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Unity – Equality - Peace

MINISTRY OF HOME, URBANISM, ENVIRONMENT AND LAND
PLANNING

DEPARTMENT OF LAND PLANNING AND ENVIRONMENT

NATIONAL BIOSAFETY FRAMEWORK

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LIST OF ACRONYMS

ADB	: <i>African Development Bank</i>
WB	: <i>World Bank</i>
CBD	: <i>Convention on Biological Diversity</i>
CERD	: <i>Study and research Centre of Djibouti</i>
NBC	: <i>National Biosafety Committee</i>
COMESA	: <i>Common Market for Eastern and Southern Africa</i>
DATE	: <i>Department of Land Planning and Environment</i>
IMF	: <i>International Monetary Fund</i>
ACP Group	: <i>Africa, Caribbean and Pacific Group of States</i>
IGAD	: <i>Intergovernmental Authority on Development</i>
GMO	: <i>Genetically Modified Organism</i>
UN	: <i>United Nations</i>
OAU	: <i>Organisation of African Unity</i>
LMO	: <i>Living Modified Organism</i>
PANE	: <i>National Action Plan for the Environment</i>
GDP	: <i>Gross Domestic Product</i>
Cartagena Protocol	: <i>Cartagena Protocol on Biosafety</i>
SIN-CED	: <i>Community of Sahel-Saharan States</i>
SPANDB	: <i>National Strategy and Action Programme for Biodiversity</i>
AU	: <i>African Union</i>
EU	: <i>European Union</i>
rDNA	: <i>recombinant DNA</i>

DEFINITIONS

For the purposes of this law, it should be understood by:

- “Advance Informed Agreement”: agreement obtained on the basis of all required information and committed liability by the information supplier as far as the accuracy and its complete character before the beginning of any activity.
- “Modern Biotechnologies” :
 - (a) Nucleic acid recombining techniques leading the formation of new combination of genetic material by the insertion of molecules of nucleic acids produced by any means external to the organism, in a virus, a bacteria, a plasmid or another vector, and their incorporation in a host organism in which they are not found naturally but they are capable of continuing their activity;
 - (b) Techniques leading to the direct introduction in a genetic material organism that is hereditarily transmissible, and ready outside the organism. This include the micro-injection and micro-encapsulation; and
 - (c) the cellular fusion (including the protoplast fusion) or the hybridization techniques lead to the formation of living cells containing new combinations of genetic material hereditarily transmissible by fusion of two or more than two cells.
- “**Deliberate release**” or “**release**”: any intentional introduction in the environment of a GMO or a product thereof. This introduction can serve the commercial, the food aid, the remediation, research experiment purposes. This arrangement is also about the contained use of genetically modified organisms in the greenhouses, fish farming basins, the building reserved to animals, except if the contained use is authorized for a duly accredited laboratory or other installation especially to treat and eliminate wastes containing GMOs, but also to import, export or transport of GMOs or products thereof.
- “Risk assessment”: direct or indirect risk assessment in the short, medium and long term that the contained use, the release or to the placing on the market of GMOs or products thereof poses to the environment, the biological diversity or the human health, as well as the socioeconomic environment and the ethical values of the country.
- “Export” from a country: any intentional transboundary movement of a GMO or a product thereof undertaken from this country towards another country;
- “Exporter”: any natural person or moral entity that makes arrangements for a GMO or a product thereof to be exported.
- “Competent national authority”: national authority in charge of performing administrative functions that call the

- “Hostile purposes: the elaboration, the acquisition, the implementation or the release of a GMO or a product thereof with intention to cause damages to the human health, the biological diversity, the environment or to goods in a way unauthorised by the Competent National Authority.
- “Socio-economic impact”: all the direct or indirect effects of a GMO or a product thereof on the economy, the social and cultural conditions, the lifestyles or the local knowledge and technologies particular to one or more communities, and as well as to the economy of Congo in general.
- “Import” : any intentional transboundary movement towards the Democratic Republic of Congo or from another country;
- “Importer”: any natural person or moral entity that makes arrangements for a GMO or a product thereof to be imported.
- “Placing on the market”: the supply of or the availing to third party of a GMO and a product thereof that is accompanied with or without monetary exchange or should it be food aid donation.
- “**Notifier**”: any natural person or moral entity that notifies in writing in a view of obtaining from the Competent National Authority the required authorization for the import, the contained use, the release, the placing on the market of GMOs and products thereof, where, should this happen, any person to whom this authorization was already given.
- “Notification”: the presentation of documents containing the required information to the Competent National Authority, with, if need be the handing in of samples implicating the entire liability as for the accuracy and the complete character of the information;
- “Genetically modified organism (GMO)”: any biological entity capable of reoccurring or of transferring genetic material, that is the plants, animals, the micro-organisms (for example viruses, bacteria, mushrooms), cell cultures, all the gene transfer vectors (plasmids, viruses, artificial chromosomes) as well as genetic entities in the form of DNA sequences, whose genetic material has been modified by modern biotechnological techniques.
- “Person”: natural person or moral entity
- GMO derived Product or product thereof: any material obtained through the transformation or any other means, of a genetically modified organisms and a product thereof.
- “Cellular Technology”: the set of techniques for the production of living cells with new genetic material combinations by the fusion of two or more cells.

- “Genetic Technology”: any technique that involve the isolation, the characterization or the introduction of the DNA in living cells or genetic entities used as vector for the transfer of genes (plasmids, virus, artificial chromosome)
- “Contained use”: any operation carried out in a device, an installation or any other physical structure, involving living modified organisms that by particular measures that effectively limit their contact with the external environment, and their impact on this environment.

TABLE OF CONTENTS

LIST OF ACRONYMS	2
DEFINITIONS	3
INTRODUCTION	7
NATIONAL CONTEXT	8
I. STATUS OF BIOTECHNOLOGY AND BIOSAFETY	10
1.1. Status of the regulatory system of national environmental policy concerning biotechnology 10	
1.1.1. State of the law on general policy on the environment	12
1.1.2. Biosafety in the Republic of Djibouti.....	19
1.2 - Status of institutional and administrative system in biotechnology and biosafety	22
1.2.1. The institutional and administrative system in biotechnology and biosafety	23
1.2.2. The institutional and administrative system	27
II. REGULATING SYSTEM OF REQUEST NOTIFICATION AND RISK ASSESSMENT	29
2.1. Biotechnological risk assessment	29
2.2. The regulating system leading to decision-making	30
2.2.1 - General procedure in four stages.....	30
2.2.2. Analysis on a case-by-case basis.....	32
2.2.3. Functioning of the regulating system of decision-making	33
2.3. The administrative and decision-making system	34
2.3.1. The administrative system of request and notification.....	35
III – MONITORING AND CONTROL MECHANISM	39
3.1. Institutions involved in the monitoring and control mechanisms	39
3.2. Monitoring and control policy and safeguard measures	39
3.3. Diagram of Monitoring and control mechanism	40
3.4. A Monitoring and control mechanism turned towards the future	40
IV. PUBLIC AWARENESS AND PARTICIPATION	42
4.1. Public awareness	42
4.2. Public participation to decision-making	42
OUTLINE OF AN IMPLEMENTATION PROGRAMME OF THE CARTAGENA PROROCOL BOOKMARK NOT DEFINED.	
RECOMMENDATIONS	46

INTRODUCTION

The Republic of Djibouti is Party to Convention on Biological Diversity (CBD) adopted in 1992 at the Rio Conference. In January 2000, the Parties to this Convention achieved an important act in its implementation by agreeing on the text of a protocol on biosafety. This treaty known as Cartagena Protocol on Biosafety is specialized on the transboundary movements of living organisms resulting from modern biotechnology. The Republic of Djibouti ratified the Cartagena Protocol. The Ministry of Environment (MHUEAT) is the institution which is in charge of the implementation of the Protocol at the national level. It makes provisions to institute a regulatory framework on a national scale in order to create conditions favourable to the safe and respectful use of biotechnologies. This regulatory framework will have the role of managing by and large the applications of the genetic engineering on the national territory.

It is as from the point of view of the prevention of the potential biotechnological risks and the implementation of the provisions of the Cartagena Protocol as the parties are encouraged to develop their National Biotechnology Framework which will write down the bulk of the guidelines of activities in the area of biotechnology and biosafety. To prepare such a framework, the United Nations Environment Programme (UNEP) provided a financing thanks to the support of the Global Environment Facility (GEF).

The setting up of the National Biosafety Framework is a long process that the Republic of Djibouti leads with intelligence and wisdom. A first stage consisted of the carrying out stock-taking studies which made it possible to stock-take in the area of biotechnology and biosafety in Djibouti. A second stage followed. It covered carrying out two sector-based studies of the biosafety bill and of the constituting elements of the draft Framework. This third stage of finalizing the National Biosafety Framework buckles the production cycle of the document. The CNB will be articulated around four (4) main elements:

- A regulating system to tackle safety issues in the area of modern biotechnology;
- An administrative system to manage the requests and applications for introduction of genetically modified organizations (GMOs) into the national territory;
- A decision-making system including the risk assessment and management related to GMOs;
- Mechanisms of public information and participation in the decision-making;

NATIONAL CONTEXT

The Republic of Djibouti is located in the Horn of Africa between longitudes 41°8 ' and 43°4' E and the latitudes 10°9 ' and 12°7' N. It is bordered to north by Eritrea, to south-east by Somalia and to the west by Ethiopia. In the east, the country benefits from a seaside coast divided between the Red Sea and the Gulf of Aden and which extends on more than 372 km. The country occupies a strategic position, at entry of the Red Sea, the crossroads between Africa and Asia and the countries of the Indian Ocean.

Socioeconomic characteristics

For an area of 23 200 km², the Republic of Djibouti has a population estimated in 2004 at nearly 700,000 inhabitants. This population is characterized by its very unequal distribution. The density of the population is very low (26 inhabitants per square kilometre). More of two thirds of this population lives in the suburbs of the town of Djibouti which is the capital of the country. The growth rate of the population is estimated at a total value of 6% of which 3% constitute the share of migratory flows. The official languages of the country are French and Arabic. Somali and Afar are national languages. The majority of the population (98%) is of Islamic religion. The youth of less than 20 years represent nearly 53% of the population of the country.

The economy of Djibouti is heavily reliant on the service sector which contributes to a total value of 70% of Gross Domestic Product (GDP) and 80% of employment. The tertiary sector especially that of transport, constitutes the main engine of economic growth of Djibouti. The endowment in natural resources being not very important, the contribution from the primary sector to the GDP is hardly higher than 3% while the manufacturing sector contributed only for approximately 15% of the GDP during the Eighties and Nineties.

The livestock is the main activity in the rural environment. The harshness of the climate and the absence of agricultural tradition slow down the development of this sector. However fishing is a sector in growth. This tendency will be accentuated with the recent inauguration of a fishing port and a training centre on the fishing trade. The development of the secondary sector runs up against several obstacles, namely the scarcity of natural resources, the absence of qualified manpower and the high costs of production factors. After several years of recession, Djibouti knows a positive nominal economic growth of about 3.2 % in 2005.

Biophysical characteristics

The climate of the Republic of Djibouti is of the tropical, semi desert arid hot type. The relative humidity varies much, between 40 and 90%, but the average temperature of the air is around 25° C in cool season and with 35° C in hot season. The climate, far from being uniform on the whole territory, varies in times and according to areas. One distinguishes two great seasons. The cool season (October at April) characterized by a rather strong relative humidity of the air which is of 60 % to 85 % and the mild temperatures oscillating between 22°C and 30°C, January being the coolest month. The dry season (from May to September) characterized high temperatures fluctuating between 30°C and 40°C, and a s violent and wind, hot and dry blowing from the west (Khamsin) for fifty days.

Variability in time and space characterizes the climate of the Republic of Djibouti. Thus in the low areas, the harsh and inhospitable climatic conditions, the insufficiency of precipitations even their lack and consequently the absence of rivers, expose plant and animal resources to great risks of degradation.¹. This explains the fact that agriculture is little developed and that the main rural activity remains the pastoral nomadism.

Biodiversity

In spite of a difficult climatic context and a reduced surface, the Republic of Djibouti conceals a rich biodiversity as much in the land and sea area. In land environment, the vegetation of the country, under a monotonous appearance, hides a great biological diversity. On the whole, the flora includes more than 827 species of plants which are distributed in two main dissociated types of vegetations: the mountains and high plateaus vegetation and the hills and plains vegetation. The diversity of fauna also follows that of the vegetation. The mountain forests (Goda and Mabla) shelter the essential of it. The remainder of the territory contains species adapted to the due conditions of aridity. The land fauna counts more than 1417 animal species.

With regard to the marine area, Djibouti has more than 372 km of coasts - as well as islands - and a sea space of approximately 7200 km². The diversity of fauna and the sea flora is concentrated mainly in two ecosystems characteristic of the tropical region: coral reefs and mangrove forests. The mangroves cover a surface of 800 ha and consist of four species of mangroves. The sea fauna includes 409 species of invertebrates and 454 fish species, 12 species of mammals and 4 Reptiles species.²

This biological diversity knows a rapid degradation process. The zones the richest in particular forests are in clear regression. Woodcutting and overgrazing are the main causes of degradation of this biodiversity. More and more, the breeding of goats and sheep more formidable than that of cattle, develop and the degradation of the ecosystems tends rather to the increase. The reduction in wild fauna is consecutive to the destruction of the habitat.

It is under these conditions of brittleness and of unfavourable tendency to diversity maintains biological that the Republic of Djibouti fully intends to contribute to the implementation of *Convention on Biological Diversity* (CBD) and of the Protocol of the said Convention on biological safety related to resorting to genetically modified organisms (GMOs) in agriculture and food know as *Cartagena Protocol on Biosafety*.

¹*Ibid*, pp. 15-29

²République de Djibouti / Ministère de l'Habitat, de l'Urbanisme, de l'Environnement et de l'Aménagement du Territoire / The Regional Organization for Conservation of the Environment of the Red Sea and Gulf of Aden, «Profil côtier de la République de Djibouti», Direction de l'Aménagement du territoire et de l'Aménagement, Djibouti, 2005, pp. 62-71

I. STATUS OF BIOTECHNOLOGY AND BIOSAFETY

Taking into account the importance of issues of modern biotechnology, the Cartagena Protocol grants the necessary time to the Parties, especially those in development, to assess the national conditions with regards to biotechnology. It is in this direction that a certain number of studies known as of stock-taking were carried out by the Ministry in charge of the environment. These studies of stock-taking related on one hand to the regulatory and legislative aspects and on the other hand the administrative and institutional framework. If in this latter case, the results of the stock-taking present an embryonic table to us which deserves to be reinforced to allow the least initiative of implementation of the Cartagena Protocol and the National Biosafety Framework, the report is not as much more encouraging as in the first case. Indeed, the stock-taking on the regulatory and legislative framework concerning biotechnology and biosafety concluded that there is the absence of a law specialized in biosafety to govern the activities in this area. Admittedly, Djibouti is not an agricultural country. On the other hand, it is a service country whose port constitutes a nerve centre of regional scale for receiving, storing, handling and transiting of several thousands of tons of agricultural produce each year.

It is in this part relating to the stock-taking in biotechnology and biosafety that the Republic of Djibouti intends to share its many initiatives of setting-up of plans and strategies of environmental management and sustainable development as well as its will to take part in the movement of the international Community in favour of safely resorting to applications of genetic or bio-molecular engineering as much in agriculture as in food. Indeed, it is during the first stage of the development process of the National Biosafety Framework that the MHUEAT really obtained a pragmatic mechanism which constitutes a true environmental policy. There is no doubt that the *National Action plan for the Environment 2001-210* and the *National Action Programme and Strategy for Biological Diversity* are the main centre pieces of the first stages of a national will towards a sustainable management of the genetic resources with the emergence of a national awakening on the need for a precautionary approach for the prevention of biotechnological risks potentially associated with resorting to GMOs in agriculture and food.

1.1. Status of the regulatory system of the national environment policy concerning biotechnology

It is at the beginning of the Nineties that the Republic of Djibouti really integrated the environmental protection in its socio-economic development policy. To this end, a first national report on the environment was prepared in 1991. This report which was presented in 1992 at the Conference of the United Nations on Environment and Development in Rio (Brazil) had made the stock-taking of natural resources of the country and main threats which they were subjected to. The recommendations of this report were integrated in the Law of economic and social guideline (1990-2000) and were taken again in the second five-year plan on guidelines of economic and social development actions and projects (1991-1995). In 1995, the environment is recognized like one of the national priorities and was attached to the Ministry of Planning, Environment, Land Planning and Co-operation.

The true process of environmental planning began in 1996. It is indeed, on this date that the main guidelines regarding the environment were established and applied. The Department of

the Environment and Land Planning (DATE) is created and the development process of the National Action plan for the Environment (PANE) was launched. This plan draws the main guidelines in the area of the environmental protection. It recommends the integration of environmental dimension in the development and the implementation of economic and social development projects and programmes.

The main environmental problems which emergent in Djibouti especially the desertification due to the climatic changes combined with the anthropogenic pressures, the retreat of biological diversity and the degradation of the natural habitats, have led the country to take part in the search for the solutions to such plagues along with the international Community. This will was expressed by the signature and the ratification of a certain number of conventions, treaties and international agreements especially in relation with biotechnology and biosafety. The most relevant of these instruments are:

- The Convention on the Biological Diversity (CBD) ratified in 1995 whose implementation especially article 19, has led to the adoption by the Parties, of the Cartagena Protocol on Biosafety. This initiative of developing a national biosafety framework for the Republic of Djibouti derives from such a process.
- The WTO agreements of which the Agreement on the Application of sanitary and phytosanitary measures (SPS Agreement);
- The CITES Convention on the international trade in endangered species of wild fauna and flora
- The New African Convention on the natural resource and nature conservation;
- The Model Law of Organization of African Unity (OAU) for the protection of the rights of the local communities, the farmers and the selectors and the regulation of the access to the living resources

At the national level, the country has adopted several plans and programs relating to the environmental management, the main ones are the National Action plan for the Environment 2001-2010³ available since 2000, the *National Desertification Programme* (PAN) and the *National Strategy and Action plan for the Biological Diversity*⁴ which was adopted in 2000. One of the topics tackled in this latter document is biotechnology. In this sector, the Republic of Djibouti already provided for recommendations so as to set-up a structure of prevention against biotechnological risks. All of these national documents constitute the foundation of the process under way which should lead our country to take part in the global biosafety programme within the framework of the implementation of the Cartagena Protocol on Biosafety. That is why, the Republic of Djibouti intends, following the example other Parties, to set up a national biosafety framework and adopt a national law on the matter. The national

³ Republic of Djibouti / Ministry of Home, Urbanism, Enironment and Land Planning, «Plan d' Action National pour l'Environnement 2001-2010», Department of Land Planning and Environment, Djibouti, 2000.

This document is the main reference related to planning in the area of area of the environment and deals, among others, with the planning in relation to the sustainable management of the biological diversity especially in its section concerning "the status of the physical environment and economic pressures."

⁴Republic of Djibouti / Ministry of Home, Urbanism, Enironment and Land Planning, «Stratégie et Programme d' Action National pour la Diversité biologique», Department of Land Planning and Environment, Djibouti, 2000.

This key document deals, among others, with the planning of the implementation of strategies in order to manage sustainably genetic and Biosafety resources especially in 11th topic. Its objective is to formulate a national strategy and action action programme in order to fill the gaps observed during the assessment of biological diversity.

biosafety framework in sight aims at meeting the needs of Djibouti and contributing to find solutions to specific problems to which the country is confronted in the areas of biotechnology and the biosafety.

1.1.1. State of the law on general policy on the environment

This chapter carries out an analytical assessment of the various legal instruments concerning the issue of biotechnology and that of biosafety. We will present in a first section the international instruments ratified by Djibouti and towards which the country has obligations. The second part of this section will be devoted to the national instruments. It is a general stock-taking of the normative and regulatory or legislative activity dealing directly or indirectly with biotechnology and biosafety: environment, agriculture, trade and investments, industry, health, hygiene and safety, food, import and export, pesticides and chemicals used in industry and agriculture. The stock-taking presents in summary the objectives, the scope of the texts. In some cases, legal definitions of terms will be proposed to facilitate enough perception of the legal scope of the issues.

1.1.1.1. General international legal instruments

Far from the idea of reporting here the entire applicable international instruments concerning biosafety. We will however present the guidelines of some of most relevant. The latter are also of different nature ranging from declarations at conventions through charters and work of Commissions. We will try to present them ranked by growth of their relevance in relation with biological diversity, biotechnology and biosafety.

- Sector of agriculture, flora and fauna

The agricultural sector in the broad sense relates to not only plants, but also the livestock and fishery. With regard to vegetable products, agricultural plants are not the only ones concerned. Other components of the flora in permanent contact with man are not safe from genetic modifications. For example flowers. Because of genetic modifications several varieties of flowers already display features more than attractive in the eyes of the decorators of event rooms, heads of household and other buyers. In the same way, the fishery sub-sector is one of the favourite areas of the rDNA technology. However, obviously, the cross-breeding within domestic fauna especially between various dog races, often concerns traditional methods. However, it is not excluded that in the future, man's best companions be cloned by methods of recombining DNA to allow them to better serve man. The legislative process of the Republic of Djibouti wanting to be preventive and prudential in relation to biotechnology and biosafety, it thus appears justified to prevent the biotechnological risk potentially associated with such applications. The legislation process can already find some normative foundations in several relevant international instruments to which the Republic of Djibouti is Party.

- FAO International Treaty on Plant Genetic Resources for Food and Agriculture

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by the FAO Conference of November 2001. It is a legally constraining Treaty which aims at regulating the use of all phylogenetic resources used in food and agriculture. It

pursues a number of objectives among them the conservation and the sustainable use of phylogenetic resources in food and agriculture and the fair and equitable sharing of the benefits arising from their use in harmony with the CBD. Within the framework of this Treaty, the countries should establish a multilateral System of access and sharing of the benefits. It targets mainly more than 64 cultivated species and important fodder plants. The mechanism which it underlies is expected to be efficient, effective and transparent.

➤ The International Plant Protection Convention (IPPC)

The International Plant Protection Convention was adopted in 1951. The Parties to the said Convention however proceeded to its revision in 1979. On this occasion, the objective of Convention was refined "to secure common and effective action in order to prevent the spread and introduction of pests to the plants and the plant products and to promote appropriate measures for their control." The relevance of such a convention in biosafety is not to display much the type of damage potentially associated the introduction of organisms harmful to plants in general can display the similarities with that potentially connected to the release of LMOs in the environment.

▪ Sector of Food Security : the Codex Alimentarius

The Alimentarius Codex is one of the rare structures of the U.N. system which elaborates international standards. It enacts standards in relation to food safety the Codex Alimentarius or Food Code represents a set of elaborate food standards. It emanates from the Food and Agriculture Organization of the United Nations (FAO) and from the World Health Organization (WHO). To conduct its mission without mishap, the Alimentarius Codex was given a Commission with the same name and this, since 1961. The standards enacted by the Codex relate to the aspect and the labelling of the products, the composition, the additives and the hygiene, the residues of pesticides, the veterinary products etc. These standards are used as national minimal reference to the national authorities. The standards enacted by the Alimentarius Codex act as landmark although they do not escape from the general tendency of the international law of resorting to the goodwill of the Countries rather than constraining it.

From its technical skills of developing standard thresholds and international standards in relation to the harmlessness of the food products, the Alimentarius Codex has a considerable scope nowadays and is used as reference in WTO conflicts since the adoption of the agreement on the application of sanitary and phytosanitary measures (SPS Agreement) and of the agreement on the technical barriers to trade (TBT). The Alimentarius Codex establishes standards and does not apprehend the harmfulness potential in the name of precaution. It is a technical structure. So it can to a certain extent prove to be in a subtle conflict with Convention on Biological Diversity and the Cartagena Protocol on Biosafety which instruments recommend the precautionary approach. Though it is, it is to be hoped that the Codex can enjoy autonomy and transparency in order to effectively contribute to the definition of sufficient scientific proof for the international trade of the agricultural produce and GMOs, in fixing the thresholds of presence of GMOs in food for labelling and in developing detection methods and techniques of transgenes for the traceability and the withdrawal of the trade channels of agricultural produce questioned in the event of a problem.

- Sector of the environment and sustainable development

The sector of the environment and sustainable development is certainly one of the sectors of the biological and genetic resource management where the normative activity will have to influence more the legislative activity in Republic of Djibouti on biotechnology and biosafety. We will mention here the conventions in the area. The CBD and the Cartagena Protocol will be put off temporarily to be used as centre pieces in the next section beside the Rio Conference and Agenda 21.

➤ Declaration on the Human Environment

Strong of twenty six (26) principles referring to values that the international Community recognizes the fundamental character; the *Stockholm Declaration on the human Environment* was adopted on June 16, 1972 in Stockholm, at the time of the United Nations Conference on the Environment. This convention is rightly regarded as the starting point of the development of the international environmental law which made real great strides only towards the beginning of the Nineties. The main principles put forward by this declaration relate to general principles of the environmental law which law is increasingly complex faced with the new environmental challenges caused by technological innovation. The main principles of the Stockholm Declaration on the Environment are:

- *Principles 1*: Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations.
- *Principles 11*: The environmental policies of all States should enhance and not adversely affect the present or future development potential of developing countries, nor should they hamper the attainment of better living conditions for all.
- *Principle 21*: States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

There is no doubt that some of these principles will find their prolongation in the implementation of the CBD and the Cartagena Protocol on the biosafety knowing that the latter normative framework aims, among others, at safely resorting to GMOs in agriculture and food.

➤ World Charter for Nature

The Parties to the Cartagena Protocol which will have to take up the important challenge of liability and redress in the event of harmful effects of GMOs on biological diversity, human and animal health, could be influenced by the World Charter for Nature, adopted and proclaimed solemnly by the General Assembly of the United Nations on October 28, 1982.

This one proclaims 24 principles of conservation to the glance of which all human conduct adversely affecting nature should be apprehended, guided and judged.

Already the concept of the environmental impact assessment was pretty well anchored in the minds. Thus principle 11 concerns the control of activities which can have an impact on nature while mentioning the necessity of conducting of environmental assessment studies of the consequences of the impacts of development projects on nature. The Charter encourages each State, intergovernmental and nongovernmental organization and each individual to strive for nature conservation. Such calls will only be able to be beneficial to measures of biotechnological watch from the States to face the biotechnological risks potentially associated with GMOs.

Impacts of international trade on the environment

The international trade of agricultural produce resulting from genetic engineering is at the heart of the conflict between the WTO agreements and those of the UNEP. Admittedly, in the recital of the Cartagena Protocol on Biosafety, the Parties agreed to encourage each other to interpret this conflict situation as being an incentive with a mutual support between the agreements of the two organizations for the advent of sustainable development. However, in practice the conflicts between the environment and trade remain and will remain present. This sad situation should invite the Parties without resource faced with the potential biotechnological risks especially the developing countries developing their national biosafety frameworks and their national laws in the area.

➤ Agreement on the application of Sanitary and Phytosanitary Measures (SPS)

The Agreement on the application of Sanitary and Phytosanitary Measures (SPS) is the main agreement which governs the international trade of the agricultural produce in general. This WTO Agreement concluded during trade negotiations from the Uruguay Round is a normative framework from which the Member States will have to set up their own Sanitary and Phytosanitary Measures which seem necessary to them to protect the health of people, animals and plants. In the enactment of their measures, the Parties will have to ensure not to resort to more constraining measures of discriminatory types. For example, the SPS Agreement puts forward a condition of proportionality (article 2.2) which wants that the measure should only be applied to the extent necessary to protect human, animal health or plant and the life from the people and animals or to protect the plants. Consequently, it should not harm the liberalization of the international trade by measures consisting of more than necessary levels of protection. The SPS Agreement talks about an appropriate level of protection (art 5.6). In the same way, the SPS Agreement provides for another principle said of sincerity and of non-discrimination in its article 3.2. At the end of this provision, the adopted measure should not constitute a disguised protectionism. Lastly, this WTO measure establishes the scientific evidence (article 5.2) to maintain any measure considered to be restrictive to the trade or discriminatory to the Party which feels wronged. It is up to the member who keeps the measure to prove of the harmfulness of the undesired product. The required scientific proof is said sufficient.

➤ The Agreement of Technical barriers to Trade (TBT)

The Agreement of Technical barriers to Trade (TBT) is another WTO agreement adopted during the Tokyo Round of 1979. It deals with the preparation and adoption of technical requirements relating to the industrial and agricultural products (article 1.3). It is an important Agreement for all the commercial aspects of the environmental policies and, especially, for all that implies technical standards. It provides that the Member States can take measures being able to constitute technical obstacles with the trade, necessary to their policy of public health or environment, but under certain conditions (article 2.2 draws up a list of legitimate objectives). The TBT Agreement also envisaged a procedure of notification to allow businesspeople to adjust their exports with the necessary technical requirements (article 2.9). With the SPS Agreement, the WTO Agreement will have to be at the origin of an important jurisprudence within the WTO Dispute Settlement Body. These are two agreements which will have to be surely confronted with the environmental and socio-economic standards especially in the area international trade of agricultural produce resulting from modern biotechnology.

- Sector of intellectual property: International Convention for the Protection of New Varieties of Plants (UPOV) of 1961

The International Convention for the Protection of New Varieties of Plants (UPOV) 1961 emanates from the World Intellectual Property Organization (WIPO). This latter organization was instituted by the Stockholm Convention of July 14, 1967. WIPO is a specialized organization of the U.N. system. It has the role of managing the international regulation on the intellectual property rights and this, well before the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) came to be interested in this question. WIPO manages two Conventions: the Paris Convention for the industrial protection of 1967 and the Berne Convention for the protection of literary and artistic work. On top of its administrative function, WIPO plays a political function in the sense that it works to promote the international protection of intellectual property. Under this last function, WIPO participates in work of the Convention on Biological Diversity through its Intergovernmental Committee in charge of examining the questions of intellectual property relating to genetic resources. It is in its activities on the vegetable kingdom that this international institution joined the concerns of the Parties to the CBD. Indeed, the International Convention for the Protection of New Varieties of Plants (UPOV) establishes a mode of the rights of vegetable obtaining making it possible to protect the obtentor from the plant varieties while recognizing the exemption of research and the privilege of the farmer. It underwent a certain number of modifications (1972, 1978 and 1991) going in the sense of more strict measures, being like licence systems, for the protection of new varieties of plants.

➤ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) relates to almost all the areas of the intellectual property except for new varieties of plants and the models of utility: copyrights, related rights, marks. It extends the areas of patentability. Indeed, under the terms of article 27.1 of the TRIPS Agreement, a patent could be obtained for any invention, of product or process, in all the technological fields any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an

inventive activity and are capable of industrial application. Admittedly, the TRIPS Agreement gives way to the UPOV on the plant kingdom especially on new varieties of plants. However, with the advent of the Declaration of the TRIPS Agreement on the public health the agricultural GMOs with double pharmaceutical vocation known as the next generation GMO of will have to revive the intellectual property right in the patentability of variety of agropharmaceutical GMO.

As a conclusion to this section, we can say that the standards emanating from the international organizations to which the Republic of Djibouti is Party do not certainly fall under the constraint but are on the other hand an important source of inspiration which is at the origin of an intense legislative activity.

1.1.1.2. Outline of national legal instruments

The Republic of Djibouti led a considerable legislative activity in the area of environmental management during the last decade. It should be said that the Constitution of the Republic of Djibouti intends to guarantee to any person the right to enjoy its fundamental freedoms while establishing the duties of individuals. The environmental concerns are with the heart of such a priority; what explains the fruits of an active policy in favour of national environmental protection and human development. Several legal texts have seen the light thus making it possible for the Djibouti State to show its firm will to equip the country with a relevant legislative system with regards to the environment.

However, it is important to note that with regards to biosafety the bulk of the regulation revolves around the activities of the port which constitutes the main nerve centre of the economy. Indeed, the Republic of Djibouti draws the bulk of its foreign currencies from activities related to services. The country is not an arable land but has a port by which transits the bulk of the goods bound for landlocked countries of the sub-region among them Ethiopia. It is thus all logical that the existing legal texts target safety in the transport of dangerous products through the territory. This is especially necessary as the geomorphology and the climate of the area can constitute difficulties for the transportation of goods. However, it is desirable that the State dwells on the regulation of the agricultural sector which, though the local production is almost non-existent, calls out to the importance of the flows of agricultural produce imported mainly by neighbouring Ethiopia. This constitutes a major concern when it is known timidly that the management of the legal activity of environmental issues affects a weak agricultural sector turned towards outside and this, in a context marked by emergence of preventive national measures faced with the potential risks associated the international trade of the products resulting from GMOs.

However that may be, the texts of legal consequences coming under the general policy with regards to the environment are of different nature. These are laws, decrees or acts. They constitute the state of the Djibouti law on the matter. They are listed within the framework of the development approach of the National Biosafety Framework and are presented in four headings successively relating to trade and industry, health and food safety, agriculture and fishery and finally the environment. The table below presents the inventory of the legislation:

- The national legal instruments in force in the area of trade and industry

- Law n°70/AN/04/5th L relating to the ratification of membership at the African Trade Insurance Agency;
 - Decree n°2002-0420/PR/MCIA relating to the conditions of issuing compliance certificates and marketing licence of conditioned water;
 - Decree n°2000-0724/PR/MAEM relating to the standards of marketing of some fresh or frozen fishery products and intended for export;
 - Law n°63/AN/94/3e L relating to the membership of the Republic of Djibouti to the Bangui Agreement instituting the African Organisation for Intellectual Property (A.I.P.O);
 - Law n°150/AN/02/4th L relating to the membership of the Republic of Djibouti to the International Conventions relating to Intellectual Property;
 - Decree n°2003-0212/PR/MHUEAT relating to the regulation of transport of the dangerous products.
- The national legal instruments in force in the area of health and food security
 - Decree n°93-0581/PR/MADR relating to the establishment of a national committee of fast alarm and information on food safety;
 - Decree N°2000-0727/PR/MAEM relating to the chemical criteria with which some animal food products or of animal origin must comply;
 - Decree n°2000-0728/PR/MAEM relating to the microbiological criteria with which some animal food products or of animal origin must comply;
 - Decree n°2001-0010/PR/MCIA Regulation of the conditioned water intended for human consumption;
 - Law n°118/AN/01/4th L relating to attributions and the organization of the Ministry of Health;
 - Law n° 48/AN/99/4th L relating to the Health Policy Guideline.
- The national legal instruments in force in the area of agriculture fisheries
 - Decree n°2000-0729/PR/MAEM relating to the hygiene conditions applicable in the selling places of wholesale fishery products;
 - Decree n°2000-0726/PR/MAEM relating to the hygiene conditions applicable aboard factory ship and fishing vessels;
 - Law n°23/AN/03/5th L relating to the modification of the administrative organization of the Ministry of Agriculture, Livestock and the Sea, in charge of Hydraulic Resources;
 - Law n°113/AN/96/3e L relating to the ratification of convention on biological diversity;
- The national legal instruments in force in the area of the environment
 - Law n° 106/AN/00 4th L of 29 October 29, 2000 concerning the framework environmental law (LCE). The framework environmental law was adopted by the government of Djibouti in the year 2000. The framework environmental law is reinforced by its application decree. Both, the framework law and its

application decree contain the gist of the provisions necessary for achieving sustainable development. From its publication, the framework law and its application decree were called already to replace the previous texts whose effects are cancelled by the advent of this new basic text.

- Decree n° 2001-001/PR/MHUEAT relating to the definition of the environmental impact assessment procedure has the purpose of carrying out a "prior review of predictable potential impacts" of a project. The assessment must be based on scientific knowledge available in order to lay them down and "to bring them to an acceptable level, within the limits of available technologies and at an affordable cost". The provisions of article 2 of the decree bring back for us to the assessment study on biotechnological risks which is prior to any transboundary movement GMOs in question in the provisions of the Protocol.

The other instruments of environmental significance are as follows:

- Law n°137/AN/85/1st L of January, 27 1985 relating to the repression of prohibited hydrocarbon discharges for ships flying Djibouti flag, outside territorial waters;
- Decree n°90-0534/MPAM of June 11, 1990 regulating navigation in Djibouti water in order to prevent accidental marine pollution;
- Law n°93/AN/95/3rd L of April 4, 1996 relating to the Water Code;
- Decree n°2000-0031/PR/MAEM of February 12, 2000 taken pursuant to the Water Code and relating to the fight against water pollution;
- Law n°66/AN/00/3rd L of December 7, 1994 relating to Mining Code;
- Law n°187/AN/02/4th L of September 9, 2002 relating to the "Fishery Code";
- Decree n°99-0268/PR/MATETA relating to the creation of the National Coordinating Committee of Biodiversity;
- Law n° 186/AN/02/4th L relating to the ratification of the Convention on Wetlands / Ramsar Convention.

At the end of this section devoted to the state of law of the general policy on the environment in Republic of Djibouti, compels us to note the legal vacuum in the specific matter of biosafety. However, with the ratification of the CBD and the Cartagena Protocol by the Republic of Djibouti, it is advisable from now on to note a dynamic and a need for emergence of a national biosafety law.

1.1.2. Biosafety in the Republic of Djibouti

The International Conference of Rio on Environment and Development and its Action plan Agenda 21 constitute without any doubt an abrupt awakening of the international Community from now on eager to combine its efforts for sustainable development. The emergence of the Biosafety standard in Republic of Djibouti following the example other Parties to the CBD, finds its origins in the big meeting of Rio.

1.1.2.1. The Rio declaration

It is 20 years after Stockholm that the international Community gathered at the Rio Conference which was held from June 3rd to June 14th, 1992. This great planetary meeting saw converging towards Rio 178 delegations including 117 led by a Head of State or Government. At the time of this United Nations Conference on Environment and Development known under the term of "Earth Summit", the States completed the "globalisation" of the international law of the environment in continuity of their work started initially in Stockholm. This results in the trilogy: "sustainable development" (principle 1), equitably meeting the needs "of present and future generations" (principle 3) and "common but differentiated responsibilities" (principle 7). It was especially noted the formulation of the precautionary principle (principle 15) for our purposes. It was put forward as follows: "*Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*". The other relevant salient points in our study are the internalisation of environmental costs for redress under a principle known as of the polluter *pays* (principle 16) and the generalization of the environmental impact assessment in principle 17.

No doubt that while contributing to the awakening of the extent and the importance of the problems arising from the environmental protection, the Stockholm and Rio Conferences were at the origin of an impressive normative development.

1.1.2.2. The Agenda 21

The Rio Conference was not only satisfied to retain principles. It was also concerned with actions: Agenda 21. It rises from the report made by governments on the perpetuation of disparities between and within nations. Scourges for the first time were denounced with a sense of urgency to face them with a common will never expressed before by the international Community in all harmony. The main scourges are: the worsening of poverty, hunger, ill health, illiteracy and continuous deterioration of ecosystems on which man depends for his daily quest for well-being. Agenda 21 is a program which reflects a global consensus and a political engagement at the highest level on the co-operation regarding issues of development and environment. It produced recommendations for a global partnership founded on the need to accept an approach balanced and integrated into the problems of environment and development. It tackles urgent problems and seeks to prepare the world to achieve tasks which are essential to whole of humankind at the beginning of this 21st century. This global programme deals among others with the questions relating to the conservation of biological diversity in its chapter 15 and to the environmentally sound management of biotechnology in chapter 16. The scopes of activities retained on these two chapters are of vital interest for the prevention of biotechnological risks. These two chapters illustrate the need of applying the requirements of the Cartagena Protocol on Biosafety.

1.1.2.3. The Convention on biological diversity (CBD)

The text of Convention on Biological Diversity was the fruit of a long process of international negotiations carried out in the preparatory phase of the Rio Conference. Though this text was

adopted on May 22, 1992, during the Nairobi Conference as another concrete act, proof of commitment of the international Community in favour of sustainable development, it is on June 5 in Rio that the CDB had been signed and ratified by almost all States. From the first subparagraph of the preamble to Convention, it is asserted that the intrinsic value of biological diversity defined in article 2 as the variability among living organisms from all sources including, among others, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems, dynamic complexes of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit . The objective of conservation of the ecosystems in their diversity is accompanied by the concern of ensuring an economic development at the same time equitable, rational and profitable.

1.1.2.4. Bonn Guidelines from the CBD

The momentum of the CDB did not fade away in Rio. Strategies and action plans are born and are actively started within the framework of the implementation of the said Convention. It is in this context that it is advisable to locate the development of the Bonn Guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization. It was for the Parties to the CDB to develop and of establish legislative, administrative or policy measures on access and benefit-sharing, considering especially the provisions of articles 8 J, 10 C, 15, 16 and 19 of this Convention as well as contracts and other arrangements under conditions agreed upon by mutual agreement for access and benefit-sharing. Its Scope relates to all genetic resources and associated traditional knowledge, innovations and practices covered by the CBD. Its main objectives aim among others: 1) To provide Parties with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits; b) To provide guidance to Parties in the development of access and benefit-sharing regimes; c) To provide capacity-building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements. The Bonn Guidelines are voluntary and are not legally restrictive.

These initiatives and action plans had positive repercussions at the internal level of Parties like the Republic of Djibouti where it is noticed a response to such initiatives and plans by the development of two key documents which give a pragmatic character to the Framework Law on the environment. These documents are the National action plan for the Environment 2001-2010 and the National Strategy and Action Plan for Biological Diversity.

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1.1.2.5. Environmental management action plan and strategies

From its ratification of the CDB on August 27, 1995, the Republic of Djibouti is resolutely engaged in the process of implementing of the said Convention. For this purpose, from 1998 to 2000, important work of stock-taking on the various aspects of biodiversity was completed. The results of all these studies were brought together and gathered in the *National Monograph of the Biological Diversity* which constitutes a reference document in this area. It is also on the basis of these stock-taking, which moreover made it possible to identify gaps and needs at the national level, that was adopted *the National Strategy and Action plan of Biological Diversity* (SPANDB). This latter document tackles 18 topics of which biotechnology - biosafety. The action programme contains in each topic priority projects. The project entitled

"Setting up of the national biosafety structure" that the Republic of Djibouti currently being carried out, rises directly from this action programme.

Likewise, the ratification of the Cartagena Protocol in 2000 expresses the will of the Republic of Djibouti to engage in a process leading to obtaining a national biosafety framework. The State is aware that the signature and the ratification of the Cartagena Protocol are not enough. To prevent and manage biotechnological risks related to the introduction of GMOs and products thereof in the Djibouti territory, it appears from now on imperative that the country lays down and adopts a real biosafety policy as well as a law on the matter. The Republic of Djibouti must also set up administrative structures and an institutional framework which will have the role of implementing the said Protocol. For the Republic of Djibouti, the division fair and equitable sharing of the economic effects rising from resorting to the genetic engineering in food and agriculture, go through two main mechanisms of national development policies: 1) To completely prohibit the introduction, on its territory, of GMOs and all products thereof presenting or being able to present potential biotechnological risks 2) To benefit from the potential economic advantages of modern biotechnology through a sustainable management of the genetic resources in a strict application of the provisions of the national biosafety framework as well as national biosafety law.

With this intention, the Republic of Djibouti intends to proceed to receiving into national law the relevant provisions of the Cartagena Protocol with which normative framework; the country intends to proceed to the prevention of the biotechnological risks on its national territory and the international scene. Indeed, taking into account the socio-economic and natural conditions, the country will sooner or later need biotechnology, especially in the area of agriculture to find a solution to the climatic and soil constraints. This choice will enable it to benefit from the advantages related to biotechnology while obtaining a national biosafety framework to prevent and manage biotechnological risks.

1.1.2.6. The advent of the Law on biosafety in the Republic of Djibouti

The text of the Djibouti Law on the environment is being drafted and will be subjected to the process of adoption provided by the national texts. The biosafety bill includes four main parts. The first part is about the objectives of the law, the definitions as well as the scope. The second part of the law deals with the decision procedure as well as the risk assessment while the third part is devoted to the public participation. Finally the fourth part of the law is devoted to the liability and redress.

1.2 - Status of institutional and administrative system in biotechnology and biosafety

The prospect for setting-up of a national environmental policy centred on the biosafety faced with a possible resorting to modern biotechnology has led to the carrying out of stock-taking studies. The latter made it possible to make a certain number of findings. It was indeed noted two types of feared risks: potential risks dependent on the use and handling of GMOs and the products thereof by the national research structures and the potential risks related to the import of GMOs and products thereof.

At present, the risks related to the practice of biotechnology on a national scale can be regarded as almost non-existent. Indeed, no institution practises modern biotechnology such as article 1(i) of the Cartagena Protocol defines it. But, in the more or less long term, it could develop and generate potential risks for the environment and human health. The Research and Study Centre of Djibouti (CERD) has just obtained recently a new laboratory of plant biotechnology. Its activities are currently limited to the multiplication by *in vitro* culture of the date palms. The laboratory is not yet equipped in molecular biology but in future, it could direct its activities towards the genetic transformation of plants. Moreover, the ISERST (old name of the CERD), had made attempts at genetic transformation of two plant species: *Boswellia will papyrifera* (incense tree) and *Acacia nolitica* (fodder species).

The risks related to GMOs and products thereof coming from outside are potentially high because the Republic of Djibouti imports almost the whole of foodstuffs for national consumption and this, coming from and of all continents. To that is added the fact that the Djibouti port constitutes the main regional port by which transits the majority of foodstuffs intended for the neighbouring countries. On this subject, it was indeed noted that:

- Lack of sanitary and phytosanitary quality control and vigil structure: several foodstuffs, intended for sale on the national territory or in transit towards the neighbouring countries, especially animal and plant species, are not subject to any control.
- The absence of legislation for control and identification of products: enormous quantities among them foodstuffs and fertilizers in transit by the port of Djibouti towards Ethiopia in a current context marked by the absence of legislation for the control and the identification of such products].
- The supplying of agricultural inputs takes place, besides the port of Djibouti, at the levels of several sites on the national territory and evades the regulation in force. This fact concerns, among others, seeds, plant varieties and animal species.

It is in such a general rudimentary context that the Djibouti State will have to take up the challenge of biosafety faced with the advent and the popularization of resorting to GMOs in agriculture and food. No doubt, the absence of legislation regarding biosafety on the one hand and the failure in control systems of imported foodstuffs on the other hand, expose the country to major biotechnological risks faced with the introduction of GMOs and products thereof, potentially sources of harmful effects on the environment and human health. Consequently, this national initiative aiming at setting up and implementing a national biosafety framework and a national law on the subject is a matter of necessity.

1.2.1. The institutional and administrative system in biotechnology and biosafety

One of the centre pieces of the emergent system of planning in biotechnology and biosafety in Republic of Djibouti, in fact the national document entitled "*National Strategy and Action plan for Biological Diversity*" devotes its chapter 11 on the themes of biotechnologies and biosafety. It has been admitted that biotechnologies and biosafety are not very developed

Republic of Djibouti. In fact, there is no research institution which works directly on modern biotechnology of recombining DNA. It is also in this document which makes a stock-taking on planning regarding actions to carry out in implementing the CDB that it was stressed that several government departments deal very partially and separately, with subjects relating to biosafety management. Lastly, the *National Strategy and Action plan for Biological Diversity* proposed a project profile in order to promote a national expertise on biotechnologies and biosafety. However, even if the inadequacy of such entities faced with the prevention of biotechnological risk is no longer to prove because of the novelty of concerns on modern biotechnology, it does not remain less that the national responsibilities are present and in processes to be assumed entirely within the framework of the setting up and the implementation of the National Biosafety Framework and the National Biosafety Law. The governmental entities and other institutions on the list are the following:

- Intergovernmental Authority on Development (IGAD);
- Bureau of Standards and quality of the Ministry of Trade;
- Bureau of hygiene of the Ministry of health;
- The various departments of the Ministry of agriculture;
- The Studies and Research Centre of Djibouti (CERD);
- The Department of Land Planning and Environment.

1.2.1.1 - IGAD and biosafety

The IGAD is an institution with intergovernmental vocation. It is preparing a project report on the topics of biotechnology and the biosafety. In this project report, the IGAD seeks to define a strategy on:

- food safety;
- biosafety;
- regulatory mechanisms of GMOs.

The project will be submitted to donors for financing. There is a plan to organize a workshop for the IGAD sub-region in order to harmonizing the three topics above-mentioned.

1.2.1.2. The Ministry of Trade

The Ministry of trade is one of the most important links of the prevention mechanism of biotechnological risks in emergence in Republic of Djibouti. It is known that the CDB and the Cartagena Protocol are instruments with strong commercial component. However that maybe, the Ministry of trade has, among others, the mission of taking care of

- rationalization,
- monitoring of imports,
- promotion of Export trade,
- well organizing the distribution so as to especially ensure that there is a regular provisioning of the market.

There is within the Ministry of trade, has Bureau of Standards and Quality Control whose mandate is to protect the consumer against local products imported that are harmful, falsified, deteriorated or contaminated. It is also in charge of the regulation of foodstuffs, especially production, preparation, conservation, transport and sale. It is also the Bureau of standards

and Quality control which is entitled to issuing certificates of origin for products exported to countries of the Common Market of Eastern and Southern Africa (COMESA). This bureau plans to construct a quarantine centre for the animals for export in the small district of Douda. However, the personnel and the infrastructures of the Bureau of Standards and Quality control are far from effectively facing up to the prevention of biotechnological risks of products resulting from genetic modification. The fact that this service does not have analysis laboratory partly explains its limitations. Moreover, it calls upon the laboratories of the Department of Public Epidemiology and Hygiene of the Ministry of Health and that of the CERD to trace the major chemical elements and heavy metals of imported bottled mineral water.

1.2.1.3. The Ministry of Public Health

The Ministry of Public health is at the centre of any biosafety concern. From the point of view of resorting to GMOs in food and agriculture, it has to play an important part. In the implementation of the Cartagena Protocol, the international Community fears indeed, the potential risk related to the transboundary movement GMOs on biological diversity, also taking into account human and animal health. The Department of Epidemiology and Public Health known in the past as the Department of Prevention and Public Health includes three services: a national laboratory of public health; a service of communicable diseases and a service of public health. Here, biotechnologies and biosafety hardly constitute spheres of activity even though four laboratory technicians are involved in the area of the banal microbial flora considering cases involving *E.coli bacillus* and in serology.

1.2.1.4. The Ministry of Agriculture and the food security issue

The sector of agriculture is certainly the one that which challenges more the international Community when it is a matter of policies and strategies of prevention of biotechnological risks. The Ministry of Agriculture operates in the following areas: livestock production, fishery production, plant production and improvement of plant canopy and forests, veterinary and food control, the study and exploitation of the water resources at the rural and urban level. This Ministry has to play an important part in the fight against poverty by supporting the setting up of conditions necessary to the increase in the agricultural production in a difficult context characterized by desertification. Already, the ministry makes the promotion of oasis agriculture where the date palm will play a central part. The recent creation of the laboratory of *in vitro* culture at the CERD specialized on the culture of *in vitro seedlings* of date palm comes to support the Ministry of agriculture in its national policy of promotion of perennials adapted to the harsh soil and climatic conditions. No doubt that an adequate capacity building of this biotechnology laboratory will largely contribute to take up the challenge of biosafety in Republic of Djibouti.

Following the example plant sector of agriculture, those of livestock and fishery are also favourite grounds of applications of technological innovation of recombining ADN. From such a point of view, the Department of Livestock and the Department of Fishery are sectors which will play a part in the prevention of biotechnological risks in the advent of practicing of modern biotechnologies.

1.2.1.5 - The Study and Research Centre of Djibouti (CERD)

The Research and Studies Centre of Djibouti (CERD) gathers in within it several research institutes. It is a publicly-owned establishment of administrative nature. It has a juristic personality as well as financial and administrative autonomy. It is attached to the Ministry of Presidential Affairs.

The CERD contains five institutes:

Name of the Institute	Subjects covered
Earth Science Institute	<ul style="list-style-type: none"> ➤ geology ➤ hydrogeology ➤ geochemistry ➤ geophysics ➤ Arta seismological observatory ➤ new and renewable energy ➤ geothermal science
Life Science Institute	<ul style="list-style-type: none"> ➤ Biotechnology ➤ Pedology ➤ Fights against desertification ➤ Biodiversity Conservation
Social Science Institute	<ul style="list-style-type: none"> ➤ History ➤ Archaeology ➤ Anthropology ➤ Oral traditions ➤ Social studies
Language Institute of Djibouti	<ul style="list-style-type: none"> ➤ Studies and standardization of national languages ➤ Studies and analyses of cultures of languages ➤ Studies of languages of the Indian Ocean and East Africa
Science and New Technologies Institute	<ul style="list-style-type: none"> ➤ Research and development of sciences ➤ Technology transfer ➤ Scientific, Computer and Internet popularization, Research and development of information technologies

Among these various institutes, the Life Science Institute is the only one that deals with the themes relating to plant biotechnologies. However, the practice of biotechnology does not concern the genetic modification yet.⁵ The laboratory is not equipped to conduct DNA recombining activities. It is only contended to conduct the *in vitro* culture.

1.2.1.6. The Ministry of Home, Urbanism, Environment and Land Planning

⁵République de Djibouti / Ministère de l'Habitat, de l'Urbanisme, de l'Environnement et de l'Aménagement du Territoire, «Synthèse des Études sur les biotechnologies modernes et la biosécurité en République de Djibouti», Direction de l'Aménagement du territoire et de l'Aménagement, Djibouti, 2005, à la p. 20

It is within the Ministry of Home, Urbanism, Environment and Land Planning which is housed the Department of the Environment and Regional planning (DATE). The DATE is the national service in charge of the design, the planning and the implementation of policies and national strategies for the safe use of GMOs in food and agriculture. It was created in September 1996. Since this date, the DATE implements a big number of international treaties relating to the environment such as:

- The Convention on Biological Diversity. Membership 27/08/95.
- The Cartagena Protocol on Biosafety, which the Republic of Djibouti ratified in 2002.
- The United Nations Framework Convention on Climate Changes. Membership 22/08/95.
- The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), signed in Washington (United States) in 1973. Membership 7/02/92.
- The Jeddah Convention on the conservation of the environment of the Red Sea and the Gulf of Aden. Membership in September 1997.
- The Vienna Convention on the protection of the ozone layer. Membership 16/05/99.
- The Basle Convention of on the control of the transboundary movements of dangerous waste and of their elimination. Adhesion 26/05/01.
- The Convention on wetlands adopted in Ramsar (Iran) in 1971.
- The Stockholm Convention on persistent organic pollutants.

In the current context of implementing of the Cartagena Protocol, the DATE works at developing a national biosafety framework as well as the national law on the matter to govern all the activities relating to the international trade of products resulting from modern biotechnology. The DATE constitutes the competent national authority as regards biosafety and is in this sense the UNEP discussion partner within the framework of the implementation of the Cartagena Protocol on Biosafety.

1.2.1.7. Ministry of Education and Higher Learning

The Ministry of Education and Higher Learning is a young institution like the Republic of Djibouti itself. The university pole of Djibouti exists since 1997 which becomes the University of Djibouti in 2005.

The University of Djibouti (UD) aims at ensuring a teaching in the first and second university degrees and at preparing the emergence of a Djibouti university capable of meeting the national development objectives.

The university streams which are taught at the University of Djibouti are 7: Mathematics and Information Technology applied to Sciences, Physical Sciences, Law, Economics-Management, Modern Literature, history and English and for what concerns us, the life sciences. The Faculty of Medicine and related subjects are not yet taught but are programmed in the evolution of the UD.

1.2.2. The institutional and administrative system

There is today, in Republic of Djibouti, no structure which is directly in charge of biosafety. Some Ministries and departments have however, among others missions and duties, the

responsibilities corresponding to these themes. Unfortunately, the structures inserted in these departments to deal with biosafety suffer from a chronic lack of qualified human resources. Indeed, the majority of them only have very few competences in this area and their means of action are very limited. This situation, added to the absence of an appropriate policy and a specific regulation regards biosafety, exposes the country to high risks of introduction of genetically modified organisms (GMO) and products thereof being able to have negative effects on the environment and human health. The advent of the national biosafety framework whose implementation will require the setting-up of a specialized agency is thus an initiative coming to meet a need. The objective of the national biosafety framework of the Republic of Djibouti is indeed to establish the appropriate procedures for the conservation of biological diversity and the sustainable use of its elements in resorting to modern biotechnology in food and agriculture. While pursuing such a goal, the Republic of Djibouti resolutely turned to fully contribute to the implementation of the provisions of the Convention on biological diversity⁶ and its Protocol on Biosafety.⁷

Let us recall that the national biosafety framework of the Republic of Djibouti will be articulated around four principal elements: a regulating system, an administrative and institutional system, a decision-making system and a public information and participation mechanism. The process of its development started with stock-taking studies undertaken on the various aspects from the problems from biosafety. These studies aimed to take stock and make analysis of the situation concerning the introduction and use of biotechnology products in the Republic of Djibouti. The results obtained will be used as basis for the development of this national biosafety framework.

To allow an optimal implementation National Biosafety Framework, it is necessary to have a law on the matter. This is why the Parties to the Cartagena Protocol proposed the emergence of national biosafety laws parallel to the process of development of the national officers.

6 On May 22, 1992, after tough negotiations, the Parties to the Convention on biological diversity (CBD) agreed, from the first article of the instrument, to express their common objective of adopting the text of CBD by affirming that: “The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding” UNEP, *Convention on Biological Diversity ; Texts and annexes*, UNEP/CBD/94/1 94-04229, Montreal, Canada, 1998, at p. 4

7 In January 2000, the same Parties adopted the text of the Cartagena Protocol, Protocol to the CBD, thus confirming their determination to implement article 19 of the CBD on the handling of biotechnology and the distribution of its benefits. This issue was moreover one of the highlights of the UN Conference on Environment and Development also known as Rio Summit. In this way, the latter confirmed that: “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”

UNEP, *Cartagena Protocol on Biosafety to the Convention on biological diversity; Texts and Annexes*, UNEP/CBD/92-807-1924-6, Montréal, Canada, 2000, at p. 3

II. REGULATING SYSTEM OF NOTIFICATION OF REQUESTS AND RISK ASSESSMENT

Being inspired by the provisions of the Cartagena Protocol especially in its articles 7, 8, 9, 10, 11 and 12, the proposed regulating system aims at controlling and lessening the risks related to transboundary movements of GMO and products thereof, on the national territory. The main guidelines of this framework were defined in the light of the potential harmful effects of the risks apprehended in Republic of Djibouti but also according to the reports made following the studies of inventories carried out in the country reported above. The available capacities, the registered needs in this area and the potential of the contribution of modern biotechnology to the economy of Djibouti are also taken into account.

2.1. Biotechnological risk assessment

The mechanism of regulation retained by the Republic of Djibouti proposes as a whole a coherent approach promoting, according to the Cartagena Protocol, the advance informed agreement procedure for the introduction of GMO and products thereof on the national territory. It however provided, thereafter, for provisions targeting with more details, at case-by-case situations and national realities.

According to article 10 of the Cartagena Protocol on Biosafety, the mechanism of transcribing in Djibouti national law of the advance informed agreement procedure, intends to support any decision-making supported by undeniable scientific evidence and starting from a scientific study of risk assessment carried out according to recognized methods. Taking into account the more than embryonic character of the Djibouti biosafety sector which let us recall that it is characterized by shortcomings of all kinds, the competent national authority will have to require of the exporting Party to make this risk assessment and to meet its expenses.

The decision will be made on the basis of information provided in accordance with article 8 of the Protocol. Though it is up to the CNA to make the final decision concerning the requests for authorization, the process which leads to such a decision will include on the other hand, several stages. The process of risk assessment is necessary throughout these stages. Those are pointed out hereafter:

- The procedure of decision-making starts as of the reception of the request. After first study of the request, the competent national authority checks whether all the necessary documents are complete or not. As the case may be, it can decide:
 - o That the notifier provides further information in order to allow a decision-making;
 - o To examine the request;
 - o To conditionally examine or to reject the request.
- The Competent National authority must notify the applicant its written response with copy addressed to the Clearing House, within ninety (90) days from the date of reception of the request.
- The Competent National authority can request before making any decision, all the additional elements of information considered to be necessary. Any notifier which will

be unable to provide the required information or documents will be regarded as having withdrawn its request.

2.2. The regulating system leading to decision-making

The Republic of Djibouti agreed to retain a system of assistance in the decision-making in four stages going from the notification to the declaration of the final decision. The second important aspect of this system that Djibouti shares with the majority of the Parties to the Cartagena Protocol is the notification on a case-by-case basis for all types of requests: import for release in the environment, import for research in contained environment, import for human or animal consumption and transit.

2.2.1 - General procedure in four stages

2.2.1.1. Notification

In accordance with article 8⁸ of the Cartagena Protocol on Biosafety, the exporting Party or the exporter must address its request to the competent national authority (CNA) of the importing country. The Ministry of Environment which was appointed for the implementation of the Cartagena Protocol is the competent national authority. The main challenge of the CNA will be to continue without fail its mission in a current context where the services relating to biosafety are managed separately by several ministries. This being, it appears that a Ministry of Environment acting as CNA will have however to work together with the contribution of the national institution most concerned by the notification according to each case⁹.

2.2.1.2. Risk assessment of LMO introduction on the environment and human health

Let us specify from the outset that it is up to the applicant or to the exporting Party to carry out the study of risk assessment¹⁰ and to meet all the inherent expenses.¹¹ Then, it must be

8 In fact, article 8 of the Cartagena Protocol dealing with the notification stage stipulates that: “1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I. 2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.” *Ibid*, at p. 6

9 If the exporting Party has the obligation of notifying to the importing Party its intention to export a LMO, the latter Party should show some courtesy to acknowledge receipt of the notification even if non-delivery of the acknowledgment of receipt has limited implications (paragraph 4 of article 9). In fact, according to the terms of the Protocol especially in its article 9 relating to the Acknowledgement of receipt of notification : “1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt. 2. The acknowledgement shall state: (a) The date of receipt of the notification; (b) Whether the notification, prima facie, contains the information referred to in Article 8; (c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10. 3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol. 4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement. “ *Ibid*, at p. 7

10 Government of Djibouti thus takes advantage of the provisions of article 15 of the Cartagena Protocol especially in its paragraph 2 which stipulates that: “2. The Party of import shall ensure that risk assessments are

done by ad hoc groups constituted within the National Biosafety Consultative. The documentation provided as well as the assessment work carried out by the exporting Party or the exporter will be used as support to the study of risk assessment at the national level. The national experts involved in biotechnological risk assessment, can ask for further information on the product in question either directly the exporting Party or the Biosafety Clearing House (BCH).

2.2.1.3. Final decision

It is expected that at the end of this study, the national experts provide their opinion to the CNA, which communicates this opinion at the National Biosafety Consultative Committee (NBCC) on which falls the last decision. In case of an approval, the competent national authority will reply the applicant in writing and will issue it the licence for the import of GMOs or products thereof. If not, the notifier must be informed in writing of the decision taken in this respect. In all the cases, the Republic of Djibouti intends, within the framework of this legislative approach in the area of biosafety for GMOs and the products thereof, to adopt and put forward the precautionary approach in accordance with the provisions of paragraph 6¹² of article 10 of the Cartagena Protocol dealing with the decision procedure in general as those of paragraph 8 of article 11 of the same normative framework which deals with specific case of decision procedure relating to the living GMO intended for direct use as food or feed, or for processing.¹³

2.2.1.4. Declaration

Following the approval, the holder of the licence of introduction will have to imperatively declare all the other related products containing the authorized GMO. Once that the product arrives on the national territory, the competent national authority will call upon the national experts who will carry out the verification of received information. It is in the sense that the setting up of a structure of biotechnological analysis and scientific and technical opinion

carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment. “*Ibid*, at p. 12

11 The same goes for the costs of the risk assessment study. Paragraph 3 of the same article of the Protocol doesn't stipulate that : “3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires”*Ibid*

12 Paragraph 6 of article 10 of the Cartagena Protocol reads as follows: “6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.” *Ibid*, at p. 8

13 As to paragraph 8 of article 11, it specifies that : “8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects. » *Ibid*, at p. 9

(laboratory of modern biotechnology) is going to be essential. It will be only at the end of such a verification and authentication of provided information that the product will be definitively authorized with being marketed on the national market.

2.2.2. Study on a case-by-case basis

The handling of applications of authorization of GMO on a case-by-case basis is a prudential approach adopted universally because of the variability of the genetic modifications adopted according to the reasons having led to the production of each GMO in particular.

2.2.2.1- Use and handling of GMOs and products thereof at the national level

If the release of GMOs and products thereof knows some slowness within the European Union (EU) countries, in some emerging economy countries and especially in the majority of the developing countries of the South, it remains in continual ascending phase in several other great global economic powers especially in North America. It is thus in all logic that the national territory should be the potential scene of operation of the liberalization of the international trade of the products resulting from modern agricultural biotechnology. From such a point of view, it seems logical to consider the creation of research laboratories in biomolecular engineering which will be brought to handle living GMOs (LMOs) especially of the animal and plant kingdoms. Such laboratories will be able to fall under the initiative of nationals or natural persons or legal entities with mixed composition of nationals and foreigners. In one case as in the other, the interested parties must submit their research project to the CNA and this, before any handling. The project could only be carried out after the authorization of the latter which acts in the light of the results of the studies on the possible effects on the environment and human health of the involved GMOs. The studies will be carried out by groups of national experts created for this purpose.

2.2.2.2. Deliberate transboundary movements

Any introduction of a GMO or a product thereof whatever it is will have to be done in accordance with articles 6¹⁴, 7¹⁵ and 8 of the Cartagena Protocol. Under no circumstances, it

14 Article 6 of the Cartagena Protocol relating to transit and contained use of living GMOs especially stipulates that: "1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit. 2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import." *Ibid*, pp. 5-6

15 As for article 7 which is about the application of the advance informed agreement procedure, the Parties to the Cartagena Protocol agreed that: "1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import. 2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing. 3. Article 11 shall apply prior to the first transboundary movement of living

should not be made without the licence granted by the competent national authority (CNA). For that, the exporting Party or the exporter has the obligation to address its request to the importing Party.

- **Import of GMO and products thereof for the human or animal consumption.** With regards to GMOs and products thereof intended for human or animal consumption, the interested party will have to address his notification to the CNA which will make its decision with the collaboration of the National Biosafety Consultative Committee especially of the representatives of the Ministry of Trade within this body.
- **Introduction for research purposes.** The living modified organisms could be introduced on the national territory research purposes. The objective often sought after in a similar case remains the transfer, from the imported living modified organism towards other organisms, genetic or phenotypical characters like the resistance to salinity, resistance to insects and diseases and other advantages. In some cases, the projects can be carried out by simple techniques of crossbreeding. In all cases, the project of introduction of GMOs and products thereof for research purposes must initially arrive at the CNA by specifying the objective, the contents as well as the motivations of the project. This one will advise the NBCC which will subject it to the usual process for the possible issuance of an authorization according to selected process (see diagram with accompanying notes for details).
- **Transit of products consisting of GMOs or products thereof:** the products consisting of GMOs or products thereof which transit by the port of Djibouti or another national channel can be accidentally introduced on the national territory. To prevent and manage these risks, the transit of the products containing of entire GMOs or in derived products in the form of ingredients, additives or supplements will have to be made by mutual agreement between the country for which the products are intended and the Djibouti Government whose territory is used as transit with such products. The importing Party of final destination must inform the Republic of Djibouti by which is done the transit of the presence of GMOs or products thereof in the concerned products. For this purpose, a document containing of clear and precise information on the identification of the products must arrive at the CNA. This document will have to also mention of the expected date of entry in Djibouti territory for these products but also over the expected duration of their transit and their conditions of storage, if necessary.

2.2.3. Functioning of the regulating system of decision-making

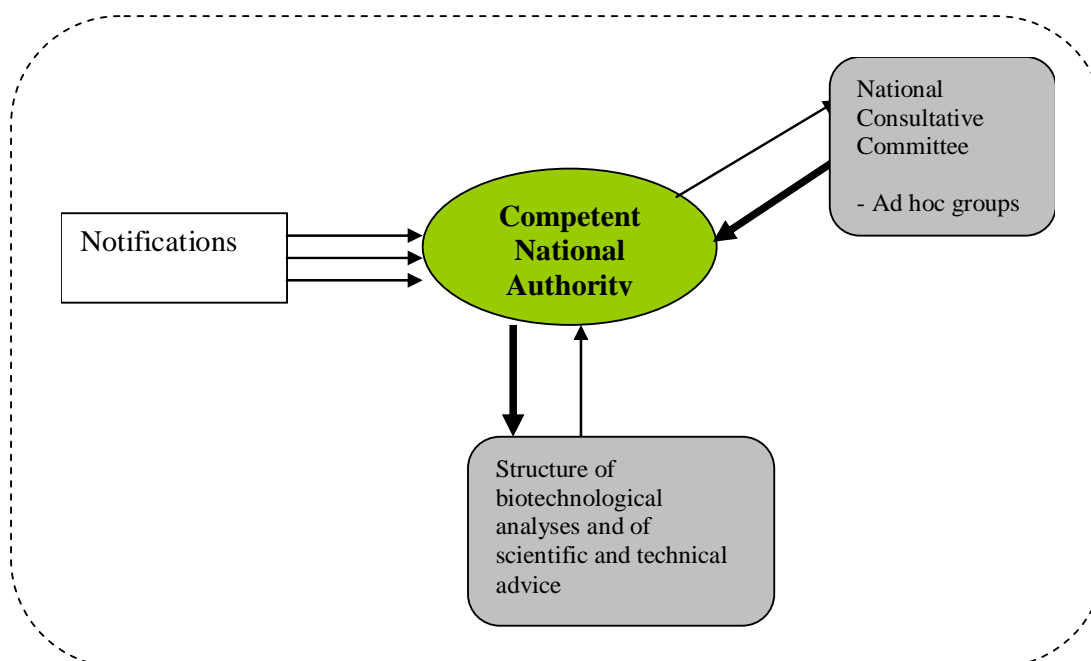
As the diagram shows it hereafter, the regulating system of decision-making will function in the following way: In the centre will be the competent national authority (CNA) who will manage the introduction, the use and the handling of LMO/GMO. The requests will be addressed to him/her directly. After reception of the request, an acknowledgement of receipt will be addressed to the interested party. The requests will be then submitted to the National

modified organisms intended for direct use as food or feed, or for processing. 4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.” *Ibid*, at p. 6

Biosafety Consultative Committee which will subject them to the study by the various ad hoc groups made up of the national experts in various areas of competences. It is only at the end of these studies and on the basis of scientific and technical advice that the competent national authority will have to make its final decision. In the event of approval, the CNA will issue the licence or authorization of introduction of the GMO or the product thereof to the interested party.

It will also be up to the same CNA to inform the notifier of the unfortunate outcome of its notification in the event of rejection of the request for introduction, and this within 264 days. On this last situation, the Cartagena Protocol provided for methods of possible revision of the decision especially in its article 12 relating to the review of decisions.¹⁶

Diagram of the functioning of the regulating system of decision-making



2.3. The administrative and institutional system

The establishment of the regulating system in the previous section logically leads us to the setting up of administrative and institutional structures necessary for the application of the aforesaid system and this, in accordance with article 19¹⁷ of the Cartagena Protocol on

¹⁶ In fact, according to the terms of article 12 of the Cartagena Protocol on the review of decisions: “1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.” *Ibid*, at p. 10

¹⁷ In fact, article 19 of the Cartagena Protocol dealing with the issue of *Competent National Authorities and national correspondents* specifies in this respect that: “1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent

Biosafety. The suggested system should allow the Republic of Djibouti to undertake flexible mechanisms in the implementation phase of the Cartagena Protocol. The administrative and institutional system, which underlies the decision-making in the area of biosafety in the Republic of Djibouti, is thus conceived to respond to the requirements of receiving in national law of the provisions of the Cartagena Protocol while taking into account the limited means and capacities of the country faced with the prevention of the biotechnological risk potentially associated with resorting to GMOs in agriculture and food.

The studies of inventories of the national capacities regarding the prevention of the biotechnological risk have allowed, in the preceding section, to make the stock-taking in Republic of Djibouti in this specific area. They showed, among others, that at the administrative level, the Djibouti public institutions are characterized by the insufficiency of competences and the lack of coordination of the existing institutional pseudo organization. The situation within the ministries confirms this sad report even more. We will recall that among the noted shortcomings, insufficiencies and inconsistencies at the time of the studies of inventories in the areas of biosafety and biodiversity, appear on the first line the fact that some rare potential especially in human resources unfortunately is scattered in the various ministries and consequently very badly made use of. The wise use of these available human resources and the building of institutions involved in biosafety are two factors which one must take into account in the development of the administrative and institutional system. Thus, the administrative and institutional machinery of the national biosafety structure should include on one the hand, a system of administration of requests and notifications and of a consultative body. The first will be represented by the competent national authority and the second by the National Biosafety Consultative Committee and the scientific and technical advice Body. To ensure the proper running of the whole, it is advisable to define duties of each one of two as well as the relationship which bind them.

2.3.1. The administrative system of request and notification

It is a requirement to set up an administrative structure specialized to lead without mishap the implementation of the Cartagena Protocol and the National Biosafety Framework. The administrative vacuum must be filled. The suggested institutional environment will benefit from the National Biosafety Law which will have the role of governing in all transparency and in all biological safety, transboundary movements of GMOs in which the Republic of Djibouti will take part. The administrative and institutional biosafety framework for the Republic of Djibouti will include mainly: a competent national authority, a National Biosafety Consultative Committee and a Biosafety Scientific and Technical Advice Body.

national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority. 2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities. 3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House. *Ibid*, at p. 9

2.3.1.1 - The Competent Authority (CNA)

The Ministry of Home, Urbanism, Environment and Land Planning (MHUEAT) will be the competent national authority of the National Biosafety Framework. This one will ensure coordination with the whole of institutions directly or indirectly involved in the process of biotechnological risk management. The CNA will be especially in charge with the issuance of the authorizations as regards biosafety on the basis of the recommendations made by the National Biosafety Consultative Committee (NBCC) and body of scientific opinion and technical. Within the Ministry, the Department of Land Planning and Environment and the Minister's advisers will constitute the framework of the competent national authority. The CNA will also include the biosafety office and a National Focal Point.

- **The Biosafety Office:** a biosafety office will be officially created within the Department of Land Planning and Environment (DATE). This one will be in charge the administrative management of requests and will assist the DATE/CNA.
- **National The Focal point of the Clearing House and Information-sharing:** The National Biosafety Coordinator which is currently in charge of carrying out the project of setting up a national Biosafety structure within the MHUEAT, will be at the same time the National Focal Point. This one will ensure among others, the connection between the MHUEAT and the Biosafety Clearing House located at the secretariat of the CBD¹⁸. It will carry out its duties under the direct responsibility for the DATE. The idea of clearing house to the benefit of the sustainable management of the genetic resources germinated already in the concerns of the Parties during negotiations the text the CBD. The need for such a mechanism answered the aspirations regarding scientific co-operation among the Parties to the said Convention. The intentions of the Parties on

¹⁸ The Biosafety Clearing-House is a central mechanism of the implementation of the Cartagena Protocol. The Parties have recorded their intentions concerning information-sharing in article 20 of the instrument which stipulates that : "1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention , in order to: (a) Facilitate the exchange of scientific, technical , environmental and legal information on, and experience with, living modified organisms; and (b) Assist Parties to implement the Protocol , taking into account the special needs of developing countries , especially the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity. 2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms. 3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and: (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure; (b) Any bilateral, regional and multilateral agreements and arrangements; (c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding 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; (d) Its final decisions regarding the importation or release of living modified organisms; and (e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure. 4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter." *Ibid*, pp. 16-17

this question were expressed in paragraph 3¹⁹ of article 18 of the CBD. To fully conduct its mission, the national focal Point will benefit from the services of the imminent national biodiversity/biosafety clearing house of which it will ensure operation. In the development and the management of the provided for reports²⁰ the national focal Point will ensure the respect of the obligations of the Republic of Djibouti with respect to the Cartagena Protocol. It will be in charge of communicating with the Biosafety Clearing House, the national legislative projections in the area of the biosafety. If need be, the dynamics of the national legislative process regarding biosafety will be enriched via such a house, by the contribution of the legislations, regulations and guidelines of other Parties as well as the scientific progress noted throughout the World from the perspective of possible approval of GMOs and products thereof intended for agriculture and human and animal consumption.

2.3.1.2. Consultative bodies of support to the decision

The Competent National Authority will be supported by two bodies: the National Biosafety Consultative Committee and the structure of biotechnological analyses and scientific and technical advice, which will be created in the framework of the development of the National Biosafety Structure. The National Biosafety Consultative Committee will have the mission of assisting the Biosafety Competent National Authority in the decision-making, in the light of technical information supplied by the structure of biotechnological analyses and scientific and technical advice.

- The National Biosafety Consultative Committee.

The National Biosafety Consultative Committee will be primarily made up of representatives of the administration, political decision makers, and non governmental organizations but also of representatives of the private sector as well as any other institution concerned however with the questions of biotechnology/biosafety. A provisional list of these institutions is presented below while the precise details on the composition and designations as on duties of the committee will be the subject of a decree of application:

- Ministry in charge of Trade and Industry;
- Ministry of Finance and Economy;
- Ministry in charge of Agriculture;
- Secretariat of the President Office;
- Ministry in charge of the Environment;

¹⁹ Paragraph 3 of article 18 of the CBD specifies that: “3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.” *Supra* note 1, at p. 15

²⁰ came back to article 33 of Protocol to specify the objectives sought after by the Parties in the monitoring and reporting: “Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.” *Supra* note 2, at p. 24

- Ministry of transport and the Maritime businesses
- Ministry of health
- The Civil Society represented by associations which work in this area;
- The private sector
- The international Port of Djibouti
- The University of Djibouti

Each institution will name a representative for the ad hoc groups which will be set up in the following areas:

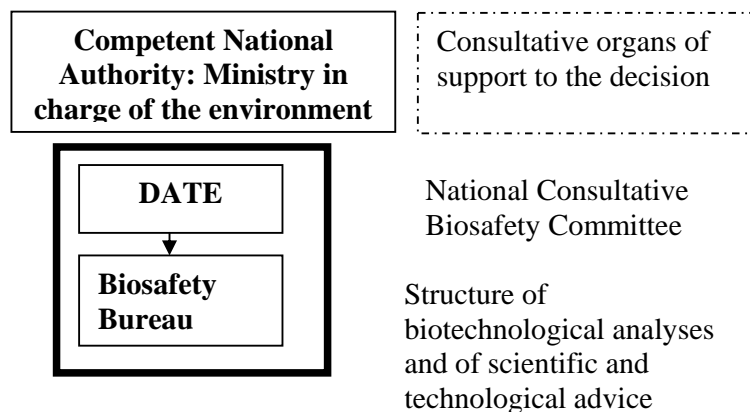
- Risk assessment and management
- Legal and Regulation
- Ethics and culture
- Public participation

The Committee will be put under the authority of a President and a Vice-president who will be elected for a renewable two-year mandate. The principal mission of the NBCC will consist in making recommendations on the approval or the refusal of GMOs and products thereof and this, on the basis of advice of the Biosafety Technical Committee, taking into account also the economic, social and cultural stakes of our country.

▪ *Consultative organs of support to the decision*

These consultative bodies of support to the decision will be made up on one hand by the National Biosafety Consultative Committee (NBCC) which will have the role of providing technical advice on the various aspects related to the biotechnological risks and, on the other hand, the structure of biotechnological analyses and scientific and technical advice that the CNA will notify at the time of the authentication of the information provided by the applicant or to detect suspected GMO products. The objective of the National Biosafety Consultative Committee will be to mobilize and make aware the national experts about the issues relating to biotechnology and biosafety. It will be composed of three Committees of which each one will conduct studies and research in its area of competence:

Administration system of requests and notifications



By adopting such a system of assistance to the decision-making, the Republic of Djibouti intends to put forward the most flexible mechanism of to avoid slowness throughout the advance informed agreement procedure. The proposed mechanism is also a source of transparency.

III – MONITORING AND CONTROL MECHANISM

Let us recall that the institutions whose missions and duties come under biosafety were the subject of studies in this approach of carrying out the national biosafety framework. On top of the numerous shortcomings noticed following these studies, it has allowed us to list a certain number of structures from which a monitoring and control system will have to be conducted. These structures, directly involved in the expected implementation of the national biosafety framework of the Republic of Djibouti are primarily:

3.1. The institutions involved in the monitoring and control mechanism

Several institutions take part in the system of monitoring and control measures of release of GMOs and products thereof. The following list specifies them to us:

- The Customs Service;
- The Standards and the Quality Control Service of the Ministry of Trade and Industry;
- The Phytosanitary Service of the Ministry in charge of Agriculture;
- The Public health Service of the Ministry of Health;
- The Study and Research Centre of Djibouti (CERD).

These structures will be brought together within a Committee known as watch on biotechnologies. It is indeed starting from these institutions that the Competent National Authority will have to draw and carry out the monitoring and control mechanism of the benefits of the national biosafety Framework especially the information and the monitoring of projects in progress authorized from the regulatory perspective following the application of the advance informed agreement procedure.

In all the cases the monitoring and control mechanism will have to contribute to preserve the benefits and to continue the projects, if necessary, from the biosafety perspective resorting to GMOs and products thereof in agriculture and food.

3.2. Monitoring and control policy and safeguard measures

The national biosafety Law constitutes an important link of the whole of the monitoring and control system. This one in fact mentions safeguard measures specified by the text and giving the action to be taken in case difficulties would have occurred following assessment studies of favourable risks. In such cases of figures, it is indeed provided, if necessary:

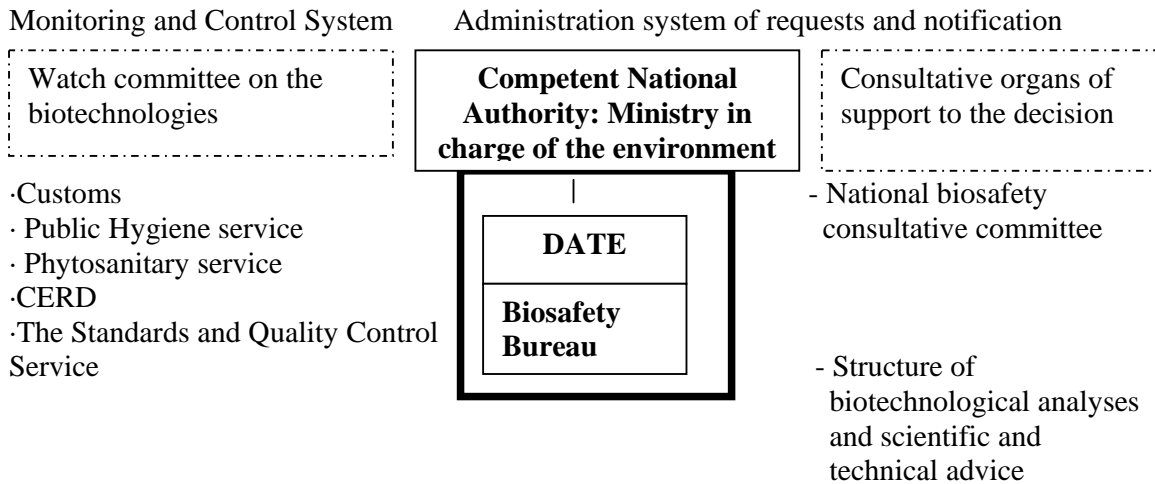
- To make modifications to the initial terms of the authorization;

- To withdraw purely and simply the GMO from the circuit;
- To suspend the activity while waiting for additional information favourable to the continuation;
- To impose to the author of the notification to the terms of the release of the GMO;
- To order the destruction of the GMO in the event of acknowledged breach and obviousness of risk;
- To sanction by appropriate measures if necessary.

Effective and transparent management of such measures of monitoring, control and safeguard requires a good collaboration between the various technical departments involved in the system and mentioned in the previous section.

3.3. Diagram of monitoring and control mechanism

The following diagram summarizes the monitoring and control system. It notes the administrative and institutional structures involved. On the whole the mechanism proposed aims primarily at biosafety in Republic of Djibouti throughout process of activities concerning GMOs and products thereof.



3.4. A monitoring and control mechanism turned towards the future

At the image of the Cartagena Protocol which is a dynamic normative framework, the national biosafety framework of the Republic of Djibouti and the national biosafety Law which accompanies it, are dynamic instruments. The current texts of these two documents only made it possible to lay the groundwork which will help the Republic of Djibouti to start a work of setting-up continual and updating of its national biosafety regime and this, as the development of the international law goes by in this area but also the contributions and the development of innovations in modern biotechnology.

In such a process, the Republic of Djibouti will be able to find in the CBD and its Conference of the Parties acting as Parties with the Cartagena Protocol, a sure ally. Djibouti will be able to also greatly benefit from the activities of the Clearing-House of the CBD which has among other missions that of coordinating the changes and the assets as well as the repercussion of those in the national modes of biosafety. The main avenues by which the Protocol will continue to contribute to the implementation and with the update of the national modes of biosafety are the risk assessment and management, labelling, the traceability, the liability, the redress and the resolution of the commercial disputes. On these issues, the Parties are sorting themselves out and will be sorting themselves out during next years in the process of negotiation and implementation of the Cartagena Protocol. Acting of the resolution of the commercial disputes involving the agricultural produce based on GMOs, the prospects for a jurisprudence in right of the international trade of the products resulting from modern agricultural biotechnology let to us foresee the control of activities of mutual support between the young mechanism of settlement of the disputes of the CBD and the powerful dispute settlement body (DSB) of the World Trade Organization (WTO)²¹. Thus in the recital to the Cartagena Protocol, the Parties "agree to understand that the text does not aim at subordinating the Protocol to other international agreements"²². Well rather, these last "agreed to stress that the said Protocol will not be interpreted like indicating an unspecified modification of the rights and obligations of a Party under the terms of other international agreements into force".²³

Better still; the States specified "that trade and environment agreements on should be mutually supportive with a view of achieving sustainable development". In addition, in this relates to the evaluation and the biotechnological risk management, the intensity of the activities concerning biosafety within international organizations, States, NGOs and in industry, let predict a convergence, in a nearer future, towards efforts of harmonizing of means and techniques of prevention of biotechnological risks.

One indeed can, hope that the goodwill and the good faith of the various contributors will help to provide the means to the Biosafety Clearing House to allow this to work towards standardization of biotechnological risk assessment methods of detection of transgenes as well as traceability processes and techniques. Let us specify in this latter case that the traceability techniques should allow, in the event of problems, to withdraw the products based on GMOs from food and trade channels. It is the same for the standardization of the thresholds of harmfulness and harmlessness as well as standardization of the thresholds of presence of GMOs in food for purposes of labelling for the consumers to practise free choice.

By adopting its texts of National Biosafety Framework and the National Biosafety Law, the Republic of Djibouti engages in international trend of the prevention of the potential risks related to the resorting to modern biotechnology in agriculture and food.

²¹ The Biosafety Protocol and the WTO agreement on sanitary and phytosanitary measures that are the main normative competent frameworks in the international trade of agricultural products should mutually support each other. The Preamble of the Protocol stipulate on this matter that: "*Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development, *Emphasizing* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements, *Understanding* that the above recital is not intended to subordinate this Protocol to other international agreements,..." *Ibid*, at p.2

²² *Ibid*

²³ *Ibid*

IV. PUBLIC AWARENESS AND PARTICIPATION

The Republic of Djibouti, like several other countries, became aware of the importance of public awareness as well as participation in the prevention of biotechnological risks. The Parties to the Protocol Cartagena on Biosafety devoted article 23²⁴ of the aforesaid Protocol to the expression of their desires to see the public involved in the efforts made by the international Community to ensure the safeguarding of biodiversity and human health in the international trade of the products resulting from modern biotechnology.

4.1. Public awareness

Modern biotechnology and especially biosafety are new topics not well known by the Djibouti public. This ignorance could lead to the aversion of the public with regard to GMOs and products thereof. The public awareness thus has all its importance. The adherence of the population will constitute without any doubt one of the success factors of the biosafety programme. For this purpose, it will be advisable to take up the challenge to reach the largest possible general public. With this intention, it will be necessary to effectively exploit the channels and the methods of information and popularization having proven reliable in Djibouti and in the World. Among these tools of awareness and popularization, it is advisable to note radio, television and newspapers. With the Radio, as for television, it will be advisable to disseminate information in the three languages of the country, namely Afar, Somali and the Arabic. The *Environment* heading of the *Nation* newspaper could be used as an opening of communication of information and news on issues relating to modern biotechnology and biosafety.

4.2. Public participation to decision-making

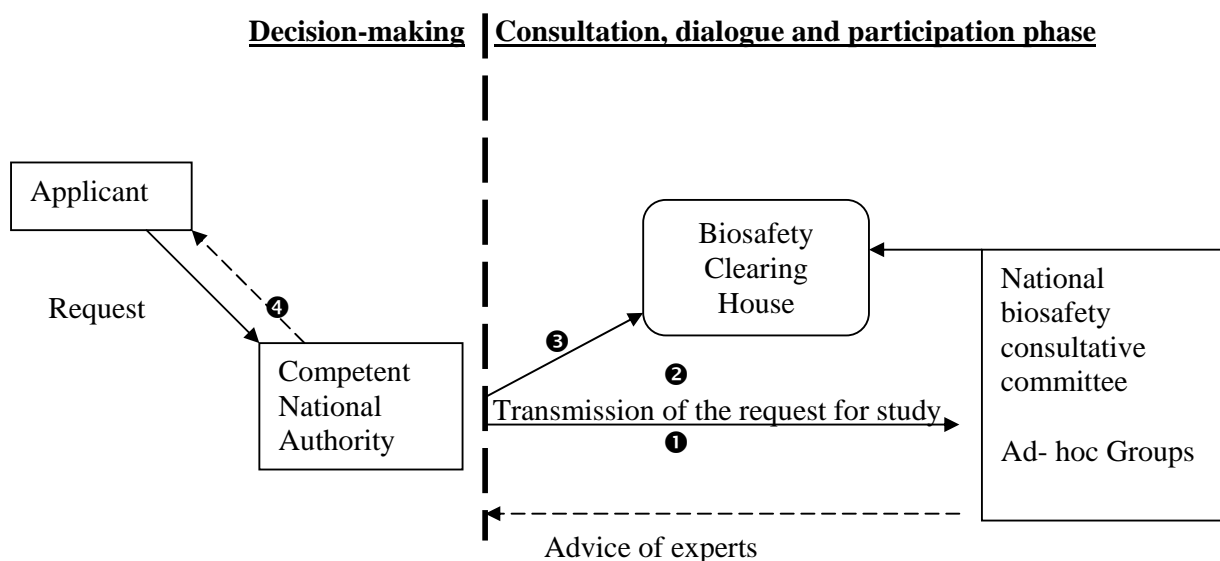
So that it can take part in an effective way, the public will have to be well informed on the issues of modern biotechnology and biosafety. This can be done by employing the spreading and information methods above-mentioned. The public participation should thus start with the collecting of information at the public the level (Feedback). The creation of a body specifically in charge of information, spreading and collecting information which would also represent the public in the decision-making system is thus essential. For that, a public participation group will be created within the National Biosafety Consultative Committee. This one will be especially made up of the socio-professional groups most directly concerned

²⁴ Article 23 of the Protocol on the public awareness and participation reads in fact as follows: "1. The Parties shall:(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported. 2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21. 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House." *Ibid*, à la p. 19

with the issues relating to modern biotechnology and biosafety but also of NGOs, religious leaders, etc. A provisional list of the components of this Commission is proposed hereafter:

- agricultural cooperatives;
- importers of seeds;
- pharmacists;
- cereal importers;
- notable religious leaders;
- representatives of NGO and the sociocultural as well as ethical movements;
- representatives of the socioeconomic organizations and the native populations.

The group which will also make socio-economic considerations²⁵ its priority will attend all the meetings held by the National Biosafety Consultative Committee and this, in order to spread technical and scientific information which will arise from the studies undertaken by the national experts and to put forward the public opinion in the decision-making. The latter will have to also take part in the monitoring and control mechanism and in any other initiative where its participation will be necessary in order to contribute to the transparency in the implementation of the procedures and mechanisms of the execution of the biosafety programmes which underlie this national biosafety framework and the national biosafety law. The diagram hereafter summarizes the various stages of consultation which must lead to the decision:



In no way, the decision should not be made by a restricted unit. It must be the result of a series of consultations and dialogues with an effective public participation, only pledge of the

²⁵ The taking into account of socio-economic considerations during the import of GMOs has been wished by the Parties. Article 26 of the Protocol dealing with socio-economic considerations notifies us of the wish of the Parties on this problematic: "1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities." *Ibid*, at p. 20

taking into account of the aspirations of the population in the process of decision-making under article 23 of the Cartagena Protocol on Biosafety.

OUTLINE OF AN IMPLEMENTATION PROGRAMME OF THE CARTAGENA PROTOCOL AND RECOMMENDATIONS

The Republic of Djibouti expresses through this National Biosafety Framework project its firm intentions to fulfil its obligations as a Party to Convention on Biological Diversity and its Biosafety Protocol. We will recall in this section national the broad outline of application of the advance informed agreement procedure for the participation of Djibouti in the trade of GMOs and products thereof. On the other hand, as we will also show it in this section, the country is more than deprived in specialized human resources as well as of adequate supply of materials. The specialized laboratories are missing as well as financial means to face the national Biosafety policy outlined within the framework of this project. It is thus more than necessary for the Republic of Djibouti to take part in the international activities concerning capacity building in this specific area of resorting to GMOs in agriculture and in food.

STATUS: THE THORNY BIOTECHNOLOGICAL RISK ASSESSMENT/MANAGEMENT

The sector of the modern biotechnology of the Republic of Djibouti is more than embryonic. One notes the absence of any laboratory specialized in biomolecular engineering and the institutional potential is summarized in a handful of structures which could however shelter the first initiatives of resorting to GMOs in agriculture and food. These latter, already mentioned above are: the Department of Agriculture, the Departments of Livestock and Fishery, the Faculty of Science of the University of Djibouti, the Department of Land planning and Environment, Public health Services, the Health laboratory and the Inspectorate of Sciences and Life of National Education. To these structures are added some elements with required technical and scientific potentials: the Study and Research Centre of Djibouti with its Institute of the Life sciences, the rudimentary equipment of the Customs Authority, the Bureau of Standards and Control of the Ministry of Trade and Industry and the Phytosanitary Service of the Ministry in charge of Agriculture.

The potential in specialized human resources is summarized in an insignificant number of scientists and lawyers having the required qualifications for the control of any biosafety program. It would not be exaggerated to say that without the creation and the building of capacities, the Republic of Djibouti could not take part in the prevention of biotechnological risk in the international trade of GMOs and products thereof.

Indeed, in a current state of the things, the challenges of risk assessment²⁶ and risk management²⁷ constitute battles lost in advance by an abandoned Republic of Djibouti. And

²⁶ In article 15 of *risk assessment*, the Parties to the Cartagena Protocol suggest that: “1. 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. 2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter

yet, the Republic of Djibouti, as a Party to the CBD and to its Protocol on biosafety known as Cartagena Protocol on Biosafety, is quite willing to actively participate in the creation of biotechnological standard next to the other Parties especially with regard to liability and redress.²⁸

Lastly, of all the stakes of the setting-up and the implementation of the biosafety standards, the issues relating to handling, transport, packaging and identification²⁹ of GMOs and

to carry out the risk assessment. 3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.” *Ibid*, at p. 12

²⁷ It is in the article 6 on *risk management* that the Parties also agreed on the terms and conditions relating to this problematic: “1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms. 2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import. 3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism. 4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use. 5. Parties shall cooperate with a view to: (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.” *Ibid*, pp. 12-13

²⁸ Article 27 of the *liability and redress* doesn’t it specify that: “The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.” *Ibid*, at p. 20

²⁹ Article 18 of handling, transport, packaging and identification allowed the parties to the Cartagena Protocol to draw important outlines on these difficult questions that will retain the attention during the next years in the area food security in general and biosafety especially. This one stipulates that: “1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. 2. Each Party shall take measures to require that documentation accompanying: (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol; (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter. 3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for

products thereof, are certainly more problematic next to methodologies of detecting transgenes and risk assessment.

INSTITUTIONAL PROSPECTS OF THE NATIONAL BIOSAFETY FRAMEWORK IN THE REPUBLIC OF DJIBOUTI

The National Biosafety Framework of the Republic of Djibouti is resolutely turned towards a future where the international co-operation will play a central part. The national ambitions regarding biosafety described in this document are indeed tributary of an active participation of the Republic in the activities of international co-operation in the area. The assistance of the UNEP-GEF which allowed the execution of the National Biosafety Framework could only constitute the first stages of the desired necessary co-operation. No doubt, left alone, our country could not achieve the goals which it set for a fruitful participation in the international trade of products resulting from genetic engineering. The training, the construction of a specialized laboratory or the capacity building of an existing laboratory, the equipping in research materials, the acquisition of financing for research and partnership, the search for collaborators (universities, industries, NGOs and others), are as many loopholes through which, the country will have to contribute along sides other Parties of its region, of the sub-region of the international Community, to take up the challenges of biological safety related to resorting to GMOs in agriculture and food.

RECOMMENDATIONS

The evaluation studies on the stock-taking of biotechnologies and biosafety in the Republic of Djibouti showed the absence of adapted law and regulatory framework. They also made it possible to note the harsh lack of infrastructures and an insufficiency in human resources. The development of a biosafety law and the capacity building, prove to be impossible to be overlooked for the effective implementation of the national biosafety framework. This capacity building must relate to all the aspects of biosafety more especially the four (4) elements of the national biosafety framework.

- At the administrative and institutional level, it will initially be, to institute all the structures which make the administrative and institutional system and to define the functions and duties of each one of them. Then, the capacity building will consist of equipping such structures with financial, logistical means, with equipment materials and with training in biotechnology and biosafety. These institutions are: the biosafety office, the national biosafety consultative committee and the scientific and technical advice body.
- At the technical and scientific level it is strongly recommended the setting up of a modern laboratory of biotechnology or the reinforcement of an already existing laboratory in order to minimally interact during the advance informed agreement procedure with the applicants of notifications and risk assessment studies.

and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.” *Ibid*, pp. 14-15

- At public participation level it arises from the consultation and restitution workshops biotechnologies and biosafety are concepts very little known by the public. It is recommended to organize workshops on a regular basis make the public aware of the issues of biotechnology.
- At the legislative level it proves to be imperative to support conditions of building the national biosafety law by adopting application decrees with an aim of giving substance to the law on the specific problems according to a quite precise and well structured work planning.

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