MINISTRY OF ENVIRONNEMENT AND SANITATION

PERMANENT TECHNICAL SECRETARIAT OF THE INSTITUTIONAL FRAMEWORK FOR THE MANAGEMENT OF ENVIRONMENTAL ISSUES (STP/CIGQE)

REPUBLIC OF MALI
One People One Aim One Faith

National Biosafety Framework Project (GFL-2328-2716-4524)

UNEP-GEF Global Project (GF/2716-01-4319)

NATIONAL BIOSAFETY FRAMEWORK FOR MALI

***Part I**: Context and history of biosafety, current status of the Regulation, the actual Framework of biosafety (administration, decision-making, risk managemnt, Public Participation)*

***Part II**: Draft bill relating to the biosafety in the Republic of Mali*

***Part III**: Annexes to the draft bill relating to the biosafety in the Republic of Mali*

APRIL 2005

TABLE OF CONTENTS

ACRONYMS AND ABREVIATIONS

DNA	*Deoxyribonucleic Acid*
TRIPS	*Trade-Related Aspects of Intellectual Property Rights*
WARDA	*West Africa Rice Development Association*
IAEA	*International Atomic Energy Agency*
NCA	*National Competent Authority*
ANSSA	*National Agency for Food Health Security*
APCAM	*Permanent Assembly of Chambers of Agriculture in Mali*
RNA	*Ribonucleic Acid*
ASCOMA	*Association of Consumers of Mali*
BCH	*Biosafety Clearing House*
CAFO	*Coordination of Women Associations and Organisations*
CCIM	*Chamber of Commerce and Industry of Mali*
UNFCCC	*United Nations Framework Convention on Climatic Change*
CBD	*Convention on the Biological Diversity*
ECOWAS	*Economic Community of West African States*
CILSS	*Inter-State Committee to combat Drought in Sahel*
CIRAD	*International Centre for Agronomic research for Development*
CITES	*Convention on International Trade in Endangered Species of Wild Fauna and Flora*
CMDT	*Mali Textile Development Company*
CNAM	*National Support Centre against Disease*
CNESV	*National Committee for Ethics and Life Sciences*
CNRA	*National Committee for Agricultural Research in Mali*
CNRST	*National Centre for Scientific and Technical Research*
CORAF	*West and Central African Council for Agricultural and Development Research*
CRU/CNU	*Regional Committee of Users of Research Results / National Commission of Users of Research Results on Environmental Issues*
DGRC	*Regulation and Control Services*
DNAMR	*National Board of Rural World Support*
DNCN	*National Board of Nature Conservation*
DNI	*National Board of Industries*
DNS	*National Board of Health*
FAO	*Food and Agriculture Organisation*
FAST	*Faculty of Sciences and Techniques*
FLASH	*Faculty of Literature Arts and Social Sciences*
FMPOS	*Faculty of Medicine Pharmacy and Ondonto-Stomatology*
ICRAF	*International Centre of Research on Agro-Forestry*
ICRISAT	*International Crops Research Institute for Semi-Arid Tropic*
IER	*Institute of Rural Economy*
IITA	*International Institute of Tropical Agriculture*
INRSP	*National Institute of Public Health Research*
INSAH	*Institute of Sahel*
IPGRI	*International Plant Genetic Resources Institute*
IPR/IFRA	*Rural Technical Institute / Institute of Applied Training and Research*
IRD	*Research Institute for Development (ex ORSTOM)*
ISFRA	*Higher Institute of Training and Applied Research*
LBMA	*Laboratory of Applied Molecular Biology*

LCV	*Central Veterinary Laboratory*
LMS	*Laboratory of Soil Microbiology*
LNS	*National Laboratory of Health*
MAEP	*Ministry of Agriculture, Livestock and Fisheries*
ME	*Ministry of Environment*
MEA	*Ministry of Environment and Sanitation*
MEATEU	*Ministry of Equipment, Land Development, Environment and Urban Planning*
OAPI	*African Organisation of Intellectual Property*
OEPP	*European and Mediterranean Plant Protection Organisation*
OHVN	*Upper Niger Valley Authority*
WTO	*World Trade Organisation*
NGO	*Non Governmental Organisation*
OAU	*Organisation of African Unity*
GMO	*Genetically Modified Organism*
PAGEEM	*Action Plan for the Generalisation of Environmental Education in Mali*
WFP	*World Food Programme*
PCR	*Polymerase Chain Reaction*
PCAE	*Environmental Communal Action Programme*
PFIE	*Training and Information Programme on Environment*
GDP	*Gross Domestic Product*
PNIEC	*National Programme on Information Education and Communication on Environment*
UNEP	*United Nations Environment Programme*
PNPE	*National Programme for the Protection of the Environment*
POP	*Persistent Organic Pollutants*
PPP	*Purchasing Power Parity*
REOA	*Network of Companies in West Africa*
RIPE	*Computerised Directory of Environmental Projects*
RYMV	*Rice Yellow Mosaic Virus*
SISEI	*Environmental Information and Monitoring System on the Internet in Africa*
SNGIE	*National Management System of Environmental Information*
SSN	*National Seed Service*
STP/CIGQE	*Permanent Technical Secretariat of the Institutional Framework for the Management of Environmental Issues*
SUKALA	*Upper Kala Sugar Plan*
TYCLV	*Tomato yellow curl leaf virus*
AU	*African Union*
UPOV	*Union for the Protection of New Varieties of Plants*
USAID	*United States Agency for International Development*
HIV/AIDS	*Human Immunodeficiency Virus*

INTRODUCTION

The National Biosafety Framework (NBF) is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the human health, conservation and sustainable use of biological diversity and the environment.

The document of the National Biosafety Framework contains three parts:

Part 1: Context and history of biosafety, current status of the Regulation, the Framework itself of biosafety (administration, decision-making, risk management, Public Participation);

Part 2: Draft bill relating to the biosafety in the Republic of Mali

Part 3: Annexes to the draft bill relating to the biosafety in the Republic of Mali

The first part gives an overview of the status of Biosafety and Biotechnology, that of the current situation concerning the regulation, and the actual framework of biosafety, including the concrete provisions set aside to manage the introduction of genetically modified organisms and their products.

The second part is the law itself that complete the biosafety framework.

The third part consists of the appendices to the law, four in total, on the provisions concerning the information, the assessment criteria and the risk management.

PART I

I. HISTORY AND NATIONAL CONTEXT OF BIOTECHNOLOGY AND BIOSAFETY IN MALI

1.1. Current Status of Biotechnology in Mali and in Africa

Despite its strong potential in improving the agricultural production, modern biotechnology especially, the use of genetic transformation has experience few application in Mali

Currently, the national development, research and training structures involved in the field of biotechnology in Mali are: the Institute of Rural Economy (IER), the Central Veterinary Laboratory (LCV), the National Institute of Public Health Research (INRSP), National Laboratory of Health (LNS), the Faculty of Medicine, Pharmacy and Odontology & Stomatology (FMPOS), the of Rural Technical Institute / Institute of Applied Training and Research (IPR-IFRA), the Laboratory of Applied Molecular Biology (LBMA-FAST), Laboratory of Soil Microbiology (LMS-FAST).

Institute of Rural Economy, it is the most important of institution in the National Agricultural Research Systems (NARS) in Mali. It has however a low capacity in biotechnology currently. But it has future plans for equipping itself in the field. The overall objective of applying biotechnology is to quickly and more efficiently respond to the development issues raised in various fields.
The current research programmes involving biotechnologies revolve around molecular markers for resistance to *Eurystinus marginatus,* a sucking insect pest of sorghum grains and the molecular characterization of sorghum for tolerance to drought, activities developed in the training framework of American universities.

The Central Veterinary Laboratory is in charge of the production of vaccines, research and diagnosis of Animal diseases. It produces many vaccines. The LCV is equipped to carry out diagnosis based on the PCR and the ELISA tests and the production of vaccines (antigen bio-fermentation), the production of recombinant vaccines.

The Faculty of Medicine, DNA equipments exist. There is however no application in the plant field.

The Laboratory of applied molecular biology, In terms of education and scientific research, this is the most equipped institution. It carries out research and training activities on various areas of pathology (frequency of genetic recombination in the parasite of malaria, HIV AIDS, yellow fever, glossina). In perspective, the LBMA intends to equip itself for the genetic transformation.

IPR Katibougou has a tissue culture laboratory. This laboratory is particularly involved in the production of potato seeds by micropropagation. On the other hand, it is not yet equipped for molecular biology.

The Laboratory of Soil Microbiology (LMS-FAST), has personnel trained in molecular biology. Its research activities revolve around the biotechnology of nitrogen fixing symbioses, the ecology, the diversity of nitrogen fixing bacteria and the follow-up of inocula in the tropical soils.

There are no national capacities in the GMO/LMO development and control but institutional components and competent human resources must be built in that direction.

Mali signed and ratified the Convention on Biological Diversity and the Cartagena Protocol.

Being aware of the necessity to acquire knowledge on transgenic cultures, it undertook the elaboration of a national regulation on the genetically modified plants.

There exists a real will to develop biotechnology in many countries of Africa. The Organisation of African Unity (OAU), became African Union (AU), has adopted an African law on biosafety and recommends the countries to get inspired from it in conceiving national biosafety frameworks. A real commitment was noted during the 5th Conference of Parties for the conservation of Biodiversity, by the use of biotechnology and the observation of the precautionary approach. The development of law and regulation is in progress in the countries that ratified the Cartagena Protocol.

Another essential event that must be noted is the 3rd session of the Executive Council of the African Union that adopted the decision Ref/CL/Dec. 26 (III) for an extended system for biosafety for Africa and an extended programme on capacity building.

Equipped laboratories exist in the West Africa sub region (Ivory Coast, Nigeria, Ghana, Burkina Faso and in the CORAF network). But it is in South Africa that Biotechnology has experienced important development. This country already sells transgenic cotton and maize. In Burkina Faso, tests on the transgenic cotton started in 2003.

Furthermore agencies exist for the promotion of biotechnology; it is the case of the African Biotechnology Agency (ABA).

1.2. National Biosafety Framework context

According to Article 19, paragraph 3 of the Convention on the Biological Diversity ***"The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."***

In the biosafety framework, le Cartagena Protocol prescribes to the Parties in its article 2 Paragraph 1, to take ***"…the necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol"*** and in its paragraph 2 to ensure ***"… that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health".***

To support the African countries in implementing this Protocol, the African Union has initiated a model law on biosafety in Africa. This approach aims at encouraging relations among the States in order to lay the groundwork for an integrated legal system on biosafety issues.

In the framework of implementing the Cartagena Protocol, Mali has benefited from the support from the United Nations Environment Programme – Global Environment Facility (UNEP-GEF) for the development of the National Biosafety Framework. This project started on December 26, 2002 and ended in September 2004.

The National Executing Agency for the UNEP-GEF is the Permanent Technical Secretariat of the Institutional Framework for the Management of Environmental Issues (STP/CIGQE).

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The National Steering Committee has been instituted by the Decree N° 04-058/PM-RM of 04 March 2004 relating to the creation of a National Steering Committee of the Elaboration Project of the National Biosafety Framework. In its article 3, the National Steering Committee of the Elaboration Project of the National Biosafety Framework is composed of:

President:

The Minister in charge of the Environment or his representative

Members:

A representative of the Ministry in charge of Justice,
A representative of the Ministry in charge of Health,
A representative of the Ministry in charge of Communication and New Technologies of Information
A representative of the Ministry in charge of National Education
A representative of the Ministry of Defence,
A representative of the National Board of Nature Conservation,
A representative of the Regulatory and Control Services,
A representative of Trade and Competition Services,
A representative of the National Board of Industries,
A representative of the Permanent Assembly of Agricultural Chambers of Mali,
A representative of the Customs Services,
A representative of the National Board of Civil Protection,
A representative of the National Assembly,
A representative of High Council of Territorial Communities,
A representative of Permanent Technical Secretariat of the Institutional

Framework for the Management of Environmental Issues
A representative of the Institute of Rural Economy,
A representative of the Central Veterinary Laboratory,
A representative of the University of Mali (IPR-IFRA),
A representative of the United Nations Development Programme,
A representative of the Coordination Committee of Associations and NGO,
A representative of the Secretariat of NGO Forum,
A representative of the CAFO,
A representative of the Consumer Association of Mali.

II – THE CURRENT STATUS OF THE REGULATION

2. 1. Regulatory System

The control and implementation systems are governed by the international Conventions, Agreements and Treaties, the Constitution, the regulatory texts that are linked to biosafety and biotechnology issues and to the environment, natural, animal resources management, to the sanitation, to the human health, to the decentralisation as well as the criminal texts.

2.1.1 International Conventions, Agreements and Treaties

The United Nations Framework Convention on Climate Change (UNFCCC) signed by Mali on 22 September 1992, adopted on 09 May 1992 and ratified on 28 December 1994.

The Convention on Biological Diversity (CBD), adopted on 05 June 1992 in Nairobi, ratified on 29 March 1995.

The Cartagena Protocol on Biosafety, adopted on 29 January 2001 in Montreal, ratified on 04 June 2002.

The United Nations Convention to Combat Desertification, adopted on 15 October 1994, ratified on 31 October 1995.

The International Plant Protection Convention, adopted on 06 December1951 in Rome, ratified by Mali on 31 August 1987.

The Convention on the African Migrating Crickets, adopted on 23 May 1962 in Kano, signed by Mali on 13 April 1963.

The Bonn Convention on Migrating Species and the African-Eurasian Water birds Agreement (AEWA-Bonn-CMS), adopted on 23 June 1979 in Bonn, ratified on 1st October 1987.

The Convention relating to the Protection of the Fauna and Flora in their Natural Habitat, adopted on 08 December 1933 in London.

The RAMSAR Convention on Wetlands adopted on 02 February 1971 in Teheran, ratified by Mali on 25 September 1987.

The Convention on the Protection of World Cultural and Natural Heritage, adopted on 16 November 1972 in Paris, signed by Mali on 05 April 1977.

The Convention setting up an Inter-State Committee to Combat Drought in Sahel, adopted on12 September 1973.

The African Convention on the Conservation of Nature and Natural Resources also known as Alger Convention, adopted on 15 September 1968 in Alger (amended on 11 July 2003 in Maputo), ratified on 20 June 1074.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), adopted on 07 March in Washington DC, ratified on 16 October 1994.

The Treaty establishing the African Economic Community on the Coordination Environmental Protection Policies among States, adopted on 03 June 1991 in Abuja, ratified by Mali on 27 January 1992.

The Economic Community of West African States (ECOWAS), created on 28 May 1975 in Lagos.

The West African Economic and Monetary Union (WAEMU), created on 10 January 1994 in Dakar.

The Liptako-Gourma Authority (ALG) for the promotion and the development of mining, energy, water supply, agriculture, livestock and fish breeding resources, created in December 1970 in Ouagadougou.

The Revised Complementary Agreement concerning the Supply of Technical Assistance by the International Atomic Energy Agency (IAEA) to the Government of the Republic of Mali adopted on 20 December 1988 in Vienna, signed by Mali n 1989.

The Regional Intergovernmental Agreement on the Cooperation for the Research, Development and Training relating to the Nuclear Science and Technology, signed by Mali on 02 December 1996

The Stockholm Convention on the Persistent Organic Pollutants adopted in Stockholm on 22 May 2001 ratified by 24 April 2003.

The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, adopted on 10 April 1972 in Moscow, signed by Mali on 13 January 1993.

The Rotterdam Convention, adopted in Rotterdam in 1998, ratified on 13 November 2002.

The International Treaty International on Plant Genetic Resources for Food and Agriculture adopted on 03 November 2001 in Rome and ratified in 2004.

The World Trade Organisation (WTO) came into force on 1st January 1995, Mali membership on 31 May 1995.

The Bangui Agreement revised on 29 February 1999 relating to the protection system by patent.

Have served as reference tools for the elaboration of the National Biosafety Framework:

- The African Model Law on Biosafety, adopted in April 2002;
- African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, adopted in June 1998.

2.1.2- The Constitution

Adopted on 25 February 1992, it stipulates in its article 15 that: *"Everyone has a right to a clean environment; the protection, the defence of the environment, the improvement of the quality of life are a duty of all and of the State"*.

2.1.3- The Laws relating to the Environment and Natural Resources Management

Environment and Sanitation Management Laws:

-Law N° 01-020 of 30 May 2001 relating to pollutions and nuisances. This law, in its articles 2, 3, 4, 5, 6, 7, 15, 22, 33, 36, 43, 44 and 49 define the essential concepts on the issues, the activities that are susceptible to undermine the environment, the conditions of audit, access to information, the nature of wastes, the type of pollution and the system of sanctions. The National Board of Sanitation and Pollution and Nuisance Control is in charge of enforcing the provisions of this law.

-Decree N° 03-594/P-RM of 31 December 2003 relating to the impact study on the environment, in its articles 3, 5, 6, 17, 29, 31, 32, 33, 34 and 36 define the fundamental concepts on the issues, prescribe the obligations, the seriousness of the risk, public consultation, required deadlines, monitoring and inspection, violations and sanctions, the responsible institutions and organs. The National Board of Sanitation and Pollution and Nuisance Control is in charge of enforcing the provisions of this decree.

-Order N°01-2699/MICT-SG of 16 October 2001 listing prohibited products for importation and exportation, in its article 1 specifies the list of prohibited products in absolute terms and a restrictive charter. The various technical services, inspectorates and the Police, who are in charge of enforcing this Order.

Forestry Laws:

- Law N°95-004 of 18 January 1995 sets the conditions of forestry resources management: it stipulates in its article 16 *"The protected species are those that, because of their economic, socio-cultural or scientific interest, enjoy a special protection. Their felling and uprooting are prohibited without formal authorisation…"* The article 17 lists the protected species. The protection of such species consists in the non-issuance felling permits, the monitoring and the forestry control. The National Board of Nature Conservation (DNCN) is in charge of enforcing this Law.

-Law N°95-031 of 20 March 1995sets the management conditions of the wild fauna and its habitat, in its articles 34, 39, 52, 54 and 59 prescribe the protection of a list of species of scientific importance and the preventive measures against the introduction of exotic species. The National Board of Nature Conservation (DNCN) is in charge of enforcing this Law.

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-Law N°95-032 of 20 March 1995 sets the management conditions of the fishing and fish farming in its articles 19, 40 and 60 prescribe the partial or full protection certain species of aquatic animals and plants and the measures relating to the import and introduction of species. The National Board in Fishery is in charge of enforcing this Law.

-Law N°01-063 of 04 July 2001 relates to the classification of the Baoulé Buckle National Park and its adjacent reserves in Biosphere Reserve, in its article 12, it prescribe the prohibition of the introduction of exotic animal and plant species. The National Board of Nature Conservation (DNCN) ensures the enforcement of this Law

-Law N° 02-017 of 3 June 2002 regulates the possession, trade, export, re-export, import, transport and transit of specimen species of wild fauna and flora. It has been adopted in the enforcement of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The DNCN is in charge of its enforcement.

Laws relating to the Plant protection:

-Law n°02-013 of 03 June 2002 institutes the Phytosanitary Control in the Republic of Mali, in its articles 2, 3, 4, 5, 15, it defines the concepts, prohibits the import of some plant products, regulates the official review of plants and plant products, and identifies the harmful organisms. The Regulatory and Control Services (DGRC) is in charge of enforcing this law.

-Law n°03-104 of 03 June 2003 institutes the Approval and Control of Pesticides in the Republic of Mali, in its articles 2, 6, 8, 11, it defines the basic concepts, regulates the approval and control procedure as well as the chemical, biological and physical modifications of a product used in agriculture and of the change in the destination for which a product has been authorised or approved. The Sahelian Pesticide Committee is in charge of the Approval. The Regulation and Control Services of the Rural Development Sector (DGRC/SDR) is in charge of enforcing this law.

Laws relating to Animal Resource Management:

-Law N°02-001 of 16 January 2002 regulates the production, transformation and marketing conditions of milk and dairy products. This law sets in its articles 1 and 7, the production, transformation and marketing conditions of milk and dairy products and puts obligations on the dairy producers submit to the sampling operations for analysis. The Ministry of Rural Development, the Ministry of Industry and Commerce and the Ministry of Health are in charge of enforcing this law.

-Law N°01-004 of 27 February 2001 sets the Pastoral Charter in the Republic of Mali. This law, in its articles 7, 8, 24, 25 and 26, subjects the exercise of pastoral activities to the obligation of preservation of the environment and the rights of present and future generations.

There, the rules of international transhumance are subject to the principle of reciprocity. The State and the Local Authorities enforce the principles and rules contained in this Pastoral Charter.

-Law N°00-083 of 22 December 2000 which relates to the ratification of the Edict 00-044/P-RM of 21 September 2000, regulates the production, release, control, import and export of seeds and embryos of animal origin and breeders. In its articles 2, 3, 5, 6, 7 and 17 this law defines the type of seeds of animal origin, the fundamental concepts on the issues, the control procedure and the sanction of production, release, import, export operations of seeds and embryos of animal origin as well as the import of breeders.

The Decentralisation Laws

-Law N°93-008 of 11 February 1993 determines the conditions of the self administration of territorial authorities modified by the Law 96-056 of 16 October 1996;
-Law N° 95-034 of 12 April 1995 sets the Territorial Authorities Code in the Republic of Mali;
-Law N°96-050 of 16 October 1996 sets the constitution and management principles of the area of the territorial authorities.

These laws define the roles and responsibilities of regional and local authorities on the issues of managing their territories.

Laws relating to the human health:

-Law N°01-078 of 18 July 2001 sets up the Drugs and Precursor Control, in its articles 1, 3, 11, 38 and 51, it defines the basic concepts, classifies the types of plants and substances according to the potential risks, regulates the manufacturing conditions of these substances, prohibits the import or the export of these substances in a consignment form addressed to an organisation or to a different person account, authorises the natural persons and legal entity licence holders to acquire or to keep the substance plants and manufacturing according to the professional demands. The National Pharmacy and Drug Board enforces its application.

-Law N°03-043 of 30 December 2003 sets up the National Agency for Food Health Security (ANSSA). The Agency has the mission of ensuring food health security. To this effect, it is in charge among other things of the assessment and communication on the risks.

-Law N°92/013 AN-RM of 17 September 1992 sets up the national system for standards and quality control. It regulates the standardisation system in the Republic of Mali. The National Industry Board enforces its application.

-Decree N°02-2000/P-RM of 22 April 2002 sets up the National Committee for Ethics and Life Sciences (CNESS) in its article 2, it stipulates, that CNESS voices its opinions on the ethical problems raised by the progress in knowledge in the areas of medicine, pharmacy, biology, health and other life sciences and makes recommendations on these subjects. The article 10 stipulates that the CNESS refers to itself on issues relating to the research, to the technological and scientific development, or to the promotion and protection of human rights brought up by natural persons or moral entities other than those mentioned in article 9.
The above list is not exhaustive. It refers to the texts regarding directly the biological resources, the human health and environment issues.

It must be noted however that these legislative and regulatory provisions do not explicitly take into account issues of biotechnology and biosafety. To fill this gap, we recommend that, in the framework of developing a biosafety law to:

- keep the provisions of the article 2 of the OAU Model Law on Biosafety in providing for, however, a paragraph that will give exemption to the research and development;
- harmonise the content of the draft bill with the scope of the Cartagena Protocol and to open up to the sub-regional prospects;
- proceed to the development of a draft bill by a multidisciplinary team including an experienced Malian legal expert with experience in Malian law and international law, an expert in biotechnology, a specialist in biosafety and a specialist in public health.

Another important aspect is that the current regulatory framework does not take care of sanctions, does not consider that the hazardous wastes as crimes against the environment. It does not therefore cover the specific cases of genetically modified organisms.

Criminal Laws

- Law n° O1-079 of 20 August 2001 sets up the criminal code
- Law n°O1- 080 of 20 August 2001 sets up criminal procedural code

III- THE NATIONAL BIOSAFETY FRAMEWORK

3.1- Administration systems and institutions

It is composed of a Focal Point who is also the notification contact point. This focal point is the Permanent Technical Secretariat of Institutional for the Management of Environmental Issues (STP/CIGQE), under the Competent National Authority which is the Ministry in charge of the Environment, the National Biosafety Committee with its three specialised commissions and the Public Biosafety Committee.

3.1.1. Competent National Authority, National Correspondent/National Focal Point, Notification Contact Point

The National Competent Authority (NCA) is the Ministry in charge of the Environment.

The NCA Secretariat, liaising with the Protocol Secretariat, - the Permanent Technical Secretariat for Institutional for the Management of Environmental Issues (STP/CIGQE) which is the Protocol Focal Point and the Notification Contact Point. This Focal Point ensures that all the obligations towards the Protocol are met and periodic reports are provided.

The STP/CIGQE will set up a National Biosafety Clearing House. This will ensure information exchange with the central Protocol Biosafety Clearing House, in the form of the laws, rules and directives issues for the approval of LMO and products intended as food and feed. It is also in charge of all relevant information for the Protocol Biosafety Clearing House, especially those indicated in the articles 11, 13, 14, 17, 20, 25 and 33 of the said Protocol.

The National Competent Authority is in charge of the issuance of authorisations regarding biosafety on the basis of recommendations formulated by the National Biosafety Committee. Every department concerned will name the appointed structure and people from within itself.

The design of the structures and responsibilities on the LMO types will be part of an enforcing decree.

3.1.2. The National Biosafety and Biotechnology Committee

The National Biosafety and Biotechnology Committee consist of the representatives of the following organisations and departments:

- The Ministry in charge of the Environment,
- The Ministry in charge of Agriculture,
- The Ministry in charge of Livestock and Fishery,
- The Ministry in charge of Education,
- The Ministry in charge of Health,
- The Ministry in charge of Industry and Commerce,
- The Ministry in charge of Justice,
- The Ministry in charge of Transports,
- The Ministry in charge Finances,
- The Civil Society,
- The Private Sector,
- And the Socio-professional Organisations and Associations.

Each of the various Ministries will design appropriate structures within itself and staff. The details of these appointments and way of working will be subject to a decree as part of a law for its enforcement.

The National Biosafety and Biotechnology Committee will function as a National Agency with great autonomy.

The National Biosafety and Biotechnology Committee can have recourse to any scientific and technical competence required for the assessment and management of cases.

The National Biosafety and Biotechnology Committee write to the specific NCA, the recommendations based on the work of various **specialised commissions**.

The specialised Commissions conduct the studies and researches in their field of competence and give report to the National Biosafety committee. The Committee is constituted of the following specialised commissions:

- the Risk Assessment and Management Commission;
- the Public Participation Commission;
- the Legal and Regulatory Commission.

* **The Risk Assessment and Management Commission** has the following as its mission to:

- assess the risk types: health risks, environment and biodiversity risks, socio-economic and cultural risks;

- make proposals to ensure an appropriate risk management.

The assessment could be entrusted if need be to a natural person or a legal entity on decision of the National Competent Authority.

The opinion of the National Committee for Ethics and Life Sciences if need be by the Assessment Commission.

* **The Public Participation Commission** is in charge of following the required procedures to gather public opinion.

* **The Legal and Regulatory Commission** is in charge of putting forward legal opinions on presented requests, their compliance with the established norms and their applicability.

3.1.3- The Public Biosafety Committee

This committee ensures the transparency in the decision-making, in the monitoring of the implementation of authorisations. The bio-vigilance/bio-surveillance activities all come under the competence of the public committee.

The status, the composition, the functions, the competence the scope of each organ or institution as well as the procedures will be determined if need be by the application laws

3.2- Information and Public Participation, Future Plans for the Information System and the Information-Education-Communication Strategy, Capacity building Needs.

3.2.1 Information Mechanisms and Public participation

This mechanism makes reference to the policies and the best practices.

3.2.1.1-Policies

*** National Policy on Environment Protection (PNPE):**

This policy is justified, among others, by the necessity of setting up an appropriate institutional and legislative framework for the coordination and attacks to the quality of the environment and an information system on the status of resources and their evolution.

The aim is to guarantee a safe environment and sustainable development by taking into accounts the environmental dimension in every decision that touches the conception, the planning and implementation of development policies, programmes and activities, by giving responsibilities to all actors.

The global objective is, among others, the development of national intervention capacities (technical and financial) at various levels and the promotion of the participation of all stakeholders of the Malian society in the environment protection task.

The strategy consists of developing a partnership among the actors basing it on the prevention of any new form of degradation, the set up of a framework of consultation and monitoring system, of continuous monitoring and surveillance.

The following programmes support this strategy:

- The National Programme of Environment Information Management (PNGIE): this programme is in the process setting up through the National System of Environment Management (SNGIE).

- The Computerised Directory of Environmental Projects (RIPE), which is a component of the SNGIE, is a computerised tool to facilitate the STP of its tasks of environmental monitoring: monitoring of the implementation of decisions of the Inter-ministerial Committee and the Consultative Committee of the Institutional Framework of the Management of Environmental Issues, monitoring of the implementation of the Programmes of the National Environmental Action Plan, and monitoring of financial mechanisms and the financing mobilization about the environment protection and the combat against desertification.

Its specific objectives are: to give an overview of environmental protection and management efforts and allow the classification of various interventions, to identify and to take in accounts the set of existing interventions according to the guidelines of Conventions and Action Plans in force, and to feed the System with processed data.

- The National Programme of Information, Education and Communication on the Environment (PNIEC): It aims at improving the coordination of the set of actions and interventions, at creating the bases of an environmental culture and at building national capacities so as to produce adapted communication tools and their correct use. It is essential to support the multiple transformations under way and to integrate the requirements of a participative approach.

- The Environmental Information and Monitoring System on the Internet in Africa (SISEI). Its general objective is to support African countries and their regional organisations in implementing systems allowing the validation, the circulation and development of the relevant environmental information so as to reinforce the participative approach of the various decisional and operational levels, and thus favour enlightened decision-making.

3.2.1.2- Examples of best practices and lessons learnt:

- Methodological Guide of the Implementation of the Environmental Communal Action Plan (PCAE). Its objective is to take into accounts the environmental dimension in the Communal Development Programme. It specifies the actors and the responsibilities. It gives the duration and the approach to followed as well as the implementation tools;
- The Environment Training and Information Programme (PFIE) in Mali is translated by the introduction in the current school programmes on the protection of the fauna and flora and the implementation of small projects especially the school reforestation carried out the students to give them the love of nature. The gains of this programme

have led its generalisation to the fundament education level under the name of Action Plan for the Generalisation of Environmental Education in Mali (PAGEEM).

3.2.2- Future Plan for the Information System and the Strategy regarding Information-Education-Communication

a) An information sub-system on biosafety will feed the Biosafety Clearing House (the BCH).

b) Components of the Strategy regarding public awareness, education and participation:

Communication Axes:
- Modern means of communication;
- Traditional/cultural communication techniques

Strategy
- Bulletin development and circulation in national languages;
- Setting up of information networks at national, regional and local level;
- Creation of a communication unit within the structure in charge of implementing the Protocol;
- Information exchange with the other countries;
- Information, training and awareness workshops;
- Constitution of a database, create of Website, decentralised structures;
- Use of traditional communication techniques (Sketch, Drama, Town Criers, Griots);
- Sub-regional and international cooperation.

Implementation means
- Human means (Capacity building)
- Financial means (State, Development Partners, National and International Private Sectors)
- Material means

3.2.3- Capacity building and Training

A "training" component is a necessity because it constitutes a need as far as biotechnology and biosafety is concerned.

It will contribute to the development and the building of national capacity in the areas of biotechnology and biosafety. It will involve the education, research and development sector.

Table - Development prospects of biotechnology in Mali

Constraints to overcome	**Applicable Biotechnologies**
Fight against cotton and cowpea pests	Genetic transformation (Bt)
Fight against the striga of millet, sorghum, maize, cowpea	Molecular markers Genetic transformation
Fight against the cotton weeds	Genetic transformation
Fight against the of the tomato (TYCLV), the rice (RYMV, cecidomy), the groundnut, the potato	Genetic transformation Molecular characterisation

(bacterial withering) and the millet (mildew) viruses and diseases	Molecular markers
Improvement of the amino-acid content for the cereals (maize, rice)	Genetic transformation
Fight against the millet, sorghum, maze, groundnut drought	Molecular markers
Production of healthy potato seeds and seedlings	Tissue culture (micropropagation)
Transformation of fruits into vinegar… (mango)	Fermentation
Improvement of forestry resources (jujube tree, shea tree, cowpea...)	Tissue culture Molecular and enzymatic characterisation
Improvement of bovine and ovine races	Molecular characterisation, Genetic cartography Aided selection of molecular markers
Diagnostic and fight against the disease agents (contagious bovine pneumonia …)	Molecular characterisation PCR, ELISA Vector/germ characterisation Production de vaccines recombinants Development of specific monoclonal antibodies
Improvement in the efficiency of the animal reproduction	Artificial Insemination Super-ovulation and embryo transfer Techniques
Plant (collections) and animal genetic resource management	Enzymatic, molecular or DNA characterisation

Consequently, we notice that no specific policy exists yet in Mali on biosafety, therefore the above-mentioned policies and strategies take into accounts some of the national concerns on biotechnology and biosafety.

Thus, the development of a specific biosafety policy is essential.

It must take into accounts:

* the creation of a national organ in charge of managing biosafety, especially the risks associated with the transfer Genetically Modified Organisms (GMO);

* the integration specifically in the laws the impact studies, the risk assessments associated with the manipulation of GMO, the introduction of new species and the taking of responsibilities of their consequences by the promoters;

* the building of competences that Mali has as far as biotechnology is concerned, especially within the research institutes (IPR/IFRA Laboratories, Central veterinary Laboratory, and National Research institute in Public Health) at the university and the Institute of Rural Economy;

* the promotion of sub regional and international scientific and technical cooperation as far as biotechnology and biosafety development is concerned.

3.3- Mechanisms and Procedures

3.3.1- Notification

- Any person wishing to engage in the import, or in the release, or in the contained use or in placing on the market of a genetically modified organism or a derived product of a genetically modified organism must notify it in writing to National Competent Authority.

- This notification must be accompanied by the following information:

    - the information listed in Annex I as well as those required the National Competent Authority;
    - an assessment report of the risks the genetically modified organism or the derived product of a genetically modified organism can run to the human health, to the biological diversity or to the environment, as well as the consequences of an unintentional release;
    - The information relating to a previous or current transfer of the genetically modified organism or the derived product of a genetically modified organism within the country or in an other country;
    - the information relating to the authorizations already granted or denied in another country;
    - the public biosafety Committee recommendations if the authorization request is intended for research & development;
    - a clear and sequential description of steps that will be followed during the implementation of the project, the monitoring and assessment procedures that will be carried out at the end of each step, as well as the waste elimination method;
    - the location and aim for which the genetically modified organism or the derived product of a genetically modified organism was made, used, conserved, commercialised or marketed, as well as the conditions of use and a labelling and packaging procedure according to the provisions catered for in the Annex II of the law; and
    - a sworn statement testifying the accuracy of supplied information signed by the notifier, including, depending on the case, a commitment from the supplier of this information guaranteeing that this information is accurate and complete.

- Nobody should engage in the import, the transit, the contained use, the release or the placing on the market of the genetically modified organism or the derived product of a genetically modified organism without prior authorisation with full knowledge of the facts or without the written explicit authorisation of the National Competent Authority, depending on the case.

- If the notification was sent within the prescribed the time limit, the concerned activity can go on until the decision is taken by the National Competent Authority according to the provisions of the law.

    The pending notifications at the time of the coming into force of this act will be governed by the provisions of this law.

- The import, contained use, release or marketing of the genetically modified organism or the derived product of a genetically modified organism prior to the National Biosafety Framework will be subject of notification to the National Competent Authority according to the provisions of the law.

- Any person wishing to import a genetically modified organism or the derived product of a genetically modified organism intended for direct use as food or feed or for processing, must submit to the National Competent Authority a written request including a reference to the information on the material found in the Clearing House.

3.3.2 Public Participation

- The National Competent Authority must, when receiving the notification mentioned at the article 11 and at article 12, make public the relevant information and inform the concerned ministries. .

- The can give its written opinion within the time limit that will be specified by the National Competent Authority. Any person that challenges the National Competent Authority can seek a counter expertise while bearing the costs pertaining to it.

- The National Competent Authority can decide to organise a public consultation concerning a project of import, contained use, release or placing on the market of a genetically modified organism or the derived product of a genetically modified organism. The consultation can then be announced in the national media and take place at least 15 days before the decision is taken.

- The National Competent Authority must, during the review of its decision, take into accounts opinions and concerns of the public, especially the counter expertise requests if need be.

- The National Competent Authority makes public the following information:

    - those relating to genetically modified organism or the derived product of a genetically modified organism for which the import, the contained use, the release or the placing on the market is authorised or denied;
      and
    - in particular, any risk assessment report about the genetically modified organism or the derived product of a genetically modified organism

3.3.3- Decision Procedure

- The National Competent Authority ensures that the import in the country of a genetically modified organism or the derived product of a genetically modified organism is carried out only after has handed out a written authorisation.

- The National Competent Authority assesses the information presented to him by the notifier or available at the Clearing House. Depending on the case, it can decide:

- that the notifier supplies further information so as to allow a taking of decision;
- to review the request;
- to review under conditions; or
  to reject the request.

- The National Competent Authority must notify to the notifier its decision in writing, with a copy addressed to the Clearing House within a time limit of ninety (90) days counting from the date of the receipt of the request.

- The National Competent Authority can, before taking a decision, request all the pieces of additional information judged necessary. Any notifier who will not be able to supply the requested information, its request will be considered as withdrawn.

- Any authorisation must specify the successive steps of the implementation of the decision procedure and indicate that the risks must be assessed at every step. However, if the National Competent Authority considers that there are no significant risks to the human health, the biological diversity or the environment, it can only do with a simplified procedure.

- In response to another Party on the import decision of a GMO as food or feed, in the absence of a regulatory framework, the decision of the National Competent Authority can be based on a risk assessment according to Annex III in a time limit not exceeding two hundred and seventy (270) days. A declaration will be made to the Biosafety Clearing House.

- The last decision concerning the use of a GMO as food or feed or processing on the national territory, including the placing on the market, is communicated to the Clearing House within fifteen (15) days following the decision together with the information in Annex II of the Protocol. A copy of the information will be supplied to the States that do not have access to the Clearing House. It will be the same for all the Parties that make requests for additional information targeted in paragraph b) of Annex II.

3.3.4- Simplified Procedure

- The simplified procedure allow the importing party, subject to adequate measures being applied to ensure the safe intentional transboundary movement of living modified organisms according to the objective of the protocol, to specify in advance to the Biosafety Clearing House:

  a) the cases where an intentional transboundary movement where it is the destination can occur at the same time when it is notified of the movement;

  b) the import of living modified organisms exempted from the advanced informed agreement procedure.

  The notifications aimed at in paragraphs a) above can be valid for similar prior movements to the same Party destination.

  - To obtain an authorisation for the import, the contained use, the release or the placing on the market of a genetically modified organism, the notifier must conduct

a study to continuously control and assess the risks for a period proportionate to life cycle of the species, such as determined by the Competent National Authority.

- No authorisation will be granted if the proof is established that the genetically modified organism or product of such genetically modified organism has no significant risk to the human health, to the biological diversity or the environment.

- In the event of serious and irreversible damages, the precaution principle should be applied as a rule.

- The National Competent Authority cannot issue an authorisation unless it ensures that the import, contained use, release or placing on the market of the genetically modified organism or the derived product of a genetically modified organism:
    - benefits the country without causing serious risk to human health, the biological diversity or the environment;
    - participates in sustainable development;
    - does not harm the socio-economic environment; and
    - responds to ethical values and community concerns and do not threaten the community knowledge and technologies;

- The notifier must supply to the National Competent Authority the proof that he has the means to fulfil its obligations, as provided for in this law (insurance certificate or other) for fear of seeing its request ended up not being accepted.

3.3.5- Review of decisions

- Any authorisation can be withdrawn, or submitted to additional conditions other those already imposed, if the National Competent Authority later obtains new information elements on the genetically modified organism or the derived product of a genetically modified organism indicating that there exists a risk to human health, to biological diversity or the environment.

- If the notifer has knowledge of new pertinent information elements, he must inform the National Competent Authority in the shortest time period.

3.3.6- Risk assessment

- The notifier must proceed or have proceeded to a risk assessment linked to genetically modified organism or product of such genetically modified organism for which he/she introduced a request.

- No decision on import, contained use, release or placing on the market of a genetically modified organism or product of such genetically modified organism can be taken by the National Competent Authority without prior assessment of risks to human health, to biological diversity and the environment, especially its socio-economic and cultural consequences.

- The risk assessment linked to a genetically modified organism or product of such genetically modified organism will be performed by either the notifier or the National Competent Authority, depending on the cases, according to the Annex III.

- The National Competent Authority must review or have reviewed the risk assessment report and, depending on results, rule on the import, contained use, release or placing on the market report of a genetically modified organism or product of such genetically modified organism.

- If after review, it seems that the risks are unavoidable, the national Competent Authority can authorise the import, contained use, release or placing on the market of the genetically modified organism or product of such genetically modified organism.

- In case that an authorisation is not given due to reasons of unacceptable risks , any certificate or any certificate request linked to a genetically modified organism or product of such genetically modified organism will not be recognised or will be rejected, according to the case.

- The National Competent Authority makes the notifier bear all the costs linked to the drawing up of the risk assessment or the risk management report.

- Any person participating in the risk assessment related to a subject in he has any direct or indirect interests, must declare it and withdraw the assessment process.

- If it is not possible for conducting a risk assessment free of any dependence towards interests of producers or if it is not possible to verify that the risk assessment was conducted in an independent way, the National Competent Authority can reject the request.

- The National Competent Authority sees to respect as regards to the Protocol especially:
  - to communicate to the Clearing House a summary of risk assessments and environmental studies relating to LMO, and the final decisions concerning their import or their discharge,
  - to inform the Clearing House of any modification of communicated information,
  - to produce the periodic exports to the Protocol Secretariat.

3.3.7- Risk management

- The National Competent Authority can develop, maintain and use if need be, a strategy aiming at containing the accidents from genetic engineering or deriving from the use of genetically modified organisms or their products likely of endangering the human health, the biological diversity or the environment.

- The National Competent Authority can take the necessary measures in implementing Article IV and the easing of negative effects that a genetically modified organism or product of such genetically modified organism can have on

the human health, the biological diversity or the environment as well as the socio-economic environment.

- The National Competent Authority can also:

  - request that any genetically modified organism be submitted to an observation period to study its life cycle or its generation cycle, at the notifier's expense, before and/or after any use;
  - ban the import, the contained use, the release or the placing on the market of a genetically modified organism or product of such genetically modified organism, if its characteristics or its specific traits lead to unacceptable risks to the human health, the biological diversity, the environment, the socio-economic and cultural conditions;
  - order the stopping of any use done in violation of the provisions provided for by this law;
  - order the stopping of any use of a genetically modified organism or product of such genetically modified organism that constitute a threat to the human health, the biological diversity and the environment.
  - request to any person having an activity governed by this law to take the necessary measures to avoid or to limit the risks to the human health, the biological diversity, the environment, the socio-economic and cultural conditions, or to restore the environment, as much as possible, in its initial state;
  - take all necessary measures, at the expense of any person that fails to the obligations as far as security is concerned as prescribed by the National Competent Authority
  - take all the necessary measures in case of imminent and serious danger to the human health, the biological diversity, the environment, the socio-economic and cultural conditions, or public order caused by genetically modified organism or product of such genetically modified organism, at the expense of the person;
  - require the notifier, at regular intervals to produce a follow-up report on the implementation of easing or suppression measure of risks identified in the assessment report;
  - assess, if need be ban, the import, the contained use, the transit or the release of a genetically modified organism or product of such genetically modified organism likely of being used for hostile purposes.

3.3.8- Unintentional release and emergency measures

- To manage any unintentional release and any emergency situation resulting from an accident caused by a genetically modified organism or product of such genetically modified organism, the National Competent Authority must, if necessary ensure:

  - that a emergency plan be established in the view of protecting the human health, the biological diversity as well as the environment, located outside the release or contained use area in case of accident; and that competent emergency services be aware of danger and be informed in writing;

- that the people likely of being affected by an accident be informed, in an appropriate way and without having to make the request on the security measures and on the behaviour to adopt in case of an accident. This information must be repeated and updated at appropriate regular intervals. It will be accessible to the public.

- In case of accident, the notifier must inform the National Competent Authority in the shortest possible time and supply the following information:

  - the circumstances of the accident;
  - the identity of the genetically modified organism or derived products of such genetically modified organisms that have been released and the released quantity;
  - any information that allow to assess the effects of the accident on the health of the whole population and on the environment; and
  - the emergency measures taken or that must be taken.

- From the time of the reception of the information relating to the article 43, The National Competent Authority sees to:

  - ensure that all possible measures have been taken to neutralise the risks to human health and the biological diversity; and
  - inform the competent governmental and non-governmental organisations of the countries likely of being affected, as well as the Biosafety Clearing House.

3.3.9. Identification and labelling

- Any genetically modified organism or product of such genetically modified organism will be clearly identified and labelled as such. The identification must mention specifically its own traits and characteristics sufficiently in details to ensure its traceability.

- Any genetically modified organism or product of such genetically modified organism must be clearly labelled and packaged according to the terms provided for in the Annex II, part C, and according to any other obligations, if possible, imposed by the National Competent Authority, so as to indicate that it is a product of genetically modified organism and, eventually, if it can lead to allergic type of reactions or cause other risks.

3.3.10- Confidential Information of Commercial Nature

- The National Competent Authority will not divulge to third parties any information of confidential nature if the notifier requests for confidentiality in writing.

- Under no circumstances the following information can be held as confidential:

  - the description of the genetically modified organism or product of such genetically modified organism, the name and address of the notifier, the aim and place of the import, the contained use, the release or the placing on the

market of a genetically modified organism or product of such genetically modified organism
- the control methods and plans of genetically modified organism or product of such genetically modified organism and the emergency intervention measures;
- the assessment of probable effects especially the pathogenic/ecologically disturber effects.

- The National Competent Authority can, after informing the notifier, decide that some of the information on the notification, the public participation despite their confidential nature, be put to the knowledge of the public and the concerned ministries and that, in the general interest.

- If for whatever reason the notifier withdraws the notification before obtaining the requested authorization, the National Competent Authority must respect the confidential nature character of the supplied information except for as far as the information supplied by notifier is concerned.

- Any person performing one of the any activities covered by this law must supply the information elements required by the National Competent Authority so that they can perform the monitoring the tasks of follow-up, monitoring, and implementation that lie with him, or take any emergency measure relating to the activity in question and no confidentiality can be claimed relating to this information.

- The NCA will see to consulting the authors of notification and to review the decision in case of disagreement on the information confidentiality.

3.3.11- Export

- Any person that intends to export a genetically modified organism or product of such genetically modified organism must supply to the National Competent Authority an advance informed agreement issued in writing by the National Competent Authority of the importing country,

- The presentation of an advance informed agreement in no way exempts the exporter of all his other obligations provided for by the international trade rules.

- The advance information agreement does not prevent the exporting country from taking into accounts other elements before authorizing or not the export.

- If a genetically modified organism or product of such genetically modified organism is subject to a legal ban in the country of origin, its export can in no way be authorized.

3.3.12- Socio-economic Considerations

The decisions on the import of genetically modified organisms or products of such genetically modified organisms in implementing the Protocol or national measures to reinforce it will take into account socio-economic impacts for the conservation and sustainable use of the biological diversity, especially those concerning the local or native communities.

The necessary provisions, if need be, to minimize the incidences and/or to correct them will be at he expense of the importer of the genetically modified organism.

The socio-economic considerations cover the socio-economic, cultural impacts, the ethical aspects, the traditional/indigenous knowledge and practices directly or indirectly caused by the genetically modified organism.

3.4- Cooperation, capacity building, priority actions, accompanying measures

3.4.1- Relations with the Protocol Clearing House and Cooperation with the States

The NCA must maintain in the framework of an exchange relations and cooperation partnership with the Clearing House as well as with the other States.

In this capacity the NCA is in charge of facilitating the information access and circulation between the National Clearing House and that of the Cartagena Protocol Secretariat. He must supply scientific, technical, ecological and legal information as well as experience data relating to the living modified organisms such as the risk assessment results and the import permits.

Concerning the transboundary movement le government of Mali can conclude agreements and bilateral arrangements with other States Parties to the Protocol or not so long as they have nothing contrary to the objective of the said Protocol.

The NCA can organise or participate in the organisation of sub-regional workshops and other initiatives to harmonise the national legislation with that of the neighbouring countries, especially in the context of sub-regional integration (African Union, West African Economic and Monetary Union Economic Community of West African States, Liptako-Gouma Authority or other sub-regional or international Organisations having an interest in the subject), and the reinforcement of biosafety.

3.4.2- Capacity Building

To train the scientific personnel to the molecular biology, biosafety assessment and management techniques
to build the capacity of structures to analyse the risks linked to food deriving from the modern biotechnology;
to acquire adequate equipments in the research and training fields on the GMO and the quality control of GMO products ;
to put in place a structure of reference equipped for performing the product traceability and conduct research and production activities on biotechnology and biosafety matters ;
to train specialists (sociologists, economists, lawyers, environmentalists, medical doctors, etc) on the impact monitoring-assessment of products developed through this technology ;
to train and organise the communities for the bio-vigilance/bio-surveillance ;

- to institute the National Competent Authority (NCA) and the National Biosafety Committee;
- to build the STP/CIGQE capacities; to build the capacity of the judiciary structures;
- to put in place a coherent communication system on the biotechnological risks ;
- to put in place a risk assessment system.
- to constitute a database and create a website (to participate to the Cartagena Protocol Clearing House, the BCH).

3.4.3- Priority Actions

From the situation analysis, emerged the following priority actions:

- the conception and implementation of a programme ;
  - of setting up and putting into operations national institutions of biosafety,
  - of Communication of Information of Education and of public participation,
  - of training of actors (legal experts, journalists, researchers,…) involved in the biosafety issue,
  - of research support in modern biotechnology,
  - of equipment for the training, the research, the assessment and the traceability

- the implementation of bio vigilance/bio surveillance system;

- the creation of a Clearing House in relation with the Protocol Clearing House.

3.4.4- Accompanying Measures

3.4.4.1- Information and Public Participation Mechanisms

- To develop the collaboration and exchange of information among the various research structures;

- To involve through the training, the media , the NGO and the cadre services in the public awareness on the products and technologies ;

- To introduce biosafety and biotechnology in the school education programmes ;

- To diversify the sources of information by :

the implementation of an institutional framework for promoting the exchange of information between the GMO promoters and the users and consumers,
the public information in French and/or national languages through debates, traditional and modern channels, the availing, by the research structures, of diversified information intended to feed the public debate;

- To create an information network at national, regional, local and international levels and contribute to the creation of an international network;

- To ensure the representation of the population especially the women within the leadership of the National Competent Authority;

- To take into account the opinions and needs of the rural population through their representatives (Chamber of Agriculture, Peasants Organisations, Consumer Organisations etc.);

- To draw up and circulate bulletins in the national languages
- To constitute a database, to create a website, to participate in the Cartagena Protocol Clearing House the BCH)

3.4.4.2. Legal and Regulatory Plan

- To provide for a monitoring and application mechanisms of the law;

- To preserve the community property rights on the biological resources;

- To conceive a clear and concise regime of proportionate sanctions to the established violations.

PART II

DRAFT BILL RELATING TO BIOSAFETY IN THE REPUBLIC OF MALI

Given the Constitution,
Given the Law N°94-026 of 24 June 1994 concerning the ratification of the Nairobi Convention on Biological Diversity,
Given the Law N°00-083 of 22 December 2000 **a**bout the ratification of the Edict 00-044/P-RM of 21 September 2000, governing the production, the release, the control, the import and the export of seeds and embryos of animal origin and breeders'
Given the Edict N°02-052/P-RM of 04 June 2002 about the ratification of the Cartagena Protocol on Biosafety,
Given the Law N°02-013 of 03 June 2002 instituting the the Phytosanitary Control in the Republic of Mali,
The National Assembly deliberated on its session of:
and adopted the law which contains the following:

CHAPTER I: OBJECTIVES

First Article:
This law aims at ensuring an adequate level of protection in the field of the transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity and the environment also taking into accounts the human health risks.

CHAPTER II: SCOPE

Article 2:
This law shall apply to the import, the export, the transit, contained use, the release or the placing on the market of any living modified organism should it be intended to be released in the environment or used a food or feed or for processed product, or a product of genetically modified organism. It also applies to the GMO with double pharmaceutical and food function of agricultural interest.

CHAPTER III: DEFINITIONS

Article 3:
For the purposes of this law the definitions will be the following:

a. "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. This agreement concerns the GMO introduction on the national territory and the subsequent uses: scientific, agricultural or commercial.
b. " Modern Biotechnologies" : include the following techniques

- nucleic acid recombination techniques causing 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 to propagate;

- techniques causing the direct introduction in a material organism that is hereditarily transmissible, and ready outside the organism. This include the micro-injection and micro-encapsulation; and

- the cellular fusion (including the protoplast fusion) or the hybridisation techniques lead to the formation of living cells containing new combinations of genetic material hereditarily transmissible by fusion of two or of more than two cells.

c. "Voluntary release" or "release": any intentional introduction in the environment of a genetically modified organisms or a product of genetically modified organism. This introduction can serve to commercial, food aid, remediation, experiment in the research field objectives. This concerns also the use of genetically modified organisms or products of genetically modified organisms in the greenhouses, fish farming basins, the building reserved to animals, except if the contained use is authorised there for a laboratory duly accredited or other installation one hand; the waste treatment and elimination containing genetically modified organisms, the import, the export or the transport of genetically modified organisms or a products of genetically modified organisms on the other hand.
d. "Risk assessment": direct or indirect risk assessment in the short, medium and long term that the contained use, the release or the placing on the market of genetically modified organisms or products of genetically modified organisms poses to the environment, the biological diversity or the human health, as well as the socioeconomic environment and the ethical values of the country.
e. "Export" from a country: any intentional transboundary movement from this country to Mali;
f. "Exporter": any natural person or moral entity that makes provisions for a genetically modified organisms or a product of genetically modified organism be exported.
g. "Hostile purposes": the elaboration, the acquisition, the implementation or the release of a genetically modified organisms or a product of genetically modified organism with intention to cause damages to the human health, the biological diversity, the environment or to goods in a way unauthorised by the National Competent Authority.
h. "socio-economic impact": all the direct or indirect effects of a genetically modified organisms or a product of genetically modified organism on the economy, the social and cultural conditions, the lifestyles or the local knowledge and technologies particular to one or to more communities, and as well as to the country economy.
i. "Import" to a country : any intentional transboundary movement towards this country and from Mali;
j. "Importer" any natural person or moral entity that makes provisions for a genetically modified organisms or a product of genetically modified organism be imported.
k. "Placing on the market": the supply of or the availing to third party of a genetically modified organism and a product of genetically modified organism that is accompanied with or without monetary exchange. That include food aid donation.

l. “Notifier”: any natural person or moral entity that notifies in writing in a view of obtaining from the National Competent Authority the required authorisation for the import, the contained use, the release, the placing on the market of genetically modified organisms and genetically modified organism products, where, if possible, any person to whom this authorisation was already given.

m. “Notification”: the presentation of documents containing the required information to the National Competent Authority, with, if need be the deposit of samples. The entire liability as to the accuracy and the complete character of the information lies with the notifier.

n. “Genetically modified organism”: any biological entity capable of reoccurring or of transferring genetic material, that is the plants, animals, the microorganisms (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.

o. “Person”: is understood any natural person and moral entity.

p. “Precautionary Principles”: the absence of concluding scientific proofs does not justify the non-intervention in particular when this risks having catastrophic consequences or that the intervention costs are negligible.

q. “Product of derived genetically modified organism”: any material obtained through the transformation or any other means, from a genetically modified organisms and a product of genetically modified.

r. “Cellular Technology”: set of techniques for the production of living cells with new genetic material combinations by the fusion of two cells or plus.

s. “ Genetic Technology “: any technique that involve the isolation, the characterisation or the introduction of the DNA in living cells or genetic entities used as vector for the transfer of genes (plasmids, virus, artificial chromosome)

t. “Use”: This is use for scientific research purposes. This is not concerned with the acquisition on the local market or the sources authorised by the national authorities, food aid included, free of charge or at a cost, by a third party or the use or the redistribution unless if specific conditions have been established regarding this use.

u. “Contained use”: any operation in which genetically modified organisms or the derived products of the genetically modified organisms are cultivated, stocked, used, transported, destroyed or used in whatever manner in a volume smaller than x cm^3 , and for which physical barriers or a combination of physical, chemical and/or biological barriers, are used in view to limit the micro-organism contact with the whole population and the environment.

CHAPTER IV: INSTITUTIONAL FRAMEWORK

Article 4: The institutional framework is made up of: A National Focal Point/National Correspondent, the National Competent Authority, the National Biosafety Committee and the Public Biosafety Committee.

Article 5: **National Focal Point**
The Mali National Focal Point for the Cartagena Protocol is the Permanent Technical Secretariat for Institutional for the Management of Environmental Issues (STP/CIGQE), it liaises between the Secretariat of the Cartagena Protocol on Biosafety, the with the Clearing House, and will facilitate the information exchange between the National Competent Authority and the different organs.

He is also the notification contact Point.

Article 6: **National Competent Authority (NCA)**

The National Competent Authority is the Ministry in charge of the Environment.

Attributions:

The NCA is in charge of monitoring and control of the application of this law. This national competent authority will have the following powers and tasks of:

- defining the criteria, the norms, the instructions and the rules necessary to the application of objectives of this law;

- taking into accounts the recommendations and instructions of the National Biosafety Committee during the deliberations relating to the import, to the transit, to the contained use, to the distribution of to the placing on the market genetically modified organisms and GMO products;

- ensuring the establishment of biosafety committees in the concerned institutions or nominate groups or independent consultants if necessary who will serve as technical or scientific consultants subjects relating to biosafety;

- closely monitoring the genetically modified organisms and genetically modified organism products everywhere in the World and when one of them is suspected of posing a serious risk to human health or the environment; to ban the transit on the national territory and notify the Clearing House, the customs services and the officials in charge of external trade;

- monitoring the accessibility and spreading of information between the National Clearing House and that of the Cartagena Protocol Secretariat;

- keeping and availing to the public in case of request; a database on the genetically modified organisms and genetically modified organism products; intended for direct use as food or feed, or for processing;

– declaring through the Biosafety Clearing-House that:

    i. a genetically modified organism or genetically modified organism product intended for food or feed or for processing can not be imported unless it subjected to a full risk assessment according to the terms of this law;
    ii. it is the import permit request that triggers the risk assessment and this will automatically be done whenever a new genetically modified organism is submitted to the Clearing House.

– assessing or reviewing the risk assessment on the genetically modified organisms or the genetically modified organism products. Whenever a genetically modified organism or products of genetically modified organism must be imported, the costs will be borne by the exporter;

– taking legal measures at national and international levels so a to protect the human health and the environment from risks that could be provoked by the genetically modified organisms or their products; in violation of this law and the Cartagena Protocol on Biosafety;

– appointing inspectors and undertaking inspections and other control measures to ensure the respect of law;

– other functions specified by the government :

Article 7: **The National Biosafety and Biotechnology Committee**

A National Biosafety and Biotechnology Committee is instituted. It establishes according to its general responsibilities, its terms of reference and its own rules of procedures.

It brings together the representatives from the administration, non-governmental organizations, and members of parliament, private sector representatives, the media and the civil society.

This Committee has the task of making recommendations and advising, if necessary, the National Competent Authority on the decisions to take concerning the genetically modified organisms or their products according to the article 6.

The Composition:

The National Biosafety and Biotechnology Committee consist of the representatives of the following organisations and departments:

- The Ministry in charge of the Environment,
- The Ministry in charge of Agriculture,
- The Ministry in charge of Livestock and Fishery,
- The Ministry in charge of Education,
- The Ministry in charge of Health,
- The Ministry in charge of Industry and Commerce,

- The Ministry in charge of Justice,
- The Ministry in charge of Transports,
- The Ministry in charge of Finance,
- The Civil Society,
- The Private Sector,
- And the Socio-professional Organisations and Associations.

The mandate of National Biosafety Committee will be of 3 years. It is renewable by two thirds of the members.

A decree specifying how a law should be enforced will set the detailed on the representatives and operating mode of the National Biosafety Committee.

Article 8**: The public biosafety committee**

The institutions involved in the import, the export, the handling and contained use, the release or the placing on the market of genetically modified organisms or products derived from genetically modified organism will set up the public biosafety Committees to institute and control security procedures as well as authorization procedures.

CHAPTER V: NOTIFICATION

Article 9: Nobody should engage in the import, the transit, the contained use, the release or the placing on the market of the genetically modified organism or the derived product of a genetically modified organism without prior authorisation with full knowledge of the facts or without the written explicit authorisation of the National Competent Authority, depending on the case.

Article 10: Any person wishing to engage in the import, or in the release, or in the contained use or in placing on the market of a genetically modified organism or a derived product of a genetically modified organism must notify it in writing to National Competent Authority.

Article 11: This notification must be accompanied by the following information:

- the information listed in Annex I as well as those required the National Competent Authority;
- an assessment report of the risks the genetically modified organism or the derived product of a genetically modified organism can run to the human health, to the biological diversity or to the environment, as well as the consequences of an unintentional release;
- The information relating to a previous or current transfer of the genetically modified organism or the derived product of a genetically modified organism within the country or in an other country;
- the information relating to the authorizations already granted or denied in another country;
- the public biosafety Committee recommendations if the authorization request is intended for research & development;
- a clear and sequential description of steps that will be followed during the implementation of the project, the monitoring and assessment procedures that will be carried out at the end of each step, as well as the waste elimination method;

- the location and aim for which the genetically modified organism or the derived product of a genetically modified organism was made, used, conserved, commercialised or marketed, as well as the conditions of use and a labelling and packaging procedure according to the provisions catered for in the Annex II of the law; and
- a sworn statement testifying the accuracy of supplied information signed by the notifier, including, depending on the case, a commitment from the supplier of this information guaranteeing that this information is accurate and complete.

Article 12: Any person wishing to import a genetically modified organism or the derived product of a genetically modified organism intended for direct use as food or feed or for processing, must submit to the National Competent Authority a written request including a reference to the information on the material found in the Clearing House

CHAPTER VI: PUBLIC PARTICIPATION

Article 13: The National Competent Authority must, when receiving the notification mentioned at the article 11 and at article 12, make public the pertinent information and inform the concerned ministries.

Article 14: The public can give its written opinion within the time limit that will be specified by the National Competent Authority. Any person that challenges the National Competent Authority can seek a counter expertise while bearing the costs pertaining to that.

Article 15: The National Competent Authority can decide to organise a public consultation concerning a project of import, contained use, release or placing on the market of a genetically modified organism or the derived product of a genetically modified organism. The consultation can then be announced in the national media and take place at least 15 days before the decision is taken.

The public consultation, according to the national law and regulation will respect the confidential nature of information

Article 16: The National Competent Authority must, during the review of its decision, take into accounts opinions and concerns of the public, expressed according to the articles 13 and 14 of this law.

Article 17: The National Competent Authority makes public the following information:

- those relating to genetically modified organism or the derived product of a genetically modified organism for which the import, the contained use, the release or the placing on the market is authorised or denied; and
- in particular, any risk assessment report about the genetically modified organism or the derived product of the genetically modified organism

CHAPTER VII: DECISION PROCEDURE

Article 18: The National Competent Authority ensures that the import in the country of a genetically modified organism or the derived product of a genetically modified organism is carried out only after has handed out an authorisation in writing.

Article 19: The National Competent Authority assesses the information presented to him by the notifier or available at the Clearing House. Depending on the case, it can decide:

- that the notifier supplies further information so as to allow a taking of decision;
- to review the request;
- to review under conditions; or
- to reject the request.

Article 20: The National Competent Authority must notify to the notifier its decision in writing, with a copy addressed to the Clearing House within a time limit of ninety (90) days counting from the date of the receipt of the request.

Article 21: The National Competent Authority can, before taking a decision, request all the pieces of additional information judged necessary. Any notifier who will not be able to supply the requested information, its request will be considered as withdrawn.

Article 22: Any authorisation must specify the successive steps of the implementation of the decision procedure and indicate that the risks must be assessed at every step. However, if the National Competent Authority considers that there are no significant risks to the human health, the biological diversity or the environment, it can only do with a simplified procedure.

Article 23: The simplified procedure allow the importing party, subject to adequate measures being applied to ensure the safe intentional transboundary movement of living modified organisms according to the objective of the protocol, to specify in advance to the Biosafety Clearing House:

a) the cases where an intentional transboundary movement where it is the destination can occur at the same time when it is notified of the movement;

b) the import of living modified organisms exempted from the advanced informed agreement procedure.

The notifications aimed at in paragraphs a) above can be valid for similar prior movements to the same Party destination.

Article 24: To obtain an authorisation for the import, the contained use, the release or the placing on the market of a genetically modified organism, the notifier must conduct a study to continuously control and assess the risks for a period proportionate to life cycle of the species, such as determined by the Competent National Authority.

Article 25: No authorisation will be granted if the proof is established that the genetically modified organism or product of such genetically modified organism has no significant risk to the human health, to the biological diversity or the environment.

Article 26: In the event of serious and irreversible damages, the precaution principle should be applied as a rule.

Article 27: The National Competent Authority can not issue an authorisation unless it ensures that the import, the contained use, the release or the placing on the market of the genetically modified organism or the derived product of a genetically modified organism:

- benefits the country without causing serious risk to human health, the biological diversity or the environment;
- participates in sustainable development;
- does not harm the socio-economic environment; and
- responds to ethical values and community concerns and do not threaten the community knowledge and technologies;

The last decision concerning the use of a LMO as food or feed or processing on the national territory, including the placing on the market, is communicated to the Clearing House within fifteen (15) days following the decision together with the information in Annex II of the Protocol. A copy of the information will be supplied to the States that do not have access to the Clearing House. It will be the same for all the Parties that make requests for additional information targeted in paragraph b) of Annex II.

Article 28: The notifier must supply to the National Competent Authority the proof that he has the means to fulfil its obligations, as provided for in this law (insurance certificate or other) for fear of seeing its request ended up not being accepted.

CHAPTER VIII: REVIEW OF DECISIONS

Article 29: Any authorisation can be withdrawn, or submitted to additional conditions other those already imposed, if the National Competent Authority later obtains new information elements on the genetically modified organism or the derived product of a genetically modified organism indicating that there exists a risk to human health, to biological diversity or the environment.

Article 30: If the notifer has knowledge of new pertinent information elements, he must inform the National Competent Authority in the shortest time period.

CHAPTER IX: RISK ASSESSMENT

Article 31: The notifier must proceed or have proceeded to a risk assessment linked to genetically modified organism or product of such genetically modified organism for which he/she introduced a request.

Article 32: No decision on import, contained use, release or placing on the market of a genetically modified organism or product of such genetically modified organism can be taken by the National Competent Authority without prior assessment of risks to human health, to biological diversity and the environment, especially its socio-economic and cultural consequences.

Article 33: The risk assessment linked to a genetically modified organism or product of such genetically modified organism will be performed by either the notifier or the National Competent Authority, depending on the cases, according to the Annex III.

Article 34: The National Competent Authority must review or have reviewed the risk assessment report and, depending on results, rule on the import, contained use, release or placing on the market report of a genetically modified organism or product of such genetically modified organism.

Article 35: If after review, it appears that the risks are unavoidable, the national Competent Authority can authorise the import, contained use, release or placing on the market of the genetically modified organism or product of such genetically modified organism.

Article 36: In case that an authorisation is not given due to reasons of unacceptable risks , any certificate or any certificate request linked to a genetically modified organism or product of such genetically modified organism will not be recognised or will be rejected, according to the case.

Article 37: The National Competent Authority makes the notifier bear all the costs linked to the drawing up of the risk assessment or the risk management report.

Article 38: Any person participating in the risk assessment related to a subject in he has any direct or indirect interests, must declare it and withdraw the assessment process.

Article 39: If it is not possible to conduct a risk assessment free of any dependence towards interests of producers or if it is not possible to verify that the risk assessment was conducted in an independent way, the National Competent Authority can reject the request.

CHAPTER X: RISK MANAGEMENT

Article 40: The National Competent Authority can develop, maintain and use if need be, a strategy aiming at containing the accidents from genetic engineering or deriving from the use of genetically modified organisms or their products likely of endangering the human health, the biological diversity or the environment.

Article 41: The National Competent Authority can take the necessary measures in implementing Article IV and the easing of negative effects that a genetically modified organism or product of such genetically modified organism can have on the human health, the biological diversity or the environment as well as the socio-economic environment.

Article 42:
Without being detrimental to article 40 and 41, the National Competent Authority can also:

- request that any genetically modified organism be submitted to an observation period to study its life cycle or its generation cycle, at the notifier's expense, before and/or after any use;
- to ban the import, the contained use, the release or the placing on the market of a genetically modified organism or product of such genetically modified organism, if its characteristics or its specific traits lead to unacceptable risks to the human health, the biological diversity, the environment, the socio-economic and cultural conditions;
- to order the stopping of any use done in violation of the provisions provided for by this law;
- to order the stopping of any use of a genetically modified organism or product of such genetically modified organism that constitutes a threat to the human health, the biological diversity and the environment.
- to request to any person having an activity governed by this law to take the necessary measures to avoid or to limit the risks to the human health, the biological diversity, the environment, the socio-economic and cultural conditions, or to restore the environment, as much as possible, in its initial state;
- to take all necessary measures, at the expense of any person that fails to the obligations as far as security is concerned as prescribed by the National Competent Authority
- to take all the necessary measures in case of imminent and serious danger to the human health, the biological diversity, the environment, the socio-economic and cultural conditions, or public order caused by genetically modified organism or product of such genetically modified organism, at the expense of the person;
- to require the notifier, at regular intervals to produce a follow-up report on the implementation of easing or suppression measure of risks identified in the assessment report;
- to assess, if need be ban, the import, the contained use, the transit or the release of a genetically modified organism or product of such genetically modified organism likely of being used for hostile purposes.

CHAPTER XI: UNINTENTENTIONAL RELEASE AND EMERGENCY MEASURES

Article 43: To manage any unintentional release and any emergency situation resulting from an accident caused by a genetically modified organism or product of such genetically modified organism, the National Competent Authority must, if necessary ensure:

- that a emergency plan be established in the view of protecting the human health, the biological diversity as well as the environment, located outside the release or contained use area in case of accident; and that competent emergency services be aware of danger and be informed in writing;
- that the people likely of being affected by an accident be informed, in an appropriate way and without having to make the request on the security measures and on the behaviour to adopt in case of an accident. This information must be repeated and updated at appropriate regular intervals. It will be accessible to the public.

Article 44: In case of accident, the notifier must inform the National Competent Authority in the shortest possible time and supply the following information:

- the circumstances of the accident;
- the identity of the genetically modified organism or derived products of such genetically modified organisms that have been released and the released quantity;
- any information that allow to assess the effects of the accident on the health of the whole population and on the environment; and
- the emergency measures taken or that must be taken.

Article 45: From the time of the reception of the information relating to the article 43, The National Competent Authority sees to:

- ensure that all possible measures have been taken to neutralise the risks to human health and the biological diversity; and
- inform the competent governmental and non-governmental organisations of the countries likely of being affected, as well as the Biosafety Clearing House.

CHAPTER XII: IDENTIFICATION AND LABELLING

Article 46: Any genetically modified organism or product of such genetically modified organism will be clearly identified and labelled as such. The identification must mention specifically its own traits and characteristics sufficiently in details to ensure its traceability.

Article 47: Any genetically modified organism or product of such genetically modified organism must be clearly labelled and packaged according to the terms provided for in the Annex II, part C, and according to any other obligations, if possible, imposed by the National Competent Authority, so as to indicate that it is a product of genetically modified organism and, eventually, if it can lead to allergic type of reactions or cause other risks.

CHAPTER XIII: CONFIDENTIAL INFORMATION OF COMMERCIAL NATURE

Article 48: The National Competent Authority will not divulge to third parties any information of confidential nature if the notifier requests for confidentiality in writing.

Article 49: Under no circumstances the following information can be held as confidential:

- the description of the genetically modified organism or product of such genetically modified organism, the name and address of the notifier, the aim and place of the import, the contained use, the release or the placing on the market of a genetically modified organism or product of such genetically modified organism
- the control methods and plans of genetically modified organism or product of such genetically modified organism and the emergency intervention measures;
- the assessment of probable effects especially the pathogenic/ecologically disturber effects.

Article 50: The National Competent Authority can, after informing the notifier, decide that certain information stated in articles 11 and 12 in accordance with provisions provided for in the article 13, despite their confidential nature, be put to the knowledge of the public and the concerned ministries and that, in the general interest.

The NCA will see to consulting the authors of notification and to review the decision in case of disagreement on the information confidentiality.

Article 51: If for whatever reason the notifier withdraws the notification before obtaining the requested authorization, the National Competent Authority must respect the confidential nature of the supplied information except for those mentioned in paragraph 2 and 3 of the article 49.

Article 52: Any person performing one of the any activities covered by this law must supply the information elements required by the National Competent Authority so that they can perform the monitoring the tasks of follow-up, monitoring, and implementation that lie with him, or take any emergency measure relating to the activity in question and no confidentiality can be claimed relating to this information.

CHAPTER XIV: EXPORT

Article 53: Any person that intends to export a genetically modified organism or product of such genetically modified organism must supply to the National Competent Authority an advance informed agreement issued in writing by the National Competent Authority of the importing country.

Article 54: The presentation of an advance informed agreement in no way exempts the exporter of all his other obligations provided for by the international trade rules.

Article 55: The advance information agreement does not prevent the exporting country from taking into accounts other elements before authorizing or not the export.

Article 56: If a genetically modified organism or product of such genetically modified organism is subject to a legal ban in the country of origin, its export can in no way be authorized.

CHAPTER XV: LIABILITY AND REDRESS

Article 57: Any person that imports, uses in confined environment, releases or puts on the market a genetically modified organism or a product of such genetically modified organism is strictly held responsible for damages caused by this genetically modified organism or this product of such genetically modified organism. These damages must be fully redressed.

Article 58: The redress of a damage lies with the person responsible for the activity that caused the damage, the nuisance or the loss as well as with the supplier, of the trustee or of the developer of genetically modified organisms or products of such genetically modified organism.

Article 59: If there is more than one person responsible for the damage, the nuisance or the loss, each will jointly share the responsibility.

Article 60: In case of damage to the environment or to the biological diversity by a genetically modified organism or a product of such genetically modified organism, the compensation amount will include the costs of the extent of restoration, rehabilitation and sanitation that would have really been incurred and in some cases, the costs associated with the preventive measures.

Article 61: In case of damage to the human health, the compensation will include:

- the total costs incurred to find and obtain the required and appropriate medical treatment;

- the amount of allowances for disability, for the reduction of the quality of life and the total costs incurred to restore, if possible, the quality of life that the person enjoyed before he suffered the damages ;

- the amount of death benefit and the total costs incurred for the funeral;

Article 62: The liability and redress will also extend to the socioeconomic **considerations:**

- the nuisances and the damages directly or indirectly caused by the genetically modified organism or the product of such genetically modified organism to the economy ;
- the social and cultural conditions, especially the negative effects on the life styles, the traditional knowledge and technologies of one or more communities ;
- the damages and losses caused by public unrests emanating from the genetically modified organism or the product of such genetically modified organism;

- the complete or agricultural partial destruction of industrial or production systems, the loss of harvests, the contamination of soils ;
- the damages caused to the biological diversity, the economy of a region and any other direct and indirect damages;

Article 63: In case of damage provoked by a genetically modified organism or a product of such genetically modified organism, the right to take legal action can only be null and void after a time limit of 10 days from the damage awareness by the affected person or community, taking into accounts the following elements:

- the time required for the damage manifestation; and

- the time required to make a link between the damage and the genetically modified organism or the product of such genetically modified organism, taking into account the situation of the person(s) or the affected community(ies), or the circumstances in which they are found.

Article 64: Any person, group of persons or private or public organisations can sue and request for redress in case of breach or risk of breach to the obligations of this law, especially the provisions linked to the damages caused to the human health, the biological diversity, to the environment or even to socioeconomic conditions :

- in the interest of this person or the group of persons;

- in the interest or in the name of a person who, for practical reasons, is incapable to launch such a procedure;

- In the interest or in the name of a group or class of people whose interests are threatened;

- in the general interest; and

- for the protection of the environment and biological diversity.

Article 65: No request for a claim for damages coming from a natural person and moral entity being sued can validly be accepted if the above law suit was intended in a disinterested way or in the general interest or the aim of protecting the environment or the biological diversity.

CHAPTER XVI: VIOLATIONS AND SANCTIONS

Article 66: Constitutes violations as far as biosafety is concerned:
- the import, - export, transit, marketing, putting on the market in a confined environment of whatever GMO or GMO product, without prior authorization of the National Competent Authority,
- the use of GMO or GMO products for hostiles purposes,
- any violation to the obligations and rules in biosafety,
- the false information, deceitful declaration and any other fraudulent manoeuvre in a view to obtain an authorization; the hindrances to the smooth running of the NCA,
- any illicit GMO movement.

Article 67: Will be punished with a 6 month to 5 year prison sentence

- those in a view of obtaining an authorisation will have supplied to the NCA during the risk assessment false information or will have made deceitful declarations ;
- those while being authorisation holders will have concealed or will have knowingly abstained from supplying information elements that have reached them and capable of modifying the assessment of risks caused by their projects;
- those while being authorisation holders will have refused or omitted to fulfil the formalities relating to the labelling, the packaging and eventually the indication of the essential characteristics of the products.

Article 68: Will be punished to 5 to 10 year prison sentence and a fine of CFA 1,000,000 to CFA 5,000,000 or only one of these sentences:

- those that, without prior authorisation of the NCA, will have imported, exported, made transit, marketed, put on the market, used in confined environment any one of GMO or GMO product
- those that knowingly will have made obstructions preventing the correct fulfilment of the tasks passed to the NCA ;

those while being authorisation holders, will have refused or omitted to inform the NCA in the shortest period of time in case of accident or in an emergency situation implicating a GMO or GMO product.

The sentences could be doubled when it is established that these GMO and derived products are of nature to bring about serious risks to the human and animal health, the biological diversity, the environment, and the socioeconomic and cultural conditions.

Article 69: will be punished of 10 to 20 year prison sentence and a fine of CFA 10,000,000 to CFA 30,000,000 or to only one of these sentences and optionally a 5 to 10 20 year persona non grata sentence:

- those who will have used a GMO or GMO derived product for hostile purposes.

The sentence will be life imprisonment without prejudice to fine sentences when it is established that these GMO and derived products are of a nature to bring about serious risks to the human and animal health, the biological diversity, the environment, and the socioeconomic and cultural conditions.

Article 70: In all cases of violation concerning biosafety, the confiscation of GMO or GMO products will be ordered.
The author of the illicit transboundary movement will eliminate at his own expense the GMO, by destruction or repatriation, being subject to illicit movement.
Article 71: Any person that commits whatever one of violations to this law can banned from any activity, in Mali, linked to genetically modified organisms or products of such genetically modified organism.
This ban will be extended to any company, physical or moral entity that could be used to avoid the effects of the said ban.

Article 72: At the time paying the fines, their amounts will be calculated according to the legal tender of the currency in force in Mali at the time of pronounced decision.

Article 73: If the violation is committed by a company and if the repressive jurisdiction pronounces a prison sentence, the highest responsible person in office at the time of the violation will be liable for this sentence.

CHAPTER XVII: APPEAL

Article 74: The means of appeal against the NCA decisions are those provided for by the law.

CHAPTER XVIII: SPECIAL PROVISION

Article 75: The damages caused by genetic resources to communities following the transfer, the use, the handling of GMO and GMO products and their use in the biotechnology, will be subject to redress and/or sharing to the benefit of the said communities.

CHAPTER XIX: TRANSITIONAL PROVISIONS

Article 76: For any import, contained use, release or trading of a genetically modified organism or product of such genetically modified organism that already started before the coming into force of this law, a notification must be addressed to the National Competent Authority according to the article 11.

CHAPTER XX: FINAL PROVISIONS

Article 77: Concerning the transboundary movements the government of Mali, can conclude agreements and bilateral arrangements with other States Parties or not as long as they have nothing contrary to the objective of the said Protocol.

Article 78: This law repeals all other prior conflicting provisions.

Article 79: The decrees, annexes and the rules determine the modes of enforcement of this law.

Done at Bamako, on ……..

The President of the National Assembly

The session secretary

PART III

Annex 1

INFORMATION REQUIRED FOR THE APPLICATION

The following information is required during an authorisation request for release in the environment of a genetically modified organism or product of genetically modified organism especially during a use in a closed system, of the importation of products intended for human or animal consumption, or to industrial or pharmaceutical purposes which don't justify an authorisation certificate delivered by a duly mandated agency for the protection of human health and biological diversity of the country.

GENERAL INFORMATION

The notifications must include the names, addresses and complete details of the importer and the exporter.

INFORMATION ON PERSONNEL AND TRAINING

The name, the qualifications relating to training or others of the responsible person(s) of the implementation and the realisation of the project, especially those people in charge of the supervision, the surveillance and the security, in particular the name and qualifications of scientific officials.

INFORMATION RELATING TO GMO OR PRODUCTS OF SUCH ORGANISMS

A. Characteristics: a) of donor, b) of host or c) (if possible) of parental organisms(s):

1) Scientific name;
2) Additional taxonomic information;
3) Other names (usual name, strain name, cultivar name, etc.)
4) Phenotypic and genetic markers;
5) Degree of relatedness between the donor and the host or between the parental organisms;
6) Description of identification and detection techniques;
7) Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques;
8) Description of the geographical distribution and of the natural habitat of organisms especially information relating to predators, preys, parasites and competitors, symbionts and hosts;
9) Potential for genetic transfer and exchange with other organisms;
10) Verification of the genetic stability of organisms and factors affecting it, taking into accounts the relevance of laboratory experiments undertaken for authentic ecological conditions under which these organisms live or are used;
11) Pathological, ecological and physiological traits:

Classification of hazard according to the existing national rules relating to the protection of human health and the environment;

Generation time of in the natural ecosystems, sexual or asexual reproduction cycle ;

Information on survival, especially the seasonability and the ability to form survival structures, for example, seeds, spores, scelerotia;

Pathogenicity, infectivity, toxigenicity, virulence, allegenicity, carrier (vector) of

pathogen, possible vectors, host organisms especially those that are not targeted. Possible activation of latent viruses (provirus). Possibility for colonising other organisms.

Resistance to antibiotics and possible use of antibiotics in human or domestic organisms with prophylactic or therapeutic aims;

Implication in the environmental process: primary production, nutritional yield, decomposition of the organic matter, respiration, etc.

12) History of previous genetic modifications.

Vector characteristics:

1. Nature and source of vector;

2. Sequence of transposons, vectors and other non-coding genetic segments used to build the GMO or products of such organisms and to construct the introduced vector and function of insertion in the GMO or products of such organisms;

3. Frequency of mobilisation of inserted vector and/or the genetic transfer capacity and determination methods;

4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

5. Factors (chemical, biological, climatic, etc.) influencing the functional level of promoter/simulator and modification of the functional level,

Characteristics of GMO or products of such organisms

6. Information relating to the genetic modification

a. Methods used for modification;

b. Methods used to construct and introduce the insert(s) in the host or to cancel a sequence;

c. Description of the insert and/or of vector construction;

d. Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

e. Number of intact and truncated vector inserts. Sequence, functional identity and location of the altered, inserted deleted nucleic acid segment(s) in question, with a particular reference on any known harmful sequence;

f. Sequence and methylation pattern of the host DNA as far as 100 kpb up or down from all DNA inserts.

7. Information on the final GMO or such organisms

a. Description of the genetic traits of the phenotypic characteristics and in particular of any new trait or characteristics which may be expressed or no longer expressed;

b. structure and quantity of any vector and/or donor nucleic acid remaining in the final construction of GMO or product(s) of such organisms;

c. Stability of the organism in terms of genetic traits;

d. Rate and level of expression of the new genetic material. Method and measure of measurement;

e. Activity of the expressed protein(s);

f. Expression levels of the recipient’s genes situated as far as 100 kpb up and down stream from all DNA inserts;

g. Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques;

h. History of previous releases or uses of GMO or product of such organisms:

i. Health considerations:

i. Toxic and allergenic effects of the non-viable GMO or product of such organism and/or metabolic products;

ii. Product hazards;
iii. Comparison of GMO of such organisms on the donor, the host or (if necessary) the parental organism regarding pathogenicity;
iv. Capacity for colonization;
v. If the organism is pathogenic for the humans who are immunocompetent

- Diseases caused and mechanisms of pathogenicity including the invasiveness virulence
- Communicability
- Infective dose
- Host range, possibility of alteration
- Possibility of survival outside human
- Presence of vector and means of release
- Biological stability
- Antibiotic-resistance patterns
- Allergenicity.
- Availability of appropriate therapies

INFORMATION RELATING TO RELEASE CONDITIONS AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. Description of the proposed deliberate release, including the purposes and the foreseen products;
2. Foreseen dates for the release and time planning of the experiment including frequency and duration of the release;
3. Preparation of the site previous to release;
4. Size of site;
5. Method(s) used for the release;
6. Quantities of GMO or products of such organisms released
7. Disturbance on the site (type and method of cultivation, mining, irrigation or other activities);
8. Worker protection measures during the release;
9. Treatment of site after release;
10. Techniques foreseen for elimination or inactivation of the GMO or product(s) of such organisms at the end of the experiment;
11. Information on, and results of, the previous GMO or GMO product releases, and especially if at different scales and in different ecosystems;

B. Information relating to the environment

This information relates to as much the site as the extended environment. Note that in the case of genetically modified organisms or product of such organisms intended for human or animal feeding or for industrial purposes, the environments also include the transportation roads, the market places as well as the market baskets.

1. Geographical location and grid reference of the site(s) (in the case of notifications according to the present annex; the site(s) will be the foreseen areas of use of the product)

2. Physical or biological proximity of human groups or important biotopes;

3. Proximity of biotopes or protected areas;

4. Size of the local population;

5. Local population economic activities based on the natural resources found in the region;

6. Distance in relation with the closest protected zones (potable water and environment to preserve);

7. Climatic characteristics of the region(s) risking to be affected;

8. Geographical, geological, educational characteristics;

9. The flora and fauna, notably the cultivations, the livestock and the migrating species;

10. Description of target or non-target ecosystems risking to be affected;

11. Comparison between the natural habitat of the host organism and the proposed site(s) for the release;

12. Any project intended to develop or modify the land use in the region that could influence the environmental impact of the release, if it is known.

INFORMATION RELATING TO THE INTERACTIONS BETWEEN GMO(s) **OR PRODUCTS OF SUCH ORGANISMS AND THE ENVIRONMENT**

A. Characteristics and factors affecting the genetic survival, multiplication, expression and release.

1. Biological characteristics that the survival, the multiplication and the dispersion

2. Known and expected environmental conditions that can affect the survival, the multiplication and the release (wind, soil, temperature, pH, pollutants such as pesticides, heavy metals or others, etc);

B. Interactions with the environment

1. Planned GMO habitat;

2. Behaviour and characteristics studies on GMO or product of such organism and their ecological impacts performed on the simulated natural environments such as the microcosms, breeding rooms, the greenhouse…;

3. Genetic transfer capacity:

a. Transfer of GMO or product of such organisms' genetic material in the organisms of the concerned ecosystems after release;

b. Transfer of indigenous organisms' genetic material into the GMO or product(s) derived such organisms;

4. Selection risks leading to the expression of unforeseen or undesirable traits of GMO or products of such organisms after release;

5. Measures taken to guarantee and to verify the genetic stability. Description of genetic traits that will allow avoiding or limiting the spreading of genetic material. Methods of verifying the stability;

6. Biological dispersion risks, interaction modes with the release agent, notably the inhalation, the ingestion, the contact with surface, holing, etc., should these modes be known or potential;

7. Description of ecosystems where the GMO or products of such organisms would be released.

C. Potential environmental Impact

1. Risks of excessive increase of the population on the environment;

2. Advantages of GMO or product(s) of such organisms in comparison to the host or non modified parental organism(s)

3. Identification and description of target organism;

4. Mechanisms and results anticipated from the interactions between the released GMO or products of such organisms and the target organism;

5. Identification and description of non target organisms that could indirectly be affected;

6. Risks of modification of biological subject or host after release;

7. Known or expected effects on the non target organisms in the environment, impact on the levels of competing, prey, host, symbiote, predator, parasite and pathogenic populations

8. Known or expected implication on the biochemical process;

9. Other possible important interactions with the environment.

INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring Techniques

1. Methods to trace the GMO or products of such organisms and to monitor their effects;

2. Specificity (to identify the GMO or products of such organisms, and distinguish them from the donor, from the host, if possible, from the parental organisms), sensitivity and reliability of monitoring techniques;

3. Techniques for detecting the transfer of given genetic material towards other organisms;

4. Methods of detecting aberrant gene expression.

B. Control of the release

1. Methods and procedures to avoid or minimise the release of GMO or products of such organisms outside the release site or the intended zone of use;

2. Methods and procedures to protect the site from any intrusion from unauthorised people;

3. Methods and procedures to prevent any other organism from entering the site.

C. Waste treatment

1. Type of wastes generated;
2. Expected of amount of wastes;
3. Possible risks;
4. Description of treatment envisaged.

D. Emergency response plan

1. Implementation methods and procedures to keep GMO or products of such organisms in control in case of unplanned release;
2. Decontamination methods in infected zones, for example eradication of GMO or products of such organisms;
3. Destruction means and hygiene measures planned for the installations, the animals and the soils, etc. which have been exposed during or after release;
4. Implementation methods for isolating the zone concerned by the release;
5. Provided plans to protect human health and the environment in case of undesirable effects;

ANNEX II

ADDITIONAL INFORMATION REQUIRED IN CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information must be provided in the notification of placing on the market of products, in addition to that of Annex 1:

1. Name of product and name(s) of GMO that it contains;
2. Name of the manufacturer or distributor and his address, including address in the country;
3. Specificity of the product, exact conditions of use, when appropriate the type of environment and/or the geographic area(s) of countries for which the product is suited;

4. Type of expected use: industry, agriculture, specialised sale, commercial use intended for the general public.

B. The following information must be provided when required/relevant :

1. Measures to be taken in case of unintended release or misuse;
2. Specific instructions or recommendations for storage and handling;
3. Estimated production in and/or imports in the country;
4. Proposed packaging. This must be conceived so as to avoid an unintended release of LMO during the storage or at a later stage;
5. Proposed labelling. This should mention, at least in summary, the information listed in points A1, A2, A3, B1, and B2.

The following information, concerning labelling of the product shall be provided on a label and/or in accompanying documents:

1. The words “This Product contains LMO”, whenever the LMO presence is established;
2. The words “Product might contain LMO”, each time that the LMO presence could not be excluded, but that the LMO presence is not demonstrated;
3. The words “Product may cause (specify the particular reactions, allergies or other secondary effects)”, when it is known that a particular reaction, allergy, or other secondary effect, could might be caused by the product ;
4. Where applicable, to specify or describe the words provided in points C1 or C2, in Annex I the words “This product contains genetic material (nucleic acids) from LMO” or “Thisroduct manufactured with LMO based raw material”

ANNEX III

RISK ASSESSMENT CRITERIA

The user will have to carry out an assessment before the use and the release of living modified organisms or products such organisms relating to the risks to the human and animal health, biological diversity, the environment and the socio-economic well being of the societies concerned. This assessment will have to take into account the following criteria like any other criterion considered to be relevant.

Characteristics of donor and recipient organisms or the parental organisms:

1. Scientific name and taxonomy;
2. Strain, cultivar or another name;
3. Species to which it is related and degree of relatedness;
4. Degree of relationship between the donor and host organisms or between the parental organisms;
5. All the sites where the donor and host or organisms or the parental organisms were collected, if they are known;

6. Information as for the type of reproduction (sexual/asexual) and cycle duration of reproduction or time of regeneration. According to cases, as well as the formation of stages of rest or of survival;
7. History of any previous genetic manipulation, if donor and host or organisms genetically were already modified;
8. Phenotypical and genetic markers of interest;
9. Description of the identification and detection techniques of the organisms and the degree of accuracy of these techniques;
10. Geographical distribution and natural habitats of the organisms, with information on their predators, preys, parasites, competitors, symbions and hosts in natural environment;
11. Climatic characteristics of the habitats of origin;
12. Capacity of the organisms to survive and colonise the environments of a release;
13. Genetic stability of the organisms and factor affecting the stability;
14. Presence of endogenous mobile genetic elements of virus which can affect the genetic stability;
15. Capacity for these organisms to transfer or exchange genes with other organisms, vertically or horizontally;
16. Pathogenic capacity on the human being or the animal, if necessary;
17. In the event of pathogenic, their virulence, infectivity, toxicity and modes of transmissions;
18. Allergicinity and/or known toxicity of the biochemical and metabolic products;
19. Existence of suitable therapies in the event of pathogenicity, allergicinity and toxicity.

Characteristics of the vector(s)

1. Nature and source of the vectors (s);
2. Genetic chart of vector(s), position of inserted genes in the transfer, other sequence of coding or non coding which affects the expression of inserted gene(s) and gene marker (s);
3. Possibilities for the vector(s) to mobilise and to transfer from genes by integration and methods to determine the vector presence;
4. History of any previous genetic manipulation, if donor and host or organisms genetically were already modified;
5. Pathogenic capacity and virulence;
6. 6. Natural subjects and vector hosts;
7. Natural habitat and geographical distribution of the natural and potential hosts;
8. Possible impacts on human or animal health and the environment;
9. Measurements put in place to fight against the contrary effects:
10. Capacity to survive and multiply in the environment, or to form genetic recombining;
11. Genetic stability of vector(s), as well as the hyper mutability.

Characteristics of a living modified organism:

1. Description of the modifications made thanks to genetic technology;
2. Genetic function of the modifications and/or of new insert, especially of any gene marker;
3. Objective of the modification and intended use in terms of need or interest;
4. Methods of modification, and in the case of transgenic organisms, the methods to build the inserts and to introduce it in the host organism;
5. If the inserted gene(s) is/are integrated or extra chromosomal;
6. Numbers and structure of insert(s), for example the number of copies if in tandem or

another type of repetitions;
7. Product(s) of the transferred gene(s), levels of expression and methods of measurement of the expression;
8. Stability of the inserted genes (s) in terms of expression and integration;
9. Biochemical and metabolic differences of the living modified organism compared to the organism not modified;
10. Probability of vertical or horizontal genetic transfer towards other species;
11. Risks which the transferred inserts or genes generate in pathogenic recombining with viruses, plasmids and endogenous bacteria;
12. Non-native, toxic, pathogenic capacities and other adverse effects;
13. Self ecology of the living organism modified compared to the organism not modified;
14. Susceptibility of the living modified organism to the diseases and the plagues compared to the organism not modified;
15. Detailed information on the last uses as well as the results of all the experiments done before the previous releases;

Characteristics of resuscitated organism(s) and gene(s) and fossils DNA sequences:

Resuscitated Organisms

1. Scientific name and taxonomy;
2. Identity of the closest species and its corresponding characteristics to the intended use;
3. Site where it was found;
4. Method of reanimation used;
5. Objective of the introduction of the organism and possible interest;
6. Impacts on human and animal health as well as on the environment;
7. Measures taken to fight against the contrary effects;
8. Genetic stability;
9. Risk of a genetic transfer towards other organisms;
10. The related fossil species or living related;
11. Biological and biochemical differences with the parental living species;
12. Information relating to the previous uses since the reanimation.

DNA Sequences from fossils or resuscitated organisms

1. Scientific name and taxonomy of the reanimated or fossil species;
2. site of origin of fossil;
3. Site of gene of reanimated genome if it is known;
4. Basic sequence of extracted gene;
5. Method of extraction of gene;
6. Function of gene if it is known;

7. Objectives of use and possible interests;
8. The environment in which it lived before fossilisation;
9. Fossil species related to the species from which the gene originates;
10. Living species related to the species from which the gene originates.

Safety considerations for human and animal health

Information on the living modified organism and in case it is genetically conceived, on the donor or host organism as well as the vector before it is made if need be inoffensive or impotent, concerning:

1. Capacity of Colonization;

2. If the living modified organism is pathogenic to man or animal, the following information is required:

   a. Diseases caused and pathogenic mechanisms, especially the character of invasion and virulence as well as the virulence properties;
   b. Transmission;
   c. Infectious dose;
   d. Host subject and possible alterations;
   e. Survival possibilities outside of the human or animal host;
   f. Vectors or other means of transmission;
   g. Biological stability;
   h. Allergenic power;
   i. Existence of appropriate therapies.

Environmental Considerations

Information on the living modified organism and in case it is genetically conceived, on the donor or host organism as well as the vector before it is made if need be inoffensive or impotent, concerning:

1. The factors affecting the survival, the reproduction and the propagation of the living organism in the environment;
2. Detection, identification and control techniques of the living modified organism;
3. Detection of the genetic transmission techniques of a living modified organism towards other organisms;
4. Known and expected habitats of the living modified organism;
5. Description of ecosystems that could be affected by an accidental release of the living modified organism;
6. Possible interactions between the living modified organism and other organisms in the ecosystem that could be affected by an unintentional release;
7. Known and expected effects on the plants and animals like the pathogenicity, the infectivity, the toxicity, the virulence, being a pathogenic vector, the allergenicity and the colonisation;

8. Possible implication in the biochemical process;
9. Decontamination methods of the zone in case of accidental release;
10. Effects on the agricultural practice, as well as possible undesirable effects on the environment.

Socioeconomic Considerations

1. Expected modifications of existing social and economic habits resulting from the introduction of the living modified organism or product from such an organism
2. Eventual threats on the biologic diversity, the traditional cultivations or other products, and in particular, the agricultural varieties and the sustainable agriculture;
3. Risks caused by the eventual substitution of autochthonous technologies and cultivations and traditional products through the modern biotechnology outside the agro climatic zones of origin;
4. Expected social and economic costs because of the loss of the genetic diversity, jobs, commercial opportunities and in general the community subsistence means risking to be affected by the introduction of living modified organisms or products from such organisms;
5. Country or communities threatened by perturbations of social and economic order;
6. Threats weighing on the social, cultural, ethical and religious values of communities because of the use or the release of living modified organisms or products from such organisms.

ANNEX IV

RISK MANAGEMENT DIAGRAM

The user must employ the present risk management outline and procedures, all through the living modified organism or product from such organism experimentation, from its elaboration to its intended use or its commercialisation.

1. Importation of products from living modified organisms for human or animal health (e.g. antibodies, medicines and hormones):

a. Verify that there is little change in food, nutritional or other habits that could modify the expected effects;
b. This observation could be limited in its reach if the products in question have clearly been subjected to an adequate human or animal experimentation, depending on cases, in countries other than that of importation.

2. Importation of living modified microbial organisms intended to human and animal health:
On top of the specified observation in point 1, the experiments must be carried out to assess the viability and the risks of virulence reacquisition or provoking virulence to other micro-organisms in the body or in the environment, because we can not avoid to spill them.

3. The importation of living modified microbial organisms intended for a contained use.

a. The products from living modified organisms will be treated according to the texts in force;
b. The experiments will be performed in laboratory environment totally contained so as to determine: (i) the living modified organism longevity in case of unintentional release in the premises and in the neighbouring environment and (ii) the genetic transfer towards other micro-organisms and their implication on the human and animal health, as well as the environment; and
c. The methods of fighting reverse effects of an unintentional release must be specified.

4. Locally produced products from living modified organisms:

a. An animal experiments must be performed if the product from living modified organism is intended to man;
b. In all the other cases, tests will be performed on the species for which the product from living modified organism is intended.

5. Living modified organisms locally produced and intended to be used as human or animal vaccines:

a. Studies concerning the original molecule, the tissue culture, serologic study and others performed in a totally contained laboratory environment;
b. The animal experiments in totally contained environment;
c. Experiments in totally contained environment allowing to assess the importance of genetic transfer of the introduced vector or other genes through the vector to the living modified organism or any other species in association with the living modified organism to guarantee that the virulence is not acquired by the living modified organism or other micro-organisms;
d. Animal experiments in totally contained environment without any contact with a related species or any other species known to be susceptible to the gene hosting micro-organism that helped in the making of the living modified organisms;
e. Statistically validated experiments in normal living conditions of vaccinated people within the community.

6. Importation of vegetable or microbial living modified organisms intended for the release:

a. The reports relating to releases in regions other that of the importation country will be examined in details by the national biosafety committee which would particularly endeavour to determine whether the applicable rules during the previous release allowed to guarantee the safety;

b. If the mentioned rules in point a) above have not been judged sufficient, the national biosafety committee will decide at what stage of the process, the observation should restart;
c. If it seems that the previous release mechanisms have been rigorous enough, the observation will be done in experimental conditions totally contained environment and preserved from the environment, while respecting the same type of soil, humidity, air temperature, vegetable or animal community, as those found in the intended zone for the release;
d. The observations concerning the health of the living modified organism, the health of the organism in the limited release zone and the biologic diversity and the zone ecology;

e. Trials of nationally approved partial releases will be performed in accordance with emergency procedures which will allow facing the risks of leakage;

7. Importation of animal organism living modified organism intended to release:

a. The reports relating to releases in regions other that of the importation country will be examined in detail by the national biosafety committee which would particularly endeavour to determine whether the applicable rules during the previous release allowed to guarantee the safety;
b. If the mentioned rules in point a) above have not been judged sufficient, the national biosafety committee will decide at what stage of the process, the observation will restart;
c. If it seems that the previous release mechanisms have been rigorous enough, the observation will be done in experimental conditions totally contained environment in the same ambient, climatic, nutritive and environmental conditions to control the physiological functions, the adaptation and genetic transfers;
d. If the observation results meet the requirements, a release trial could be authorised according to emergency procedures which will allow facing risks of leakage.

8. Living vegetable or microbial organisms locally produced for eventual release:

a. Molecular biology experiments in laboratory on the transformation or the reanimation and any other phenomenon will be affected performed in totally contained environment;
b. Experiments on the tissue culture to elaborate the living modified organism, if necessary, will be performed in totally contained environment;
c. Observations aiming at understanding the nature of the living modified organism will be performed in totally contained environment;
d. Experiments on the soil, the micro-organism soil, the vegetable and animal species, in the environmental conditions of the intended release zone will be performed in totally contained environment;
e. Complete observation on the interaction of the living modified organism with the environment (soil with micro-organisms and terrestrial populations) will be performed in closed fields but partially contained environment. At the end of the experiment, the products of the living modified micro-organisms could be used for experimental purposes; otherwise they must be destroyed;
f. The product of living modified organisms must be submitted to the procedure provided for in point 4;
g. The control of the propagation and of behaviour of any living modified released vegetable or micro-organisms will be determined case by case by the national biosafety committee.

9. Living animal organisms locally produced for eventual release

a. Molecular biology experiments in laboratory on the transformation (or the reanimation if possible) and any other phenomenon will be performed in totally contained environment;
b. The incubation of the transformed generative cell or the reanimated animal will be performed in totally contained environment;
c. The breeding and observation the living modified organism will be performed in

totally contained environment;
d. The living modified organism must be observed in totally contained experimental environment which simulate the intended zone for the release in climatic, microbial, and vegetable and animal populations terms. That is especially to observe the condition of the transgenic animal as well as that of its micro-organisms, particularly any genetic transfer.
e. A limited release will be performed in a correctly closed zone and emergency measures will be taken to avoid the leakage;"
f. If the animal is supposed to produce, the rule of the product will be in conformity with the procedure described in point 4;
g. The control of the propagation and of behaviour of any living modified released animal organisms must be followed during at least thirty years.

10. General Obligations

a. All the tests, experiments or observations specified in each of the above cases (1-9) are numbered in a logical sequence and must be approved, in the hierarchical order, by the lowest institutional organs to the highest national organs, that are the institutional biosafety committees, to the national biosafety commissions and the national biosafety committee.
b. The experiments starting at the transformation of the living organisms or the reanimation of fossil organisms performed in laboratory in totally contained environment and continuing in the elaboration of living modified organisms or products of such organisms must be approved by the institutional biosafety committee or the national biosafety committees according to the cases.
c. Any experiment outside the strict isolation conditions of laboratory and initial experiments involving imported living modified organisms or products of such organisms must be approved by the national biosafety committee. The national biosafety committee must give its final approval to the user of living modified organisms or products of such organisms.
d. Once the approval of national biosafety committee is obtained after the procedure of test, experiments, and observations, the living modified organisms in question or the products of this organism can be used as intended. The national biosafety committee must notify its decision in writing to the competent authority.
e. If it is necessary to destroy the living modified organism or the product of such an organism at the end of the test or experiment period, they have to proceed to the complete incineration or any other means of total destruction;
f. The release of living modified organisms or products of such organisms must be controlled in appropriate way and emergency measures let to avoid a leakage or an accident must always be put in place.

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