize the resorting to modern biotechnology as a tool for promoting development, the use of biotechnology will have to be subordinated to the requirement of advance informed agreement.

In any event, the purpose of the National Biosafety Policy is no doubt to ensure the protection of socio-economic fabric and natural resource, environment, public health by the application of the precautionary principle in the use of modern biotechnology. From this point of view and taking into account of the above mentioned guidelines, the development, the production and the marketing of LMOs and their derived products must be done in the respect of the national legislative and regulatory provisions on the matter.

2.2. Guidelines for the legal framework of biosafety management

The legal framework of biosafety management in order to ensure the implementation of the Cartagena Protocol in the DRC aims principally at preserving human health, the environment and the socio-economic fabrics vis-à-vis with the potential risks related to the use of modern biotechnology.

To meet the requirements of the implementation of this Protocol, the biosafety law in the DRC will have to approach the following important aspects: the scope, the intentional and unintentional movements, the institution of advance informed agreement, the information-sharing mechanisms, the protection of confidential information, risk assessment and management mechanisms, measures for prevention and repression of offences, liability and redress regimes as well as the mechanisms of the public participation to decision process.

Globally, the scope will have to cover all forms of use of LMOs and products thereof, with particular reference to the production, release, putting into circulation, import, handling, storage, transport and elimination. In particular, this legislation will have to be applicable to the import, export, the transit, the contained use, the release or the placing on market of any genetically modified organism that it is intended to be released in the environment or to be used like pharmaceutical product, food, feed or for processing, should be a product derived from genetically modified organism.

2.3. Guidelines for the institutional framework of biosafety management

Institutional arrangements of the National Biosafety Framework in the DRC will be articulated around the following organs: the Biosafety Focal Point, the National Biosafety Consultative Council, Competent National Authority, the Technical and Scientific Committee,

the National Biosafety Clearing House. These roles of the organs are elaborated further in section 3.4 of this document dealing with the guidelines of the Institutional and Administrative Framework in the DRC

2.4. Guidelines for the biotechnological risk assessment and management mechanisms in the DRC

Risk assessment is based at least on the information provided in accordance with article 8 of the Cartagena Protocol and on other scientific evidence available making it possible to determine and evaluate the potential negative effects of the living modified organisms on the conservation and the sustainable use of biological diversity, also taking into account the risks to human health. To make operational the legal framework of biosafety, it is essential to confer on the Competent National Authority the power to develop technical guidelines relating to biotechnological risk assessment and management. The process of defining of these mechanisms will have to take into account not only the analysis made on the situation as regards modern biotechnologies and biosafety in the DRC but also the UNEP technical guidelines, the provisions of the Cartagena Protocol on Biosafety and the guidelines of other countries having good experience in this area and this, without damaging the commitments superscribed by the DRC, especially within the framework of the Southern Africa Development Community (SADC).

2.5. Guidelines for the public awareness and participation system

The public awareness and the participation on the biotechnological risks constitute one of the requirements of the Cartagena Protocol because a sufficiently sensitized and informed public on the biotechnological risks would be more prepared to involve itself in the process of biosafety management.

To achieve the goals of the Protocol and the National Biosafety Framework, the following activities must be carried out:

- Public awareness through all the appropriate communication means and channels, on the impacts of LMOs;
- Public education for a better knowledge at the plans scientific, economic and legal levels of LMOs;
- Facilitation of the public to access information on LMOs;
- Public participation in the decision processes relating to LMOs.

The public participation will be organized through the National Biosafety Consultative Committee of and other consultative organs representing of the target groups, especially NGOs, the civil society, the private sector, consumer associations, grassroots organizations.

3. Accompanying Measures

3.1. Human, institutional and technical capacity building

The DRC has several institutions and human resources which are potentially qualified in biotechnology and biosafety. The results of the inventories carried out showed that

structures are in place to allow the start of the analyses of LMOs with the provision of additional equipment and training/re-training of personnel in the identified institutions.

The concerned ministerial departments are:

- the Ministry in charge of the Trade which has under its supervision the Congolese Control Authority (of which the mission will be described later on), for the capacity building of its quality control laboratory of imported products and standards;
- the Ministry in charge of the Public health which is equipped with a Department in charge of the Quality control of the foodstuffs and pharmaceutical products. This ministry should build its laboratories of physicochemical analysis of foodstuffs, of detection of pathogenic organisms, and of toxicology especially at the INRB;
- the Ministry in charge of Agriculture and Livestock in order to especially support the National Seed Service (building of its capacities of design and quality control of the national seed production, the set-up of a molecular biology laboratory and the acquisition of the basic genetic material), the Maize Research Centre (set-up of a molecular biology laboratory and the acquisition of the basic genetic material), the of Animal and Plant Quarantine Service in order to build its capacities of zoosanitary and phytosanitary monitoring as well as the management of animal and plant quarantine on the whole of the national territory) and the Department of Plant Production and Protection having many regional offices through the various provinces of the country and the Department of Animal Production and Health;
- the Ministries respectively in charge of National Education and Scientific and technological Research: for the acquisition and the rehabilitation of various laboratories of university institutions and national research centres: CRSN-Lwiro, INERA, the CREN-K, CRAA-Lubumbashi, etc;
- the Ministry in charge of the Environment and related provincial institutions,
- the Ministry for Industry: which has as its responsibilities the management of patents and other intellectual property rights

In all these institutions, there is an obvious and permanent need for rehabilitation and capacity building of laboratories to make them ready to face the challenges of managing of LMOs. The State is invited to play a prominent role in the success in the biosafety programme especially in the appropriate remuneration of the researchers and the active and sustained investment in educational systems and regarding scientific research.

All in all, within the framework of the implementation of structures of the institutional Framework defined by the National Biosafety Framework, it is urgent to set up a capacity building programme. The areas of capacity building are specific to each structure targeted within the organic framework of the institutional framework defined by the National Biosafety Framework in the DRC through especially seminars, workshops or specialized training or advanced training courses. These institutional structures or arrangements are:

- the Biosafety National Focal Point
- the National Biosafety Consultative Committee ;
- the Competent National Authority;
- the Scientific and Technical Biosafety Committee ;
- the National Biosafety Clearing House.

Concerning seminars and workshops, the training will relate especially to the control of the relevant provisions of the Cartagena Protocol and the legal and institutional framework for

national biosafety management, the mastery of the risk assessment and management procedures, the mastery of the techniques of evaluation of study reports on biotechnological risks, the inspection and control techniques of the products likely to contain LMOs, the detection methods of LMOs of using PCR, the financing mechanisms of donors, the control and monitoring of releases of LMOs, the evaluation of the research programmes on modern biotechnology, the development of bilateral and multilateral co-operation programs, the techniques of use of data of the Clearing House of the Protocol secretariat and national Clearing House, etc.

The trainings of long duration will be provided to certain specialists in the areas such as genetics, toxicology, related sciences, biosafety and biotics, inspections, etc.

The training itself only is not enough to ensure the implementation of National Biosafety Framework in the DRC. Equipment in infrastructures and office and communication materials must be provided to the institutions involved in the running of this framework. Moreover, quality control laboratories and research centres or organizations regarding LMOs will have to be equipped with the essential equipment like the laboratories of biotechnologies and the laboratories of DNA recombining techniques.

3.2. Terms and means of implementation the National Biosafety Framework

The implementation of the National Biosafety Framework requires that the whole of the expected activities are placed under the responsibility for a national coordinating team, placed under the supervision of the Department of Sustainable Development of the Ministry in charge of the Environment.

This team will be followed up by the National Coordinating Committee especially in charge of ensuring the good conduct of the implementation phase of the National Biosafety Framework.

The set up of a national biosafety framework in the DRC also depends on the level and the capacity of mobilizing the financial resources necessary for the legal, institutional, human and technical capacity building. Three approaches of mobilizing the resources are conceivable: internal resources, resorting to the financing mechanisms provided for by the Cartagena Protocol Convention on Biological Diversity and resorting to the traditional partnership. Currently, the resources of the State Budget are insignificant in comparison with smallness of the credits allocated to the Ministries which can intervene, from their responsibilities, in the favourite sectors of modern biotechnology.

I - GENERAL ENVIRONMENTAL POLICY CONCERNING BIOTECHNOLOGIES

I.1. Biophysical data

I.1.1. Geomorphologic, climatic and pedological data

The relief is characterized by a vast basin of 750,000 m² surrounded by plateaus and mountains. Altitude goes from the sea level to the South West of the country at 5.119 meters to the East (Mount Ruwenzori). The basin is bordered to the South by the plateaus of KWANGO and KASAI, prolonged by the high plateaus of Katanga, with the limit of the splitting of the waters of the Basin of Congo and that of Zambezi. The Eastern limit of the country is marked by the immense fracture of the African Rift occupied by a series of lakes and surrounded by mountainous masses, locally volcanic.

The climate is of tropical type, characterized by annual precipitations going from 810 mm at the coasts to up to 2000 mm in the central basin. The annual average temperatures oscillate between 24 and 25° C and can go down up to 18 or 20° C in high altitudes. The relative humidity varies between 70% and 85%. The variety of its climate results in a great diversity on the level of the flora and fauna which makes the DRC one of the ten countries with high biological diversity.

The lands above the water levels of the DRC represent 226.705 million hectares, i.e. 97% of the national territory. They are grouped in six main types of lands: andosols (0.5% of the whole of the soils), vertisols (1%), hydromorphic soils (5%), nitosols (ferrisols) (14%), feral soils (53.5%) and arenoferrals (26%). The truly fertile soils (andosols) are of restricted area. Nevertheless, 80 million hectares are considered to be relatively suited for agriculture of which only 10 million is devoted to cultures and pastures.

The DRC has a relief constituted of a central basin surrounded by plateaus and mountains and a dense hydrographic network (lakes, river, sea reach and Atlantic coast).

The forest resources of the DRC are estimated at approximately 135.207 million hectares out of the 235 million hectares of the national territory.

The DRC is one of the first ten countries qualified of mega-diversity. The DRC has many listed species: nearly 480 species of mammals, 1,117 species of birds, 1,069 fish species, 350 species of reptiles, 20 species of chameleons, 15 species of terrestrial and fresh-water tortoises, 105 water mollusc species, 167 species of chironomidae and more than 10,000 species of angiosperms of which approximately 3,000 would be endemic. A relative protection of biological diversity is ensured in the context of the protected areas (approximately 9.7 % of area of the territory). The forest resources of the DRC are estimated at approximately 135.207 million hectares on the 235 million hectares of the national territory.

I.1.2. Freshwater, marine and coastal ecosystems

DRC has a very dense hydrographic network. The water plans represented by the vast river network, the flooded plains and the lakes cover approximately 86,080 km² (3.5% of the area of the country). These can be subdivided in three types of natural ecosystems:

- Lake ecosystems, represented by the lakes of the East, those of the central Basin and some depression lakes;
- River ecosystems, including the Congo River, its main and secondary tributaries;
- Marine ecosystems represented by the sea reach of the South West and the Atlantic coast.

The great lakes peripheral of the East cover an area of approximately 48,000 km² of which 47% are of Congolese jurisdiction. The respective areas for Congo are: Lake Tanganyika (14,800 km²), Lake Albert (2,420 km²), Lake Kivu (1,700 km²), Lake Edward (1,630 km²) and Lake Moero (1,900 km²).

The Congolese lake system includes moreover two important interior lakes, Lake Tumba and Lake May Ndombe. They cover together between 2,300 and 7000 km² depending on the seasons (weak in dry and strong season in rainy season). One also includes the depression lakes of Kamalondo (1,700 km²), Lake Tshangalele (446 km²), Lake Nzilo (280 m), Lake Upemba, Lake Kisale, Lake Mukamba, etc. The river system covers approximately 34,000 km² on a network of more than 33,000 km² constituted by the River, its main tributaries and secondary rivers.

The DRC has also approximately 40 km of sea frontage covering an area of more or less 2,000 km² of water plan. The national fisheries potential is estimated at some 707,000 tons maximum of which approximately 63% would be in the waters of great lakes of the East (Tanganyika, Edward and Kivu), 28% in the river system, 8% in the depression lakes and those of reserve lakes of Katanga and only 1% in the sea water of the Atlantic coast.

I.2. Outline on the socioeconomic data

I.2.1. Evolution of the population

The population of the DRC was estimated at 58 million inhabitants in 2003 of which about 70% in the rural area. The population is projected to 92.20 million inhabitants in 2020. Between 2000 and 2005, the annual population variation rate is around 2.8 % per annum. The density, estimated at 22 inhabitants per km2 in 2000 is projected to 39 inhabitants per km2 in 2020.

I.2.2. Economic and social context

The DRC registered bad results since 1990 (with the suspension of the international co-operation), which were exacerbated between 1997 and 2003 by armed conflicts. The efforts of the Government led especially to the balancing in 2002 of the arrears of external debt of the DRC vis-a-avis the international financial institutions and bilateral creditors but also the obtaining in

July 2003 of a reduction of its debt in the name of the HIPC Initiative whose extension was obtained until July 31, 2006.

The Government Economic Program (PEG) which covered initially the period from April 2002 to June 2005 was supported by the Poverty Reduction and Growth Facility (PRGF) of the IMF, the Credit for Economic Revival and the support credit to the Multisector Emergency Programme for Rehabilitation and Rebuilding (PMURR) of the World Bank as well as resources from other donors such as ADB, European Union and UNDP. The PEG has as main objectives to consolidate macroeconomic stability and to revive growth so as to reduce poverty. Moreover, the Government has just developed the second version of the Poverty Reduction Strategy Paper (PRSP). Important reforms were undertaken in the economic sector, especially in the financial and natural resource management sectors.

The Competitiveness and Private Sector Development Project, set up in 2002, pursues as objective the introduction of a business climate likely to promote the growth of the competitive companies, able to create new jobs. This project in particular allowed the promulgation of the investment Code, the forest Code, the mining Code, the Labour Law and the laws on posts and telecommunications and the Post and Telecommunications Regulatory Authority, the signature of the mining Regulation, the creation of the National Agency for the Promotion of Investments (ANAPI), the adhesion of the DRC at the Africa Trade Insurance Agency (ATIA), the set up in 2003 of a national arbitration Centre, the commitment of the DRC to adhere to the OHADA Treaty and organization of the seminars on the OHADA Law, etc. In the *area of natural resource management*, the reforms undertaken by the Government aim especially at ensuring that these resources contribute to the economic revival, the rural development and the fight against poverty, while preserving on the long term the integrity of ecosystems and the environmental protection. With regards to the mining sector, it is important to note that the reforms have led to the promulgation of the Mining Code, the signature of the Mining Regulation and the set up of the Mining Land Register, etc.

Concerning the sectors likely to use modern biotechnologies, it is necessary especially to mention agriculture, livestock, processing industry and health.

The agricultural sector occupies a predominant place in the Congolese economy these last years. Agriculture rests mainly on:

- food production including especially cereals, roots, tubers, oil plants, vegetables and leguminous plants,
- modern farm estate concerning revenue or export cultures, with as main products especially coffee, cotton, tea, rubber, palm oils, cocoa, hevea, quinquina, onion, sugar cane, fruits and vegetables;
- the breeding of cattle, sheep, pigs, goats and poultry;
- forest productions, etc.

The contribution of agriculture to the GDP is on average 38.33% and this sector ranked second after the mining sector. In 2003, the value added of the branch "Agriculture, Sylviculture, Animal Husbandry, Fishery and Hunting" which increased by 1.2% in 2003 is estimated at 0.6% in 2004. Brought back to their levels of 2003, the activity indices of the food production and the agricultural production for export have stagnated in 2004, settling respectively at 103.6 points and 60.5 items compared to 103.8 and 60.8 points one year earlier.

Despite of this increase, the DRC never reached food self-sufficiency and the Congolese State is obliged to resort so far to importing foodstuffs to make up the deficit.

The food production represents most of the agricultural production. It is the work of small farmers. It is practiced on forest lands considered as fertile. It is of the extensive type and is done on small farms on average not exceeding 1.5 ha. It is mainly centred on manual activities, the very limited use of organic and mineral manure and the resorting to fallow land for the reconstitution of soil fertility. The use of external manures and other inputs is very little developed. Food production is dominated by cassava, banana, maize, groundnut, rice paddy, sweet potato, bean, pea, millet, sorghum, yam, etc.

We will mention as an indication that, from 1995 to 1998, the production passed from 1,225,000 to 1,310,000 tons for maize grains, from 19,378,000 to 18,264,000 tons for cassava tubers, from 2,424,000 to 1,950,000 tons for banana plantain. Still in terms of production, the annual report 2003 - 2004 of the Central Bank of Congo notes the following:

- an increase in the food production of about 20,722 thousands tons versus 20,688 thousands in 2003;
- an improvement of 4.2% of the production of cereals in 2002 compared to 2001, that is 1,604 thousands tons versus 1,539 thousands in 2001;
- an increase of 1.7% of the production of the roots and tubers, which account for 76.8% of the food production, going from 15,952 thousands tons in 2001 to 16,233 thousands in 2002 and this, thanks to the intervention of the international organizations and NGOs specialized in training and fight against plant diseases;
- an increase of 1.3 % of the production of the oilseeds in 2004.

The modern farm estate relates mainly to the revenue or export cultures. During the years 1980-1990, the DRC played an important role on the international markets for a certain number of the agricultural produce, which represents important sources of foreign currencies for the country. These are especially coffee, cotton, tea, rubber, palm oils, cocoa, hevea, quinquina, onion, sugar cane, fruits (bananas, mangoes, etc.) and vegetables. The evolution of the production and the exports of these cultures registers however a constant fall since 1990, which fall is due to the conjugation of several factors, especially weak competitiveness at the international level (quality), the outdatedness of production equipment, the dilapidation of infrastructures, the insufficiency of research and sensitization, the various epidemics, etc.

It arises from the annual report 2003 - 2004 of the Central Bank of Congo that the analysis of the production statistics of the main cultures of export lets appear divergent evolutions of the components of this branch compared to 2002 especially with regard to:

1) tea (12.4%) and the coffee arabica (10.9 8%), of which the increase in the production leads to the improvement of socio-economic environment of North-Kivu and South-Kivu in the East of the country;
2) sugar cane (22.5%), in which the increase is attributable especially to the use of artificial fertilisers of good quality and to an abundant pluviometry;
3) cocoa (9,2%); and
4) palm oil (25%) whose improvement of the production is favoured especially by the progressive restoration of factories and the rehabilitation of plantations abandoned during the war in the Eastern Province and that of the Equator but also by the resumption of private river traffic.

On the other hand, the same report notes a fall in the production of the palm-kernel oil (less 10%), rubber (less 10.3%), quinquina (less than 3.6 %) as well as fibre plants and their derivatives.

The same report also presents the situation of the production of the main food crops: the cereals (maize grains, rice paddy, millet and sorghum, wheat and barley), roots and tubers (cassava tubers, sweet potato, taro, potato, onion, garlics, yam), vegetables and leguminous plants (beans, vandzou, sheet of manioc, peppers and peppers, cabbage, other vegetables), the oilseeds (groundnuts, soya, palm nuts, other oilseeds), the fruits (bananas, plantains, other fruits) etc.

Among the main foodstuffs imported by the DRC are maize, rice, salted and smoked fish products, meat and offals as well as wheat. Some of these imported foodstuffs are likely to contain LMOs. It is the case especially for maize, rice, meat and offals, wheat and wheat flour, salad oil, fruit and juices, etc.

As for animal husbandry, it includes two types of main activities: short cycle animal production dominated by poultries, pigs and goats and the traditional and extensive rearing of big cattle. The traditional rearing is especially practised in Bandundu, the Eastern Province, both Kivus and Katanga. The overgrazing and the seasonal migration of the herds do not promote at all the quantitative and qualitative production of the cattle. The consequences of these practices, combined with the pressure that is exerted on the livestock a human consumption always sustained by the uncontrolled demographic growth, constitute a serious threat for the agricultural and animal resources. This situation relates especially to the North and South - Kivu, the Lower - Congo, the Katanga, Western Kasaï and the Eastern Province.

Besides the National Livestock Authority (ONDE), many business people invest in the livestock sector. In the absence of the national land allocation plan, it is difficult to have reliable data on the land area allocated to pasture. It is estimated that nearly 4.5 million hectares of pasture would be occupied by this sector versus 9.2 million available. It is thus urgent to finalize the national land allocation plan (or zoning plan of forest territory).

With the exception of porcine whose production increased by 2.5 % compared to 2002, all the other products recorded decreases in 2003 and 2004 (going from 963 thousand animals to 987 thousand). The production of the cattle decreased by 10.0 %, that of eggs 7.9%, that of poultry by 5.0%, that of milk by 4.5% and those of sheep and goats by 1.0%. This situation is attributable especially to the insufficiency of distribution structures of the veterinary products and training of the cattle breeders, to the persistence of the animal diseases, to the high costs of animal feed as well as to the competition from imported similar products.

As for the consumer goods industry, the annual report 2003-2004 of the Central Bank of Congo shows the following main productions: pasteurized milk, maize flour, wheat flour, peeled rice, sugar, chocolate and biscuit factories, bread, grains and salad oils, palm oils, margarine, animal feed, etc.

The production index of the sub-branch "Consumer goods Industries" which had increased by 14.6 % in 2003 is improved by 12.5 % in 2004. This improvement relates to the production of almost the whole of industries of the component. In 2004, the production index of food industries increased by 31.3 % spurred by the production of palm oil (102.9 %), of wheat

flour (19.8 %), of margarine (10.0 %), sugar (9.4 %) and maize flour (4.7 %). The following products recorded falls of 50.0 % for the chocolates and biscuits, 5.0 % for animal feed and of 3.6 % for peeled rice.

I.3. Foundations of an emerging general environmental Policy concerning biotechnologies in the DRC

The main sectors of potential intervention in biotechnologies are: environment, industry, agriculture, health, pharmacy and food and nutrition sub-sector.

I.3.1. National environmental action plan

The National Environmental Action Plan initiated actions in the short and medium term, which actions are distributed in the eight following areas: i) institutional development, ii) water resource management; iii) land resource management; iv) air and atmosphere pollution; v) urban environment management; vi) natural ecosystems; vii) cultural and historical heritage; viii) natural disasters.

In fact, the problems concerning the forest are dealt with under the heading about land resource management. They can be summarized in the following way: i) the physical degradation of the lands resulting from erosion of already stripped soils for various reasons and sedimentation; ii) the ambiguity of the land law (duality between the State and the customary authority); iii) the rendering of lands as assets iv) the chemical degradation of soils (production and of productivity drops), and vii) the increasing deforestation of the forest lands. Among the priority actions selected, it is suited to announce, by way of examples, the capacity building with regards to the planning of natural and environmental resource management, the productivity improvement of the industrial development lands and the zoning of the territory.

During the national Dialogue workshop on the implementation of the Global Environment Facility held from March 10 to 12, 2005 in Kinshasa, the participants recommended the updating of the National Environmental Action Plan (PNAE) in order to take into account the requirements arising from new international conventions on the environment to which the DRC has just adhered (Convention and Protocol of Basle, Convention POPs, Rotterdam Convention, Ramsar Convention on the wetlands of international importance, Kyoto Protocol, Cartagena Protocol). Apart from it not being carried out due to the lack of appropriate financing, the PNAE thus did not define the main guidelines on the National Biosafety Framework in the DRC. From the foregoing, there is the need of adopting an appropriate national policy to accompany the PNAE.

Besides the multisector and multidisciplinary dimension, the global and sub-regional character, issues relating to the environmental protection require a definition in the general legal framework of environmental protection as an instrument of implementing the national environment management policy (PNAE). It is within this framework that a draft bill on environmental protection was developed since 1999 with the support of UNDP/FAO. This text takes into account some basic principles regarding the environment and on which rests the management of the use of modern biotechnology: the precautionary principle, the preventive principle, the polluter payer principle and the principle of public participation to the decision

process. It is unfortunately not yet approved by the Government to be submitted for the adoption by the Parliament.

The adoption of this legislative text and its enforcement measures will make it possible for the country to have the tools for natural environmental protection and sustainable development of the country. A second reading of this text is necessary in order to create a synergy with the fundamental principles which underlie environment law (precautionary principle, preventive principle, polluter payer principle) and to clear the way for the environmental impact assessment in order to ensure the protection of the environment, biodiversity and health against the potentially negative effects and to adopt the precautionary approach regarding modern biotechnologies in accordance with the requirements of implementing the Cartagena Protocol.

I.3.2. National strategy and action plan on biological diversity

Developed in 1999 and updated in October 2001, the National Strategy and Action Plan on Biological Diversity is a management tool which aims at the conservation and the sustainable use of the biological resources. Its formulation took into account some considerations having to allow:

1) building institutional capacities in the conservation and sustainable use of biological diversity ;
2) improving the management capacities by educational measures, training, research and consolidation of the institutions;
3) mobilizing the internal resources and developing training programs and a legislation on biodiversity resource management;
4) making the population aware, not only of the intrinsic value of biodiversity, but more especially of the ecological, scientific, social, cultural and ethical values in order to lead it to adopt a positive attitude during the implementation of the programs and actions aimed at the conservation and the sustainable use of the biological resources;
5) revitalizing the co-operation with other countries with regards to sustainable management of the environment in general and the biological diversity in particular.

The objective pursued by the development of the national Strategy and Action plan is to provide to the DRC with a framework plan within which action plans will be carried out prevent, to remedy or repair the damage caused to the biological resources by an irrational exploitation.

Among the main recommendations made by this strategy are:

- the amendment of the legislation on nature conservation in order to adapt it to the requirements of Convention on biological diversity and other relevant legal instruments;
- the development or the review of the master plans of the national parks and other protected areas;
- the improvement of knowledge of the ecosystems and the taxonomic groups;
- the promotion of scientific research and the technical training in particular in the areas of taxonomy, biotechnology, phytosociology, zoo-sociology, biological diversity and the conservation;

- the involvement of local communities, NGOs and private sector in the conservation and the management of biodiversity and protected areas;
- the promotion of the development of the ecotourism in the protected areas, etc.

The National Strategy and Action plan on Biological Diversity was approved by the Government on August 13, 2002. The Government still has found the financing for its implementation.

Currently, only the forest Code has been developed and promulgated on August 29, 2002. Enforcement measures of the forest Code are under development. In addition, the GEF/World Bank Project of supporting the amendment of the legislation on nature conservation started in July 2005.

In any event, no instrument of nature conservation dedicates clear guidelines on the national policy regarding biosafety.

I.3.3. Poverty Reduction Strategy Paper

The planning and the programming of the policy of economic and social development of the DRC, the coordination of interministerial projects and the promotion of private and public investments appear among the duties of the Ministry of Plan. It is for this reason that the Poverty Reduction Strategy Paper (PRSP) appear among the planning instruments of the development policy of the DRC.

The first version of the Poverty Reduction Strategy Paper was prepared and adopted in June 2002. Its satisfactory implementation made it possible to reach the point of decision of the Heavily Indebted Poor Countries (HIPC) Initiative in July 2003. The objective pursued before the end of the year 2005 was to finalize the formulation and to adopt a complete PRSP prepared in a participative way. The PRSP rests on the following four pillars:

(a) ***To rebuild the State*** through the consolidation of peace, the continuation of the democratization process and the administrative and legal decentralization; for the Government, the keeping of peace and the improvement of the economic and political governance constitute the essential conditions of economic growth and fight against poverty. The PRSP emphasizes the consolidation of peace through disarmament, demobilization and reintegration of ex-combatants.

(b) ***To improve the economic governance*** for a sustainable economic stability and growth, while passing by economic and financial decentralization, the harmonizing the economic programs of the Government, the continuation of economic and structural reform, the promotion of the public/private partnership. The Government makes a point to fight against corruption which undermines a good number of sectors of the economy and to improve the management of public finance at the national level, to finalize especially the reform of the civil service, the legal system and the local administration (decentralization). With regard to public finance reforms, the concern of the Government is to improve the capacities of mobilizing the revenues through especially modernizing the tax instruments as well as financial administrations, to control the expenditure management by reinforcing the of the expenditure chain and to ensure a great transparency and traceability of its operations thanks to the set up of a State accounting system with double entry.

(c) ***To rebuild the key sectors*** (Agriculture, Health, Forests and Biodiversity, Education, Transport, Mines, and Energy) through sectoral strategies and the revival of the private sector (see development further especially the first three sectors).

(d) ***To support the community dynamics and the vulnerable groups:*** the policy on the matter is articulated around the improvement and the consolidation of the institutional and governance framework at the grassroots but also around the creation of a federated framework of mobilizing the community dynamics, of creating a national device of support to the community dynamics, of creating at the grassroots the conditions of an equitable growth and a sustainable development. It is also from this point of view that it is advisable to control the involvement of local communities in the management of the forests and the protected areas (principles already put forward in the forest Code and the bill on the nature conservation).

This paper does not unfortunately give main guidelines of the national policy regarding biosafety and nor the impact of the use of modern biotechnologies in poverty reduction.

Finally, it is recommended that the last version of the PRSP takes again the main axes of the priority development Agenda in the forest sector with regard to the development of alternative activities and poverty reduction, especially:

- the reduction of the pressure on wild fauna in the name of alternative activity to the poaching;
- the projects allowing to redirect the bordering populations towards economic activities with reduced impact on the forest ecosystems;
- the involvement of local communities in the management of forests and protected areas;
- the principle of the retrocession of 40% of the rental fees to the provinces and the decentralized administrative entities;
- the definition of main guidelines of the national policy regarding biosafety and the impact of the use of modern biotechnologies in poverty reduction.

I.3.4. Agricultural policy

The DRC enjoys natural conditions particularly favourable to agricultural activities: precipitations in sufficient quantities, important hydrographic network, fertility of the soils, great sunshine, diversity of the climatic and geological conditions. The DRC has approximately 135 million hectares of arable lands of which 10% are developed on account of 3% for agriculture and 7% for livestock. These lands include wetlands (56%), semi-wet zones (20%), zones located along the rivers (17%) and lands of which the use for agricultural purposes does not require very important improvements (7%).

Agriculture comprises the following activities

- food agriculture: which represents the most important of the production through peasant small-scale farming in the rural zones and the peripheral zones of some big urban centres; the food production is dominated by the cassava, maize, plantain, fruits, groundnuts, vegetables, rice, potato, sweet potato, etc
- export farming especially coffee, tea, rubber, palm oils, cocoa, quinquina, onion, fruits and vegetables, etc

- livestock dominated by two types of main activities: (1) a livestock production with short cycle dominated by poultries, pigs and goats and a traditional and extensive rearing of cattle especially in Bandundu, both Kasaï, Katanga and the Eastern Province.

According to the decree n°03/027 of September 16, 2003 above mentioned, the Ministry of Agriculture intervenes especially in:

- the agricultural production and food self-sufficiency;
- the planning of the national objectives of production in the areas of agriculture, fishing, pisciculture, sylviculture and livestock;
- the supervision of peasant associations;
- the development of the national policy regarding agriculture, fishing and rearing;
- the monitoring of zoosanitary and the management of animal and plant quarantine within the country and the border posts and the permanent update regulatory measurements related to it, etc (it relates to mainly medical zoosanitary control of wild species of fauna and flora and the invading exotic species).

Within the framework of the Government implementation policy in this sector, the Ministry of Agriculture defined as follows the main axes of the policy and strategies especially:

- the promotion of research - development (sensitization and supervision of the farmers);
- the development of a regulation on the seeds and phytosanitary protection;
- distribution of seeds, agricultural inputs and tools;
- the rehabilitation of agricultural service roads in order to allow the agricultural producers to have access to their traditional markets and to promote the competitiveness of export productions;
- the rehabilitation of industries, in particular installations of storage and small processing units (mills, slaughter-houses) in order to encourage the processing of agricultural produce;
- the revival of the marketing and processing companies;
- repairing of the abandoned farms (plantations and farms);
- the support to community initiatives in the agricultural sector;
- the revival of credit system in the name agricultural campaigns and the creation of a stabilisation fund of the prices of agricultural produce;
- the promotion and the diversification of trade with the neighbouring countries; etc.

A particular emphasis has also been put on:

- the set up of a monitoring framework of veterinary and phytosanitary protection in order to prevent and to fight some epidemics but also to reduce the effects of epizooties and epiphyties;
- the improvement of the business climate in order to allow the restarting of the plantations and the commercial rearing, but also of the set up of processing and marketing intermediaries.

The main guidelines relating to the transgenic farming do not seem to be the subject of a concern in the document of agricultural policy of the ministry in charge of agriculture. What appears comprehensible insofar as it is important that first this question is subject to a wide-ranging national debate.

I.3.5. Industrial development policy

The development of the industrial development policy is one of the prerogatives of the Ministry of Industry and Small and Medium-sized Enterprises. Under the provisions of the article 1 of the Decree n°03/027 of 16 September 2003 fixing duties of the ministries, the Ministry for Industry and Small and Medium-sized Enterprises is in charge of:

- the industrialization of the country and industrial integration;
- the promotion of the set up and extension of the industrial plants;
- the promotion, the technical supervision and the protection of national industry;
- the management of the patent rights;
- the technical inspection of the industrial plants;
- the promotion of standards as much for goods consumed locally as for those intended for export, etc.

Within the framework of its economic Program, the Government has made a choice in the running of its policy, that of reserving for the State the normative, inciting and regulating role and gradually leaving most of the productive activities on the private initiative. It was set up with the support of the World Bank the "Competitiveness and private sector development" project, which makes the private sector the engine of development, economic growth and fight against unemployment and poverty. This project primarily aims at the following objectives:

- of improving the e business environment by setting up a legal, tax and financial framework;
- of encouraging the widest participation of the private sector in the economy, especially in, mining, telecommunication, energy, industrial processing and financial sector...;
- of revitalizing the mining province of Katanga within the framework of mining reforms, etc.

In addition, the efforts of the Government resulted in institutional reforms for the improvement of the businesses environment. The economic operators went as for they are concerned especially towards the resumption of the many industrial activities and the diversification of the economic fabric for enhancing the value of raw materials and the promotion of the extractive industries, the manufacturing industries (the consumer goods industries and equipment goods and procurement industry and) and those of the export products.

With regard to the manufacturing industries, the objective is to build the resumption of the production activities especially in the branches of consumer goods industry and that of equipment goods and procurement.

In the food industries, a particular attention was given to the repairing of factories and to the rehabilitation of plantations abandoned during the period of conflict so as to increase of the production of maize and palm oil. In 2004, the production index of food industries increased by 31,3% under the impulse of productions of wheat flour, the palm oil, margarine, sugar, greases, the salad oil and maize flour. This was one of the objectives having crowned the efforts of the Government and the private sector.

Concerning the beverage industry, the private sector dedicated its efforts in the acquisition of the most performing equipment by the main companies in the sector to face especially the additional demand induced by the unification of the country and, to a lesser extent,

by the price stability observed during the period. The production of brewery industries was also registered on the rise. Its production index increased in 2004 by 29.9% under the effect of the increase in production of all industries of the sub-branch: lemonades and soda waters, beer and alcoholic drinks and this, thanks to the regular procurement of inputs.

With regard to the industry of fabric, clothing and hosiery industry, the production of cotton fabrics reduced by 62.6%, that of printed fabrics by 55.1% and that of polyester fabrics by 2.9%. This bad result is due especially to the slowing down of activities following the competition by imported similar products and especially with the sale of the biggest unit of the sector to a Chinese company.

The efforts made by the Government and the private sector for the industrial development, do not seem to take into account the prospects offered by modern biotechnologies.

I.3.6. Health policy

I.3.6.1. Outline of the health sector

The health situation in Democratic Republic of Congo is one of the most worrying social problems. It is especially characterized by:

- a deterioration of health indicators of in general. In addition to malnutrition, diseases, especially malaria, tuberculosis, trypanosomiasis, onchocercose, leprosy, the childhood diseases and HIV/AIDS, weigh much on the health status of the Congolese populations;
- an unequal coverage of the national territory, despite the system of health zones set up in the 970's, with a serious imbalance between the provinces on the one hand and between urban zones and rural zones within the same provinces on the other hand as well as between Kinshasa and the rest of the country;
- a weak commitment of the State, at the same time in terms of financing the system, regulating the sector, remunerating the health personnel and providing quality healthcare services.

I.3.6.2. Strategy and Policy

The Government strategy is to promote the right to health for all through the building of mechanisms guaranteeing ethics and equity in the distribution of the health care and services, the community solidarity and the humanization of health services. With this intention, the National Health Policy emphasizes on the quality of treatment and services, the efficiency and effectiveness of health development projects and programs, the coordination intra- and inter-sector provisions of health services, the community participation, the public-private partnership, the decentralization of decision-making centres, the service devolution in providing treatment and the integration of specialized services within the basic health services.

The general objective is to increase accessibility to treatment and provision of quality health services to the population in general and more particularly to the poorest, especially the woman and the child.

The specific objectives for the three next years are:

- the definition of a national health policy and the supply essential drugs;
- the increase in the availability of health services offering quality treatment;
- the increase in the use of the health services to all the population and more particularly to the poor, the woman and the child.

To that effect, the strategic axes of interventions in this sector are:

1. ***Institutional support*** to the various levels of the health system of including the formulation of a health policy:

- The review of the health policy and of the legislation, the regulation and the financial mechanisms of the management standards of the health system;
- The review of the organization and the organic framework of the Ministry of Health in order to clarify the responsibilities;
- The mobilization of human, material and financial resources by the important allocation of the State budget, the building of the community participation and the public-private partnership for health;
- the subsidized and regular supply of essential drugs, including biological products and other laboratory reactants;

2. ***Development of health zone*** especially by:

1. The rehabilitation and/or the construction of health infrastructures to meet the health needs of the Democratic Republic of Congo;
2. The improvement of the geographical distribution of the personnel of health fairly and to improve the availability of the health services;
3. The increase in healthcare performances and the development of the programs of support to the health services such as research on health, the set up of public health and quality control laboratories, the regulation of traditional medicine, etc.

3. ***Support to the special health programs***, especially:

- The fight against diseases such as the HIV/AIDS, tuberculosis and malaria;
- The management of epidemics, catastrophes and emergencies thanks to the revitalization of early warning and response system;
- The promotion of traditional medicine while starting by its recognition and its regulation as well as the identification of the traditional doctors; etc.

In the health area, a first outline of the Health – Poverty Status Report (RESP) was finalized in December 2004, thus constituting a background document for the development of the sector strategy, which will be finished by the end of August 2006.

In addition, it is suitable to note that the DRC does not have yet a framework legislation on public health. It is advisable however to announce that the bill developed and submitted to the Parliament in 2002 could not be adopted given many detected gaps.

With regard to the ***pharmaceutical sector***, it is appropriate to recall that the negotiations on the Cartagena Protocol made it possible to wonder about the need for taking into account of the future evolutions of the genetic therapies and the use of genetically modified plants and animals to produce pharmaceutical substances next to the problems of the potential negative effects of viruses and genetically modified pharmaceutical micro-organisms on human health and the environment. In the DRC, the project could find document defining a specific

policy on the research and the use of such modified pharmaceutical micro-organisms and on the import of the pharmaceutical products in general as well as on the transboundary movements of genetically modified plants, animals and micro-organisms which are raw materials for the production of pharmaceutical products intended for the human beings, like genetically modified vaccines (example of genetically modified micro-organisms in order to allow the development of the vaccine of hepatitis B). However, article 5 of the Cartagena Protocol of recognizes with the Parties the right to subject any living organism modified to a risk assessment before making a decision concerning its import.

It would be desirable, with regard to the pharmaceutical products intended for human beings, to refer especially to the Certification Scheme on Pharmaceutical Products Moving in International Commerce developed by the World Health Organization and to the provisions of Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products (1970).

As for ***traditional medicine***, the organization of the practice of this activity in order to integrate it in the health system has been the subject of the concerns for the Ministry of Health which signed the following documents:

- Ministerial decree n°1250/CAB/MIN/SPF/12/97 concerning the creation of the National Co-operation and Coordination Research Committee regarding medicinal plants;
- Ministerial decree n°1250/CAB/MIN/S/CJ/KIZ/32/2002 of October 25, 2002 concerning the organization of the practice of the Traditional Medicine professional practioner;
- Ministerial decree n°1250/CAB/MIN/S/AJ/DJK/12/2002 of November 6 2002 concerning the creation and organization of a National Programme for Promotion of Traditional Medicine and Medicinal Plants (PNMT/PM).

In July 2005, the results of the preliminary works relating to the institutionalization of traditional medicine were made public. They comprise especially:

- the National Policy Paper on Traditional Medicine in the DRC;
- the bill concerning the regulation of the practice of traditional medicine in the DRC;
- and the Ethics and Practice Code of Traditional Medicine in the DRC. Currently, no provision of the Congolese legislation protects the obtaining of plants, especially those coming from traditional medicine.

I.3.7. Food security policy

Generally, the Government makes food self-sufficiency one of the priorities of its food policy. During the marketing year 2002-2003 and with the support of Multisector Emergency Programme for Rehabilitation and Rebuilding - PMURR, the Government put a programme of multiplication of seeds (cassava, maize, leguminous plants). Moreover, a pilot programme of rehabilitation of 32 ha rice perimeters had started with the support of China. The general objective of this project was to rehabilitate 850 ha of rice perimeters from 2005. The Government supports the implementation of a program aiming at the improvement of the poultry farming and the rearing of small ruminants and the revival of pisciculture and traditional fishing.

In addition, the main objectives of the rural development 2004-2005 included the improvement of the food security of the rural populations and the development of a rural development strategy in the medium and long term for a sustained high growth of the production and agricultural incomes.

Moreover in this program, the Democratic Republic of Congo continues to resort to the import of some foodstuffs. The import of some of these food products is subjected to prior restrictions or authorization. The Interministerial decree n°016/CAB/FIN/MENIPME/96 of June 20 1996 referred to above subjects the import of wheat flour to a mandatory subscription to an import licence in accordance with the exchange control.

With regard to the processing and the importation of wheat flour, they must conform to the Congolese standard set by the Ministerial decree n°012/CAB/MINE-CI/2001 of March 31, 2001 concerning approval of the standard relating to the wheat flour. It acts of the standard n° NC 002-A presented in five series quoted from NC 002-A-100 to NC 002-500, such as developed by the national standardization Committee, as well as its appendices. In the exercise of their mission, the officers under oath of the Ministries of Health, Agriculture and the Environment have the right to penetrate at any time in places containing of the wheat flour, especially in the stores, warehouses, public markets, ports, stations, ships, coaches, etc. In the event of nonconformity to the standard, the availing for consumption is automatically prohibited. Consequently it is preceded to the seizure for destruction, put under sequestration, or for use other that the initial project of food processing intended for human and animal consumption.

In general, the Government carries out the legislative and regulatory provisions in force on food security. These provisions are examined in the chapter devoted to the status of biosafety management in the DRC. Generally, in all these programs or initiatives, articles or sections devoted to biosafety are not taken advantage of.

I.3.8. Scientific and Technological Research Policy

The objectives of the scientific and technological research sector are defined by the Minimal Partnership Programme for the Transition and the Revival in the DRC (PMPTR). They consist of the implementation of the new vision of research so as:

- to contribute to the sustainable development of the DRC by Science and Technology;
- to carry out the necessary reform compatible with the vision of research like government agent in the design and the implementation of the sectoral programs;
- to rehabilitate the existing infrastructures and to equip the research centres so as to carry out priority projects in support with the rebuilding and development of the country.

On the plan of institutional reform, a priority was given:

- to the holding of the General Meeting of Scientific and Technological Research in the DRC in April 2005;
- to the revival and the completion of the work of mastering the scientific and technological potential;
- to the continuation and the consolidation of the coordination effort of research activities and to the reform of the texts and structures in accordance with the new vision of research:

On the plan of the priority investments, the needs were defined to achieve the following objectives:

- the priority rehabilitation of the targeted institutes and research centres (National Institute for the Agronomic Study and Research, the Natural Science Research Centre, the Geographical Institute of Congo, etc.) ;
- the research projects in support to rebuilding and development;
- the building of capacities in terms of institutional support and operational capacities (actions of institutional support in terms of equipment, training and technical assistance).

From the onset, the program in progress does not seem to give an attention to the rehabilitation and/or the acquisition of analysis laboratory for transgenic products or research on modern biotechnologies, despite the fact that INRB of Kinshasa, CRSN-Lwiro and CRAA of Lubumbashi give already a detailed attention to research on modern biotechnologies. The building of national capacities in molecular biology, biotechnology and biosafety was never planned.

It appropriate to recall that in April 2005, the Ministry of Scientific Research organized the General Meeting of Scientific and Technological Research which prepared the main elements of the draft new national policy regarding Scientific and Technological Research. Once again, this document does not set any research guideline in molecular biology and genetic engineering, GMOs/LMOs (Living genetically modified organisms).

In addition, within the framework of the implementation of the project on agricultural Research and development, the Southern African Development Community of the (SADC) set up in April 2003 a Consultative Committee on biotechnology and biosafety including researchers from the region with the mandate of developing harmonized legislations on biotechnology and biosafety at the national and regional level. The committee prepared a draft regional framework relating to the handling and the transboundary movements of genetically modified organisms as well as a proposal for a regional project on modern biotechnology and biosafety. The project could not obtain information on the progress update of the SADC project.

Generally, scientific research or scientific work relating to the area of biosafety/biotechnology is limited in the DRC to some institutions for the moment: CRAA, CRSN-Lwiro, University of Kisangani... This research sector suffers not only of the deficiency in well trained human resources but also in state-of-the-art infrastructure.

I.4. Emergence of a general biosafety policy in the Democratic Republic of Congo

On August 13, 2002, the Government of the DRC adopted the National Environmental Action Plan (PNAE) and the National Strategy and Action Plan on Biological Diversity, which fix the political framework and the management strategy of the environment in general and biological diversity in particular. However, none of these documents could lay down the main guidelines of our country relating to biotechnological risk prevention and management. Even the national research policy in the area of agriculture, livestock, health or food security also remains silent on the questions relating to modern biotechnology.

This silence can by no means be interpreted as the absence of political good-will in the implementation of the obligations rising from the Cartagena Protocol on Biosafety. To be convinced about it, the DRC adhered to the principles stated in the Agenda 21, of which Principle 15 of the Rio Declaration on Environment and Development devotes to the precautionary approach (principle), and chapter 16 of Agenda 21 relating to the "environmental sound management of biotechnology". These principles which recognize the potential risks of the use of modern biotechnology made it possible to adopt of a prudential approach and to be convinced of the need for ensuring the safety in the development, the application, the exchanges and the transfer of biotechnologies by means of international agreement consigning the principles to apply concerning risk assessment and management. The DRC also adhered in February 2005 to the Cartagena Protocol on Biosafety to which the DRC is Party.

According to article 2 of the Cartagena Protocol, each State takes necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

The policy adopted by the DRC in this respect is based on the precautionary principle. If the resorting to modern biotechnology is of importance, this policy recommends to take necessary precautions so that the resorting to this new technique is made without putting the environment, human or animal health as well as socio-economic fabrics of the country at the some risks such as the disappearance of some secular practices of selection, of conservation and distribution of the traditional seeds, pollution by herbicides, contamination of the biodiversity, destruction of the habitat, etc.

I.4.1. Guiding principles on biosafety management

The management of the environment in general and the use of modern biotechnology and GMOs/LMOs in particular is based primarily on the precautionary principle and other general principles of the international law on the environment, currently devoted by the national Policy regarding environment materialized by the National Environmental Action Plan.

I.4.1.1. Precautionary principle/ Precautionary approach

The precautionary principle gives the approach to adopt towards the presumptions of the risks known as "development" whose existence is not corroborated by the scientific approach and the causality links between the activity and the potential damage. It is distinguished from the prevention principle in the fact that it operates only in the event of uncertainty due to the weakness of scientific knowledge.

Thus, the taking into account of the concern of ensuring environmental protection, health and the food security of the populations led, in the absence of scientific certainty, to the adoption of the precautionary principle as one of the bases of the national legal framework of biosafety and the implementation of the provisions of the Cartagena Protocol on Biosafety.

However, the adoption of the precautionary principle is subordinated to the reliability and the legibility of the structures and the procedures like to the definition of the operational responsibilities and the expertise for each actor.

I.4.1.2. Preventive Principle

The prevention principle resulted in implementing the measures aiming at ensuring the protection of human health and the environment when a risk is established.

The management of some established biotechnological risks is based on the prevention principle reaffirmed by the PNAE and through the carrying out of the environmental impact assessments following the rules of procedure defined in application of the framework legislation the environmental protection.

However, the current level of the impact assessments of modern biotechnology for example on health and the environment bring to consider rather more the precautionary principle devoted by principle 15 of the Rio Declaration on Environment and Development.

I.4.1.3. Public information and participation principle

The public information and participation principle in the decision process regarding the environment is devoted by the PNAE, the National Strategy and Action Plan of Biodiversity, the forest Code, the framework bill on Environmental protection and the bill on Nature conservation.

Indeed, the public sufficiently made aware and informed on the biotechnological risks would be more prepared to involve itself in the process of biosafety management.

I.4.1.4. Polluter Pays Principle

One of the principles which govern the liability and redress regimes of the damage caused to the environment is the polluter pays principle.

This principle aims at charging to the polluter the ecological, economic and social costs of the pollution which it generates. This translates a liability mechanism for ecological damage covering all the effects of pollution not only on goods and people, but also on biological diversity and habitats.

This principle is devoted by the PNAE and the draft framework law on Environmental protection.

I.4.1.5. Knowledge development for biosafety management

The biosafety management in general and the risk assessment and management procedures in particular require that the DRC develop scientific knowledge on which such procedures rest. This implies the obligation to build national capacities concerning training and use of scientific knowledge in faculties, institutes and research centres.

It is from this perspective that it is urgent to develop biotechnology sciences, in general and of genetic engineering in particular and to sufficiently involve researchers, institutions, ministries and administrations in charge respectively of agriculture, livestock,

fishing, industry, health, pharmacies, food, the environment, waters and forests, of trade, economy, etc.

I.4.2. Objectives of biosafety management policy

I.4.2.1. General Objectives

Many studies carried out acknowledged modern biotechnology has some advantages, especially the improvement of agricultural performances, animal feeds, etc.

However there are some potential risks associated with the use of modern biotechnology, the main purpose of the national policy will have to make it possible to guarantee public health and to ensure the environmental protection, biological resources, socio-economic fabrics by the applying the precaution principle.

I.4.2.2. Specific objectives

The specific objectives which aim at the achievement of the general objective consist especially **in**:

- the development and the implementation of a legal framework on biosafety, including especially the legislation and the regulatory texts fulfilling the requirements of the Cartagena Protocol;
- the integration into the existing sectoral development policies favouring biotechnologies (environment management, health, agriculture, livestock, fishing, food, scientific and technological research, industrial development, etc.) of main guidelines of the national policy regarding biosafety;
- the development and the implementation of the biotechnological risk assessment and management mechanisms by taking into account the environmental, economic, medical, social and cultural concerns;
- the adoption and the implementation of the institutional framework of biosafety management and of public awareness and participation mechanisms in the decision process of the risk prevention;
- the building of the national capacities in biosafety management.

I.4.2.3. Strategy elements of GMOs/LMOs and products thereof

I.4.2.3.1. Import and export of GMOs/LMOs and products thereof

In the area of import of GMOs/LMOs and derived products, the national policy will have to reinforce the provisions of the national legislation and of Cartagena Protocol on Biosafety requiring:

- An advance informed agreement through an authorization written by the CNA;

- This prior authorization must be given on the basis of result of risk assessment carried out in accordance with the provisions of the national legislation and of the Protocol;
- The application of the penal sanctions to the applicant of the illegal import of GMOs/LMOs and derived products.

Concerning the export of GMOsLMOs, the DRC will have to respect international legal instruments and in particular the advance informed agreement procedure.

I.4.2.3.2. Development of GMOs/LMOs and products thereof

The national policy will have to favour:

- the fundamental research;
- the nutritional conservation and improvement with regard to the agri-food industry;
- the development of livestock, especially by the use of the animal species tolerant to epizooties;
- the agricultural development: the use of varieties tolerant to pest insects (maize, potato of the Bt group), to herbicides, to viral diseases (maize, potato), to salinity;

I.4.2.3.3. Management of GMO-based humanitarian aid

The humanitarian situation of the DRC is alarming. The country authorities seem still hesitant on the attitude to adopt vis-a-vis with the food aids brought to the disaster victims and others displaced by conflict.

It would be very appropriate to apply the procedure relating to the living modified organisms intended for direct use as food, feed or for processing before the acceptance of any humanitarian aid.

II. LEGAL AND REGULATORY ENVIRONMENT

The DRC has, since February 8, 2005, adhered to the Cartagena Protocol on Biosafety. Article 2 of the Cartagena Protocol provides that each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations as regards development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

II.1. Status of the legislative and regulatory concerning biosafety

A review of the legislation in force in relation to biosafety in general as well as administrative structures involved whichever way you look at it in biosafety leads us to make a certain number of observations.

II.1.1. Legal framework of biosafety management

II.1.1.1. Constitutional provisions

Generally, article 54 of the Constitution of the Transition promulgated on April 04, 2003, stipulates that all Congolese have the right to a healthy environment and favourable to his/her integral fulfilment. The authorities and the citizens have the duty to ensure the environmental protection under the conditions defined by the law.

In addition, the new Constitution of the DRC promulgated on February 18, 2006 provides, in its article 53, that any person has a right to a healthy environment and favourable to his/her integral fulfilment. He/she has the duty to defend it. The State sees to the environmental protection and public health. Moreover, article 202, point 36, m, gives to the central authority exclusive competence as regards development of legislation concerning among others, the artificial insemination in human being, *the handling of genetic information* and on organ and human tissue transplantation. The constitution thus provides the foundations of legislation on the use of modern biotechnologies.

II.1.1.2. Legal framework on trade and pricing

II.1.1.2.1 Legislation on the practice of trade

The Law n°73-009 of January 5, 1973, as modified and supplemented to date, fixes the specific rules on trade.

According to article 5 of this law, commercial activities are divided into:

- import trade;
- export trade;
- transit trade;
- wholesale trade;

- wholesale trade (dealing in retail quantities);
- retail trade;
- services considered commercial by the law.

Article 13 of this law gives power to the minister having foreign trade in its duties to limit or prohibit the export of a product when the needs for supplying the country require it. In the same way, it is entitled to take *restrictive measures, to prohibit the import, the introduction and circulation in the DRC of some products considered to be dangerous for health* or committing a breach to standards of behaviour. Moreover, unless there is a contract with clause of exclusivity, article 19 of this law requires that goods and products to be imported in the DRC are ordered directly from the production or manufacturing plant.

In addition, according to article 5 of the departmental Decree n°015/CAB/004/73 of September 7, 1973 concerning measures of carrying out of the specific law on trade, all imports carried out under the conditions fixed at article 4 must be supported by a document emanating from the economic authorities of the country of origin. This document attests that the conditions of article 4 are met. This project, aforesaid article 4 stipulates that goods which are not marketed for export by the foreign producer can be imported under the similar conditions with those fixed at the articles 1st and 2; the marketing organization recognized being assimilated in this case to the producer.

In addition to the above mentioned law of 1973, the trade of import-export is governed especially by:

- the Interministerial decree n°016/CAB/FIN/MENIPME/96 of 20 June 20, 1996 concerning provisions applicable to the import of wheat and wheat flour (which provides for these products as an obligation is subscribed for an import licence).
- the Ministerial decree n°14/CAB/MIN/Fin&Bud/2000 of October 25, 2000 relating to the import and export licence and to the licence of regularization of import and export.

Concerning the control of the goods and the inspection before their export or import, the main texts governing these activities are especially:

- the legislative order n°74-13 of January 5, 1974 concerning the creation of the Congolese Authority of control (entrusting the Authority with the mission of carrying out conformity and quality controls of goods);
- the legislative order n°78-219 of May 5, 1978 concerning statutes of the Congolese Office of Control (whose article 3 entrusts to the Authority the mission of carrying out, quantity and conformity quality controls of all goods, analyses of all samples and products, as well as technical inspection of all devices and work);
- the Ministerial decree n°002/CAB/VPM/MEIC/91 of February 18, 1991 concerning obligation of control of the Congolese Authority of Control;
- the Ministerial decree n°13/CAB/MIN/Fin&Bud/2000 of October 21, 2000 create a commission in charge of control at import of protected goods.

II.1.1.2.2. Price legislation

The methods of fixing and controlling prices are governed by the following main texts:

- Legislative decree of March 20, 1961, as modified and supplemented to date, fixes the legal regime of prices;
- Ministerial decree of July 1, 1996 concerns measures of execution of the Legislative decree of March 20, 1961 relating to prices (and especially fixes methods of calculation of cost price of some categories of goods);
- Interministerial decree fixes the scale of the economic sanctions pursuant to the Legislative decree of March 20, 1961 relating to prices.

II.1.1.2.3. Legislation on the import and export rights and taxes

The law n°04/015 of July 16, 2004 fixes the naming of administrative, legal, domanial and participation revenue generating acts as well as their collection methods. In relation to the production, the import and the export of living modified organisms, this law lists the generating acts for the following Ministries:

- ***Agriculture***

  - Import Authorization of Plants;
  - Export Authorization of Plants;
  - Certificate of origin of the plants;
  - Phytosanitary Certificate;
  - Import Authorization of Phytosanitary products;
  - Setting in quarantine;
  - Import Inspection

- ***External trade***
  - Import/export Number
  - Import Licence

- ***Environment***
  - Import, export or re-export Licence of completely or partially protected CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) animal species;
  - Import, export or re-export Licence of unprotected animals;
  - Phytosanitary Certificate;

- ***Health***
  - Import Authorization of the Medicines;
  - Authorization of opening of a scientific laboratory;

- ***National Economy***
  - Compromise Fine for offence to the price and trade legislation.

No legislative or regulatory provision sets up an advance informed agreement procedure before starting an export/import notification and a decision-making procedure relating to the import of LMOs intended to be deliberately released into the environment of the importing party as articles 8, 9, 10 and 12 of the Cartagena Protocol prescribe it.

In the same way, except the decree on sanitary policing of animals, the conditions of delivery of import and export authorizations of plants and phytosanitary products or certificates of origin, the phytosanitary control and inspection procedure a as well as the methods of setting in quarantine plants concerned in the law referred to above are not clearly defined by any text.

II.1.1.3. Legal framework on the environment

II.1.1.3.1. General Legislation on the environment protection

Currently, the outline bill for environmental protection already developed in 1999 is still not approved yet by the Government before its examination by Parliament.

In substance, this bill contains provisions which take into account some guiding principles as regards the environment and on which rests the management of the use of modern biotechnology: the precautionary principle, the preventive principle, the polluter pays principle and the principle of public information and participation in the decision-making process.

II.1.1.3.2. Biodiversity legislation

Articles 3, 24, 34, 46, 49, 50 and 72 of the Law n°011-2002 of August 29, 2002 concerning forest Code provides for provisions relating especially to protection of biodiversity and natural habitat, sylviculture, forest research, transformation and trade of forest products, to protection of forest species protected and the conditions of introducing on the national territory of forest plant material, etc.

Article 34 of the Code governing forest research relates especially to the management, the inventory, the development, the conservation, the exploitation, the transformation, the *forest genetics, sylviculture,* the wood technology and the marketing of forest products.

According to article 46, the introduction on the national territory of any forest, live or dead plant material, is subjected to the prior authorization of the Minister or his delegate, on presentation of a certificate of origin and a phytosanitary certificate delivered by the competent organization of the country of consignment. The decree relating to the conditions of introduction on the own territory of the forest plant material is not yet elaborate. However, the decree n°05/162 of November 18, 2005 concerning phytosanitary regulation devotes provisions on the production, the conservation and the import plant products.

Article 49 confers to the Minister in charge of Forests the power to set up the list of the *protected forest species* is fixed by decree of the Minister and is subject in the same form of periodic updates. The Ministerial decree of March 2003 determines the list of the forest species protected in the DRC.

According to article 72 of the forest Code, the forest area is subdivided in forest production units for purposes of executing the tasks of planning, management, conservation, reconstitution and exploitation of the forest resources. Forest development can be directed towards:

- sustainable production of all the forest products and products for *biotechnology*;
- environmental services;
- tourism and hunting;
- other objectives compatible with the maintenance of the forest cover and the protection of fauna.

Moreover, a bill on the nature conservation is under development. Article 4 of this bill makes obligation to the Government to take necessary measures to prevent the introduction of the exotic species which threaten the ecosystems, the habitats or the species. It sets up control and quarantine measures at the borders so as to ensure that the deliberate introductions are duly authorized and those accidental or not authorized are reduced to the minimum. It leaves to the ministers in charge nature conservation and agriculture to fix, by way of related decree the methods of preventing accidental introduction and of control of the movements at borders of invading exotic species.

II.1.1.3.3. Restrictive measures relating to the trade of protected species

The trade of the protected species is subjected to certain restrictions provided by specific texts, especially:

- the Ministerial decree of 2000 regulating the international trade in endangered species of wild fauna and flora applies the provisions of CITES;
- the Ministerial decree n°CAB/MIN/AFF.ENV.DT/124/SS/2001 of March 16, 2001 fixing the periods of taking away of the gray parrots in the Democratic Republic of Congo;
- the Draft-agreement signed in 2000 fixing the methods of administrative collaboration between the CITES Management Organ, the OFIDA and the Congolese Authority of Control for the fight against the illicit trade of CITES species.

II.1.1.4. Food and food hygiene legislation

Following the example of other sectors and sub-sectors, hygiene and food safety are subject of an active normative activity. The Democratic Republic of Congo subscribed to this international tendancy regarding the following texts:

- *The Decree of July 26, 1910 which determines measures relating to the manufacturing and the trade of foodstuffs*

According article 6 of this decree, the Government is authorized to regulate and supervise, by way of decree or legislative order, the import, the trade, the sale, the turnover, detention for turnover or sale of fuels, drinks, commodities, any food substances, but only from the point of view of hygiene or with an aim of preventing frauds and falsifications. It will be able, in the same way, but only in the interest of hygiene, to supervise the manufacturing or the preparation of fuels, drinks, commodities, any food substances, and to prohibit the use of harmful or dangerous matters, ustensils or objects.

- *The Ordinance of October 17, 1911 which fixes the precautions to be taken for packing, preparing and manufacturing foodstuffs.*

The 1st article of this ordinance prohibits using for preparation, conservation and packing of liquids and foodstuffs intended for sale or turnover of these food products, vases, various ustensils, containers, devices or object whose contact with the aforementioned liquids or food products could bring a composition, a solution of poisonous or harmful substances to health. Are regarded as poisonous and harmful to health according to article 2, lead and zinc as well as alloys, tinnings, weldings and enamels containing these metals, arsenic, antimony or their compounds, like also the toxic colors listed in the ordinance of October 16, 1911 concerning the colouring.

This ordinance will have to be re-examined in order to take into account the requirements of the implementation of the Cartagena Protocol, on the labelling of packing of transgenic products.

- *The Ordinance of June 17, 1913 - relating to the artificial colouring of the foodstuffs.*

The 1st article of this ordinance prohibits using for colouring of foodstuffs such as candies, dragees, pelletizings, sweet things, pastries, pasta, jams, marmalades, syrups, liquors, wines, fruit and vegetables, intended for sale, no poisonous colouring. A list of inoffensive colouring and a list of colors considered toxic are annexed to the ordinance referred to above by way of information.

Article 2 of this ordinance prohibited to sell, display for sale, to hold or transport for sale any foodstuff manufactured or prepared contrary to the provisions of the 1st article.

Article 3 requires that the containers or envelopes in which will be reinforced, for wholesale or in semi-wholesale, coloured or coloured in artificially foodstuffs will have to bear in quite readable characters the name and the legal status as well as the address of the seller.

For the application of the ordinance of October 17, 1911 relating to ustensils and containers and the devices being used packing, preparation and manufacturing of foodstuffs, article 5 of the ordinance of June 17, 1913 regards as harmful to health: colourings specified in paragraph 2 of the annexed list, except:

a) compounds of copper perfectly vitrified in the mass, the glaze,the enamel or the varnish of objects which they decorate;

b) vermilion;
c) derivatives of tar constituents.

- *The Ordinance n°74-453 of December 31, 1952 relating to the protection and the healthiness of foodstuffs.*

According to the 1st article of this ordinance, the people affected by contagious diseases as well as those whose health state or body dirtiness constitutes a danger of contamination, cannot take part in the production, manufacturing, preparation and handling for sale or the sale of substances serving or intended for human consumption. It is prohibited to employers to employ at this work the services of people referred to above.

Article 4 requires that the buildings used for the sale, manufacturing, preparation, packing or detention for sale of food substances just as well as the material which are found there, will be

washed daily by means of water containing a detergent product. They will have to be in a constant state of cleanliness. It is prohibited to hold in these buildings harmful matters to their healthiness or unsuitable for human consumption.

Moreover, article 6 requires that packing, detention and sale of substances serving or intended for human consumption, be made in order to avoid any contamination or taint. It is prohibited to put in direct contact with these substances papers or other materials which are nonwashable, tainted or having been used for another purpose. Before carrying out the closing of packing, any manufacturer or businessman must make sure that foreign materials or bodies are not mixed with the food substances.

Lastly, article 7 requires that identification marks affixed on packaging must not contain products likely to disseminate or permeate the goods.

- *The Ordinance n°41-412 of December 07, 1953 relating to the trade of the salad oils.*

According to the 1st article, the containers holding of salad oil intended for human consumption and imported, offered on sale, held for sale, transported, sold or delivered must be provided with a label mentioning in a visible and indelible way:

a) the name and legal status of the manufacturer, and possibly the brand;
b) the exact naming of the product, in conformity with the provisions of article 2 and excluding any other qualification, this naming guarantees at the same time the quality of the product;
c) the minimum capacity guaranteed of the container expressed in litres or centilitres.

Article 2 requires that:
A. To be able to be sold under the naming "peanut refined oil" or “refined peanut oil guaranteed pure", the product must fulfil the following conditions:
a) being extracted from the endosperme of various varieties of groundnuts (*Arachis hypogaea*);
b) deodorized and deacidized being;
c) not to contain more than 0.25% of oleic acid, 0.01% of impurities and water 0.15%.

B. The oil which, although meeting the standards defined in sub a) and d) of point A, does not meet the minimal conditions given in sub b) and c) must be sold under the naming "peanut oil".

C. The product obtained by the mixture of peanut oil, refined as defined in sub a) or not, with another foodstuff cannot be sold under the naming "peanut oil". If necessary, the label will be marked "salad oil".

II.1.1.5.Patent rights legislation

The law n°82-001 of January 7, 1982 governs the patent rights. This law is subject to a deep examination within the framework of the implementation of the agreements concluded under the auspices from the World Trade Organization.

Concerning the protection of plant production, a bill is under development and will have to be validated at the time of a national workshop with the support of FAO before its deposit to the Government.

II.1.1.6. Legal framework of work health and safety

The law n°015/2002 of October 16, 2002 concerning the Labour Law provides in its Title VII of the provisions on work health and safety.

There are not however application texts of nor guidelines on the protection of staff used in the research centres on modern biotechnologies.

II.1.1.7. Legal framework of the agricultural and livestock sector

II.1.1.7.1. Sanitary policing of domestic animals

The decree of July 28, 1938, as modified and supplemented to date, fixes the sanitary policing domestic animals. Under article 4, is considered:
1° *as affected by a contagious disease* any animal displaying, during life or during autopsy, symptoms or lesions such as, according to the current scientific data, it can remain no doubt about the existence of the disease;
2° *as suspect to be affected of a contagious disease*, any animal displaying symptoms or the lesions which make someone suspect its existence;
3° *as suspect to be contaminated* any animal which will be found in the conditions of possibility of infection. Those are specified for some categories of contagious diseases examined in chapters II and III of this decree.

Article 5 regards as veterinary authorities within the meaning of this decree Government veterinary doctors, private veterinary doctors or those attached to companies and Government registered and the civil servants and agents nominated as such by the Minister in charge of Livestock and its delegate, but within the limits of duties that he/she determines (...)

Article 6 governs the isolation, which consists in either holding animals contained in a room (sequestration), or to hold them gathered in a suitable pasture (confinement). As for article 7, it governs quarantine, which consists of the setting in observation of animals introduced into a determined region with an aim of ensuring itself of their sanitary state. Qurantine is applicable to imported animals; it can be applied to the animals subjected to displacements within Congo. The duration of quarantine is fixed by the competent territorial authority, the agreed veterinary authority.

Article 140 prohibits the import, the export and the transit of domestic animals affected, suspect to be affected or suspect to be contaminated by one of the contagious diseases cited in the 1st article as well as tick-bearing animals.

The same prohibition applies to the material, fodder, products and all objects likely to be used as intermediaries in the propagation of one of these diseases when they are rampant in the country of consignment of these objects (article 141).

Article 143 subjects the import, the export and the transit of domestic animals to the cover by a certificate of origin and health delivered by the official veterinary doctor of the country of consignment of the animals. The President of the Republic determines by ordinance the information to give in this certificate and all the conditions it should be filled in.

Article 144 confers on the qualified authority the capacity to indicate the veterinary stations and the entry or exit quarantine stations opened, on a permanent or temporary basis, to the import, the export and the transit of domestic animals. It can fix the days and the opening hours of these stations. The qualified authority regulates all that relates to the conditions of stay of animals, the equipment and the correct operation of the entry veterinary station and the quarantine station which are annexed there. It prescribes prophylactic and diagnostic measures to practise at the entry or the exit of animals and the possible treatment to apply to the held animals.

Article 156 subjects to the veterinary inspection of imported, cooled, frozen, preserved fresh meats or prepared by salting, smoking, drying or in any other way, except for the meats said preserved enclosed in hermetically closed containers not exceeding a weight of 5 kg. This obligation, applicable to the meats coming from domestic animals, extends to, smoked, salted, dried, refrigerated fresh fish or prepared in any other way, as well as molluscs and shellfish, poultry and game (article 157).

Article 159 requires any person who wishes to import food products aimed at in articles 156 and 157 above to prior obtain the authorization of the qualified authority, , the agreed veterinary authority.

According to article 161, the imported meats will have to relate on each quarter or piece of meat or to labels sealed to them the stamps of the slaughter-house of origin as well as the slaughter date.

Article 162 subjects any meat import aimed to article 156 to the presentation of a certificate issued by an official veterinary doctor of the place of origin or port of shipment. An ordinance of the President of the Republic will stipulate all the information that this certificate must contain; this certificate will be given to the inspector in charge of carrying out the examination of this meat at the entry of the DRC.

Article 163 subjects the import of meats and foodstuffs of animal origin aimed at in articles 156 and 157 with the monitoring and to any inspection subsequent veterinary surgeon in all places where they will have been placed for sale or for conservation.

II.1.1.7.2. Legislation on the marking of livestock

The ordinance-law n°166/Vet of June 11, 1943 fixes the methods of marking of cattle.

The 1st article authorizes the province governors to impose, on opinion veterinary authorities, with any owner or keeper of cattle:

1° the marking of any bovid recognized unsuitable for livestock and intended to be sold to butchery;
2° the marking of good reproductive subjects and prohibition to slaughter them without prior authorization;
3° the castration of male subjects unsuitable for reproduction;
4° the declaration of the composition of their cattle.

II.1.1.7.3. Regulation of products and substances intended as animal feed

The subject is governed by the ordinance n°41-361 of October 27, 1953 as modified and supplemented to date - preparation and trade of the substances intended for animal feed.

According to the 1st article, substances intended for animals must be healthy, of fair standard commercial quality, not to contain an abnormal proportion of water, sand, clay, nor to have undergone a treatment modifying their nature or their qualities in a measure such as food do not match any more, by their composition, the normal product.

Article 3 prohibits importing, offering on sale, holding for sale, transporting, selling or delivering:

a) substances intended for for animal feed containing:
- coal or decay spores (ustilago and tilletia) in a proportion higher than that modern cleaning devices leave;
- seed or oil cake of purging nut, croton, illipe, mowrah, belladonna, jusquiame, bitter almonds, intoxicating ryegrass, shells of flour, pin, sawdust, peat, vegetable ivory, plaster, compounds of barium, salts ammoniacal, urea, mineral phosphate, carbon bisulphide, disinfecting substances and all other products toxic or harmful to animal health;
- mustard seed or oil (black, white or wild) of cameline, in proportion higher than 2% for their whole;
- more than 2% insoluble mineral matter in the hydrochloric acid normal solution.

b) food made up containing more than 1% of shells from peanuts, 1% of cocoa shells, 1% of rice balls;

c) substances intended for animal feed, spoiled, damaged or corrupted, without the buyer being made aware that they are corrupted for animal feed and that they must be reserved like "manure".

Article 4 prohibits any deterioration of simple or composite food after their production or their manufacturing under the conditions defined in articles 2 and 3.

Article 7 requires that any composite substance intended for the animal feed, offered on sale, held for sale, transported, sold or delivered have to be provided with a label mentioning:

1) the name or legal status of the manufacturer;

2) minimum guaranteed proportion, expressing the percentages of the essential nutritive elements (digestible rough albumin, grease, sugar, starch) contained in the mixture, with specification, with regard to the proteins, of the percentage in which the proteins of animal origin intervene;

3) maximum content of moisture, total mineral matters, crude fibre;

4) the date of manufacturing;

5) the destination (use) of food;

6) possibly: the presence of smut;

7) the nature and the content of the products sodium chloride, carbonate calcium, phosphate, charcoal, sulfur, when the content exceeds 2% for one of these products. However, the content for the whole of these products cannot exceed 6%;

8) the nature and content of other trace elements not mentioned above.

II.1.1.7.4. Phytosanitary regulation

On November 18, 2005, the President of the Republic signed the decree n°05/162 concerning phytosanitary regulation in the Democratic Republic of Congo.

This decree governs:

- the sanitary protection of plants and crop products by the prevention and the fight against harmful organisms as much at the level of their introduction as at that of their propagation on the national territory;
- the spreading and the popularization of appropriate techniques of phytosanitary protection;
- the organization of the approval of phytosanitary products and their control at the import, the placing on market and their use;
- the control at import and export of plants and crop products;
- the control of sanitary status of foodstuffs of plant or mineral origin likely to carry pathogenic germs.

Within the meaning of this decree, one understands by:

a) *Quranatine Organism*, a harmful organism which has a potential importance for the economy of the threatened zone and which is not yet present in this zone or which is present there but which is not largely spread and is subject to an official fight

b) *Phytosanitary products*, active substances and preparations containing one or more active substances which are intended to:

- fight harmful organisms to plants and crop products or prevent their action;
- To exert in a determined aim, a control action of on the vital processes of plants;
- To ensure the conservation of plants.

These are regarded as phytosanitary products: insecticides, fungicides, weedkillers, rongicides, rat poisons, acaricides, nematocides, plant hormones, vegetable oils.

c) *Crop products*, unprocessed products of plant origin including seeds as well as manufactured products which, given their nature or that of their transformation, can constitute a risk of harmful organisms appearing, being introduced or released;

d) *Plant Quarantine*, together of the activities and measures which aim at preventing the introduction and/or the release of organisms of forty or to ensure an official fight their opposition.

II.1.1.7.5. Restrictive measures to the import-export of forestry, plant and seed species

- *Ordinance n°53-5 of April 9, 1915 - relating to forest and shrubby species - measurement of conservation and safeguarding,*

This ordinance subjects any sending of seeds or plants imported to Congo to the issuing of an accompanying document consisting in a certificate of origin declaring these plants

free from any cryptogamic disease or infection agents. The farming elements known as affected by cryptogamic diseases or others will be treated at the expenses of the importer and, if necessary, will be destroyed.

- *Ordinance n°51-432 of August 24, 1959 – relating to the ban on exporting plantation material from Congo:*

The 1st article of this ordinance banned exporting seeds, fruits, seedlings, plants or parts of plants likely to be used as reproduction elements of referring to the following cultivated or spontaneous plants whatever the species, the variety, the hybrid or the line: Cocoa (Theobroma L), Hevea (Hevea, Aublet), Quinquina (Cinchona L), Coffee (Coffea L), Oil palm (Elaeis L), Tea (Thea L).

According to article 2 of this ordinance, the ban provided for the 1st article does not apply to:

1°) exports made in agreement with the Ministry in charge of Agriculture;

2°) exports in quantities lower than two kg made by the INERA within the framework international collaboration policy with regard to scientific research;

3°) exports of palm kernels in quantities higher than five tons.

- *Ordinance n°51-81 of February 22, 1960 – relating to the import of reproduction elements of tea plants in order to prevent the appearance of the Exobasidium vexans parasite (tea plant blister):*

The 1st article of this ordinance prohibits the import of plant material of tea plant or tea plant seeds originating from countries located outside Sub-Saharan Africa. However, it confers to the Minister in charge of Agriculture the power to grant exemptions for imports for scientific purposes and according to the conditions which he/she prescribes.

Article 2 of this ordinance authorizes the import of plant material of tea plant or tea plant seeds originating from countries located within Sub-Saharan Africa at the condition which the consignements are accompanied by a phytosanitary certificate specifying that the tea plant disease caused by Exobasidium Vexans was never discovered in the country of origin.

- *Ordinance n°51-167 of June 4, 1957 - relating to regulating the import of plantain trees and perforated polyethylene bags*

Under article 1st, the importation of seedlings of cultivated or wild banana trees is prohibited, except preliminary authorization of the Minister for agriculture. The article 1st (a) of this ordinance subordinates the importation of bananas and their admission in ordinary transit to the presentation of a certificate of origin the cryptogamic informant unscathed of any disease and agents of infection (...)

- *Ordinance-law n°72-030 of July 27, 1972 relating to the farming and trade of coffee*

According to the 1st article, the seeds, seedlings or fragments of seedlings of coffee-trees cannot be imported without the special authorization of the minister for Agriculture and in the conditions fixed by him/her. These conditions stipulate especially the presenting of a sanitary certificate of origin, the port of entry, possibly the inspection of seedlings at the entry of the Republic, the disinfection of seeds or any other measurement considered to be useful.

Article 13 of this ordinance-law entrusts the monopoly of export of coffee produced in the DRC to the National coffee Authority. To be allowed for export, the coffee must according to article 14:

a) meet the conditions of quality and packing fixed by the Minister for Agriculture;

b) be subject to a certificate of origin and quality established by the National coffee Authority.

It is important to stress that no provision of these various ordinances makes reference to plants, seeds, seedlings or transgenic reproduction materials intended for agriculture.

II.1.1.8. Compatibility of the legislation in force with the WTO Agreements

II.1.1.8.1. Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS)

During of the WTO ministerial Conference which was held in Doha in 2001, a Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health was adopted on September 14, 2001. Although not constituting an amendment to Trade-Related Aspects of Intellectual Property Rights, this decision of Ministers insists on the need of implementing and interpreting the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in a way favorable to public health, by promoting at the same time the access to the existing medicines and the development of new medicines. This distinct Declaration on TRIPS and public health is intended to answer the concerns about the possible consequences of the Agreement on the TRIPS on the access to medicines.

In other words, the Agreement on TRIPS does not prevent and should not prevent the governments of WTO Member States from acting to protect public health. But two provisions of this agreement deserve a detailed attention.

Article 41 requires Member States to ensure that their legislation comprises enforcement procedures on intellectual property rights and allows the granting of expeditious remedies. And to comply with the requirements of the Agreement on TRIPS, these procedures must be fair and equitable and allow the granting of decisions within reasonable time-limits. These decisions will have to be returned in writing and reasoned. Appeal should however be possible against any decision.

Concerning the art 27 which provides, notwithstanding the general spirit of the agreement for the Parties to the agreement to ensure the protection of plant varieties by patent by means of a sui generis system or by a combination of two (patent and sui generis), one notes that faced with this provision Art 12 subparagraph 5 of law 82-001 governing the patent rights does not require a specific remark as for its compatibility. It is likely however to restrict in an excessive way the possibilities of patent delivery, according to the way in which the concept of "body already existing in nature is interpreted". Indeed, according to the spirit of this article, the discovery of an existing body in nature is not regarded as patentable subject to some provisions and without damage.

What about then biotechnologies and patentability of human genome for example? Is it about an existing body in nature, where any human intervention, be either any genetic engineering whatever it is, is enough to exclude the application of article 12 subparagraph 5.

It results from it that the Congolese law will have to be adapted on this point especially by taking advantage of the gap left by Art 12 subparagraph 5 found in the law in fine.

Article 48, subparagraph 2, of the law n°82-001 of January 7, 1982 governing the patent rights is in conformity with article 34 of the Agreement on TRIPS. However, it is suitable to ensure that this provision is interpreted so that, in the event of patented process, any third has the right to obtain an identical product by a different process. Thus, a refrangible presumption should nevertheless be introduced into the Congolese legislation as follows: *"any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process"*

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Article 50 of the law n°82-001 of January 7, 1982 governing the patent rights devotes to the principle of transferability and transmissibility. However, there remains silent on the possibility of concluding licencing contracts as article 28 subparagraph 2 of TRIPS requires it which makes it possible to avoid any ambiguity.

Ultimately, many provisions of this law deserve an attentive second reading in order to adapt them to the requirements of the Agreement on TRIPS, especially the requirements of sections II, III and IV of the third part of the Agreement on TRIPS, relating to the civil procedures and administrative, the provisional measures and the special requirements relating to border measures. The law will have to also take into account the concern of ensuring the plant variety protection like the Bangui Agreement revised within the framework of the WTO Agreement on TRIPS, especially its appendix 10 relating to the plant variety protection with a view of especially securing the traditional innovations and practices likely to have a positive impact on the safeguarding of biodiversity.

II.1.1.8.2. Agreement on agriculture (article 12, 14)

The DRC does not have a law on agriculture as such. The only text in the process of being adopted is the bill on seeds initiated by the ministry in charge of agriculture and currently under discussion in the Cabinet. Other legislative provisions are applicable, especially the specific law on trade, various rules on pricing of agricultural produce, the circular n°DENI/CAB/03/0608/89 providing for control measures so as to guarantee the supplying and the distribution of goods as well as the interministerial decree n°016/CAB/FIN/MENIPME/96 of June 20, 1996 concerning the provisions applicable to the import of wheat and wheat flour (which provides for these products the mandatory subscription to import licence).

These provisions will have to be in harmony with article XI (2) (A) of the GATT Agreement which provides:

"Article XI - General Elimination of Quantitative Restrictions"

1. *No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or*

maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

The provisions of paragraph 1 of this Article shall not extend to the following:

(a) Export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party, to find a remedy to this situation…"

In this particular case, the upholding of this measure will have to be justified in accordance with prescribed point 2 (A) of this agreement. The GATT Agreement is not opposed to the fact that the Government takes restrictive measurements dictated by public health requirements.

II.1.1.8.3. Agreement on the application of sanitary and phytosanitary measures

Article 3 of the legislative decree n°74-13 of January 5, 1974 entrusts to the Congolese Authority of Control the mission of carrying out conformity and quality controls of goods.

Moreover, the Congolese Authority of Control (OCC) is governed by the decree n°78-219 of May 5, 1978. Under article 3 of its statutes, the Authority has the aim of carrying out, quantity and conformity quality controls of all goods, analyses of all samples and products, as well as technical controls of all the devices and works.

It can manage and run silos, bonded warehouses and customs warehouses.

To date, in comparison with the provisions of the Law n°73-009 of January 5, 1973 specific to trade, such as modified and supplemented to date, the OCC seems to have the responsibility of ensuring the control of any product likely to have harmful effects on public health by providing technical advice to the minister for an appropriate proposal.

It is appropriate to clarify competences of the OCC in the eyes of prescribed decrees n°05/161 and 05/162 of November 18, 2005 concerning respectively the creation of the Animal and Plant Quarantine Service and phytosanitary regulation.

This clarification is also is required in the eyes of the law n°04/015 of July 16, 2004 fixing the nomenclature of acts generating administrative, legal, national and participation revenues as well as their levying methods which respectively confers specific competences to the Ministries in charge of Agriculture and the Environment and imposes some formalities and the obtaining of documents to deliver by the aforementioned Ministries (cfr. above-mentional point 2.1.1.2: legal framework on trade and pricing)

The decree concerning phytosanitary regulation (provides for some provisions relating to the phytosanitary inspection and the formalities of preliminary quality control of plants and phytosanitary products) seems adapted to the requirements of the International Plant Protection Convention not yet ratified by the DRC.

Generally, there should not be apparent conflict between this decree and the provisions of the Agreement on the application of sanitary and phytosanitary measures. However, for being in conformity with article VIII (4) (g) and (h) of GATT Agreement, the various above-mentioned fees and formalities should be limited to the formalities of analyses and checks and with the documents relating to quarantine, sanitary inspection and disinfection.

Lastly, the DRC should formally notify WTO the national authority responsible for the implementation of the provisions on the notifications of sanitary and phytosanitary measures as provided in paragraph 10 of the Appendix B of the Agreement on the sanitary and phytosanitary measures.

II.1.1.8.4. Agreement on Technical Barriers to Trade (TBT)

The concerns raised in the area of the Agreement on the technical barriers to trade are almost similar with those posed within the framework of the examination of the compatibility of Congolese legislation with the provisions of the Agreement to the sanitary and phytosanitary measures. The article 13.2v of the TBT establishes a Committee on Technical Barriers to Trade made up of representatives of each member. The DRC is member of this Committee.

The implementation of these provisions is responsibility for the Congolese Authority of Control, as an organization of quality and quantity control and quantity to import-export goods, and the National Standardization Committee in accordance with the provisions of the legislative decree n°75-271 of August 1975.

It is appropriate to note however that the responsibilities between these two services are not clearly well shared.

However, the applicable texts in this particular case are those aimed within the framework of the Agreement on SPS. The other text which governs the activities of the OCC in the field of WTO is the Ministerial decree n°002/CAB/VPM/MEIC/91 of 18 February 18, 1991 concerning obligation of control by the Congolese Authority of Control of the industrial production.

Concerning the administration of WTO Agreement, it is appropriate to stress that the DRC has a national enquiry point as provided for in articles 10.1 and 10.3 of this agreement. It also has a national authority responsible for the notifications as provided for in article 10.10 of the WTO Agreement although in the eyes of the texts in force it is the Congolese Authority of Control and the ministry for the foreign trade.

II.1.1.8.5. Agreement on the pre-shipment inspection

Article 20 of the Law n°73-009 of January 5, 1973 specific to trade provides that *"apart from exception instituted by regulation, control, at the place of embarkation, of the quantity, the quality and the prices of goods and products dispatched bound for Congo is mandatory"*.

The main goal of the pre-shipment inspection is to allow control in the DRC of the quality and quantity of goods although it is also to guarantee the customs duties for the Treasury. This

objective thus fulfills the requirements of article 1.3 of the Agreement on the pre-shipment inspection under the terms of which *" Preshipment inspection activities are all activities relating to the verification of the quality, the quantity, the price, including currency exchange rate and financial terms, and/or the customs classification of goods to be exported to the territory of the user Member."*.

The implementation phase of this national framework and the biosafety law could be based on the experiment in progress in particular with regard to the national biosafety clearing house as well as the Competent National Authority in charge of processing import requests of GMOs/LMOs and products thereof.

II.1.1.8.6. Agreement on import licensing procedures

According to article 1.1 of the Agreement on the Import Licensing, the formalities of import licensing are defined as, " a*dministrative procedures used for the operation of import licensing regimes requiring the submission of an application or other documentation (other than that required for customs purposes)"*.

The regime on import licensing is used by the WTO members for the administration of quantitative restrictions, the price controls and the collection of the commercial statistics. It is important to stress that under article 1.3 of Import Licensing Agreement, *"The rules for import licensing procedures shall be neutral in application and administered in a fair and equitable manner"*. In this respect, the Ministerial Decree n°14/CAB/MIN/FIN&BUD/2000 of October 25, 2000 relating to import and export licensing and to regularizing of import and export licensing imposes to importers and exporters the obligation of obtaining an import-export licence.

II.1.2. Analysis of the legislation in force in comparison with the requirements of the Cartagena Protocol: Status assessment of the ratification multilateral environmental agreements

The DRC is Party to some multilateral agreements on the environment, by the fact of ratification or adherence. These are especially:

- The Convention on biological diversity;
- The Cartagena Protocol on Biosafety
- The United Nations Framework Convention on climatic changes
- The Kyoto Protocol
- The United Nations Convention to Combat Desertification
- Convention concerning the Protection of the World Cultural and Natural Heritage
- Convention on International Trade in Endangered Species of Wild Fauna and Flora
- (CITES);
- Ramsar Convention on Wetlands;
- International Convention on the Harmonization of Frontier Controls of Goods;
- The agreements signed within the framework of WTO.

Moreover, the DRC signed on February 5, 2005 the Treaty creating the COMIFAC as well as the convergence plan. It will have to thus engage in the process of the ratification of this treaty in accordance with the constitutional provisions.

It appropriate to emphasize that from some conventions, protocols and agreements referring to the questions of the genetically modified organisms emanate fundamental principles as obligatory legal standards that the Parties are obligated to respect. These are especially:

- *Convention on the biological diversity* whose article 8 fixes the protective and precautionary principles which impose the following obligations:
  - development of national strategies, plans or programmes for the conservation and the sutainable use of biodiversity (article 6);
  - identification and monitoring of biodiversity (article 7);
  - conservation (of biodiversity) in situ and ex situ (articles 8 and 9);
  - research and training (article 12);
  - public awareness and education (article 13);
  - impact assessment of development projects on biodiversity (article 14);
  - exchange of information (article 17);
  - scientific co-operation (article 19);
  - development of an international instrument having obligatory force intended for the prevention of biotechnological risks (article 19, paragraphs 1,2 and 3)

- *Cartagena Protocol on Biosafety*, which endorses the precautionary principle and makes obligation to Parties:
  - to regulate transfer, handling and use of GMOs/LMOs 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.
  - to create a biosafety clearing house and information-sharing (article 20);
  - the risk assessment (article 15) and their notification (article 17);
  - the set up of a competent national Authority and a focal Point (article 19);
  - the set up of an advance informed agreement, etc.

- *Agreements concluded within the framework of WTO*, especially:
  - the General Agreement on Tariffs and Trade
  - the Agreement on the application of sanitary and phytosanitary measures
  - the Agreement on agriculture
  - the Agreement on technical barriers to trade
  - the Agreement on pre-shipment inspection
  - the Agreement on Trade-related Aspects of Intellectual Protperty Rights
  - and the Agreement on the import licensing procedures; etc.

II.1.3. Status of the implementation of the Multilateral Environmental Agreements (MEA): Towards the transcribing in internal law of provisions of the Cartagena Protocol

II.1.3.1. Implementation plan or programme

Within the framework of the implementation of the multilateral agreements on the environment and with the support of the Global Environment Facility, the DRC already developed:

- the National Environmental Action Plan (PNAE);
- national Strategy and Action plan on biological Diversity;
- Activities entitling additional on biological Diversity
- the First national communication on climatic Changes;
- the second national Communication on climatic Changes;

Currently, the DRC benefits from a financial support from UNEP/GEF for the development of the National Biosafety Framework which project started since March 2005 and, since September 2006, the DRC is busy setting up its national Biosafety Clearing House. . Within the framework of the climatic changes, it also benefits from a support of UNDP for the implementation of the National Action plans for Adaptations (PANA) within the framework of climatic change. Moreover, within the framework of the setting of Convention to Combat Desertification, the GEF financed the development of the Action plan for the fight against the land degradation in the DRC.

At the level of institutional reform, the DRC since August 29, 2002 has acquired a new forest Code. With the support of UNEP/GEF, three bills are already developed, namely the outline bill on the environmental protection, the bill on water resources and the bill on fishery. These bills are yet to be formally approved by the Government before being submitted to the Parliament. Within the framework of the GEF/World Bank Project "Support to the rehabilitation of protected Areas", currently under management of the Congolese Institute for the Nature conservation, the DRC started in July 2005 the study on the amendment on the nature conservation in order to adapt it to the requirements of the implementation of Convention on biological diversity, of Convention on the protection of the world inheritance, of Ramsar Convention on the wetlands as well as the African Union Convention on the conservation of natural resources. This bill answers certain requirements already especially the setting up of general measures of biodiversity conservation, the communities local involvement in the preservation and sustainable management of biodiversity, the protection of knowledge, innovations and traditional practices likely to have an impact on the preservation of biodiversity, the fight against the introduction in the environment of exotic and/or dangerous species, etc.

With regard to the agreements concluded within the framework from the World Trade Organization, the assessment of compatibility of the national legislation with the provisions of these agreements will be done in point III.4.3.

II.1.3.2. Main advantages and weaknesses of the legislation regarding the requirements of the Cartagena Protocol

II.1.3.2.1. Advantages

The Congolese legislation in force presents some advantages within the framework of the implementation of the Cartagena Protocol on Biosafety.

On the constitutional level, it arises from article 53 of current Constitution which the Congolese constituent recognizes to any person the right to a healthy and favourable environment with its integral fulfilment and the obligation imposes to him to defend it. It also makes obligation to the Congolese State to take care of the environmental protection and public health. It gives, in its article 202, point 36, m, with the central capacity exclusive competence as regards

development of the legislation relating to (in particular) the artificial insemination in the human being, the *handling of genetic information* and organ and human tissue transplantations.

On the sanitary level, the legislation on the sanitary policing of domestic animals, on the production and trade of foodstuffs and on the trade that is already concerned with issues relating to public health in what they prescribe measures of setting in quarantine, restrictive measurements or import prohibition, the introduction and circulation in the DRC of some products or food products considered to be dangerous for health. Some provisions subordinate the import or the export of plants to the production of certificate of origin or the phytosanitary certificates and to the phytosanitary inspection. Other provisions oblige the labelling of some products or require packing them to preserve them from diseases and other harmful effects.

On the biodiversity conservation and forest research level, the forest Code governs forest research relating especially to management, the inventory, the development, the conservation, the *forest genetics* and *sylviculture*. It fixes restrictive measures on the introduction on the national territory of any forest, live or dead plant material, (prior authorization of the Minister or his/her delegate, on presentation of a certificate of origin and a phytosanitary certificate delivered by the competent organization of the country of consignment). It also provides for provisions on forest development being able to be directed in particular towards the sustainable production of all the forest products and products of biotechnology. It also devotes to the principle of involvement and participation of all the stakeholders in the development of the forest policy and the decision-making process on sustainable management of forests.

Moreover, there are several scattered legislative and regulatory texts being able to have an impact on the use of modern biotechnology, especially those relative: to food security, to the production and/or the trade of the foodstuffs, plants or vegetables, to the protected forest species, hygiene and safety in confined environment, the trade in general and the import and export of all kinds of goods in particular; to phytosanitary protection, etc.

II.1.3.2.2. Main weaknesses of the legislation

The DRC does not have a national legislation yet fulfilling the whole of the implementation requirements of the Cartagena Protocol with regard especially to:

- advance informed agreement procedure;
- transboundary movements of GMOs/LMOs (import, export and transit);
- handling, transfer, packing and identification (labelling) of GMOs/LMOs in accordance with the requirements of the Protocol;
- documentation accompanying GMOs/LMOs fulfilling the requirements of the Protocol;
- risk assessment and management procedures related to the use of GMOs/LMOs;
- nomination of the competent national authority in charge of management and control of the transboundary movements with the GMO, as well as national correspondents;
- information-sharing with the Biosafety Clearing House;
- management of confidential commercial information
- public awareness and involvement etc.

There is currently no legal or regulatory provision sets up an advance informed agreement procedure to trigger a notification of exports and a decision-making procedure relating to imports of GMOs/LMOs intended to be deliberately introduced into the environment of the importing party as articles 8, 9, 10 and 12 of the Protocol prescribe.

In the same way, in the absence of a framework law on the environmental protection and of guidelines on the environmental impact assessments, there is no procedure subjecting all GMOs/LMOs, including those which are pharmaceutical products, GMOs/LMOs intended to be used in confined environment, las well as those intended to be used directly as food or feed, to an risk assessment before making a decision relating to their import.

Concerning the import, the export and the transit of GMOs/LMOs, these areas continue to be governed by texts of general nature on import-export trade of goods. Moreover, the Congolese Authority of Control continues to ensure its mission of quality control of products and foodstuffs within the framework of the existing legislation. There is thus no legislation requiring a particular documentation having to accompany GMOs/LMOs and fulfilling the requirements of the Protocol.

It is also noted a lack of legislation in some sectors which can have an impact on the use of national biotechnology, especially the absence:

- of an outline law on agriculture as such as well as lawful texts on the seeds as well as fertilizers;
- of an outline law on health;
- of an outline law on the environmental protection
- of a regulation of the environmental impact assessments, etc.

In conclusion, several texts must be re-examined in order to adapt them to the requirements of the implementation of Cartagena Protocol, especially with regard to the institutional framework (creation and competences of the competent national authority and consultative organizations), the procedures for notification and advance informed agreement on any import of GMOs/LMOs, the documentation accompanying GMOs/LMOs, the decision procedure, the obligation of risk assessment and management, measures relating to the identification and labelling, the protection of confidential information of commercial nature, the regimes of liability, the offences and the sanctions, etc.

It should be that way particularly for some legislative and regulatory provisions in force which confer to some ministries and public organizations the missions of quality control of the goods (foodstuffs, pharmaceutical products, plants or plant material) for import or export.

In particular:

- Article 46 of the forest Code, with regard to the requirement to produce an authorization of the Ministry in charge of the forests or its delegate, on presentation of the certificate of origin and the phytosanitary health certificate issued by the competent organization of the country of consignment for the import of the forest plant material;
- Law specific to Trade and Statutes of the Congolese Authority of Control with regard to the quality control of the foodstuffs and pharmaceutical products;
- Decree of 2005 concerning phytosanitary regulation, in what it confers on the Ministry in charge of Agriculture and Livestock competence as regards control and inspection of the production and/or the trade of the plants or vegetables, of plantation or reproduction materials and measures relating to quarantine, to certificate of origin, to phytosanitary certificates and to phytosanitary inspection, etc;
- Decree of 1938 conferring on the Ministry in charge Agriculture and Livestock the application of the provisions relating to the sanitary policing of domestic animals, etc.

Lastly, the principle of public awareness and involvement in the decision-making process as regards the environment is devoted by the forest Code. This principle is also devoted by the National Plan of Environmental Action and the National Strategy and Action plan of biological Diversity.

In order to ensure the implementation of article 23 of the Protocol, it is important to define the mechanisms of public involvement in issues relating to the living modified organisms. In plain language, the DRC will have to promote and to facilitate the awareness, the education and the participation, as for the access to information on the transfer, the handling and the safe use of living modified organisms, access of the public to the Biosafety Clearing House will have to be encouraged.

The bill will have to define the national structure and the mechanisms of public consultation at the time of making decisions and of availing to it the results of these decisions. Within the framework of the national regulation and by respecting the confidential character of some information in accordance with the Protocol, the legislation will have to thus answer all these requirements.

II.2. Guidelines for the legal framework of biosafety management in the DRC

The development and the implementation of a national legal framework relating to biotechnological research, development, production, release, import, export and transit and use of the genetically modified organisms and derived products constitute one of the requirements of the implementation of the Cartagena Protocol.

To fulfill the requirements of the implementation of this protocol, the national biosafety legislation will have to approach the following important aspects: the scope, deliberate and unintentional movements, institution of advance informed agreement, information-sharing mechanisms, the protection of confidential information, risk assessment and management mechanisms, the plan of sanction prevention and repression, liability and redress regimes as well as the public participation mechanisms in the decision-making process.

II.2.1. Scope of the national biosafety law

Globally, the scope covers all the forms of use of the GMO and derived products, while focusing especially on their production, release, putting into circulation, import, handling, storage, transport and disposal.

One cannot either lose sight of the fact that the areas covered by biosafety management result at the same time from the provisions of the convention on biological diversity and the Cartagena Protocol on Biosafety and the need for taking into account, at the time of developing the national biosafety framework, all the various aspects of the national life.

II.2.2. Main guidelines of the national biosafety law: towards the domestication in the national laws of the DRC the provisions of the Cartagena Protocol on Biosafety

As a reminder, the major elements of the Protocol are:

- the advance informed agreement: it covers procedures for first intentional transbundary movements of the genetically modified organisms intended to be deliberately introduced into the environment;
- the procedure of advance information applicable to the transbundary movements of agricultural produce which contains genetically modified organisms intended to be used directly as food, feed, or for processing;
- the documentation accompanying the transboundary movements of genetically modified organisms;
- the Biosafety Clearing House;
- the national structure necessary for the implementation of the Protocol.

III. ADMINISTRATIVE AND INSTITUTIONAL SYSTEM

Before proceeding to the presentation of the administrative system for the implementation of the National Biosafety Framework in the DRC, it will be suitable to present a general table on applications of modern biotechnology in the World and make the status of administrative and institutuional structures having to underlie the administrative system of biosafety in the DRC.

III.1. Use of biotechnologies in the DRC

The objective pursued by modern biotechnology remains no doubt the search for more performing products: varieties or races. It should be noted that in practice, of many stages of the agri-food production processs are concerned with genetic engineering carried out on the plants, the animals, yeasts, etc. The agri-food sector remains more affected than that the seed or agrochemical one.

III.1.1. Importance of modern biotechnology in agriculture in the World

In the agricultural area, many studies show that the principal modifications introduced by transgenesis into the plants make it possible to modify agricultural practices and to improve the varieties. They relate primarily to:

- the tolerance to insects which allow plants to produce themselves a toxic protein to produce toxic proteins against the devastating insects maize, potatoes, cotton, etc). Such proteins are generally discovered in the soil bacterium Bacillus thuringiensis (Bt);
- the tolerance to hebicide (soya, maize, colza, cotton): in this case, the herbicide destroys plants, except transgenic plants;
- the tolerance to viruses (sweet pepper, papaw tree, marrow, potato, etc);
- the tolerance to the dryness (corn, corn), the plant pushes with very little water;
- the tolerance to salinity (cabbage), the plant grows even if the salinity rate of water is high.

The same studies also show that, by conferred character, it is the tolerance to herbicides which comes on top with 74% of all GMO plants, followed by the resistance to the insects (19%), and the double feature of resistance to the insects and tolerance to herbicides (7%).

Many areas are dedicated to transgenic farming. The main concerned species are especially: soya (63% of all the GMO plants), maize (19%), cotton (13%) and colza (5%). And on the level of transgenic features, the plants were devided up in two main categories: pesticide plants (99%) and plants resistant to diseases (1%).

III.1.2. Improvement in conditions of animal husbandry

The GMOs/LMOs can contribute to the improvement of the livestock conditions, in particular **in** the fight against animal diseases, and the improvement of the animal nutrition.

III.1.2.1. Fight against animal diseases

The transgenesis makes it possible to create LMOs intended for food which allow the production of recombining antibodies or vaccines for animals.

In order to increase, the resistance of the animal, the fight against the diseases could be made by modifying the genetic material of the animal consequently especially by the transgenic modification of descendants.

III.1.2.2. Improvement of animal nutrition

The use of the genetic engineering can also allow the improvement of the nutritional quality of the plants used as cattle feed, in particular by increasing the content amino acids (methionine, lysin, threonine, tryptophan) served in the form of nutritive complements.

III.1.3. Food processing industry sector

The introduction of new genes can contribute to the improvement of the quality of a food: conservation, better texture, improvement of organoleptic qualities, etc.

The studies also showed from GMOs/LMOs, enzymes can intervene in many manufactoring processes of agri-food products: dairy products, brewery products, wines, etc.

It was noted that various applications derive from the introduction of genes, especially:

- the modification of the nutrient content (especially the modification of the composition of oils in fatty acids in order to decrease the cardiovascular risks of accidents);
- the best conservation of products, especially transgenic vegetables with delayed maturation;
- the improvement of organoleptic qualities: for example certain genes involved in the change of color, an increase in sugar content, a reduction in acidity, the synthesis of flavours, etc.

III.1.4. Improvement of human health

Many studies or researches carried out show that the production of medicines by the use of the transgenic plants presents a future prospect in medicine.

The first case of commercial application of the genetic engineering remains the production in at the beginning of 1979 of insulin, thanks to the use of genetically modified bacteria in reactors. Other medicines of everyday usage are currently produced by recombined DNA technology (vaccines, enzymes, etc).

III.2. Early stages of a turning to biotechnologies in the DRC

In the DRC, one distinguishes four great sectors covered by modern biotechnologies. These are of the plant production, the livestock production, the agri-food sector and human health:

Some programmes are currently undertaken in this sector by the following public or private organizations:

III.2.1. Research Programmes

The project identified on the level of some public organizations having in their portfolio or carrying on activities relating to biotechnology in general or, to a lesser extent, biosafety. The inventory studies showed that some public organizations have portfolios or carry out activities including of the parts connected to biotechnology and to a lesser extent biosafety. Even better, it was noted the existence of research programs already carried out or in process of being carried out.

III.2.1.1. National Institute for Agronomic Study and Research (INERA)

The INERA conducts research activities in the area of modern biotechnologies:

- Research on the conservation of the phytogenetic resources
- Research and studies on the performance and the stability of the yields of genotypes of some cultivars (cotton, cassava, maize, rice, palm oil tree, coffee-tree, cacao-tree...) in various environments throughout the country
- Tissue Culture (station of INERA-M`vuazi)

At the INERA/Lubumbashi Station, five research programs are on-going: pisciculture, leguminous plants, roots and tubers plants, cereal program (maize, sorghum and rice), the natural resources conservation and management. The studies relating to the handling of genes and the questions related to biotechnological engineering were observed more on the level of maize than to that of the roots and tubers. For example, one finds several maize genotypes which are cultivated of which some would be genetically modified to incorporate resistance to the *maize streak vir*us diseases and other viruses. Several of these varieties would currently be in promotion or in release into peasant environment.

III.2.1.2. Agri-food Research Centre (CRAA)

The CRAA ensures the industrial research in the agri-food sector by developing the agricultural local raw materials, either by new techniques, or by the improvement of the artisan

or domestic techniques. The CRAA includes the following departments: the department of food sciences, the department of agriculture and livestock, the technico-economic department, the department of quality control, the department of water quality analyses (water physicochemistry).

The main areas of research of the CRAA are as follows: nutrition and food, food technology and biotechnology. The CRAA houses several research laboratories of which the main ones are cited below:

- a research laboratory in food sciences;
- a research laboratory in food industries and biotechnology;
- a research laboratory in agriculture and livestock;
- a laboratory of bacteriology;
- a laboratory of quality control;
- a laboratory of spectroscopy.

The CRAA is among the Centres of the country which carries out scientific research in the food field.

It should be noted that these laboratories no longer fulfill the requirements of research in biotechnology not only for their outdatedness, but also for lack of materials and modern equipment of laboratory to carry out studies of molecular biology, biotechnology and biosafety. It should be equipped with modern equipment such as PRCs machines, the detection devices of virus diseases, and RNA analyses, the machines to make the DNA sequencing.

Currently, the only project in progress at the CRAA relates to enzymatic research on the MUNKOYO (fermented drink).

III.2.1.3. National Seed Service (SENASEM)

Among the duties of the National Seed Service one can note the control of the following activities:

- the design and quality control of the national seed production;
- the set up and the control of seed multiplication farms;
- the establishing of the production and multiplication plan of having to lead to the certification of the seeds;
- the planning and programming of acquisition of the basic genetic material at the level of the research structures. This office does not have any laboratory of molecular biology.

III.2.1.4. Maize Research Centre (CRM)

The CRM has many activities among which one has noted:

- Research on maize in order to obtain high and stable yields under various agro-ecological conditions and the marketing of the fruits of its research;
- The Production of high yield maize.

The CRM has several varieties (composite and lineage) in spreading, commercial and under development.

III.2.1.5. National Livestock Development Authority (ONDE)

The ONDE is in charge of promotion of livestock development and especially to improve of the production, the zoo-sanitary protection, the conditioning of products and marketing. It is in charge moreover of restoration, exploitation and management of all the ranches, of all the veterinary farms and laboratories belonging to the State that it can entrust management.

Currently, research at ONDE relates primarily to production improvement, in particular in the areas of artificial insemination, pastures and zoosanitary protection.

III.2.1.6. National Institute of Biomedical Research (INRB)

Research tasks are carried out at INRB in thefollowing areas:

- Human and veterinary biological and biochemical analyses;
- Applied research especially in research operations having an impact on primary health care, wide-spread endemic diseases and emerging and re-emerging contagious diseases;
- Epidemiologic investigations;
- national reference centre of the techniques especially through the quality control programmes for medical and health analysis laboratories;
- Main research areas: malaria, trypanosomiasis, HIV/AIDS infections, bacteriological resistance to antibiotics, hemorrhagic fevers, cassava intoxications, medicinal plants.

The INRB has laboratories of bacteriology, immunology, biochemistry, hematology, anatomy-pathology, Entomology and Toxicology. Let us note that within the framework of the studies on the hemorrhagic fevers, the INRB carries out work on the genetic material of viruses. This institution thus has some materials for the DNA analysis.

III.2.1.7. National Natural Science Resesarch Centre (CRSN-Lwiro)

This institution has several departments: department of biomedical research with a paediatric research hospital, the department of the social studies, the department of documentation and the department of geophysics. This department is in charge especially of the study of volcanos of Eastern DRC, the department of geology, the department of biology. In this last department, one finds biological research activities such as the inventory and conservation of aquatic and terrestrial ecosystems, defense of plants, biotechnology, agricultural and veterinary entomology, veterinary medicine, the livestock, the mammalogy (rodentology and primatology), ornithology, herpetology, phytochemistry, limnology, fishery and pisciculture and marine biology (Uvira station). In this department, one finds one of largest national Herbarium at the botany section. There are also several attached divisions such as the agricultural service and the forest research station of Irangi.

At CRSN-Lwiro, the Centre is having the greatest number of the qualified scientific personnel in the country; one finds some preliminary work concerning molecular biology and biotechnology in general.

III.2.1.8. General Atomic Energy Commission / Regional Nuclear Studies Centre of Kinshasa (CGEA / CREN-K.)

The CGEA is a public institution which has the mission of peaceful use of Nuclear Energy in industry, agriculture, health, the environment, etc. It is equipped with a nuclear reactor and has a Laboratory of Microbiology, Biotechnology and Molecular Biology, of Genetics and Plant Improvement, of soil Physics and Hydrology, of food Biochemistry, a central laboratory of analyses, a laboratory of immunochemical marking, animal hormones dosage and a service of protection against radiation.

The Laboratory of Biotechnology and molecular Biology has a qualified team of researchers and equipment suitable for *in vitro* tissue culture and molecular analyses within the framework of co-operation with International Atomic Energy Agency (IAEA). The undertaken activities are focused in the improvement of the food and medicinal plants by *in vitro* tissue culture techniques associated with radio-induced mutations, the *in vitro* production of secondary metabolites, the genetic engineering of the plants and research on phytobiology including the symbiotic nitrogen fixation.

1. Food plants

Several food plants are used of which cassava (*Manihot esculentum*), banana tree (*Musa* sp), the cajan pea (*Cajanus cajan*), *Treculia africana*, etc.

Research is directed towards:

- the production of healthy plants by meristem culture; the micropropagating, the somatic embryogenesis, etc
- the characterization of the mutants obtained by gamma-irradiation or genetic transformation;
- the selection of performing mutants.

2. Medicinal plants

The medicinal plants such as *Phyllanthus niruri, Euphorbia hirta, Jatropha curcas* and *Cassia alata* are studied for their production in secondary metabolites with high biological activity.

Within the framework of the technical assistance with the IAEA, the project in progress relates to the improvement of productivity of secondary metabolites of P*hyllanthus niruri* (Euphorbiaceae) by *in vitro* culture associated the gamma-irradiation. *P. niruri* is used by traditional doctors against malaria. The antiplasmodial activity was determined by the Faculty of Pharmacy of the University of Kinshasa. Recent research in the world showed that it contains also an activity against hepatitis and the HIV reverse transcriptase.

In collaboration with the laboratory of Pharmacology of the Faculty of Pharmacy, research is carried out on:
- the callogenesis of foliar explants and young stems beforehand irradiated or not;
- the phytochemical analyses (HPLC, etc.) of the mother plant and callus obtained;
- the study of the antiplasmodial *in vitro* activity of the metabolites produced;
- the regeneration of plants by micropropagation or by in vitro germination of seeds so as for their domestication;

- the study of genetic stability;
- the study of toxicity, etc.

Other studies in progress relate to the development of the transgenic roots "Hairy root" by means of *Agrobacterium rhizogenesis* to produce more stable secondary metabolites.

3. Other researches

Other research relates especially to:

- the insolation and characterization of the indigenous *Rhizobium* stems for their efficiency in nitrogen fixation process;
- the qualitative and quantitative determination of nitrogen of the air fixed by *Rhizobium* for roots of leguminous plants.

III.2.1.9. University of Kinshasa

Created in 1954, the University of Kinshasa counts several Faculties of which especially the Faculties of Sciences, Medicine, Pharmacy and Agronomic Sciences. The research undertaken to the Faculty of Sciences relates primarily to:

- The cassava Biotechnology, especially the development of the micro leavens responsible for the softening of cassava, the development of organoleptic properties, the study of toxicity by elimination of cyanogen glycosides. Future research is directed towards the development of a biotechnological process of fermentation of cassava applicable at the industrial scale, the use in this process of a nonpathogenic microferment, inoffensive to the consumers' health, therefore, the improvement of quality of cassava products and the retting duration in directed fermentation;
- The *in vitro* culture of edible mushrooms;
- Food Biochemical analyses and the development of weaning food;
- The Studies on the environmental ecotoxicologist and Biotechnologies.

At the Faculty of Pharmacy, there is a toxicological analysis laboratory of medicine (LACOMEDA). It is also carried out there: a research project on antimalaric plants in its laboratory of Pharmacognosy and a project on the phytochemical study, with the in vitro evaluation of antiplasmodial activity of the extracts, and their toxicity.

The Agronomic Faculty of Science is interested amongst other things in the conservation of the phytogenetic resources, the phytopathology of the coffee-tree, etc.

III3.2.1.10. University of Kisangani

The Faculty of Biological Sciences undertakes through its departments various activities referring to biotechnology and the biosafety. One can cite by way of examples, biochemistry of the substances, the studies of the antimicrobic activities of plants used in Traditional Medicine, the genetics and the improvement of the plants, microbial and plant biotechnology, the ecology and the study of biodiversity, the traditional pharmacopeia, etc.

A germplasm of the banana tree is found at the Faculty of Sciences where the micropropagation of the banana tree, "foumbwa", is carried out by using imported material (cultivars of the banana tree). The multiplication of the banana tree is done by decapitation of the apical meristem, somatic embryogenesis, in vitro culture of the banana tree.

There are also tests of application of the *Bt Bacillus thurungiensis* Bt on the banana tree, the transformation of cassava by bacterium, mushroom for the reduction of the cyanide rate and the extraction of the flour is also current activities at the Faculty of Sciences.

The Faculty of Sciences has a laboratory suitable for research in biotechnologie/biosafety, as well as equipment such as the spectrophotometer and the chromatograph. To make this laboratory operational and ready to make biotechnological analyses, this faculty needs, among others radioactive equipment, radioactive probes, PCR for the DNA polymerase, Thermal Cyclers, Monochromic photographic, Micropipette, Centrifugators, Incubators, Fridges, Homogenizers, Bioinformatic softwares and some reagents.

III.2.2. Use of biotechnology in the agri-food sector

Generally, the use of biotechnologies is limited in the DRC to traditional biotechnologies in the following areas:

- the production of beer and soda beverages, most of the raw materials is imported;
- the transformation and the conditioning of dairy products based primarily on the import of raw materials;
- the artisan production of fermented food (traditional cheese...) and of local drinks (yoghourt, curdled milk, palm wine, etc)
- the manufacturing of weaning food.

III.2.3. GMO development and production

The situation could not make it possible to collect enough information on the development of GMOs/LMOs on Congolese territory especially in the health, livestock, forestry and even industry sector.

III.2.4. Import of GMOs/LMOs and products thereof

To face the chronic food challenge, the DRC resorts to the import of some foodstuffs. However, many importing business people who are unaware of the exact nature of the products imported so much as it is difficult to establish a difference between conventional products and those containing of LMOs, for lack of labelling of the latter.

All in all, the following food products and products imported in the DRC are likely to contain LMOs or their derivatives:

1) ***Food*** : maize oil (maize), colza-sunflower oil (colza), biscuit (soya flour, maize grit, soya oil), chips (potato), wheat flour and grit, maize flour and grit, etc;
2) ***Drinks*** : aromatised mineral water (artificial sweetener), carot juice (artificial sweetener),
3) ***Sauces*** : Ketchup (transgenic tomatoes) ;
4) ***Canned food*** : Corned Beef Exeter (hormones), Krasdal Maize and Krasdal Beet (Crystal),

5) ***Pharmaceutical products*** : Insulin (transgenic yeast and E coli), vaccines against the rabies (transgenic);
6) ***Animal feed***: soya oil cake, egg concentrate, concentrate flesh, flesh Premix, flesh Premix;
7) ***Cosmetic products***: beauty lotion (plant extracts), soaps dermic (wheat kind of oil), pomade for capillary care (wheat kind of oil), etc.

III.3. Status of the institutional and administrative framework appropriate for carrying out a biosafety programme in the DRC

III.3.1. The Ministry of the Environment

The Decree n° 03/O27 of September 16, 2003 fixing duties of the Ministries entrusts to the Minister Environment the following duties:

- the management of the forests, the zoological and botanical gardens;
- the regulation of hunting and fishing, the protection of fauna and flora;
- the promotion and coordination of all the activities relating to the environment and nature conservation, exploitation of forest and watery resources;
- the creation of the human settlements by the set up of the green areas and amusement parks;
- the carrying of the environmental impact assessments, industrial pollution and the cleansing of the territory;
- the creation and the management of the protected areas and related reserves (national parks, watery resource and hunting preserves);
- the creation and the management of the stations known as of catching wild fauna;
- the creation and the management of water and forest ecosystems, etc.

In the exercise of its missions, the ministry in charge of the Environment comprises within it a Secretariat-general for the Environment and the Nature conservation well as some organic services and departments:

III.3.1.1. Department of Faunal resources and Hunting

This direction has the roles of:

- safeguarding the faunal resources and their habitats;
- rationally managing these faunal resources in connection with the national and international standards of conservation of faunal resources in hunting reserves and areas as well as in free zones;
- evaluating the existing wild animal populations by inventories;
- applying the exploitation standards according to science evolution;
- determining sample quotas for sporting hunting, the commercial capture, the rearing in ranch, export;
- realizing receipts on behalf of the Treasury;
- managing the data bank.

Within the framework of the implementation of the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Department ensures the missions of Management organ of CITES for the DRC.

III.3.1.2. Department of Human Settlements and Environment Protection

The Department of the Human settlements and Environmental protection is in charge of ensuring and following up on tasks aimed at cleaning of the environment, the set up of spaces and environmental protection, such as the evaluation of effects of human activities on the environment, the prevention, the retention and the fight against all the harmful effects due to air and soil, water pollution.

This department has, within it, a division of environmental standards, which is in charge especially of the development of means and techniques to evaluate the consequences of development projects on the environment and of the carrying out of of the impact assessment consultation in order to provide technical opinions, etc.

Due lack of a law on the environmental protection, this department still does not have with the standards of environmental impact assessments. Likewise, lack of means in financial resources and competences regarding development of assessment, attenuation and monitoring methodologies, its laboratory of environmental engineering and of environmental impact assessments is still not operational.

III.3.1.3. National Reafforestation Service

This service is in charge of the implementation of the national policy of reafforestation replenishment forest resources, including the normative aspects related to it. For this reason, article 77 of the forest Code entrusts to the administration in charged of forests the mission of ensuring the replensihment of forests and the application of the of natural regeneration and reafforestation programmes which it updates periodically.

The reafforestation operations are financed among others by resources of the Funds of Reconstitution of the forest Capital, become Fonds national forester. It is suitable to note that to date, there is no national forest reafforestation strategy paper in the DRC. However the Minister signed the Ministerial decree n°CAB/MIN/AFFET/049/2003 of March 18, 2003 concerning promotion measures of reafforestation work.

III.3.1.4. National Environment Information Centre (CNIE)

Created since 1998, the National Environment Information Centre has as a main objective of gathering, spreading and facilitating the information flow aimed at the environmental protection by the appropriate means. Thus, its mandate is to inform the decision makers as well as the public opinion on the dangers of environmental pollution and to put forward the corrective measures aimed at minimizing the risks of this degradation.

Given the role that this centre has to play within the framework of public information and awareness, its personnel will have to benefit from a capacity building programme and from a support of necessary equipment in order to allow it to fulfill its missions appropriately: computer equipement, Internet network, appropriate communication system, etc.

III.3.1.5. Department of Sustainable Development

This department is in charge mainly of the follow-up and the implementation of the three international conventions resulting from Rio in 1992, namely the convention on biological diversity, convention on climatic change and convention to combat desrtification.

In its capacity as GEF Operational Focal Point in the DRC, this department played a major role especially in the development of the National Environmental Plan Action (PNAE), the Strategy and Action plan of biological Diversity and the First national Communications on Climatic Change and of the National Action plans for Adaptations (PANA) within the framework of the climatic changes as well as in the development of the Action plan for the Fight against Soil Degradation in the DRC. It currently plays the coordination role in the implementation of the UNEP/GEF Project "Development of a national Biosafety Framework in the DRC".

Given that this technical department is going to institutionally, play the role of the Competent National Authority, its personnel will have to benefit from a support program for capacity building envisaged in this document. The same goes for a support of necessary equipment so as to enable it to fulfill its missions appropriately: computer equipement, Internet network, appropriate communication system, etc.

III.3.2. Ministry of Agriculture

The Ministry of Agriculture intervenes especially in:

- the agricultural production and food security;
- the planning of national production objectives in the areas of agriculture, fishing, pisciculture, sylviculture and animal rearing;
- the supervision of peasant associations;
- the development of national policy as regards agriculture, fishing and animal rearing;
- the zoosanitary monitoring and the management of animal and plant quarantine within the country and at the border posts as well as the permanent update regulatory measures related to it, etc (it relates to mainly zoosanitary control of wild fauna and flora species and exotic invading species).

Particular texts confer other dutiess on the ministry in charge of agriculture. It acts especially on the decree n°05/162 of November 18, 2005 concerning phytosanitary regulation in the Democratic Republic of Congo and the decree of July 28, 1938 relating to the sanitary policing of domestic animals, as modified and supplemented to date.

This ministry has under its supervision a considerable number of departments, services and institutions involved in the activities likely to have an impact on the management of modern biotechnologies and whose duties must be re-examined in order to avoid conflicts of competence. These are especially the following Directorates and Departments:

III.3.3.1. Central Veterinary Laboratory

The Veterinary Laboratory of Kinshasa (LABOVETKIN), the single functional one of the two currently available in the DRC, is actively involved in the routine and research handling in the area of biotechnology thanks to the assistance of the International Atomic Energy Agency (IAEA) within the framework of the use of radioisotopes for peaceful purposes. Besides this technical aid which consists primarily of equipment, training of technicians and scientists, and experts advice, the LABOVETKIN benefits from other scientific collaborations initiated by some of its scientists through topics and protocols of international nature thanks to arrangements with some foreign Universities and research institutes of international renown. It is among others the case with the University of London through the "Royal Veterinary College", the Institute of Tropical Medicine of Antwerp in Belgium, the Veterinary Institute of Onderstepoort in South Africa, and soon the Center for Disease Control in Atlanta in the USA.

Like the laboratory of animal health, the LABOVETKIN, constitutes a technical support to livestock production as well as protection of public health in relation to zoonotic diseases.

In relation to this mission, the objectives of this laboratory are defined as follows:

- To contribute to the control and eradication of animal diseases by their diagnoses and investigations through handling of routine
- To produce biological vaccines and other products intended to fight the major animal epidemics characterized by a massive destruction power of cattle, at a great speed, and at a strong spreading capacity beyond the national borders
- To take part in the quality control of food and especially of foodstuffs of animal origin;
- To undertake veterinary research regarding the above-mentioned subjects and areas;
- To supervise the cattle breeders and
- To supervise the trainee pupils and students a future career in the area of animal production and health.

With an aim of better fulfilling this mission, the LABOVETKIN has seven (7) technical services namely: General Pathology, Parasitology, Bacteriology (clinical and production of the bacterial vaccines), Virology (clinics and production of viral vaccines), Toxicology (biochemistry and bromatology), Unit of Molecular Biology, and Epizootiology.

Almost all scientific collaboration with above mentioned partners is focused on biotechnological approach of handling of viruses, mycoplasmes, bacteria, and some blood or stools protozoa.

Most of this collaboration consists of genomics and the proteomics applied to causal agents of animal diseases as indicated above. It acts more precisely of their molecular characterization by the detection of their DNAs and their antigens, as well as set up of their epidemiologic links. For this purpose, the LABOVETKIN has state-of-the-art Kits allowing the preparation of the samples intended for the molecular analyses, with the extraction of the nucleic acids and amino acids, with their amplification, their dimensioning, their visualization and their packaging for forwarding towards World referenceLaboratories for very thorough studies.

Thanks to the support of the World Bank, the LABOVETKIN saw its infrastructure rehabilitated and to the favour of this rehabilitation, the number of the rooms of the Unit of Biology went from 3 to 6, thus fulfilling the international requirements in relation to the PCR laboratories.

It is advisable however to announce that alot remains to be done with regards biosafety.

III.3.2.2. Animal and Plant Quarantine Service

Created according to the decree n°05/161 of November 18, 2005, the Animal and Plant Quarantine Service (S.Q.A.V) is placed under the supervision of the Ministry in charge of Agriculture, Fishery and Livestock. It carries out its activities within the national borders in the customs agencies and at the border posts of the Democratic Republic of Congo.

The Animal and Plant Quarantine Service has for aim to ensure the **zoosanitary** and phytosanitary monitoring as well as animal and plant quarantine management on the whole of the national territory. It ensures, consequently, the zoosanitary and phytosanitary policing.

To that effect, this service has the roles of:

- ensuring the control of the zoosanitary and phytosanitary documents accompanying the animals and the plants, like their derived products at the level of the border posts;
- guaranteeing the control of the entry and exit movements of animals, plants and their derived products in order to prevent the introduction, the release and the propagation of diseases and/or pathogenic germs and harmful to human, animal and plant health;
- carrying out veterinary and phytosanitary inspection of foodstuffs of animal, plant and mineral origin;
- taking samples of products and by-products derived from animals and plants for their macroscopic and/or microscopic analysis;
- taking care of quality control of medicines and veterinary and livestock products as well as phytosanitary products (agricultural and livestock inputs);
- controlling seeds and genetic materials of animal and plant origin as well as materials and means of transport of the animals, plants and their derived products;
- proceeding to disinfection, rodent and insect control of the machines being used for transporting animals and plants as well as their derived products;
- ordering the seizure, repression, setting in quarantine or treatment and, should that be, the destruction of animals (sanitary slaughter), plants, foodstuffs, veterinary medicines and phytosanitary products, found out-of-date, contaminated, soiled, sick or harmful to the human being, the animal or the plant;
- carrying out the certification of animals, plants and their by-products, seeds, agricultural and veterinary or livestock inputs and biological organisms of control and this, in the presence of recipients of orders or owners of products;
- applying sanctions towards of the contraveners to these provisions.

In the carrying of its missions, the service will solicit, where necessary, the csupport of specialized services of other ministries, especially those of the Ministry of Health.

The organization and the operation of the service are regulated by way of decree of the Minister having agriculture, fishery and livestock in its duties. In order to avoid any conflict of competence as regards zoosanitary and phytosanitary monitoring as well as management of

animal and plant quarantine on the whole of the national territory, it is necessary to clarify the missions entrusted to the Department of Plant Production and Health and to the Department of Animal Production and Health taking into consideration those entrusted to the Animal and Plant Quarantine Service.

III.3.2.3. National Seed Service (SENASEM)

The National Seed Service was created within the Ministry of Agriculture by departmental Decree n°00003/ECB/AGRIDAL/84 of May 12, 1984.

The Service is in charge of the design and quality control of the national seed production. It is especially in charge of:

- setting up and controlling of seed multiplication farms;
- ensuring the planning and the programming of controlled and certified seed production at the level of seed multiplication farms;
- establishing of the production and multiplication plan having to lead to the certification of seeds;
- ensuring the planning and the programming of acquisition of the basic genetic material the level of research structures;
- ensuring the quality control of all the seeds produced or introduced on the national territory.

Currently, the mission of this office runs up against the absence of a legislation on seeds, which should set the standards of quality and production as well as certification of seeds. This deficiency is in the process of being filled, because the Ministry in charge of Agriculture has just submitted to the Government a bill on seeds.

There is a ministerial decree taken in 1997 concering the application of guidelines with regards to production, conditioning and storage of the seeds as well as on the quality control of seeds introduced in the DRC.

III.3.2.4. Department of Animal Production and Health

According to the provisions of the Decree n°03/027 of 16 September 16, 2003 above mentioned and to the organic Framework of the Ministry in charge of Agriculture, the Department of the Animal Production and Health is in charge of zoosanitary monitoring and animal and plant quarantine management within the country and at border posts and permanent update of regulatory measures relating to it.

It has in particular the mission of:

1) developing and supervising the implementation of the national policy and strategies in the area of the livestock productions;
2) carrying out, making carry out and ensurng the follow-up of the Government decisions as regards livestock productions, especially for the improvement and the management of the pastures to which the control of animal feed is added;

3) declaring to the OIE and tp the UA-BIRA (African Union - International Office of the Animal Resources) major animal epidemics, especially zoonoses;
4) ensuring the sanitary policing of foodstuffs of animal origin at the production, the import, the export, the warehousing, the processing and the marketing;

This department is confronted with some constraints, especially:

1) the absence of up to date legislative or regulatory texts on the matter;
2) the absence of services of this department at the border posts in order to ensure the control measures relating to animal and plant quarantine;
3) the difficulty of accessing sanitary information published on Internet by the OIE (World Organization for Animal Health);
4) the absence of a fast alarm system in the event of major outbreak on the national territory; etc.

III.3.2.5. Department of Plant Production and Health

The Department of Plant Production and Health is in charge of developing and supervising the implementation of the national policy and strategies in the area of plant productions.

It is for this purpose entrusted especially to:

1) ensure the control and regulation relating to plant protection, the standardization and certification of seeds and the management of calamities;
2) ensure the phytosanitary control, the quality control of the products of plant origin;
3) organize the fight campaign against farming predations; etc.

III.3.2.6. National Fish farming Service (SENAQUA)

Governed by the Decree n°0055bis/CAB/MINAGRIDAR/92 of August 12, 1992, the SENAQUA received missions of:

1) managing all the fish farming stations;
2) assessing the fish farming resources and their management methods;
3) assisting the Authority in charge on the guideline of the national fish farming policy;
4) coordinating the whole of fish farming projects initiated by national or international co-operation projects and programmes;
5) relaunching the industrial research in the area of fish farming.

Within the framework of the implementation of this national biosafety framework, a need has been identified for capacity building this service to better manage the biotechnological risks**.**

III.3.2.7. National Agricultural Extension Service (SNV)

Governed by the departmental Decree n°0045/ECB/DDR/89 of June 6, 1989, the SNV has especially the role of implementing the governmental policy with regards to agricultural extension service.

III.3.2.8. National Service of Veterinary Intrants (SENIVEL)

Created by decree n°005 of October 24, 2001, the SENIVEL has as missions:

1) to suspply the country in veterinary products and livestock material and their distribution throughout the territory;
2) to improve the access to intrants with the assistance of the operators, the private importers, the groupings of stockbreeders, veterinary pharmacists;
3) to monitor and control the quality of veterinary products put on the market;
4) to supervise technical activities (organizing zoosanitary activities at grassroots and monitoring of the distribution network of intrants);
5) to coordinate the activities of the programme to fight against epizootic diseases and epidemiologic monitoring.

III.3.2.9. Maize Research Centre (CRM)

The Maize Research Centre was created by government order n°90-054 of February 17, 1990 as a public institution of scientific and commercial nature and has a jursitic personality. According to its article 2, the Maize Research Centre has as objective to conduct all research on Maize in order to obtain high and stable yields under various agroecologic conditions and to market the fruits of its research.

The Center is especially in charge of:

- creating high yield hybrid maize;
- producing, conditioning and storing basic seeds and their marketing;
- studying and popularizing maize farming techniques.

III.3.2.10. National Livestock Development Authority (ONDE)

The National Livestock Development Authority is governed by the government order n°78-213 of May 5, 1978. According to article 3 of its statutes, the National Livestock Development Authority has as mission promoting the development of the livestock and especially improving the production, the zoosanitary protection, the conditioning of products and marketing.

The authority is in charge of moreover restoring, exploiting and managing all the ranches, of all the veterinary farms and laboratories belonging to the State that it can entrust to it the management.

At the human resources level, the ONDE has a technical staff made up of veterinary doctors with a good experience in the area of the artificial insemination as well as agricultural engineers zootechnicians. The zoosanitary protection is ensured by veterinary doctors. For the moment, the ONDE has 8 veterinary doctors, 3 veterinary agricultural engineers zootechnicians, 10 assistant veterinarians and 6 technicians agronomists.

At the technical level, the ONDE does not have specific guidelines governing the use of substances or products intended for cattle feed more especially as cattle only feeds on natural grass with food supplement consisting in rock salt or cooking salt.

At present, the ONDE does not make research on genetically modified cattle feed. It greatly needs support in capacity building.

III.3.2.11. National Service of Animal Genetic Resources

This service has as mission to make an inventory on the whole of the national territory the domesticable and consumable animal species which are in the process of disappearance. Nevertheless, the national expertise consisting of basic knowledge in molecular genetics is non-existent.

III.3.3. Ministry of Rural Development

The Ministry of rural development is in charge of by decree of the following missions:

- development and control of rural development policies and strategies;
- development and equipment of rural areas;
- coordination and integration of development programmes in rural environment;
- promotion and support of fishery in rural environment, etc.

With the technical support of FAO, the Ministry prepared in August 2001 a document of Operational Strategy and Priority Actions for the development of the rural sector in the DRC, which integrates at the same time the forester, agricultural, fishery and rural development sectors.

III.3.4. Ministry of Health

The decree instituting the Ministry of health confers to it the following duties:

- Organization, creation and control of medical and pharmaceutical public services;
- Organization of the medical technical teaching at the secondary level (Nursing School A2);
- Approval and technical control of medico-sanitary, pharmaceutical instituions, laboratories and medical teaching technical institutions;
- Hygiene and public health;
- Medical and sanitary inspection and prevention, including in school and professional circles and;
- Medical assitance in medical emergencies and humanitarian medical actions;
- Medical policing at borders (human and international quarantine);
- Organization, regulation and promotion of traditional medicine, including the area of medicinal plants;
- Organization of the health system;
- Development of standards relating to health;
- Analysis and control food and medicines, etc.

Among the duties in connection with the preservation of biological diversity appearespecially the organization, the regulation and the promotion of traditional medicine including the area of medicinal plants, etc. For that matter, it is important to recall that many Congolese living as much in town as in rural areas resort to medicinal plants for their curative

virtue that is already recognized by scientific analysts. Even the households which have access to modern medicine also resort to the traditional pharmacopeia. The *barks of Prumus africanus* and *Hymenocardia acida* are used in pharmaceutical industry.

The Ministry of Health houses within it the Research Institute in Health Sciences (IRSS) and the National Biomedical Research Institute (INRB). The project of building the INRB was adopted since 1973 during the work of the Joint Franco-Congolese Committee. It however was built only in 1975 and was inaugurated on December 8, 1984. As for the activities of the Institute they only began in 1985. Even though of this institution's statutes are not clearly defined by regulation.

The INRB has as mission:

- to conduct human and veterinary biological and biochemical analyses;
- to carry out industrial research, especially operations research having an impact on primary health care, wide-spread endemic diseases and the emergent contagious diseases and réemergentes;
- to undertake activities of monitoring of the transmissible diseases, through its laboratory of bacteriology;
- to make epidemiologic investigations;
- to conduct environmental watch activities in order to secure the quality control of water, food, drinks and pharmaceutical products;
- to ensure the role of national reference Centre of techniques especially through the quality control programmes for medical and health analysis laboratories;
- to train and improve the technical staff.

To carry out its missions without mishap, the INRB has Laboratories of Bacteriology, Immunology, Biochemistry, Hematology, Anatomy-pathology, Entomology and Toxicology.

Its main research areas are: malaria, trypanosomiasis, HIV/AIDS infections, bacteriological resistance to antibiotics, hemorrhagic fevers, cassava intoxication, and medicinal plants.

III.3.5. Ministry in charge Scientific Research

The Ministry in charge of Scientific Research is dealing especially with:

a) the design, the development and the implementation of the scientific and technological research policy;

b) the supervision and follow-up of activities of organizations in charge of scientific research;

c) the guideline of scientific and technological research towards the support with the rebuilding and development efforts of the country, etc.

The ministry organized in April 2005 the General Meeting of Scientific Research with a view of especially equipping the country with a scientific and technological research master plan.

III.3.5.1. National Institute for Agronomic Study and Resesarch (INERA)

The National Institute for Agronomic Study and Resesarch is governed by the Ministerial Order n°78-211 of May 5, 1978. According to article 3 of its statutes, it has the aim of promoting scientific development of agriculture in Congo. To this effect, it is especially in charge of:

- ensuring the administration of agricultural establishments whose management was entrusted to it;
- carry out the organization of agronomic study missions and training of experts and specialists;
- conducting all studies, research, experiments and, generally, all the works which are in connection with its objective.

At the level of infrastructures, the INERA has herbaria, an arboretum, tree nurseries, concessions, plots of land and ponds assigned to its social objective. These infrastructures all are in a state of degradation. There is no programme of acquisition, rehabilitation or modernization of research infrastructures and equipment. *At the level of research*, the studies and publications carried out by INERA are not available to all. The general policy framework on agronomic research studies and on biological diversity is not suitable. There is however a collaboration between the INERA, the private sector and ONGs working in seed production and pisciculture. The INERA has a list of research projects in progress, especially in the area of plant diversity. Thes ones are confronted to constraints of a technical and financial nature. *At thelevel of human resources* available in the research area, one can find researchers specialized in taxonomy, botany, forestry, livestock and agroforestery. There are currently no personnel training and training and specialization programme, but some local recycling sessions financed by the INERA. Ultimately, these human resources are insufficient in comparison with the mandate entrusted to the INERA. Even if there are an incentive to training through study missions and training course in international research centers and institutes such possibilities prove however to be very limited.

Despite the multiple problems confronted with as time goes by, the INERA holds an important mass of data on national biodiversity, resulting from Research &Development work, the management and the conservation of natural resources, the management and conservation of the phytogenetic resources, the performance and the stability of genotype yields of some cultivars (cotton, cassava, maize, rice, palm oil tree, coffee-tree, cocoa-tree, etc) in various environments through the country, the description of various types of Congolese biomes, the biometrics and the resource assessment, etc.

III.3.5.2. Agri-food Research Centre (CRAA)

According to the government order n°82-040 of November 5, 1982 concerning the organization of scientific and technological research, the research centers and institutes have the role of carrying out the studies, scientific and technological research, experiments and, generally all works which are in connection with their respective objectives. Such is also in substance the mission entrusted to the Agri-food Research Centre of Lubumbashi.

Created by government order n° 082-04 of November 5, 1982, the Agri-food Research Centre (CRAA) has as a main objective of developing the industrial research of the

agri-food sector by developing local agricultural raw materials, either by new techniques, or by improving the peasant or domestic techniques.

Within the framework of this general objective, the CRAA has as specific objectives:

- identifying the processes of transformation and conservation of the basic local agricultural produce;
- improving the quality of food imported or manufactured locally by applying tested standards and quality control;
- ensuring the development aid technical existing agricultural processing industries in their bringing as far as possible technical aid;
- carrying out studies, scientific and technological research, experiments and, in general, all the works which are in connection with its objectives.

The main research areas of the CRAA are as follows:

- nutrition and food;
- food technology;
- biotechnology

With regard to human resources, the CRAA has manpower of 8 professors and 33 specialized researchers as well as certain number of research technicians. The possibilities offered to the researchers are very limited.

III.3.6.. Ministry of Extrenal Trade

According to the decree 03/027 of September 16, 2003 above mentioned, this ministry has as duties:

- the promotion of the trade foreign and the study of proposals on general and sectoral policy guidelines in the area of foreign trade;
- the measures likely to contribute to the restoration of external competitiveness of the Congolese exportable products, especially by identifying all structural, administrative, financial, tariff or human obstacles;
- the research of ways and means likely to get national industry new outlets through the rationalization of the country participation in fairs and other external events, the exploitation of economic information relating to the trade with foreign countries, conventions and uses governing the international trade relations;
- the negotiation and the follow-up of trade agreements;
- the quantity control, the quality and standards of all the products intended for import, export and transit.

This Ministry has under its supervision some services and organizations involved in activities likely to have an impact on the management of modern biotechnologies. Among these services and organizations, most concerned is the Congolese Authority of Control. This one is governed by the government order n°78-219 of May 5, 1978. Accorsing to article 3 of its statutes, the Authority has the role of carrying out, controls of conformity and quality of all the goods, analyses of all the samples and products, as well as technical controls of all devices and all works. It can manage and run general silos, stores and customs warehouses.

The legal framework of operation of the OCC was examined with regard to the requirements of the implementation of the agreements of the World Trade Organization (WTO).

III.4. Guidelines of the biosafety intitutional and administrative framework in the DRC

According to article 19 of the Cartagena Protocol, each Party nominate a national correspondent in charge of ensuring in its name the liaison with the Secretariat. It also nominates one or many competent national authorities in charge of performing the administrative functions that the Protocol calls for and authorised to act to act in its name in the carrying out of its functions. A Party can entrust to a unique entity the functions of national correspondents and of competent national authority.

III.4.1. Basic principles

The conservation and the sustainable management of biodiversity and the protection of human health as well as the socioeconomic fabrics for the biotechnological risk prevention and management by means of a legal framework that is going to guide the institution framework of biosafety management in the DRC. This institutional framework must take into account a certain number of parameters, especially:

- the worry to maintain an operational framework of information-sharing between the DRC and Secretariat as well as the Biosafety Clearing House ;
- the need to enforce the legal provisions concerning the follow-up, the monitoring and the control of the introduction, the handling and the use of LMOs and products thereof in he DRC ;
- the need to ensure the public information, awareness, and effective participation to the decision process and to institute and ensure the running of the dialogue framework involving all the main partners;
- the need to proceed to the permanent assessment and to the management of risk and benefits presented by the products of modern biotechnology;
- the need to see to the national legislation governing the sector.

To attain such objectives, the Protocol allows the set up of institutional arrangements likely to help the Parties for this purpose. For the DRC, these institutional arrangements can be articulated around:

- a National Biosafety Focal Point ;
- a National Consultative Committee ;
- a Competent National Authority ;
- a Scientific and Technological Biosafety Committee ;
- a National Biosafety Clearing House.

III.4.2. Institutional arrangements

III.4.2.1. Focal point of the Cartagena Protocol

The National Biosafety Focal Point, also called national correspondent in article 19 of the Protocol, is in charge of ensuring the liaison, on behalf of the DRC, with the Secretariat of the Protocol. He/she assumes its mission in close collaboration with the competent national authority.

For this reason, the National Focal Point has for main tasks the following activities:

- to facilitate at the national level the procedures of implementation of the provisions of the Protocol;
- to coordinate the activities of developing national and thematic reports and give explanation of the status of biosafety in the DRC;
- to participate in the development and, should this happen, the review of the national strategy and the action plan for biosafety;
- to ensure to the implementation of the public awareness and education programmes on biosafety and provisions of the Protocol;
- to set up partnerships with international organizations and other Parties to the Cartagena Protocol for human, technical and institutional capacity building in the area of biosafety; etc

These missions and the principle of nominating the national focal Point should be provided for by the national legislation.

III.4.2.2. National biosafety consultative committee

The national Biosafety Consultative Committee will have the status of a consultative organism and of concertation framework instituted by the Government. It will have as mission:

- to contribute to the periodic definition and revision of the main guidelines of the national Biosafety policy;
- to periodically analyze and validate activity reports of the National Biosafety Experts Committee;
- to define priorities on research and capacity building matters;
- to monitor and evaluate the national policy, legislation and public participation according to the Cartagena Protocol on Biosafety;
- to make recommendations and if necessary advising the Competent National Authority.

The composition of this Committee should take into account all ministries and administrations respectively in charge of the environment, agriculture and livestock, industry, economy, trade scientific and technological research, national education, health, public organizations, non governmental organizations, trade union associations, consumer associations, management and professional syndicates, industrial private sector, scientific and academic world, public and private research institutes and centres on biotechnologies, health, agriculture and livestock and finally traditional authorities and any structures interested in issues of biosafety and use of technology. The Competent National Authority, the Biosafety Focal Point, Biodiversity Focal Point and the GEF Operational Focal Point are automatically members of this committee

.The eligibility criteria within the committee are based on the assigned statutory mandates and the objectives pursued as well as the areas of intervention or competences in relation to the use of modern biotechnology.

A decree deliberated by the Cabinet fixes the organization and the running of the national biosafety consultative committee.

III.4.2.3. Competent National Authority (CNA)

Taking into account the multiplicity of services and organisations likely to intervene in the process of import, export and transit of LMOs and products thereof, the option for multiple competent national authorities has been chosen to coordinate biosafety activities.

In application of the provisions of article 19 of the Protocol, the mission of the Competent National Authority is entrusted to the ministries in charge respectively of the Environment and Agriculture. The former intervening as far as GMOs/LMOs or GMO derived products likely to be used in the environment. The latter intervening as far as the GMOs/LMOs products thereof intended as food, feed or for processing or for use as seeds. The ministry in charge of the Environment exercises this mission through a Technical Department, the Department of Sustainable Development. As for the ministry in charge of Agriculture, it exercises the mission through the Office of Animal and Plant Quarantine.

The Competent National Authority ensures the coordination of all the activities related to biosafety and of the functions of technical secretariat of the National Biosafety Consultative Committee and of the Scientific and Technical Biosafety Committee.

On this account and without prejudice to the royal missions recognized to other public organizations by particular laws, the Competent National Authority is especially in charge of:

- participating at the national and international level and in taking the required legal measures to protect the health and the environment against the risks associated with the use of modern biotechnology;
- ensuring the application of the provisions of the Protocol and the national legislation on the intentional and unintentional GMO transboundary movement
- implementing the policy recommendations and other guidelines of the National Biosafety Consultative Committee in making decisions on the import, transit, contained use, release or placing on the market of genetically modified organisms or products thereof;
- causing the establishment of Biosafety Committees at relevant institutions or nominate independent panels or any other body of experts, as appropriate, as technical and scientific advisors on issues of biosafety;
- keeping genetically modified organisms globally under constant review and when any one of them is suspected of posing a serious risk to human health or to the environment, to ban its transiting through the country's territories and notify the Clearing-House, the customs and officials in charge of external trade accordingly;
- keeping and availing to the public in case of request; a database on the genetically modified organisms and products thereof; intended for direct use as food or feed, or for processing;
- declaring through the Biosafety Clearing-House that:
    i) a genetically modified organism or a product thereof intended for food or feed or for processing can not be imported unless it subjected to a full assessment of the potential risks that it could cause according to the terms of this law; and

ii) it is only the import permit request that triggers the risk assessment and this will be carried out automatically each time a new or genetically modified organism is submitted at the clearing house;

- evaluating and reviewing the risk assessment on the GMOs/LMOs and products thereof. When a genetically modified organism or a product thereof must be imported, the costs will be borne by the exporter;
- coordination at national and international levels, especially by making applicable national biosafety law, the legal measures required for protecting the health and the environment from the potential risks that could presented by the GMOs/LMOs or products thereof;
- certifying the service of officers under oath and technically trained so as to carry out inspections as well as other control measures to ensure the respect of the legislation;
- carrying out any other functions likely to be determined by the Government.

III.4.2.4. Scientific and technical biosafety committee

The Biosafety Scientific and Technical Committee is a technical and scientific organ that assists the Competent National Authority in the carrying out of its mission of biosafety in modern biotechnology. On the practical level and with regards to the size of the country, it is necessary for the committee to have a reference laboratory and other analysis laboratories.

As an advisor to the CNA, it will be in charge of:

- Defining and revising, according to the development of scientific knowledge, the risk assessment and management procedures of GMOs/LMOs and products thereof;
- Proposing norms, indications and rules required for the application of the national legislation on biosafety.
- Assessing or evaluating the risk assessment reports of GMOs/LMOs and products thereof before any import, contained use, deliberate release and placing on the market in the Democratic Republic of Congo;
- Assessing the research projects and recommending the conditions in which the latter will be carried out;
- Developing and revising guidelines relating to the contained use of GMOs/LMOs and applicable control procedures according to the estimated level of risk linked to the research, development and release activities of these organisms;
- Assisting the Competent National Authority in the organization and running of public consultations;
- Giving its opinion on requests for import, contained use, release and placing to market of GMOs/LMOs or products thereof and giving its approval to the competent authority to take the decision;

The Biosafety Scientific and Technical Committee will be composed of specialists from administrations, public organizations, private sector, non governmental organizations, universities, research centres, resource people having or likely to have established skills in the subjects associated to modern biotechnology (risk assessment and management, legislation and regulation, research and development, building of institutions, social and economic sciences, public awareness and participation, education and training, etc)

III.4.2.5. Biosafety Clearing House

The National Biosafety Clearing House is in charge of collecting and exchanging all scientific, technical, ecological and legal information on the transboundary movements of GMOs/LMOs and products thereof as well as information on the national biosafety mechanisms including information on assessment and the management of such risks.

It should on this account and under the supervision of the CNA:

- gather, stock and analyze scientific, environmental, technical and legal data;
- ensure communication with the Central Portal of the Biosafety Clearing House.
- facilitates the access to information relating to biosafety in the Democratic Republic of Congo;

The management of this house is ensured by an expert appointed by the CNA according to his/her established skills and experiences in the area of biosafety and information management.

IV - BIOTECHNOLOGICAL RISK ASSESSMENT AND MANAGEMENT SYSTEM AND DECISION MAKING PROCEDURE

IV.1. Introduction and definitions

Risk is defined as the probability for an organism released in the environment to cause damages. It includes two elements: the consequences of a particular event (potential negative effects, including their importance) and the probability that this event occurs.

With regards to the above, the authorizations relating to GMOs/LMOs, including the seeds, as well as the foodstuffs and the livestock feed from GMOs/LMOs will be based on the result of risk assessments. On these grounds, the national legislation should comprise provisions relating to the risk assessment and management.

IV.1.1. Risk assessment

The risk assessment aims at reducing or preventing the potential negative effects on the environment. It is intended to enable informed decisions to be made about the transboundary movement of GMOs/LMOs.

The risk assessment should in principle be made according to Environmental Impact Assessment standards defined in the Framework Law on the Protection of the environment. These standards should be intended to assess the eventual impact of biotechnology practices on the environment, the biodiversity and the health, etc.

The cost of risk assessment should be borne by the notifier.

IV.1.2. Risk management

Risk assessment is a requirement of article 16 of the Protocol which invites the Parties to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol in relation to the risk assessment associated with the use, the handling and the movements.

To preserve the biological diversity, the human health and the socioeconomic fabrics from the potential perverse effects caused by the use of modern biotechnologies, GMOs/LMOs and derived products, the national biosafety law provides for provisions bestowing to the CNA the necessary powers to :

- Develop, maintain and use a strategy particular to this area ;
- Impose all the necessary measures to lessen the negative : risk management diagrams ;
- Be entitled to request the notifier to subject the GMO to an period of observation to assess its life-cycle or its reproductive period before and after its use ;
- Be able to order the stopping of any use of a GMO or derived product recognized for perverse effects on the health, the biodiversity and the socioeconomic fabrics ;
- Order the seizure and the destruction of the concerned LMOs and their derived products.

IV.2. Technical guidelines for the biotechnological risk assessment and management mechanisms

The national biosafety framework in the DRC proposes that no decision of import, contained use, release or placing on the market of a genetically modified organism or a product thereof be taken by the Competent National Authority without a prior risk assessment of the GMO for the human health, the biological diversity and the environment, especially its socioeconomic and cultural consequences according to the already discussed methods. The scientific research institutions involved in the process must direct or guide the decision of the competent national authority.

The risk assessment linked to a genetically modified organism or to a product thereof will be carried out by the Competent National Authority through the institutions having the required competence. The Competent National Authority should review the risk assessment report and, depending on the results, rule on the request for import, contained use, release or placing on the market of a genetically modified organism or a product thereof. The regulation of import of GMOs/LMOs and derived products must be done according the provisions provided for in the National Biosafety Framework and in the National Biosafety Law. If, following the review, it appears that the risks are unavoidable; the CNA can not authorize the import, the contained use, the release or the placing on the market of the GMO or the product thereof. As for the risk management, the CAN develops, maintains and uses if need be, a strategy aiming at containing the accidents of genetic engineering or deriving from the use of genetically modified organisms and their derived products likely to put in danger human health, biological diversity and the environment.

The CNA can also take all the measures necessary for remedy the negative effects that a GMO or a product thereof could have on human health, biological diversity and the environment, as well as on the socioeconomic environment.

The CNA could also:

- request that any genetically modified organism be submitted to an observation period to study its life cycle or its generation cycle, at the notifier's expense, before and/or after any use;
- to ban the import, the contained use, the release or the placing on the market of a GMO or product thereof, if its characteristics or its specific traits lead to unacceptable risks to the human and animal health, the environment and the socio-economic conditions;
- to order the stopping of any use done in violation of the provisions provided for by the national biosafety law;

IV.2.1. General Considerations

According to article 15 of the Cartagena Protocol, the 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.

Thus, the development of technical guidelines is required to make operational the legal framework of biosafety and formalise the biotechnological risk assessment and management mechanisms. The definition process of these mechanisms should take into account the analysis made on the status of modern biotechnologies and biosafety in the DRC however also according to the UNEP guidelines, the provisions of the Cartagena Protocol on Biosafety and the guidelines of other countries provide a good experience in these areas.

The development of guidelines relating to the deliberate release and to the contained use of GMOs/LMOs must take into account the following basic considerations:

IV.2.1.1. Deliberate release of LMOs

To ensure the protection of the environment and human health, the following considerations must be taken into account in relation to the deliberate release of GMOs/LMOs:

- the need to institute harmonized procedures and criteria at the national and regional level in the area of deliberate release of GMOs/LMOs ;
- the need to precede a prior assessment before any release (case by case method) ;
- the respect of the process of progressive introduction of GMO in the environment (the process of progress by stages where the assessment of the previous stages will serve to authorize or not the following activities) ;
- the carrying out of satisfactory field tests, especially in the ecosystems likely t be affected by use, in case of a ban of the placing on the market of GMOs/LMOs ;
- the respect of the established prior authorization procedure of placing on the market of GMOs/LMOs and products thereof ;
- the respect of the notification procedure (information on the risks, the safety measures) ;
- the obtaining of the consent of the Competent National Authority before any deliberate release of GMOs/LMOs;
- the need of establishing and maintaining, in consultation with the countries of the sub-region, information-sharing mechanisms on the deliberate releases of notified GMOs/LMOs;
- the close monitoring of the evolution and the use of GMOs/LMOs and the publication of the list of all the authorized products in application of the legislation in force.

IV.2.1.2. Contained use

In case of use of GMOs/LMOs in contained environment, the following factors must be taken into account:

- the principle of preventive action and the precautionary principle as foundation of the protection of the environment and human health;
- the potential advantages of the development of modern biotechnology for the DRC ;
- limitation of effects by granting the required attention to the prevention of accidents and to the waste management ;
- the possibility for GMOs/LMOs to breed and to spread beyond the national boundaries to that way affect other neighbouring States;
- the adoption of harmonized measures for the risk assessment and management ;
- the classification of LMOs according to the risk level ;

- the application of adequate measures of containment at the various stages of an operation so as to brig under control the leaks and prevent any accident;
- the obtaining of the consent of the CNA before any use of GMO in a specific installation;
- the taking of adequate measures relating to the information of the CNA and of any person likely to be affected by an accident (all the aspects relating to safety)
- the establishment of emergency plans so as to efficiently respond in case of an accident.

IV.2.2. General Methods of risk assessment and management

The biotechnological risk assessment concerns:

- on one hand, the development process of GMOs/LMOs and products thereof, including the laboratory research, pilot tests, the release in the environment, the marketing and the transboundary movement of GMOs/LMOs ;
- on the other hand, the categories of GMOs/LMOs and derived products, including the genetically modified animals and micro-organisms and their products thereof.

In this respect, the biotechnological risk assessment should, while taking into account te national and the international context, take into account the familiarity of GMOs/LMOs, the case by case approach and biosafety management by risk level classification.

Concerning biosafety management by risk level classification, it is suitable to note that because of the multiplicity of the potential risks of GMOs/LMOs and derived products, their development, production and use and impact on the environment and human and animal health, the socioeconomic fabrics and their cultural values to variable risk levels should be considered.

Thus, the modern biotechnology projects could be classified into the following four risk levels:

- ***Risk level I*** : the modern biotechnology projects recognized as not presenting risk for human and/or animal health, the biodiversity, the socioeconomic fabrics and/or the values ;
- ***Risk level II*** : the modern biotechnology projects recognized as presenting minor risk for human and/or animal health, the biodiversity, the socioeconomic fabrics and/or the values ;
- ***Risk level III*** : the modern biotechnology projects recognized as presenting slight risk for human and/or animal health, the biodiversity, the socioeconomic fabrics and/or the values ;
- ***Risk level IV*** : the modern biotechnology projects recognized as presenting definite or high probability risk for human and/or animal health, the biodiversity, the socioeconomic fabrics and/or the values ;

IV.2.3. Main components of biotechnology risk assessments

As for the essential components of the biotechnology risk assessment, the main points are concerned with the various forms of using GMOs/LMOs, that is the contained use and in case of deliberate release. This National Biosafety Framework on Biosafety establishes its policy on biotechnological risk. For that, the risk assessment will comprise the following stages:

- An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
- An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- An evaluation of the consequences should these adverse effects be realized;
- An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

It is suitable to note that the most important data for carrying out the various aspects of biotechnological risk assessment are the characteristics of GMOs/LMOs involved (parent organisms, organisms with new characters, vectors, etc) and the information relating to the use of GMOs/LMOs (deliberate release, contained use, use of GMO derived products) A particular accent, must be put on the negative effects and their consequences on human and animal health and the environment.

IV.2.4. The risk assessments methods relating genetically modified pharmaceutical products

The National Biosafety Framework of the DRC, taking into account the specificity of the biotechnological risk assessment linked to pharmaceutical products consisting of GMOs/LMOs, has adopted to resort to a specific method to approach the problematic related to such products.

The risk assessment method in question takes into account the category of GMOs/LMOs at stake but also the development terms of the GMO as well as the production process of potential pathogenic micro-organisms involved. Finally, the method puts the emphasis on the criteria of quality and sees to the requirements of the methodology itself as well as the risk assessment procedures and the ways and means of use of the GMO by the human being.

IV.2.5. Biotechnological risk assessment approaches and methods linked to the consumption and use of GMOs/LMOs and other derived animals consisting in GMOs/LMOs.

Any allergy and other reaction due to the consumption of food and GMO derived products must be monitored. It is necessary to proceed at the same time to the identification and to the characterization of the dangers in the context of complex food products. This national biosafety Framework provides for the creation f a national structure in a research centre whose vocation will be to make a good risk analysis of the use of GMO products consisting in LMOs by moving on to the following stages of the identification and characterization of dangers:

IV.2.5.1. Molecular characterization

The research institutions will have to carry out a general molecular characterization of the inserted genetic construction, at the same time before and after insertion. The molecular characterization will have moreover to include an analysis of the number of copies and an analysis of the sequences of the contiguous areas of the site of insertion in order to locate any unintentional effect. The equipment of the national structures in adequate material should facilitate that.

The Polymerase Chain Reaction (PCR) techniques make it possible to discover the presence of a foreign gene by amplification of this one because any gene is surrounded of a promoter (DNA sequence which initiates the reading of gene) and of terminator (DNA sequence which marks the end of the reading). The PCR technique resorts to detection kits. The universal starters that these contain recognize and are fixed on the promoter and terminator sequences. After hybridization, the enzyme of the kit is put at work and makes many copies of the gene ranging between these two starters. When the reactions are finished, the result is deposited in a revealing gel. If a band appears, the result is positive: presence of a foreign gene in the genetic inheritance tested. The contrary case shows in theory that the DNA in question did not undergo deliberate genetic modification. The national scientific institutions will have to resort to such approaches to certify the recombining character or the integrity of the DNA as well on the level of the plant kingdom as of the animal kingdom.

IV.2.5.2. Health safety of the genetic product

Health safety related to genetic products (proteins and enzymes) must be assessed case by case. The assessment of new proteins should be based on current knowledge of the toxic substances. In the best of cases this assessment will require to first include, a homology research of sequences with known toxins, and on the function of new protein. In the case of unknown proteins, a complete procedure of classic verification of the absence of toxicity will have to be part of the assessment. The genome sequencing is an important tool to facilitate this assessment.

IV.2.5.3. Allergenicity of transgenic products

The allergies contracted following the consumption of transgenic proteins as much of animal GMO products as plant GMO products will have to be subject to a particular attention in the context of trade of products in the DRC. It will be necessary to assess whether the newly synthesized proteins have modified toxicological or allergenic properties in the animal or the human being which consumed this GMO derivative the animal or the human being.

The national research structures will have to establish the degree of allergenicity of products derived from modern biotechnology which will have to be introduced on the national markets through the various trade channels. This kind of work will have to be followed by the publication of results on the source of gene, the homology of sequences, the results serum analyses of patient known to be allergic to the organism or has source food or distantly related sources, resistance to pepsin and prevalence of character.

IV.2.5.4. Genetic transfers

The DNA recombination can consist of a horizontal process when the involved gene or the promoter comes from a viral source. In such a feature case the construction of the DNA used for the modification of the GMO must be subject of a study this could be of animal type or plant type. Moreover, the materials derived from a bacterial host cannot contain additional fragments of DNA which do not have any relationship with the targeted gene. The introduction by mistake of such sequences into the germinal line of an animal or a plant genetically modified risk not only to create accidental genetic damage, but also to contribute, by recombination, with the creation of new infectious viruses. Consequently the national research structures will have to do everything to solve this problem by firmly attacking it during the implementation phase of the National Biosafety Framework of the DRC. The evaluation of the medical and food safety of genetic construction will have to also include the genes markers. The genes usually used markers are genes which code for resistance to antibiotics. The risk assessment of these detectable genes should relate to the transfer of these genes with the micro-organisms lying in the digestive tract of the human or the animal.

However, as it is not possible to completely exclude such a transfer, the safety assessment should also analyze information on the role of antibiotic in human and veterinary medicine.

IV.2.5.5. Unintentional Effects

Generally, the nutritional analysis which makes it possible to detect the unintentional effects of a product is carried out using tested and recognized scientific methods. The strategies of nutritional analysis of the foodstuffs derived from genetically modified animals do not differ basically from those used for plants, which consist in identifying and analyzing the essential substances by species. Moreover, to be able to suitably interpret the data resulting from the nutritional analysis of a given product of animal origin, it will be advisable to know the natural variation of macro, micro and, if necessary, anti-nutrient. The analyses will have to make it possible to detect the genomic, proteomic and metabiologic differences on one hand the genetically modified animals and plants and on the other hand the reference biological animals and plants of concerning, respectively, the products of transcription of genes, the proteins and the metabolites.

IV.2.5.6. Food ingestion assessment

The purpose of the study of food ingestion is to evaluate the quantity of food or a food ingredient that a person or a group of the population can consume. There are not up to now exactly definite criteria as for the factors to be taken into account in a study of food ingestion before the placing on the market of a new and complex foodstuff such as the GMO. However, the national research structures must estimate the spending patterns of certain groups of consumers. The study of food ingestion will have to be based not only on the data available concerning consumption, but also on the knowledge which we have of the bioavailability of the studied food components. Probabilistic mathematical models of integration of consumption and distribution of food can, in determined cases, being used in a comparative way to estimate more precisely the future ingestion.

IV.2.5.7. Integrated toxicological assessment

After the identification and the danger characterization phase and the study of food ingestion, an integrated toxicological assessment will combine all information relating to the medical safety of the complex foodstuffs resulting from genetically modified animals and plants. This assessment will have to determine which questions of medical safety are able to require additional studies, including traditional studies of toxicity. For example, study of the rise in the content of proteins in certain food and animals having consumed the product. The national structures of scientific and academic research should be able to determine all that.

IV.2.5.8. Integrated nutritional assessment

The micronutriments are the vitamins and salt minerals required for the normal physiological and biochemical running. The deficiency as well as the excess of one micronutriment can cause health problems, which stresses the importance of this category of compounds. The macronutriments, which include the lipids, the proteins and carbohydrates, are present in the food in large quantities. The evaluation of the replacement factor of important animal sources of micronutriments and macronutriments by products derived from transgenic animals thus takes a cardinal importance in the possibility of a modification of the contents of nutriments. The bioavailability of the micronutriments and the macronutriments important present in fabrics coming from genetically modified animals and plants is also a crucial task to which must face the national institutions competent on the matter.

IV.2.5.9. Risk characterization

The risk characterization is the final stage of the process of the biotechnological risk assessment in the DRC, and it consists in integrating the results of the complete toxicological and nutritional assessments in order to draw a general conclusion on the medical safety of the foodstuff. The basic criterion of the harmlessness of a new GMO derived food, including the transgenic animals, will should all the cases be the conclusion that this genetically similar product to the traditional reference product. The national scientific research institutions will have to publish similar results to help the Congolese Control Authority to know the standards of food imported or sold on the national markets. A guide to the importers of the products for human consumption should be produced and distributed to all the importers.

IV.2.5.10. Monitoring after the placing on the market

The resorting to the monitoring after the placing on market as an information-gathering instrument on the possible effects in the long run or the unexpected, harmful or beneficial effects, of food derived from genetically modified or traditional animals brings up the reflexion. With regard to the medicinal substances derived from transgenic animals, the existing systems of pharmacy-vigilance will be applied to follow any unforeseen and unintentional side effect of the isolated medicinal substances. It was in the same way within the veterinary framework for the genetically modified animal itself when it was modified for the production of hormonal substances or prophylactic substances: the systems of pharmacy-vigilance could contribute to detect undesirable side effects of the expression product introduced into the genetically modified animal which would not have been detected in the phase prior to marketing.

For this purpose, the genetically modified animals should then be included in the management systems accepted by the ministries of supervision in fact the ministries for Agriculture, Health and the Environment. In order to make it possible to the consumers to establish a link between adverse effects, for example allergens, and a foodstuff derived from a transgenic animal, it can prove to be necessary not only to label the product as being derived from a genetically modified animal, but also to provide information on the specific origin of the genetically modified animal, for example by adding on the label the specific identifying code of a unique integration act.

IV.2.6. Technical guidelines for control mechanisms of biotechnological risk management

The control measures must be applied according to the nature of use of GMOs/LMOs, concerning the physical, chemical and biological aspects. Various measures or combined measures must be adopted in the development process of GMOs/LMOs and derived products in relation to the various risk levels and according to the various life cycle phases.

IV.2.6.1. Physical control measures of the laboratory assessment

To ensure the physical control measures in the laboratory studies, it is necessary to:

- have the adequate equipments according to the objectives of the research at the various levels of experimentation ;
- have a planning of the laboratory, which will be established regarding the target of the experimentation and the requirements of the various risk levels;
- adopt the rules of operating a laboratory : the operating guides will be adopted in relation to the risk levels of the targets of the experiment.

IV.2.6.2. Control of experimental test and the release in the environment

Control measures will be defined according to the risk level:

- ***Control measures of risk level I*** : adoption of general biological separation for limiting the experiment to a defined class;

- ***Control measures of risk level II*** :
  - Physical control measures: adoption of appropriate separation measures to ensure the control of the entry in human beings and animals and the installation of a net to prevent the entry of insects.
  - Chemical control measures : after the test, the instruments and equipments used as well as the vector should be sterilized in time to avoid the accidental release of GMOs/LMOs ;
  - Biological control measures: biological buffer zones will be established so as to avoid any contact with other related organisms.

- ***Control measures of risk level III***:
  - Physical control measures: adoption of appropriate measures to ban the access to the people, animals and foreign vehicles according to the various objectives of the experiment.

- Chemical control measures: after the experimentation, the instruments and equipments used will be sterilized in time to avoid the exit of GMOs/LMOs outside the experimentation. The herbicides, the insecticides, the fungicides and the biological predators could be used to eliminate the plants, the insects, the micro-organisms and the animals that could threaten the experiment.

Biological control measures: adoption of appropriate separation measures so as to avoid the interactions between the GMOs/LMOs and the other related organisms.

- ***Control measures of risk level IV***: besides the control measures of level III, the adoption of specific control measures according to the specific varieties of LMOs, to the objective of the release and to the conditions of the environment of the release.

IV.2.6.3. Risk management of genetically modified pharmaceutical products

The Ministry in charge Health and the CNA will have to define the risk management measures of genetically modified pharmaceutical products.

These measures will have to take into account some requirements, especially:

- The obligation of respecting the specific rules governing the personnel, the environment, the experimentation instruments and equipments in this area.
- The experimentation conditions of these products have to be in accordance with the rules governing the quality of pharmaceutical products before the clinical use. To that effect, the Ministry in charge of Health must beforehand approve the research and clinical test, in particular the researches on the effects of medicines and the toxicology;
- The production of these products must respect the norms concerning the quality of the pharmaceutical production ;
- Any research activity in this area must be submitted to prior authorizations of Ministry in charge of Health and the CNA ;
- The treatment based on these products must strictly follow the principles of clinical treatment.

IV.2.7. Technical guidelines relating to the monitoring of the GMO release in the environment

The monitoring of the release in the environment of GMOs/LMOs should be concerned with among others the survival, the propagation and the dispersal of GMOs/LMOs in the environment, the potential of excessive reproduction of the population, the genetic contamination risks and the anarchical release of GMOs/LMOs.

For that matter, the following factors should justify the monitoring of impacts of GMOs/LMOs on the environment:

- the potential impacts of GMOs/LMOs on the ecosystems, in particular their potential impacts of the receiving environment, on the soil micro-organisms and biological and chemical cycle of the land and the responses to any organism in the environment depending on whether it is receptive, repulsive or tolerant to the released genes ;
- the potential impacts on the organisms targeted or not : the infection, the toxicity, the invasion potential, the pathogen vector, the sensibility and the transmissibility, the proven and potential impacts on the other organisms in the environment and the possibility of leakage of genes after the release ;

- the risks of the resistant harmful animals towards the anti-parasites : the risks caused by the interaction between the GMOs/LMOs.

As far as the pathogenic nature of GMOs/LMOs on the human beings and other organisms, the following factors should be taken into account:

- the infections or diseases caused by the GMO/sLMOs;
- the degree of the infection;
- the classification of hosts and possibilities of mutation or of change ;
- the possibility of existence in an environment other than the human body ;
- the vectors or ways of propagation ;
- the biological stability;
- the model of resistance of resistant genes ;
- the toxicity and sensitivity ;
- the dangers of metabolite.

As for the organization and the management monitoring, they can be carried out by the user of GMOs/LMOs, either byindependent institutions of Government, organizations or target groups.

In the monitoring process, all the possible effective measures must be taken to control the identified accidental and harmful impacts of GMOs/LMOs on human health or the environment. A report of such accidents or impacts will be rapidly submitted to the CNA.

IV.3 – Decision making procedure

The DRC undertakes, in parallel to the development process of this National Biosafety Framework, activities of writing a national biosafety legislation relating to the import, the export, the transit, the contained use, the release or the placing on the market of any genetically modified organism should the latter be intended to be released in the environment or be used as pharmaceutical product, food, feed or for processing, or should it simply be a derived product of genetically modified product.

IV.3.1. Precautionary approach: legal foundation of the biosafety regulatory activity in the DRC

IV.3.1.1. Advance Informed Agreement

The national biosafety legislation provides for the precautionary approach as a legal basis which puts forward the advance informed agreement procedure. The advance informed agreement is an agreement obtained on the basis a guarantee of the complete character of the required information supplied on the GMO candidate to the export as well as the planned activity before any start of the latter.

In practice, the advance informed agreement procedure represents the central operational factor of the Congolese legislative approach on biosafety and that, according to the relevant provisions of the Cartagena Protocol. It should allow guaranteeing that be supplied to the CNA all the necessary information to the risk assessment before any transboundary movement of a GMO. This allows the CNA to make an informed decision.

This procedure only applies before the first transboundary movement of genetically modified organisms intended to be deliberately introduced in the environment on the Congolese territory. The seeds of transgenic plants intended to the field experiment or the marketing for agricultural purposes are an example of genetically modified organisms falling into this category.

The advance informed agreement procedure leads to the establishment of a decision making process characterized by the following phases: the notification, the acknowledgement of receipt, the decision making that must be necessarily preceded by the risk assessment and the identification of the provisions for risk management.

IV.3.1.2. Notification or referring to the Competent National Authority

The National Biosafety Framework of the DRC, like the National Biosafety Law of the country, have agreed to make the notification of the requests of authorizations, a requirement for any Party and for any individual or company wishing to export GMOs/LMOs or products thereof in the DRC. This implies that the exporter must transmit, directly or through the importer to the CNA a written request containing a notification for transboundary movement. Aware of the importance of this big challenge, the DRC takes pains to anchor, in its national legislation on the matter, the principle of the responsibility of the notifier especially as far as the exactness of the supplied information on the GMOs/LMOs. It also comes back to the DRC to ensure that the exporter of GMOs/LMOs complies with and respects the requirement of the notification.

The notification must respect the requirements of article 8 of the Cartagena Protocol and contain at minimum the information required by Annex 1 of the said Protocol.
It must thus contain the following information:

- Name, address and contact details of the exporter.
- Name, address and contact details of the importer.
- 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.
- Intended date or dates of the transboundary movement, if known.
- Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- 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.
- Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- 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.
- Quantity or volume of the living modified organism to be transferred.
- A previous and existing risk assessment report consistent with Annex III.

- Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- Regulatory status of the GMO 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 GMO is banned in the State of export, the reason or reasons for the ban.
- Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.
- A declaration that the above-mentioned information is factually correct.

The obligation of the notification also lies with any person who wishes to exercise activities relating to modern biotechnology on the national territory , especially the operations of import, transit, contained use, release or placing on the market of a GMO or a product thereof.

IV.3.1.3. Acknowledgement of receipt of the notification request by the Competent National Authority

The national biosafety Framework in the DRC intends to adopt a consistent approach to the provisions of the Cartagena Protocol concerning, among others, the issue of acknowledgment of receipt of requests for transboundary movements of GMOs/LMOs and products thereof involving the country. The Competent National Authority should, within a maximum time period of 90 days, send an acknowledgement of receipt to the applicant of the notification by indicating to the notifier:

- The date of the reception of the notification, that initiates the time period of 270 days required for taking decision;
- **If** the information supplied meet the requirements of the Protocol (or the national legislation) and are sufficient;
- Details on the legal provisions applicable to the purpose of the notification are the provisions of the national legislation or those provided for by article 10 of the Protocol.

The acknowledgment of receipt indicates to the applicant of the notification the conditions to which is subordinated the deliberate transboundary movement of the GMO when the CNA will have given in writing its consent.

Under no circumstances should the fact of not acknowledging the notification be interpreted as a tacit consent of the CNA to the execution of the transboundary movement in question. The consent should, in all cases, be written.

IV.3.1.4. Decision making by the Competent National Authority

The notification of requests and the acknowledgement of their receipt constitute important steps in the normal decision-making process as to the fate to give to wish of exporter wishing to carry out activities linked to LMOs and products thereof on the Congolese territory. The CNA has a time period of 270 days to make a decision in the case of first deliberate transboundary movement of a GMO or a product thereof.

In fact, the decision making by the CNA must be based on a risk assessment provided for by article 15 of the Protocol and whose purpose is to identify and assess the potential negative

effects of GMOs/LMOs for the conservation and the sustainable use of the biological diversity, also taking into account risks for the environment and human health. This risk assessment will be undertaken in a scientifically sound method, according to annex III of the Protocol. It must communicate to the applicant of the notification as well as to the other States through the Biosafety Clearing House.

The CNA can take one of the following decisions:

- to authorize the import with or without conditions, taking into account the results of the risk assessment carried out by the competent institutions, and indicating whether the decision will apply to or not to future imports of the same LMO;
- to ban the import;
- to request for relevant additional information according to this law and the annex I of the Cartagena Protocol;
- to inform the notifier that the period specified in this paragraph is prolonged of a defined duration.

It is suitable to underline that the fact that the DRC by its CNA does not communicate it decision within the time period of 270 days does not mean that the DRC consents to the import of the GMO or the product thereof candidates for export on the Congolese territory.

Besides, in some cases, when that is necessary, the time period of 270 days will be prolonged and the applicant of the notification will be kept informed. It will be the case especially when:

- additional information will be requested from the applicant of the notification by the CNA ;
- The CNA will need an additional time period to review the proposed transboundary movement of a GMO.

IV.3.2. Characteristics of the applicable procedure of transboundary movements of GMOs/LMOs intended to be used directly as food or feed or for processing

The procedure applicable to transboundary movements of genetically modified organisms intended to be directly used for food, for feed, or for processing concerns mainly the unprocessed agricultural products (maize, colza, soya, wheat, rice and other cereals). The trade of OVMs of this category of GMO is also subjected to the application of the advance informed agreement. Any decision of the DRC approving the use on its territory of a GMO, that is likely to be exported as an unprocessed agricultural product should be communicated to other States within a time period of 15 days through the Biosafety Clearing House.

For that, the DRC by means of this National Biosafety Framework and its National Biosafety Law embarks in a process leading to the response to the requirements of annex 2 of the Protocol concerning the information to supply for any GMO intended for direct use as food, feed, or for processing. The consignments of food aid likely to contain the grain or any part of the vegetable or the plant likely to contain the GMO should be ground before any distribution to the population. The aid consignments in transit will be identified and labelled according to the national law.

According to the recommendation of SADC on food aid containing GMOs.LMOs, the National Framework provides that such GMOs or their products should be milled before entry in the national territory.

IV.3.3. Documentation accompanying the transboundary movements of LMOs and thereof products

The provisions that concern the documentation accompanying the transboundary movements of GMOs/LMOs must allow an unequivocal identification of GMOs/LMOs in the consignments.

The requirements concerning the level of details and the extent of additional information to integrate in the documentation depend on the type of planned use for the concerned genetically modified: contained use, use for food or for processing.

In general, the documentation accompanying the transboundary movements of GMOs/LMOs for a use in the environment must, according to article 18, paragraph 2c of the Protocol, contain at minimum the following information:

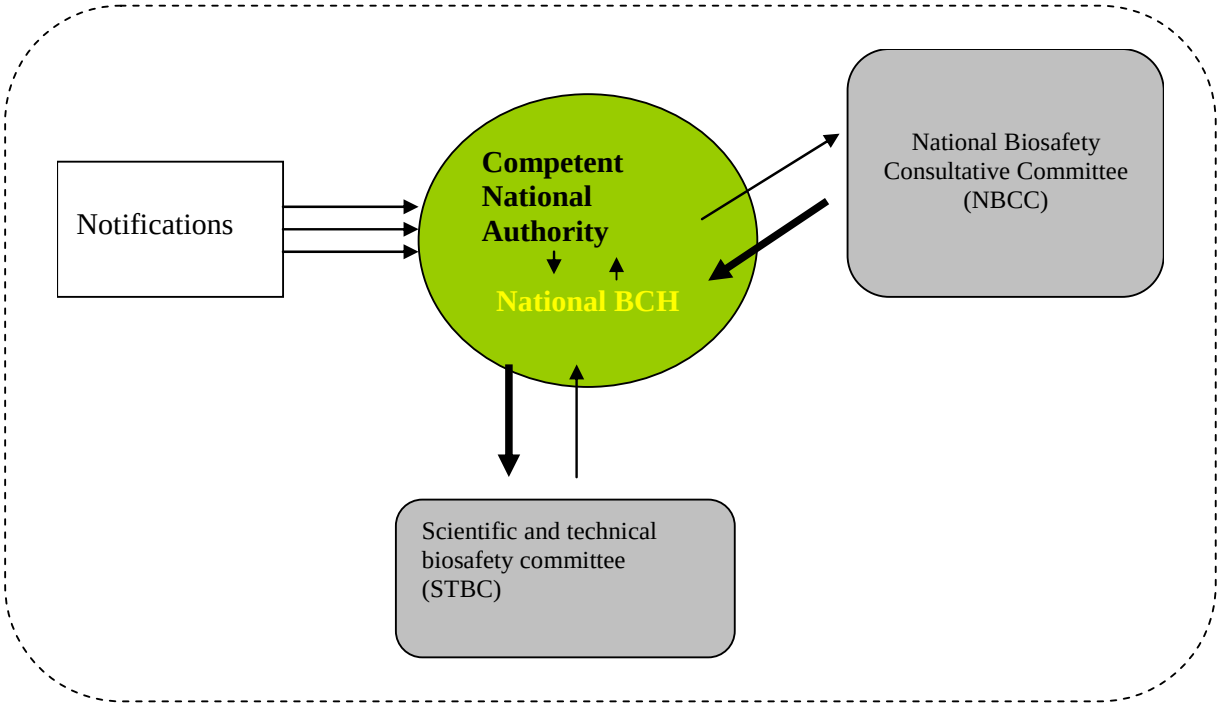
- an unequivocal indication that the material contains GMOs/LMOs and products thereof;
- an identification code recognized at the international level, which gives access to data bank containing the relevant information. If such a code is not available, then the information relating to the identity as well as to the traits and characteristics of GMOs/LMOs and products thereof are supplied in the documentation;
- the specific security rules to observe for the handling, the storage, the transport and the use of the GMO or the product thereof;
- the details of the person or the institution to contact for any additional information, especially in case of problems or accidents;
- the details of the consignee;
- a declaration certifying that the export complies with the prescriptions of the Protocol applicable to the exporter. By this declaration, the importer commits to ensure that the material has been subject to a decision according to the requirements of the procedure of granting the advance informed authorization.

IV.4. Summary diagram of the decision making, risk assessment and management mechanism

The National Biosafety framework of the DRC puts forwards a decision-making mechanism allowing the State, as a Party to the Convention on Biological Diversity and to the Cartagena Protocol on Biosafety, to actively participate in the efforts deployed by the international Community in favour of biosafety. For that, the DRC has opted for an enlightened and transparent decision-making process. Thus, the CNA, which is responsible to make the final decision and follow-up on any request for transboundary movement is assisted in this decision-making process by the National Biosafety Consultative Committee (NBCC) and the Scientific and Technological Biosafety Committee (STBC). The former leads a consultative mechanism to assist the CNA while the latter provides scientific and technical advice to facilitate final decision making.

To effectively carry out its mission, the STBC should supply its scientific and technological advice according to the risk levels recalled in point 3 above. It is in such approach that the DRC intend to solidly anchor the prerogatives of the CNA and its ultimate mission as the competent authority in the implementation of the provisions of the national biosafety Law as well as those of the Cartagena Protocol. In any cases, this National Biosafety Law resolves to grant the necessary powers to the CNA to effectively execute its mandate.

Finally, the following diagram recapitulates the whole process leading to the taking of the final decision by the CNA:



By way of conclusion**,** we will say that to manage any unintentional release and any emergency situation resulting from an accident due to a genetically modified organism, the CNA ensures that an emergency plan is put in place for the protection of human health, biological diversity as well as the environment located outside the area of the release or the contained use in case of an accident; and that the competent emergency services be aware of dangers and be informed in writing. As for identification and labelling, the CNA shall ensure that any genetically modified organisms or its product thereof is clearly identified and labelled. The identification must mention specifically its own traits and characteristics with enough detail to ensure its traceability. Any GMO or product thereof must be clearly labelled and packaged before the display in commercial areas and this, according to legislations and standards in force.

In case of infringements, the CNA can impose other punctive measures, so as to indicate that it is a GMO or a product thereof and, eventually, if the latter product can bring about reactions of the allergic types or cause other risks. As for the confidential information of commercial nature, the CNA does not disclose to third party any information of this type if the notifier requests the confidentiality in writing. This applies especially to importers, business people and to humanitarian NGOs involved in the dumping of products of any type on the national territory. Which information are you referring to, list not included

Besides, the National Biosafety Framework retains that any person that intends to export a GMO or a product thereof must supply to the CNA an advance informed agreement, delivered in writing to the Competent National Authority of the DRC. The presentation of the advance informed agreement does not exonerate in any way the exporter of any of his /her obligations provided for by the rules of international trade. The advance informed agreement does not

prevent the DRC as an export country to take into account other factors authorizing or not the export. If a GMO or a product thereof is subject to a legal ban in the country of origin, its export can in way be authorized. Finally, in the conduct of the proposed decision making mechanism, the CNA will ensure to the total respect of socioeconomic considerations of the Congolese population. The decisions on the import of LMOs in application of the Protocol or national measures to build it will be taken into account socioeconomic impacts for the conservation and the sustainable use of biological diversity, especially those concerning the local or indigenous communities. The necessary provisions, should this happen, to minimize the incidences and/or correct them will be borne by the importer of the genetically modified organism.

The socioeconomic considerations cover the socioeconomic, cultural impacts, the ethical aspects, the traditional/indigenous practices brought about directly or indirectly by the genetically modified organism. Likewise, the conservation of the indigenous cultural and biological diversity is a national priority because we want to conserve for the benefits and well-being of the future generations.

V – CONTROL, MONITORING AND SAFEGUARDING MECHANISMS

The National Biosafety framework of the DRC and national Law on Biosafety makes provisions for the environmental control and monitoring of activities linked to GMOs/LMOs as well as the products thereof. For that, the mandate of regulatory oversight is among others entrusted to the CNA and a safeguard mechanism has been provided for. In total, the control and monitoring mechanism should contribute to conserving the advantages and should that happen, pursue the projects, in a biosafety perspective of with recourse to GMOs/LMOs and products thereof in agriculture and food.

V.1. Bio-vigilance: A national reflex to develop

The DRC expect of all the national institutions to play an active role in biosafety. In this perspective, the importance of the national institutions involved in whichever way in activities linked to LMOs and product thereof should be supported. In fact, it is specifically expected from such institutions a bio-vigilant reflex in the implementation phase of this National Biosafety Framework of the DRC. The list of these institutions is indicated in section ….in the chapter dealing with the administrative and institutional system.

V.2. Monitoring, control and safeguarding mechanism

The administrative structures instituted in the process leading to the set up and the implementation of the National Biosafety Law and this National Biosafety Framework constitute mains links in the whole of the monitoring and control measure. That's why it is entrusted to the CNA to lead, among other missions; those are linked specifically to the monitoring, the control and safeguarding of the steering activities of modern biotechnology. The monitoring, control and safeguarding gives the conduct to keep in cases where difficulties would occur following the approval of GMO especially under exploitation. Let's remember that in such situations, the CNA would be in authority to:

- Order the stopping of any use of GMO or product thereof recognized for negative effects for health, biodiversity and socioeconomic fabrics ;
- Proceed to the seizure and to the destruction of concerned GMOs/LMOs and products thereof.

In such perspective intermediary measures could be envisaged:

- Bringing modifications to the initial authorization conditions ;
- Suspending the activity while waiting for additional information favourable to the going on.
- Imposing to the applicant of the notification to the release conditions of the GMO ;

It is also planned ultimate cases where the sanction could be an required appeal in the carrying out of the mission of biotechnological watch of the CNA on account of national structure responsible of the activities of biovigilance.

VI – PUBLIC PARTICIPATION AND AWARENESS

Article 23 of the Protocol invites and encourages the Parties to inform and make the public participate in the activities on issues relating the living modified organisms. In plain language, the Parties must promote and facilitate the awareness, the education and the participation, as to the access to the information on the transfer, the handling and the safe use of living modified organisms, including the access of the public to the Biosafety Clearing House.

The national biosafety legislation provides for the public awareness and consultation during the decision-making, in the framework of the national regulation and while respecting the confidential character of this information according to the national regulation and that, while respecting the confidential character of this information according to the Cartagena Protocol.

VI.1. General Considerations of public awareness and participation system

The upshot of these surveys carried out in the framework of the development of this national biosafety Framework of the DRC, is that the public expresses a certain number of concerns on the use of GMOs/LMOs especially in food and their impact on the protection of the environment but also in what relates to the impacts of such organisms on the protection of the environment. These concerns are much bigger as the DRC does not have the high-performance research structures on modern biotechnologies or a technology allowing assessing the biotechnological risks in general.

To take into account these concerns, article 23 of the Cartagena Protocol recommends to the Parties to encourage and facilitate the awareness, t he education and the participation of the public in the transfer, the handling and the safe use of living modified organisms in view of the conservation and sustainable use of biodiversity, also taking into account risks to human and animal health, Article 23 itself is based on principle 10 of the Rio Declaration, which dedicates three pillars of public participation: the right of the public to information, the right of the public to participate in the environmental decisions concerning it, the right of the public to go to court so as to obtain redress in case of violation of its rights.

Furthermore, article 14 of the Convention on biological diversity that the DRC has however ratified, encourages the public participation to the evaluation of the proposed projects that are likely to harm noticeably the biological diversity. The participation principle is also reaffirmed by other international instruments relating to the environment to which the DRC is Party, especially the United Nations Convention to Combat Desertification and the Convention for the Sustainable management of Lake Tanganika.

Likewise, the Draft Framework Law on the Protection of the Environment, the draft Framework on Nature Conservation and Forestry Code of the DRC, reaffirm the Principle of public involvement in the development of the policy and in management of the environment, the biodiversity and forests as well as the right to take to court for the protection of the environment.

In a particular way, article 23 of the Cartagena Protocol underlines three important elements in the process: the public information and awareness, the public participation to decision processes and the information on the access to the Biosafety Clearing House.

Thus, public awareness and participation on biotechnological risks constitute one of the obligations of the Cartagena protocol, because a public sufficientlyaware and informed on the biotechnological risks is in a position to understand the issues of the use of LMOs and could further be ready to involve itself in the process of biosafety management.

VI.2. Objectives of public awareness and participation

To ensure the implementation of the provisions of the Protocol and the national biosafety Framework, the following activities must be carried out:

- Making the public conscious through all the appropriate means and channels of communications on the GMOs/LMOs impacts ;
- Educating the public for a better knowledge on the issues linked to the use of GMOs/LMOs ;
- Facilitating the public to access the information on the GMOs/LMOs ;
- Making the public participate in the decision process relating to GMOs/LMOs.

The carrying out of these activities allows guaranteeing the transparency in the implementation of the precautionary principle.

VI.3. Some actions to carry out so as to involve the public

VI.3.1. Information and public awareness

The **information** must be ensured to the public so as to make it aware of the risks and advantages relating to the use of GMOs/LMOs.

The implementation of this objective can be carried out through some of the following actions or measures:

- Availing to the public forms or flyers on the provisions of the Cartagena Protocol and other international instruments dealing with issues relating to GMOs/LMOs, especially the Codex Alimentatius (labelling of food), agreements relating to the Office International des Epizooties, the International Plant Protection Convention, the WTO Agreement on Sanitary and Phytosanitary Measures ;
- Facilitating the public to access information supplied to the Biosafety Clearing House ;
- Organizing TV and radio programmes, conferences, workshops and open days on the use of GMOs/LMOs, their advantages and disadvantages, etc.

VI.3.2. Public education and training

A public well educated and trained can efficiently participate in the decision process relating to the use of GMOs/LMOs. Thus, the availing to the public of necessary and sufficient knowledge on the scientific, legal and economic plans allowing it to understand the issues relating to the use, the handling and the release of GMOs/LMOs and to react to it in appropriate manner.

To attain this objective, it is advisable to set up a capacity building programme for the representative of the civil society, the consumer associations, public and private media,

NGOs, decentralized administrative entities and the local authorities, about some themes so as the latter play a major role in the public education and awareness. This programme can concern the advantages linked to resorting to GMOs/LMOs (in the agricultural sectors, food and others) as well as the negative impacts of the use, the handling and the transfer of GMOs/LMOs (such as the contamination of the biodiversity, the risks of pollution by herbicides, etc.)

VI.3.3. Public participation

The public participation in the decision process relating to the management of GMOs/LMOs assumes its effective involvement in the decision mechanisms defined by this national biosafety Framework and in the decision-making procedures. Besides the participation of the latter in the National Biosafety Committee, the public participation involves, for the CNA, the requirement to inform the population on all the data that will be communicated to it in the framework of the notification. the process of participation provides for the requirement communicating to the population all the information and that, in the reasonable time periods and at various phases of the process. It is also about giving the possibility to the public to submit in writing or during a public hearing or a survey, any observation, information, analysis or option that it judges relevant regarding the planned activities putting at stake GMOs/LMOs.

VI.4. Target groups or audiences

To ensure public participation to the decision process, it is important to determine the target groups. These are especially the political decision-makers, officers and executives of public administration, consumer associations, farmer associations, peasant associations, NGOs, private and industrial sector, trade unions, Federation of Enterprises of Congo (import and export traders), National Federation of Small and Medium Enterprises of Congo, scientific and academic circles, etc. These target groups must be taken into account in the composition of the national Biosafety Consultative Committee and in that of others that should be created in the framework of the implementation of the National Biosafety Framework.

VI.5. Phases of public participation process

To ensure public participation in the different phases of environmental impact assessment, the Framework Law on the Protection of the Environment shall define the public participation in the consultation and in the decision processes.

To better ensure the effective public participation, the CNA will be held to organize all these activities of awareness and education with the different structures involved in biosafety.

These components hinge on four phases: communication, consultation, particpation and partnership.

VI.5.1. Communication phase

During this phase, the CNA, from the reception of a notification, triggers the process of setting up of public consultation structures by gathering the concerned actors. It is in this manner that the CNA ensures the public involvement from the beginning of the process having to

lead to the final decision-making. The CNA informs the public of the information contained in the notification through the intermediary of such structures.

Likewise, the content of the risk assessment report is informed to public through this communication phase. This report is presented to the public by the representative of the notifier/promoter.

VI.5.2. Consultation phase

The consultation phase is very important on the whole of the public participation mechanism. In fact, it is during this phase that all the partners comprising the CNA, the administrative authorities, the notifier/promoter and the consultation structures themselves, freely share information.

VI.5.3. Participation phase

It is during this participation phase that are harmonized the various points of view of partners. The participation phase makes way, should this happen, to the expression of disagreements.

VI.5.4. Partnership phase

The partnership phase intervenes when the presented project collects the favourable opinion of the CNA and the assent of the public. In such an illustration case, this national biosafety framework of the DRC is favourable to the advent of mechanism promoted by an initiative of partnership type involving the CNA the applicant of the notification and a structure representing the public and issued from the population consultation.

VII. RECOMMENDATIONS AND ACCOMPANYING MEASURES OF THE NATIONAL BIOSAFETY FRAMEWORK IN THE DRC

Under the terms of article 22 of the Cartagena Protocol on Biosafety, the Parties cooperate to the development and the building of human resources and institutional capacities in the area of biosafety, including biotechnology in case where it concerns the prevention of biotechnological risks so as to effectively implement the Protocol in the developing country. A particular accent has been put on the cooperation on matters of financial resources, access to technology and to knowledge.

The status of national capacities concerning the biotechnological risk assessment in the DRC reveals sizeable needs.

The areas of national capacity development and building that require a particular support are especially:

- the set up of national structures for biosafety management ;
- the training of human resources concerning biotechnological risk research, assessment and management;
- the equipment in laboratories and in appropriate material means ;
- the support to the development and the implementation of appropriate research programmes;

VII.1. Capacity building of national biosafety management structures

The set up of national structures of biosafety management is a requirement of the Protocol. Among these structures appear especially, the National Biosafety Consultative Committee, the Competent National Authority, the Scientific and Technological Biosafety Committee and the National Biosafety Clearing House.

VII.1.1. National biosafety consultative committee

To perform the missions assigned to it and in anticipation of its installation, it is urgent to build the capacities of the National Biosafety Committee in some areas judged priority and cited below:

- Support to set up of participative methods in the development policies and the legal framework of biosafety;
- Definition of the problematic, objectives, strategies and measures in the framework of policy development;
- Techniques of financial resource mobilization and of mastery of donor financing.

The organization of seminars and workshops seem appropriate in this respect.

VII.1.2. Competent national authority

So as allow the CNA to perform its missions, of monitoring of biotechnological risk assessment and management, its personnel has to be trained and have the required technical competences in the key areas such as:

- Mastery of the provisions of the Cartagena Protocol and the biosafety legal and institutional framework ;
- Definition of the problematic, objectives, strategies and measures in the framework of policy development;
- Techniques of using data of Clearing House of the CBD Secretariat and National Clearing House ;
- Techniques of developing study reports on biotechnological risk assessment ;
- Monitoring techniques of control and supervision actions of release of LMOs and biotechnological activities ;
- Inspection and control techniques of products likely to contain LMOs and the noticing of breaches to the national legislation and police officer with limited jurisdiction to see the application of the national legislation;

The Department of Sustainable Development (technical department) has besides to benefit from the necessary equipment so as to allow it to properly perform its missions: vehicles, IT materials, Internet network, appropriate communication system, etc.

VII.1.3. Scientific and technical biosafety committee

From the point of view of its mission, the capacity building of the Scientific and Technological Biosafety Committee concerns the following areas:

- Mastery of the relevant provisions of Cartagena Protocol and of the national legal and institutional framework of biosafety management ;
- Mastery of the risk assessment and management procedures ;
- Mastery of the risk assessment techniques of the study reports on the biotechnological risks, the inspection and control techniques of products likely to contain LMOs ;
- GMO detection methods of PCR type ;
- Traceability techniques;
- Evaluation of research programmes on modern biotechnology ;
- Techniques of using the data of the Clearing House of the CBD Secretariat and of the National Clearing House.

The Committee should have a reference laboratory and equipments intended for analysis laboratories.

VII.1.4. Biosafety Clearing House

A programme of support to build competence in the gathering, the processing and data assigned to the Clearing House should be the main focus.

The National Biosafety Clearing House has to serve as a national relay to the information-sharing mechanism provided by the Parties to the CBD in the context of

implementation of the provisions of the Cartagena Protocol in relation to international cooperation especially. In fact, in the this very specific context of biosafety, the Protocol has put in place a Biosafety Clearing House in the framework of the mechanism of information-sharing according article 18(3) of the Convention of the Biological Diversity. The Biosafety Clearing House has two main missions: to facilitate the sharing of scientific, technical, environmental and legal information as well as experience data, on the GMOs/LMOs, and to help the Parties to apply the Protocol.

In fact, article 20(3) defines some categories of information that the Parties are required to avail to the Central Portal of the Biosafety Clearing House, especially:

- any existing national laws, regulations and guidelines for implementation of the Protocol, especially those that apply to some imports;
- any bilateral, regional and multilateral agreement in the sense of article 14;
- the cases of GMO imports, exempted from the advance informed agreement procedure;
- the contact details of the person entitled to receive the information communicated by the other Parties States on the unintentional transboundary movements in accordance with article 17;
- the final decisions regarding the import or release of GMOs/LMOs;
- Summaries of its risk assessments or environmental reviews relating to GMOs/LMOs conducted in application of thrit regulation;
- the information relating to cases of illicit transboundary movements;

The national legislation should specifically should be devoted to the principle of creating a national clearing house and provide for the information-sharing with the Biosafety Clearing House.

In conclusion, the legislation of the DRC should take into account a certain number of factors, especially:

- to clearly define the objectives of the regulation ;
- to define the ministry(ies), as well as the specific organisations, in charge of the application the legislation ;
- to put in place or appoint the consultative organs providing advices on the technical aspects of the regulatory decisions;
- to put in place a system of permits or authorizations for the activities involving the GMOs/LMOs ;
- to provide for public information and consultation procedures on the requests for permits and/or on the policy issues ;
- to define information required for a request for permits likely to vary according to the type of GMO and/or the intended activity;
- to provide for a protection of confidential commercial information ;
- to provide for the permits to be able to be assorted of the risk management conditions, including the labelling and marking conditions ;
- to put in place monitoring and review activities submitted to CNA’s authorization, including the respect of conditions ;
- to put in place penalty and sanctions in case of non respect;
- to make for provisions in relation to responsibilities in case of damage caused by the activities involving GMOs/LMOs ;

- make arrangements relating to cases of unintentional introduction and emergency intervention plans, etc.

Some legislative and regulatory texts in force must be reviewed so as to adapt them to the requirements of the implementation of the Protocol. The national Legislation could, if possible, be inspired by the African Model Law on Biosafety.

The Clearing House should besides benefit from the required equipments so as to allow it to be able to properly carry out its missions: IT equipments, Internet network, appropriate communication system, etc.

VII.2. Human and technical capacity building concerning risk research, assessment and management

VII.2.1. Training of specialists

The implementation of the national biosafety policy requires the training of many categories of specialists, especially:

- specialists in biosafety and modern biotechnology (molecular and cellular biology, genetic physiology, immunology, chemical engineering, biochemistry, etc.) ;
- specialists in genetics and related sciences) ;
- biosafety inspectors;
- specialized legal experts in international trade law, in intellectual property and in conflict management;
- communicators, etc.

Training modules and contents adapted to each category of specialists must be conceived.

VII.2.2 Training institutions in potential areas

The following training institutions deserve a support in technical capacity building:

- Faculties of Sciences, of Pharmacy, of Human Medicine, of Agronomics and of Law at the University of Kinshasa,
- Faculties of Sciences, of Pharmacy, of Human Medicine, of Veterinary Medicine, of Agronomics and of Law at the University of Lubumbashi,
- Faculties of Sciences and of Human Medicine University of Kisangani
- University Institute of Agronomic Sciences of Yangambi, etc.

VII.2.3. Support to GMO research structures

The research equipments available at the national level are no longer adapted to the requirements of research and control of products following the implementation of the Cartagena Protocol. A minimum of equipment of biotechnology laboratories and DNA recombining laboratories is more than necessary.

Specific support programmes must be developped in favour especially, of INERA, of SGA-CRN_K, of the National Science Research Centre, ,, the Centre (……) etc.

VII.2.4. Capacity building of other administrations

The DRC has other ministries and administrations which are called to play an important role in the implementation of this National Framework and the National Law on Biosafety and the provisions of The Protocol.

These are especially:

- ***Ministry in charge of Trade*** which is the national notification authority according to article 1010 of TBT Agreement and having under its trusteeship the Congolese Authority of Control which is the national enquiry point according to articles 10.1 and 10.3 of the same agreement (whose mission has been described previously), so as to build capacities of its quality control laboratories of imported products of local production and of standards ;
- ***Ministry in charge of Health*** which has a department in charge of Quality Control of foodstuff and pharmaceutical products. This ministry should build the capacity of its physico-chemical analysis laboratories of foodstuffs, of detection pathogenic germs and of toxicology ;
- ***Ministry in charge of Agriculture*** so as to support especially:
    - the National Seed Bureau (capacity building in conception and quality control of national seed production and the installation of a molecular biology laboratory and the acquisition of basic genetic material) ,
    - the Maize research Centre (installation of a molecular biology laboratory and the acquisition of basic genetic material) ,
    - the Animal and Plant Quarantine Service so as to build capacities of zoosanitary and phytosanitary monitoring as well as the management of animal and plant quarantine on the whole of the national territory) and
    - the Department of Plant Protection with its representations in the various provinces of the country ;
    - the three reference veterinary laboratories of Kinshasa, Lubumbashi and Kisangani as well as the veterinary analysis laboratory of Goma.
- ***Ministries in charge of National Education and of Scientific and Technological Research***: for the acquisition and the rehabilitation of the various laboratories of the university institutions and national research centres: CRSN-Lwiro, INERA, the SGA/CREN-K, the CRAA-Lubumbashi, etc.
- ***Ministry in charge of the Environment*** so as to master the provisions of the Protocol.

Training seminars and workshops could be considered. The training would be about the mastery of the provisions relevant to Cartagena Protocol and to the national legal and institutional framework of biosafety management, the techniques of developing the legal and regulatory framework of the implementation of the Protocol, the mastery of risk assessment and management procedures, the mastery of evaluation techniques of study reports on biotechnological risks, inspection and control techniques of products likely to contain LMOs, financing mechanisms of donors, the control and monitoring of releases of LMOs, the evaluation of research programmes relating to modern biotechnology, the development of bilateral and multilateral cooperation programmes, etc.

VII.3. Practical implementation terms of the National Biosafety Framework

The effective implementation of the national biosafety framework in the DRC involves mobilizing financial means for developing the national legislation, the setting up of biosafety management structures and the capacity building in human and technical management.

In the meanwhile, the National Coordinating Committee set up during the launch of the "National Biosafety Framework in the DRC" Project will be in charge of ensuring the implementation of National Biosafety Framework.

VII.3.1. Coordination and follow-up of the implementation of the National Biosafety Framework

VII.3.1.1. National Coordinating Committee

The composition of the Committee appears as follows:

- **President** : Minister of the Environment, Nature Conservation, Waters and Forests ;
- **1er Vice-President** : Secretary General at the Ministry of the Environment, Nature Conservation, Waters and Forests;
- **2nd Vice-President** : Director of Sustainable Development;
- **Secretary** : the Project Coordinator;
- **Members** :
  - National Research Centre in Natural Science /Luiro ;
  - Agri-Food Research Centre of Lubumbashi (CRAA) ;
  - University of Kinshasa ;
  - University of Lubumbashi ;
  - Faculties of Sciences of the University of Kisangani ;
  - National Institute of Biomedical Research (INRB) ;
  - Faculty of Sciences/ University of Kinshasa ;
  - Ministry of National Economy;
  - Faculty of Agronomic, Genetic Sciences, University of Kinshasa ;
  - Congolese Control Authority (OCC) ;
  - Ministry of Scientific Research ;
  - Department of Plant Production and Protection, Ministry of Agriculture ;
  - Ministry of Rural Development;
  - Ministry of External Trade;
  - Ministry of Health
  - Department of Natural Sciences / Faculty of Agronomics, University of Kinshasa ;
  - Environment/Higher Institute of Education (ISP) ;
  - Department of Human Settlement and Environment Protection ;
  - Civil Society;
  - Private sector (Agri-Food Committee, FEC, etc.)

VII.3.1.2. Technical Coordination Team

The technical team is currently chaired by a Coordinator. It is placed under the supervision of the Department of Sustainable Development of the Ministry in charge of the Environment.

VII.3.2. Mobilization of financial resources for the implementation of the National Biosafety Framework

The setting up of a national biosafety framework in the DRC depends on the level and the capacity of mobilizing financial resources required for the legal, institutional, human and technical capacity building.

Three main sources of financing would be explored:

- The internal resources (State budget, contributions through partnership contracts with the private sector, the NGOs, the private donors, and the resources coming from the use of information available at the National Clearing House to be set up ;
- Resorting to the mechanisms provided for by article 28 of the Cartagena Protocol and articles 20 and 21 of Convention on the Biological Diversity ;
- Resorting to partnership with the support of some traditional partners (EU, WB, FAO, GTZ, etc.).

VII.3.3. Setting up of the National Biosafety Framework

The set up of national structures provided for by the institutional framework of biosafety should naturally lead to the end of the missions of the National Coordinating Committee and the Technical Coordinating Team.

These structures are:

- The National Biosafety Consultative Council;
- the Competent National Authority ;
- the Scientific and Technical Biosafety Committee**;**
- the National Biosafety Clearing House**;**
- the Biosafety National Focal Point.

CONCLUSION

The UNEP/GEF Project relating to the Development of National Biosafety Structures aims at helping the Democratic Republic of Congo to set up the national structure for the management of living modified organisms, so as to satisfy the requirements of the Cartagena Protocol on Biosafety. For this purpose, guidelines for a national biosafety policy, a legal and regulatory framework, an administrative system, a system for risk assessment and management and public participation and information-sharing mechanims have been defined.

Despite some difficulties encountered in carrying out this task, especially the lack of awareness activities on the use or not of modern biotechnology and GMOs/LMOs, the lack of convergence of stakeholders on the biosafety issues, the absence of almost the whole of documents and policies on the use of biotechnologies in general and modern biotechnologies, some advantages have favourably contributed to that among them the Government commitment in the process of ratification of the Cartagena Protocol, the availability of the identified stakeholders and the willingness of the Ministry of the Environment to facilitate the steering of the process.

According to the status of biosafety management in the DRC there is no framework law on the protection of the environment neither a specific legal framework on biosafety fulfilling the requirements of the Cartagena Protocol. The DRC has however legislative and regulatory texts on the phytosanitary protection, the forestry code, the animal sanitary police as well as the protection industrial property rights. However, the Ministries and organisations whose responsibilities are likely to concern the area of biosafety are in place. These are especially the ministries and organisations in charge of agriculture and livestock, of the environment, of health, of external trade, of the industry, of scientific research, INERA, INRB, CRN-K etc. Some competences and expertise in the area of research in biotechnologies are also present. However, the research, risk assessment and management infrastructures that these institutions have are obsolete and rudimentary. The need for capacity building in this area is criticially needed.

As for the components of the national biosafety framework, the policy on this matter should be based on the precautionary and preventive principles in conformity with the provisions of the Cartagena Protocol. The legal framework should in priority aim at preserving human and animal health, the environment and the socioeconomic fabrics faced with the potential risks linked to the use of modern biotechnology. In this respect, the scope of the law relating to the safety in biotechnology should cover all the transboundary movements, the transit, the handling, the placing on the market and the use of any GMO, should the latter be intended to be released in th environment or used as food, feed or for processing or even as derived product of GMO. In case of damages caused on the environment, human and animal health, the liability and redress will be at the cost of the applicant of the notification.

The national institutional framework of biosafety management will be managed by the Competent National Authority, the Biosafety Focal Point, the National Biosafety Consultative Council, the Scientific and Technical Biosafety Committee as well as the National Biosafety Clearing House. The Biosafety Focal Point will be in charge of liaison with the CBD Secretariat on behalf of the DRC. The National Biosafety Consultative Committee will have the status of a consultative organization and of a space of concertation framework instituted by the Government. The Competent National Authority, entrusted to the Department of Sustainable Development, coordinates all the national activities in relation with Biosafety. The Scientific and Technical Biosafety Committee that will rely on the works of reference and analysis laboratories

will be a technical and scientific organ that assists the CNA in performing its mission. The National Biosafety Clearing House will be in charge of gathering the scientific, technical, ecological, legal information as well as experience data relating to living modified organisms.

Finally the public awareness and participation on biotechnological risks has been held as an important component in the biosafety management.

So as to effectively implement this National Biosafety Framework, the human and institutional capacity building will have as a priority be considered in the following areas:

- the management of the legal, institutional and administrative biosafety framework (notification management, decision making process management, application of the regulation at the borders, etc.)
- the risk assessment and management (risk analysis for the environment, human and animal health, the taking into account of socioeconomic considerations, the setting up of a monitoring network, the intervention techniques in case of unintentional release of GMO, the laboratory equipment);
- the public awareness and participation (the introduction of considerations linked to biotechnology and biosafety in the national educational system, the awareness of biotechnology and biosafety to non specialist audiences, the public consultation methods,…)

For this reason, the internal resources and coming from some traditional partners would be made available

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