

REPUBLIC OF MADAGASCAR

Nation – Liberty – Progress

NATIONAL POLICY AND FRAMEWORK ON BIOSAFETY IN MADAGASCAR

Adopted version

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List of abbreviations

ANGAP	National Association for the Management of the Protected Areas
BNC	Biosafety National Committee
BNM	Standard Office of Madagascar
BP	Office of Public Participation
CNRE	Environment National Research Center
CNRIT	Industrial and Technological National Research Center
CTHA	Horticultural Technical Center of Antananarivo
DNA	Desoxyribonucleic Acid
FOFIFA	Foibe Fikarohana Ho an' ny Fampanandrosoana ny Ambanivohitra (National Center of Research Applied to the Rural Development)
GEF	Global Environment Facilities
GMO	Genetically Modified Organism
IA	Impact Assessment
IEC	Information – Education – Communication
IMRA	Malagasy Institute of Applied Research
IMVAVET	Malagasy Institute of Veterinarian Vaccines
IP	Pasteur Institute
LMO	Living Modified Organism
MAE	Ministry of Foreign Affairs
MAEP	Ministry of Agriculture, Livestock and Fishing
MCOS	Official Service of Mixed Control

MEFB	Ministry of Economy, Finances and Budget
MENRS	Ministry of National Education and Scientific Research
MFPC	Ministry of Civil Service
MICDSP	Ministry of Industry, Trade and Development of the Private Sector
MICE	Making Investments Compatible with the Environment
MINENV.E.F	Ministry of Environment, Water and Forests
MPE	Small Livestock Company
MSPF	Ministry of Health and Family Planning
NCA	National Competent Authority
NTIC	New Technologies of Communication and Information
ONE	National Office of Environment
PRSD	Poverty Reduction Strategy Document
SAGE	Support Service to Environment Management
SNGF	National Silo of Forest Grains
SOC	Official Service of Control
UCQDA	Control Unit of the Foodstuffs Quality

Presentation note

This National Bioafety Policy aims at providing a clear vision of the objectives pursued by the Republic of Madagascar as regards prevention of the biotechnological risks. It also presents the procedures of intervention chosen to ensure the effectiveness of the actions to be undertaken in order to achieve these goals.

It includes six chapters: the introduction points out the general context, the stakes and the situation of the step regarding bioafety; chapter 2 presents the fundamental principles of the policy; chapter 3 defines the biosecurity objectives and the strategies; chapter 4 presents the Biosecurity National Structure; then, the document assesses the policy risks of failure and eventually, the final chapter relates to the follow-up of the implementation.

The elaboration of this policy was based on a largely participative approach associating the various government departments and the whole of the actors concerned, including the associations defending the consumers, the representatives of the farmers, the academics and researchers, the private operators, the ecologists, the environmentalists, the cultural communities, the journalists, the NGOs and the private sector. Thus, in order to collect the maximum opinion on the subject and to allow all the categories of people to express themselves, workshops of information, awareness-raising and consultation were arranged at the national level as well as in the main large cities of the country.

Definitions

For the purposes of an exact comprehension of this policy and in accordance with the terminology of the Cartagena Protocol, hereafter some significant definitions.

« Living organism »: any biological entity able to transfer or replicate genetic material, including sterile organisms, viruses and viroïdes.

« Living Modified Organism (LMO) » any living organism having a combination of new genetic material obtained by having resort to modern biotechnology.

« Genetically Modified Organism »¹ (GMO) any (living or inert) organism endowed with artificially created characteristics by applying the genetic engineering in modern biotechnology.

« Genetic engineering »: is handling genes, generally in vitro, which is different from the traditional techniques of crossing or selection

"Modern biotechnology": the implementation of *in vitro* techniques to the nucleic acids, including the recombination of the deoxyribonucleic acid (DNA) and the direct introduction of nucleic acids into the cells or organoids or the cell fusion of organisms which do not belong to a same taxonomic family which surmount the natural barriers of the physiology reproduction or recombination and which are not techniques used for the reproduction and the selection of the traditional type.

¹ In this document, the term GMO implies "genetically modified organism and the by-products"

"Transboundary movement" is taken to mean any movement of a living modified organism coming from a country and bound for another country.

1. - PRESENTATION

11. - General context

Madagascar, aware of the importance of the biological diversity conservation, subscribed to the principles of the Rio Declaration at the Earth Summit in 1992 and signed and ratified the Convention on Biological Diversity. It has thus committed itself to adhere to sustainable modes of production, of consumption, to prevent pollution, to adhere to the ecosystems capacity and to preserve the chance of the future generations. Within this framework, Madagascar also signed the Cartagena Protocol in September 2000 and ratified it in November 2003.

The text of the Cartagena Protocol on the Prevention of the biotechnological risks or Protocol on biosafety was adopted in January 2000. On July 26, 2004, there were 104 countries signing the Protocol. Its objective is « *to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of the living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and the sustainable use of biological diversity, taking also into account the risks to human health, and specifically focusing on transboundary movements* » This instrument is a normative framework from which, the Parties will have to work out legal statuses in order to use and to trade the agricultural produce based on genetically modified organisms (GMO). It is within this framework that it is advisable to locate this initiative of setting-up a National Biosafety Framework (NBF)

The Protocol will have to be implemented in parallel with the agreements on the agricultural produce trade of the World Trade Organization (WTO). The latter was created in 1995, as a substitute of the General Agreement on Tariffs and Trade (GATT). It advocates the national monopolies dismantling and the investments liberalization. The phenomenon of free exchange and of lifting the trade barriers (customs tariff or something else) could make up massive LMO export opportunities of the producer countries to the detriment of the poor and underdeveloped importing countries. That represents a threat for human health and biological diversity in the countries without any political, economic and scientific arguments to refuse the introduction of LMO.

The agriculture, livestock and fishing sectors are the main fields of transgenic organisms production. The genetically modified cultivation is experiencing a considerable growth year by year. Thus in 2003, the overall surface went up to nearly 67.7 million hectares. Two thirds are in the rich countries. The main cultivations concerned are: soya, corn, colza, cotton. The main producer countries are: the USA (63% of the worldwide transgenic culture), Argentina (21%), Canada (6%), Brazil (4% of the world culture of transgenic soya), China (4% of the world transgenic cultivation), South Africa (1%), Australia, India, Romania, Spain, Germany, Bulgaria, the Philippines, Indonesia, Colombia, Honduras and Mexico, and at present some countries of Africa.

This information reveals a considerable rise of the transgenic cultivation in the world and the integration of the LMO on the international market proves to be inevitable. In fact, the situation of the producer countries overproduction, where national consumption is very limited even nil, compels them to search for outlets in the nonproducer countries, generally in situation of malnutrition.

12. - Stakes

The GMO constitute a significant stake, therefore we can sometimes notice a restraint of the political community regarding this issue. Modern biotechnology is used in the various sectors such as the food, energy, chemical industry, environment, in the agricultural sector, in the the medical and pharmaceutical sector.

Food: to improve the production, the nutritional and visual quality, the taste, the composition, the exemption from toxicity...

Chemical industry: to manufacture by-oils from colza, linseed, sunflower, soya; specific chemicals (cosmetic, dyes)...

Medical and pharmaceutical industry: to manufacture vaccines, antibiotics, insulin, vitamins, proteins of medical interest...

Environment: to decrease pollution

Agriculture: to improve cultivations and agricultural practices, animal health and nutrition, productivity and fertility...

As regards Madagascar, some agricultural stakes can be quoted:

- ✓ Improvement of the agricultural performances (production rate, getting new varieties of cultivations fast, access to varied genetic resources)
- ✓ Change of farming methods (reduction of the recourse to the tavy = slash-and-burn farming)
- ✓ Production of modified plants (plants *Bt* reducing the insecticidal treatments)
- ✓ Saving in the use of water for irrigation (heat-resistant plants)
- ✓ Reduction of the post-harvest losses.

However, the gene transfer of an organism to another one is not without any risk for the environment and for human health because that can have unforeseeable and irreversible consequences. The following table shows the various types of risks possibly resulting from the use of the GMO:

Type of Risks	Consequences
Medical	- Risk of allergy - Risk of resistance to antibiotics transfer
Environmental	-Genic pollution - Alteration of the ecological balances by a pressure of abnormally significant selection - Creation of new invading species
Geopolitical	- Increase in the North-South inequalities, countries of the south becoming gradually excluded from the worldwide economic system
Socio-economic & cultural	- Some large groups becoming exclusive suppliers of the planet

For the GMO products to be used advisedly, without any risk and in an appropriate way for a secure sustainable development, it would be necessary to have a biosecurity structure in a position to assess and manage the risks.

13. - National situation

131. - Poverty and fight against poverty

Madagascar has experienced a low economic performance during the last forty years. That resulted in a strong incidence and the utmost poverty. The latest assessment state that the proportion of 80.9% of the Malagasy population live below the poverty threshold. The

state of poverty is more accentuated for the rural populations because more than 86% of them are poor.

The development strategy of the country is mainly based on poverty reduction. In fact, poverty makes up a major blocking factor in the participation of each and every one in the development process. The poverty reduction strategy document (PRSD) provides the policy of the country as regards fight against poverty which aims at reducing by half the poverty rate within ten years. The PRSD is made up of three strategic axes including the promotion of the extended systems of human and material security and social protection. This axis includes the improvement of human health and nutrition, as well as the fight against the chronic diseases (transmissible and nontransmissible).

The actions aiming at improving the population food qualitatively and quantitatively thus remain a national priority. Faced with this need, the LMO could offer an opportunity, a short-term stopgap measure but their unfavorable effects are not controlled yet and some could be irreversible. That can affect human health as well as the whole of the environment.

132. - National environment policy

Madagascar is endowed with an exceptional biodiversity and specific natural ecosystems which represent a worldwide patrimony and which the Malagasy people with the international community support agree to protect while developing them. The National Environment Policy primarily aims at restoring a sustainable and harmonious balance between Man's needs for development and the ecological concern. The implementation of this national environment policy is based on the National Strategy of Biodiversity Sustainable Management. This strategy amongst other things aims at the conservation and the reduction of the pressures on biodiversity.

133. - Current national situation as regards Biosafety

The Biosafety Project

The GEF/2716-02-4492 Project entitled « Development of the national framework of biosafety in Madagascar » was signed on August 15, 2002, was financed by the GEF and a Malagasy counterpart completely done in kind ensured by the ANGAP. Madagascar is one of the 116 beneficiary countries including 31 ones in Africa.

The main objective of this project is to prepare the National Biosafety Framework (NBF) in agreement with the provisions of the Cartagena Protocol and to help the countries to ratify it.

This project lasts 18 months and includes three phases of six months each. Madagascar like all the other beneficiary countries has got an extension of six months to finalize the National Biosafety Framework draft. The different phases of the project are:

Phase 1: preparation of the activities focussing on the inventories of the institutions related to biotechnology, of the legislation in force, of the experts working on biotechnology.

Phase 2: analysis of the information for the preparation of the national framework of biosafety and the participation of the actors concerned through workshops and trainings.

Phase 3: working out the draft of the National Biosafety Framework : legal instruments, public consultation mechanisms, sharing information at the regional and sub-regional levels.

The result of this project will be the draft Biosafety National Framework in Madagascar.

The process of setting up the National Biosafety Framework

Within the framework of the Biosecurity Project, four national workshops have been arranged in Antananarivo since September 2003. The aims of these workshops were to inform, form and consult the Public on the full details of the Cartagena Protocol. Moreover,

workshops with the same objectives have also been held in the main large towns of Madagascar (Fianarantsoa, Majunga, Fort-Dauphin, Tuléar, Toamasina, and Antsirabe). The results of these workshops are taken into account in the proposal for a biosecurity national structure.

Existing instruments

Currently no legislation requires documents providing the details of the importation products characteristics with respect to the existence of LMO, whereas the export products must sometimes be certified non LMO without Madagascar having the authority entitled to deliver such a document.

Nevertheless, the inventory carried out within the framework of the establishment of the National Biosafety Framework highlights the existence of national legal laws related to the introduction and the use of categories of products that could integrate LMO. These laws constitute the bases for setting up a coherent and additional legal mechanism. Were identified:

- The decree MICE n° 99-954 pertaining to making investments compatible with the environment;
- The order n°86-013 relating to the phytosanitary legislation
- The law n° 97-034 pertaining to the codification of the legislative laws concerning the Public health;
- The law n°2001-014 related to animal life;
- The law n°94-038 related to seed legislation;
- The decree n° 69-434 amended by the decree 2004-041 laying down the rules for the import and export of animals, products and food products of animal origin, of seeds, fodder and food products intended for the animal food ;
- The decree n°99-798 on the biological fight agents and biopesticide;
- The decree n°93-844 related to hygiene and the quality of food and animal products;
- The interministerial decree n°3961/93 of August 6, 1993 laying down the procedures of control and determination of the radionuclides concentration rates in the food products ;
- The decree n°7450/92 pertaining to control and sampling procedures of the agro medicinal products; and the interministerial decree n°0467/93 regulating the importation, the manufacture, the marketing and the distribution of the medicinal agro products;
- The law n°2001-020 pertaining to the development of a responsible and sustainable shrimp aquaculture ;
- The order n°2004-0103 of January 27, 2004 pertaining to the creation and the organization of the quality control Unit of food products ;
- The decree n°6854/97 laying down the authority concerned for the medical and qualitative inspection of the food products and products of animal origin and related products.

Some laws are in the process of being adopted. It is the case of the Law on the Consumer Protection within the Ministry of Trade.

The national capacities in terms of biotechnology and LMO

At the scientific level, the genetic engineering field still remains relatively very little explored in Madagascar even if in some laboratories, some genetic engineering is already being carried out. . Consequently, currently the LMO methods of detection and production

remain theoretical knowledge for the Malagasy scientists for lack of specialized laboratories in modern biotechnology.

Nevertheless, in consideration of the capacity building (training, material investment, infrastructure installation and working budget), some current laboratories are able to be engaged in the necessary research relating to the LMO in Madagascar. In addition, the laboratories carrying out the food biological and physicochemical analyses before their release on the market exist. Such analyses could be extended to the detection of the LMO.

Studies carried out

Within the framework of the process of setting up the biosecurity national structure, four studies relating to examinations, analyses and surveys in the statement of facts as regards biotechnology have been carried out. They are about:

- Examination of the use in progress and the developments for a use of biotechnology without any risk and examinations of the legislations in force ;
- Surveys into the national, bilateral and multilateral programs on building structures and capacities, research and development and the biotechnology implementation ;
- Examination of the existing mechanisms for the harmonization of the risk assessment and management, mutual approval, validation of the data;
- Examination of the importance and the impact of the release of GMO and commercial products.

The achieved results have made it possible on the one hand to have basic information and on the other hand to improve the knowledge on biosecurity and biotechnology for a better reflection of the national structure.

2. - Fundamental principles

The fundamental principles governing the National Biosafety Policy primarily draw their sources from the Republic of Madagascar Constitution, the Rio Declaration, the Environment Charter and the Poverty Reduction Strategy Document. They are thus based on the need for Man's reconciliation with his Creator and his fellow men as well as with nature and his environment and also the exceptional importance of the riches and plant, animal and mining resources with a strong specificity which nature has endowed Madagascar with and which is important to preserve for the future generations. Acknowledging to every individual the right to his health protection from his conception is also a central element of these principles.

21. - Precaution principle

According to this principle, the lack of certitudes, taking into account the scientific and technical knowledge of the moment, should not delay the adoption of effective and proportioned measures aiming at preventing a risk of serious and irreversible damage to the environment at an economically acceptable cost.

The precaution strategy is implemented within the framework of this policy in order to protect the environment. Article 10 of the Cartagena Protocol provides the precaution principle. In the case of the LMO, the precaution principle is justified by their potential risks on the environment and the consumers. The precaution diverts the attention from the real risks and attracts it on the supposed risks. The regulations concerning the genetically modified plants and the micro-organisms are incoherent and nonproportional to the risk. A new risk can occur, the nature and extent of which can never have been recognized before. The challenge is to determine the risk and then, in the structure of the analysis process of this risk, to determine exactly which measures must be taken to protect health and the environment,

while guaranteeing a coherence between the measures and the objectivity with which the decisions are made. As the effects can be delayed or immediate, the action will have to rest on the precaution principles.

22. – Polluter pays principle

The polluter pays principle stipulates that the expenditures resulting from the prevention measures of reduction of the attack on environment, and of fight against this need to be borne by the one who was at the origin of the attack. The polluter pays principle, according to the OECD recommendations means that « the polluter must bear the cost of the pollution prevention and control measures which are decided by the authorities so that the environment is in an acceptable state ». The aim is not to punish the polluter but especially to issue the suitable signals in the economic system in order to internalize the environment costs in the decision-making process and thus to lead to respect for environment. The environment charter art 11 provides that the operators carrying out activities causing harmful effects on the environment will have to meet some compensation obligations or penalty payment.

23. - Participation principle

In accordance with the Rio Declaration and the Environment Charter , each citizen must have access to information related to the environment, including those relating to the harmful substances and activities. The public must be involved in the decisions within the framework of effective legislative measures. It has also the ability to take part in decisions. . The polluter pays principle, according to the OECD recommendations means that "the polluter must bear the cost of the pollution prevention and control measures which are decided by the authorities so that the environment is in an acceptable state". The aim is not to punish the polluter but especially to issue the suitable signals in the economic system in order to internalize the environment costs in the decision-making process and thus to lead to respect for environment. The environment charter art 11 provides that the operators carrying out activities causing harmful effects on the environment will have to meet some compensation obligations or penalty payment.

24. - Preventive and corrective action principle

It is a question of eliminating the attacks on environment, by priority at the very source, by using the best techniques available at an economically acceptable cost. An effective means to reach the sustainable development is to anticipate the negative effects of all the actions undertaken on the environment and to take them into account as soon as possible in the phase of any project planning. It is mostly important to anticipate and prevent the causes of the reduction or the noticeable loss of biological diversity at their sources and to address it. The Environment charter of Madagascar indicates in its article 10 that « the projects of public or private investments that are likely to attack the environment must be the subject of an Impact Assessment (I.A), taking into account the technical nature, the scope of the aforesaid projects as well as the sensitivity of the implantation environment. »

25. - Intergenerational equity principle

It is a matter of searching for a harmony between the current generation and those to come. This generation should not commit to activities that are likely to affect the quality of the future generations'life in an irreversible way.

3. - Objectives and strategies

In accordance with the principles of the Rio Declaration, the biosecurity national policy puts the man in the centre of its concerns with respect for the current and future generations. The economic and social development and the poverty eradication are the first priorities of the country and take precedence over all the others. The environment protection is an integral part of the development process, it is governed by the fight against poverty by eliminating the nonviable production and consumption modes. The implementation of the National Biosafety Policy implies the Public participation in the process of decision-making.

31. - Objective of the National Policy

The national biosecurity guidelines and the regulations are intended to protect the individuals, society and the environment by minimizing the potential hazards associated with the new implementation of the genetic material recombination (DNA) and by facilitating the sensible use of biotechnology.

The Biosecurity National Policy thus aims at the following objectives: **to address the issue of GMO in a rational, objective and secure way on the basis of well controlled information , a restricting legal tool, appropriate technical and scientific capacities and according to a process of decision-making implying the public participation.**

32. - Strategic axes

Taking into account the principles stated above and the objective assigned to this policy, by taking account the existing, four strategic axes are defined. They are about:

- Risk assessment and management;
- Mechanisms of decision-making;
- Public participation ;
- Legal regulations.

321. - Risk assessment and management

According to article 15 of the Cartagena Protocol , the risk assessments are undertaken according to scientific methods tested and recognized in accordance with appendix III These risk assessments have to meet the basic structure of minimum information resulting from the risk assessment presented in appendix I of the Protocol and other scientific evidence available making it possible to determine and assess the potential unfavourable effects of the LMO on biological diversity and human health.

Article 16 of the Cartagena Protocol on the risk management also deals with the need for each Party to take appropriate measures to prevent the nonintentional transborder movements of LMO. In this article, it is also a reference to the importance of a sufficient observation of the imported LMO and those produced locally. The risk management imposes the identification of the LMO and their specific treatments according to the cases.

Specific objectives

Considering these general requirements of the Protocol, on the risk assessment and management, Madagascar chooses the following specific objectives in the National Biosafety Policy :

- **to integrate a scientific and technical Committee in the National Biosafety Framework.** The National Biosafety Framework which needs to be set up in a short term requires the integration of a Scientific Committee considering that the steps of risk assessment and management are likely scientific. In addition, it is mandatory to refer to tested and recognized methodologies and to allot a necessary period to the preliminary observations on the possible unfavourable effects on biological diversity and human health.
- **to study the current methodological steps of risk assessment and management in the world (preventive and curative steps) and to adopt methods adapted to the realities and the needs of the country.** The production of LMO, by the methods of modern biotechnology is a common activity in the world nowadays. This fact has at the same time contributed to the finalization of various assessment methodologies for the assessment and the management of biotechnological risk in various countries. The researchers involved in the scientific Committee of the National Biosafety Framework are expected to get to know these methodologies in order to have an assessment of sufficient knowledge to lead research in risk assessment and management on the use of the LMO in Madagascar.
- **to determine a risk threshold for Madagascar.** Each Party is sovereign in the choice of risk threshold to accept or reject the imported LMO or produced locally. Madagascar, on precaution principle, would choose the most secure possible threshold.
- **to conceive differentiated diffusion forms of the investigation results.** If the results of the risk assessments are at the basis of the decision-making process in which various educational levels of the population take part, then it would be essential to make them within everyone's reach in order to facilitate their comprehension and their exploitation.
- **to take part in the activities of the international exchange center as regards Biosafety.** Article 20 of the Cartagena Protocol relates to the exchange of information and the Biosafety Clearing House (BCH). The objective of the BCH is inter alia, to help the Parties in particular the developing countries and those endowed with a significant biological diversity and providing a habitat for it. The general principles of the exchange center are based on the right granted to each Party, on the one hand, to have access to available information and on the other hand, to communicate the national information relating to the biotechnological risk prevention.
- **to create and manage a national data base on the LMO.** The implementation follow-up of the National Biosafety Policy is only possible if it managed in an effective and transparent way taking into account the relevant information. That is the very reason, why it is necessary to have a data base supplied by capitalizing the statements of facts at a given time to begin with (laboratories, researchers, national production, importation...) and then by managing the transfer, the handling and the future transfer of LMO to Madagascar.

Accompanying measures

Reaching the objectives and implementing the activities according to the strategic axis « risk assessment and management » are dependent on the following conditions:

First of all, it would be necessary to set up a programme of capacity building by providing a training on modern biotechnology to the Malagasy researchers and technicians on the one hand and by making investment in laboratory equipments on the other hand. In addition, allocating a budget for the control of the actions should henceforth be registered in the programme of public financing for the implementation of the National Biosafety Policy.

As regards training of human resources, the following priority topics would be considered:

- molecular biology;
- putting in quarantine, cultivation in confined environments or livestock in isolation;
- environmental impact study (before and after the release of GMO);
- negotiation;
- impact study on human and animal health;
- training on the standards (conditioning, labelling, specifications sheet ...);
- development rights and international trade;
- social anthropology and mass communication ;
- strategies of emergency intervention (to foresee possible detections of illicit introduction or the sudden damage resulting from the GMO).

The draft support to the Biosecurity National Policy implementation which will be set up in the short and/or medium term will also have to provide for a material allowance . In this respect , a pre-list of the potentially integrable laboratories in the implementation of the Biosecurity National Policy would be:

- The food frauds laboratory (Ministry of Health) which could ensure the activities of GMO detection and analysis directly intended for consumption through the traceability study ;
- The laboratory of the Institut Pasteur which carries out operations of DNA amplification and multiplication (sent abroad for sequencing), so this is already a stage of GMO genetic study;
- Laboratories of the SOC and the SNGF which specialized in terms of seeds;
- Laboratories at the level of the national research Centers: CNRE, FOFIFA, CNRIT...
- Laboratories in the University Centers: Faculty of Science, Agricultural Science College, Ecole Supérieure Polytechnique...
- Laboratories managed by the Private Sector or NGO, IMRA, CTHA...

Secondly, a certain idea of the scientific and technical expertises results (ecological, socio-economic, legal...) should be ensured to make up a solid basis for decision-making.

Thirdly, the standardization of the procedures of introduction , use, follow-up and control of GMO must be known by all the stakeholders and implemented on all the territory.

322. - Mechanisms of decision-making

Specific objectives

The development of modern biotechnology is a worldwide phenomenon. The use of LMO must be possible in Madagascar. What leads us to aim at the following objectives to base the decision-making process:

- to set up a system allowing to draw the maximum profit and this is done in an optimal and equitable way;
- to minimize the possible risks of the LMO use on human health and on biological diversity;
- to set up an internalization system of the recurring costs for introducing LMO;
- to have the public take part in the process of decision-making.

Accompanying Measures

- Direct participation in the decisions;
- Participation of directly concerned representatives in addition to the committee;
- Individual free choice on the products which are already on the market;
- Broad spreading of information and consultation open to the different structures of the populations.

Decision-making mechanism

- The National Competent Authority (NCA) carries out administrative duties such as the reception of the applications and the notification of the importing party;
- the NCA refers to the National Biosafety Committee (NBC);
- the NBC will call on the service of the Scientific and Technical Committee (STC) and the Committee of Public Consultation (PC);
- The STC carries out studies of risk assessment then gives opinions to the NBC;
- The PC examines the information provided by the applicant and the results of the risk assessment provided by the STC;
- the NBC formulates the decision
- the NBC forwards the decision to the NCA for notification of the applicant (importing party);
- the NCA notifies the importing party.

323. - Public Participation

Specific objective

The objective is to make the country able to address the GMO issues in a rational, objective and secure way, on the basis of well controlled information and participation of an educated public aware of the matter

The public participation has five main objectives :

- the ministries and the decision makers are informed and their awareness is raised on the GMO stakes ;
- a mechanism of information circulation is operational with an active contribution of all the structures at all the levels;
- the GMO issues are integrated in the education system (formal and nonformal systems);
- the decisions taken relating to the GMO correctly reflect the results of the public participation and specific capacity building is carried out as regards GMO

Accompanying measures

- Information on the LMO should be:
 - accessible, comprehensible stating the advantages and disadvantages;
 - controlled (existence of LMO or not) on the introduced products;
 - based on clear criteria of confidentiality.
- Taking into account the short term, medium term and long term as well as the sociocultural specificities and ethics in awareness-raising and education;
- Developing education and Public awareness-raising programmes as regards conservation and the sustainable use of biological diversity.

Methods

The public has the right to know the decisions which can alter their environment or have an influence on their health. Within this framework, it is a matter of setting up the mechanisms which contribute to raise the public's awareness on the environmental problems, which give them the possibility of expressing their concerns and help the public authorities to duly take these issues into account.

The preferred approach will be the participative approach, with mechanisms of feedback information to mobilize the public.

This public will be categorized to better be able to pass updated and appropriate information, specific to each category, through qualified actors.

Education on a longer term will be undertaken according to a progressive approach, in chains, counting on the « spread » effect.

The use of communication supports to inform the public and to collect their opinions is mandatory (audio-visual, mass media, culture and art, Internet...). In addition, a strict system of labelling and/or certifying the products is mandatory so that the user is informed before making his decision and that the customs officers can fulfil their role as a controller. The regulation laws regarding biosecurity should be very widely distributed.

The stakeholders

The effectiveness of the strategic choices would depend on taking into account the interests of the various stakeholders.

The consumers

Because of the increasing poverty of the Malagasy people, a large portion of the population is seeking to have easily accessible food, therefore at a cheap food. However the law of the market fixes the selling price in accordance with the availability. In other words, the least expensive goods are those which are available in large quantity. In the probable case where there are plentiful of LMO or derivatives on the market, the consumers would be inclined to buy them to meet their needs.

However, the consumers have also the right to have safe products that is without any risk and for health and welfare in general. Even if the unfavourable effects of the LMO remain ignored but the consumers are informed about the possibility of contracting an unspecified disease or of coming across other problem in using them, the consumers would tend to avoid them by spirit of precaution.

Thus, it would be essential to prohibit the release of food that are likely or sure to integrate LMO before getting clear information on their harmlessness.

The farmers

The low level of agricultural productivity in Madagascar implies that the peasants seek to have seeds endowed with a resistance to diseases and attacks, with a high output and a suitable nutritional value. Biotechnological research in the world can meet this demand by integrating these various characteristics in the transgenic seeds. It is thus necessary to raise the farmers' awareness on the possible unfavourable effects of the use of these seeds. The distribution of such seeds should thus be preceded by actions of control in addition to what is usually carried out at the phytosanitary level.

The economic operators

The economic operators potentially concerned with the LMO are the industrialists, the tradesmen, the importers and the exporters.

The industrialists are those who seek to produce on a large scale, therefore need raw materials in large quantity and with a high output rate. So they invest to get these materials that could be made up of LMO in the sectors of livestock, agriculture, aquaculture ... (raw materials of provender products, seeds...). If such raw materials are not available locally, the industrialists have inevitably recourse to the imports. Thus, the demands to suppliers of LMO remain possible and the demands must be managed on precaution principles in order to avoid the irreversible harmful effects.

The LMO export could also expand if modern biotechnology develops in the short or the long term in Madagascar. However, part of the production could be consumed by the local market which should then be checked for preliminary risk assesment.

The imported food products of all sizes are plentiful on the tradesmen shelves, in all the towns of Madagascar. It is possible that these goods can be produced from transgenic elements. It is therefore recommended to tighten up the control of these products directly intended for consumption for the sake of concern over protecting the public health.

The ecologists, environmentalists and researchers

The ecologists and the environmentalists' main ambition is to preserve the quality and the inheritance of the ecosystems so that these latter can fulfil their essential role in the (biological, climatic, hydrological, edaphic) regulation. This introduction of LMO into these ecosystems could do harm to this integrity because of the change brought by new components which could affect others. The genetic inheritance would be the most likely to be affected because of the phenomenon of natural reproduction inside a species or among the species. At that point, it would be important to carry out research based on the genetic characterization of the species, the varieties and the local races available in the country in order to detect the genetic changes of a possible introduction. In addition, the Malagasy researchers are expected to invest themselves in modern biotechnology to get the necessary capacities for achieving the scientific tasks to be carried out in the risk assessment and management as regards Biosafety.

The public services and the State

The responsibility for ensuring the population welfare in order to manage to make them take part in the development process of which they are the main beneficiary falls to the State and its dismemberments. Considering the supposed risks of LMO, it is then very significant for the State to act in a spirit of good governance and effective partnership with the other interest groups.

324. - Legal prescriptions

Specific objective

The objective is « to have a legal tool enabling people to manage the LMO release in the territory ». In this respect it is logical to consider the regulation principles related to the LMO import and export in order to promote repressive measures of the fraudulent scheming.

Elements on importation:

- Drawing up laws and regulations by the sectoral Ministries concerned under the coordination of the MINENV.E.F;
- Reference to the specialists and consultation in their centres by the sectoral Ministries concerned on the importation files presented by the importing party;
- Preparation of the list of necessary documents to make up the importation file by the sectoral Ministries concerned;
- Clearance through customs as soon as the above-mentioned formalities are completed in addition to the results of risk assessment and the conditions of use of the LMO imported products;
- setting the products in quarantine
- obligation to mark and label all the LMO products, as well as to produce a certificate of origin and conformity, a document issued by the exporting party and officially visaed by the public department concerned of the country of origin;
- analyses of the samples in a specialized laboratory, in confined environments or direct release according to the case.

Elements on export and re-export:

- Procedure of traceability;
- Methods of controlling LMO products in transit;
- Giving the qualified national authority a sense of responsibility for issuing the non LMO certificate for export;

Accompanying measures

- Drawing up the national law on biosecurity and this is in accordance with the provisions of the Cartagena Protocol which constitute a minimum constraint while taking all the laws related to biosecurity into account;
- Updating or amending the sectoral laws in force to insure the conformity with the national law on biosecurity.

325. – Capacity building

The country has several institutions and human resources which are qualified or potentially qualified as regards biosecurity.

The results of the inventories that have been carried out showed that structures are set up to enable the start of the analyses on the GMO with the help of an allowance of adequate materials and a staff training. The government departments concerned are:

- the Ministry of Trade which houses the Standardization and Quality Management supported by a Microbiology and Chemistry laboratory. The decentralization of this structure is in progress;
- the Ministry of Public Health has a Management of food products quality Control and is supported by a laboratory of physicochemical analysis for food products, of

pathogenic germs detection and of toxicology. The decentralization of this last structure is under study.

- The Ministry of Agriculture, Livestock and Fishing and among others : the Official Department of Seed Control and its laboratory, and the Plant Protection Management ;
- The Ministry of Higher Education and Scientific Research: the various laboratories and university training institutions, the national research centers (FOFIFA, the IMVAVET and CNRE)
- The Ministry of Environment and the attached institutions: ANGAP, ONE, SAGE, SNGF

326. – Cooperation and increasing the existing

Partnership and co-operation make up one of the key points of the national policy as regards Biosecurity. It is obvious that the various phases of the process of decision-making, and follow-up and control of GMO introduction and use impacts require at least a good coordination of the actions and exchanges of information.

Thus, it is not a question of setting up additional structures which would do nothing but weigh the current system down but, through building the institutional as well as the technical capacity, it is relevant to optimize the resources in hand.

4. - National Biosafety Framework

The bases of the National Biosafety Framework would be as follows:

- A regulation system set up to watch over the use of modern biotechnology in complete security ;
- An administrative framework in order to centralize the management of all the documents related to the use of GMO (import, export, re-export, handling...);
- A process of decision-making including the risk assessment and management related to the GMO release;
- Mechanisms of public participation and information ;
- Setting up and effective working of a National Biosafety Committee (NBC).

5. - Limits of the Policy

This outline of the National Biosafety Policy , was drawn up further to the signature and the ratification of the Cartagena Protocol by the Malagasy State and resulting from running dialogue and consultation workshops between the various stakeholders . However it does not meet all the needs related to the GMO. Nevertheless, it should make it possible for the country to adopt adequate measures in order to address the fast development of the GMO production resulting from modern biotechnology in the world.

The interpretation of the comments on this policy could be differentiated according to its readers' interests and its effective implementation would thus run the risk of taking time until one manages to have the various tools and instruments essential to its complete implementation (regulation laws, laboratories of detection ...). Meanwhile, appropriate and

transparent management measures of a transitional stage are mandatory [and this is] according to the aforementioned precaution principles.

6. - Follow-up

A system of adequate follow-up will be set up. This system will be based around the performance indicators impact indicators. This system will watch over the implementation of the National Biodiversity Policy.

61. Follow-up of the performances

Indicators related to the achievements within the framework of the biosecurity national policy implementation will be identified and followed up:

- Setting up the national structure: the structures and the instruments must be effective and functional;
- Facilitating the access to information: the center of exchanges must be operational and visited by a large number of actors;
- Capacity building: getting the required materials and equipment, training Malagasy technicians and scientists on the biotechnological risk assessment, training responsible for the center of exchanges management.

62. Follow-up of the impacts

The follow-up of the impacts should make it possible to follow up the effects of the measures taken on the degree of effective protection of the population and the ecosystems with respect to the risks related to biotechnology

63. – Update of the biosafety policy

Taking into account the uncertainties and extremely fast development of modern biotechnology, the national biosafety policy comes up in an adaptive step based on a periodic review of its contents. The components of the Policy as well as the degree of constraint which is accepted there will have to be the subject of a constant appropriate update in accordance with the development of knowledge as well as the emergence of new national and international problems as well as new innovating implementations of modern biotechnology.

Appendix 1

DRAFT OF NATIONAL BIOSAFETY FRAMEWORK

1. - CONTEXT

The Cartagena Protocol on Biosafety, makes up a normative reference framework on the basis of which the Parties will have to work out their biosecurity systems. It is in this context that it is advisable to locate the efforts made by the Malagasy State with a view to develop the National Biosafety Framework (NBF). The NBF is based on the mechanisms allowing to make decisions related to the transfer, handling and judicious use of the LMO without any risk.

2. - BASIC COMPONENTS OF THE NBF

The bases of the National Biosafety Framework would be as follows:

- A regulation system set up see to watch over the use of modern biotechnology in complete safety;
- An administrative framework whose objective is to centralize the management of all the documents related to the use of GMO (import, export, re-export, handling...);
- A process of decision-making based on the risk assessment and management related to the release of GMO;
- Mechanisms of public participation and information ;
- Setting up and effective working of a National Biosafety Committee (NBC).

These various bases of the NBF should make it possible to implement the National Biosafety Policy. This implementation is however dependent on the existence of a clear and effective institutional framework, on a fluid information circulating among the various entities involved and on a systematic procedure of operation. In addition, the Policy for which NBF requires coherent and realistic legal bases and considering the regulations in force for the various sectors concerned.

3. - INSTITUTIONAL ORGANISM

Considering that Biosafety is applicable to the national scale and that various fields of competences are necessary, the NBF should include a couple of units to harmonize the actions implementating the national Biosafety Policy. The Ministry of Environment is currently carrying out the coordination of the various considerations and setting up as regards Biosafety in Madagascar. However this situation needs to be developed to achieve the complementarity between the various ministerial departments concerned as well as with the private sector, the civil society and the Public.

NBS UNITS	COMPOSITIONS	FUNCTIONS
NATIONAL COMPETENT AUTHORITY (NCA)	<ul style="list-style-type: none"> - Managing Director of Environment - Focal point of the Cartagena Protocol 	<p>Taking on the administrative duties related to the BNS:</p> <ul style="list-style-type: none"> • Implementing the national regulatory procedures and ensuring their conformity with the Cartagena Protocol, • Managing the correspondences with the Cartagena Protocol Secretariat (Focal point), • Carrying out the connection with the Center of exchange • Presiding over the National Biosafety Committee
NATIONAL BIOSAFETY COMMITTEE (NBC)	<ul style="list-style-type: none"> - Interministerial committee made up of the representatives of the respective Ministers (MINENVEF, MAEP, MENRES, MINSAN, MIC, MFB, Ministry of Economy and Planning, Ministry of Communication) - representative of the NAC - representative of the Scientific and Technical Committee - representative of the committee of public participation - representatives of the civil society 	<ul style="list-style-type: none"> - Watching over the implementation of the Biosafety national policy ; - Working out the laws related to biosecurity and carrying out their enforcement; - Ensuring that sectoral laws are made compatible with the national law on Biosafety; - Settling the national and sectoral priorities as regards Biotechnology development ; - Settling and implementing a national programme of training in terms of modern biotechnology and biosafety - Calling on the scientific and technical Committee and the public Biosafety Committee for the applications forwarded by the NCA - Collaborating with the Media for any need of communicating to the Public - Coordinating the activities of the various units of NBF - Formulating the decisions to be taken on the basis of investigation of the Scientific and Technical Committee and the opinions collected by the Committee of public participation and forwarding them to the NCA - Setting up and commissioning a mixed coordination cell which will carry out the follow-up of the GMO release (see composition hereafter)

OFFICIAL DEPARTMENT OF MIXED CONTROL	Persons in charge of inspecting in the decentralized public services (MINENVEF, Scientific Research, MAEP, Army, Trade and Industry...)	<ul style="list-style-type: none"> • Inspecting the inter-institutes sites of observation, the fields of experimentation , the fields of release , the distribution stores and the production laboratories . • Working with the biovigilance Committees to detect anomalies or the unusual phenomena
SCIENTIFIC AND TECHNICAL COMMITTEE	Multidisciplinary researchers and technicians (agronomists, doctors, pharmacists, environmentalists, foresters, economists, sociologists, lawyers...)	<ul style="list-style-type: none"> • Analyzing and exploiting the specification sheets of the imported products (food, seeds with or without GMO) • Taking part in the Biosafety Clearing House to have references on the various GMO • Measuring the risk degree : typological study of the risks and the negative impacts of GMO use (on the environment and on human health) • Studying the advantage/risk ratio to direct the decision-making • Making the argued recommendations on the GMO acceptability or not • Giving the results of the assessments to the NBC • Issuing the certificate according to the results of the analyses in the laboratory and/or the field • Drawing up the list of the measures to be taken according to the risks and proposing a risk management programme <ul style="list-style-type: none"> • Specifying and studying the standards: determination of the requirements compared to the GMO, tolerance threshold

<p>COMMITTEE OF PUBLIC PARTICIPATION FOR THE PREVENTION OF BIOTECHNOLOGICAL RISKS (CP)</p>	<ul style="list-style-type: none"> - ONE and other resources institutions and entities 	<ul style="list-style-type: none"> - facilitating education, awareness-raising and the public participation in the decisions concerning the GMO and modern biotechnology - being used as an interface between the public and the decision makers. - popularizing scientific, technical and legal information, as well as the data of experiments related to the GMO, - collecting the public opinions by ensuring the information feedbacks, - producing a collection and making known the national laws, regulations and guidelines in force contributing in the implementation of the Cartagena protocol , - working with the Center of Exchanges to update the information on the GMO.
<p>MEDIA</p>		<ul style="list-style-type: none"> - Exploiting the IEC approach - disseminating information emanating from the BNC through the media,, audio-scripto-visual aids (Radio, TV, press) and through the exploitation of the NTIC - conveying information in the Malagasy language

4. – NBF PROCESS OF OPERATION

41. - Risk assessment and management

The scientific assessment of the risks related to biotechnology must precede the GMO release in the country and the food chain to reduce to a minimum, even to prevent possible harmful effects on the environment and human health.

The biosecurity is based on the identification, the risk assessment and management which take into account :

- the characteristics of the organisms involved (the living modified organism and the receiving organism) including the new features introduced ;
- the vector used
- the information related to the draft use of these organisms including the management practices which will be implemented;
- characteristics of the probable receiving environment

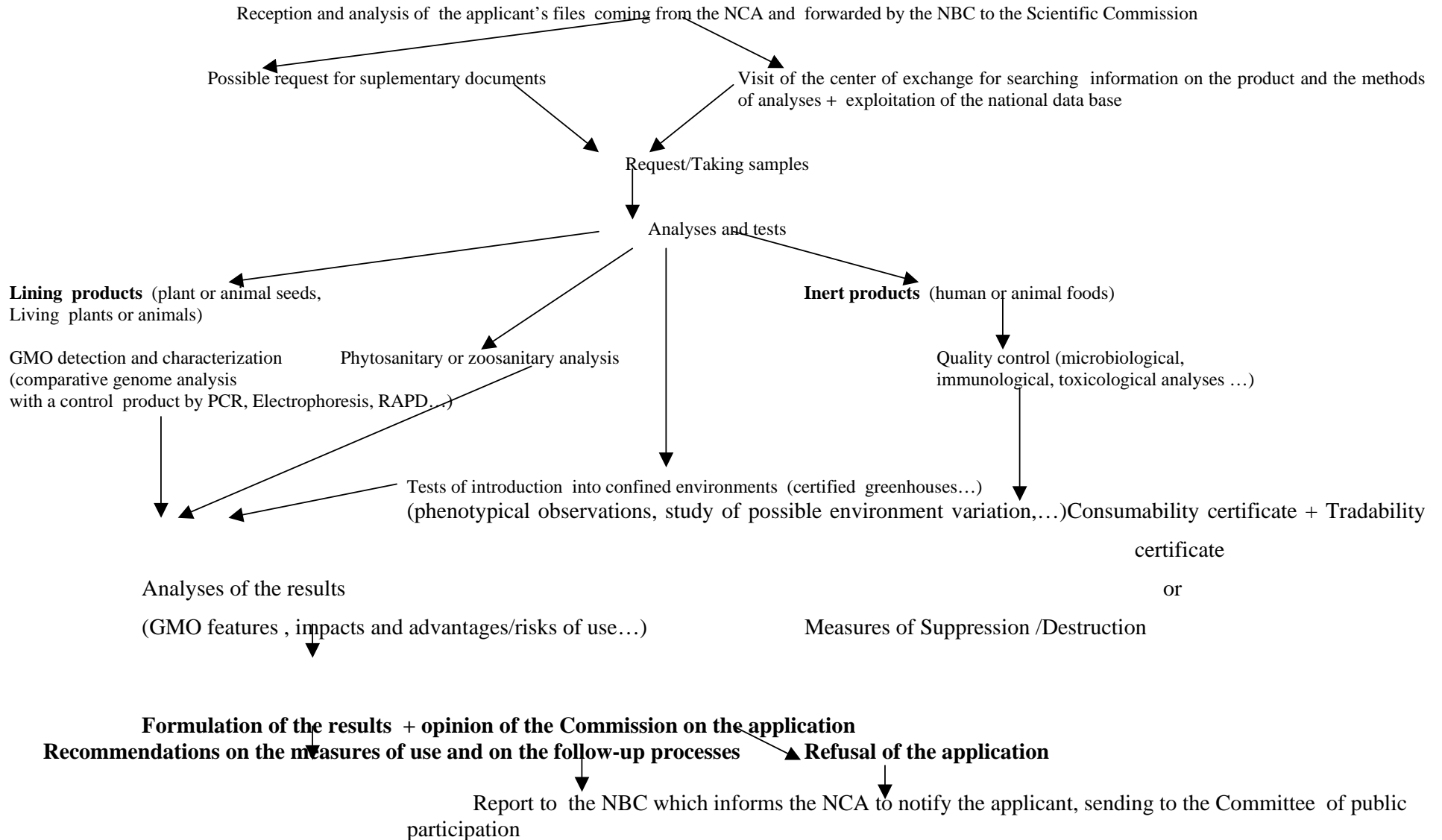
The risk assessment is carried out before the GMO introduction on a purely preventive basis and after the release in order to follow-up the expected effects or the unforeseeable effects of GMO use. It is then a question of anticipating the ways the risks could occur in the environment of introduction or through the use of the GMO: the degree of the damage, the frequency of damage occurrence and the probability of introduced genes transmission. While the risk management takes place only after the GMO introduction, the purpose is to minimize the damage that might be brought about through the use of the GMO by adopting some measures such as the introduction in confined environment , establishing a risk threshold , the prescription of strict procedures of handling and follow-up (of transgenic plants or animals and possible patients after ingestion of GMO products).

The Scientific and Technical Committee plays the main role in **the risk assessment and management after being referred to by the NBC on the basis of a file coming from the NCA.**

The ministerial departments and the attached organisms which would involve their qualified Personnel in the National Biosafety Framework would be as follows:

Ministerial departments	Attached organisms
MINENVEF	SNGF – ONE – SAGE - ANGAP...
MAEP	Tranoben' ny Tantsaha – MPE – CTHA – FIFAMANOR – FIFATA...
MICDSP	BNM – ASSOCIATION OF THE CONSUMERS – THE CHAMBER OF COMMERCE
MSPF	UCQDA
MENRES	National Research Centers, University Laboratories
MAE	
MEFB	SGS
MFPC	

INTERVENTION DIAGRAM OF THE SCIENTIFIC AND TECHNICAL COMMITTEE
FOR THE RISK ASSESSMENT AND MANAGEMENT AS REGARDS BIOSECURITY



42 . Public Participation

The public participation will have to allow:

- expression of the free opinion,
- consensual decision-making,
- mutual confidence between the administration and citizens,
- and giving people a sense of responsibility, transparency, awareness-raising, free choice....

The public must be segmented in taking into account the various sectors and strata of the population in order to be able to identify the participation and procedures of information which respectively correspond to them. Thus must be distinguished and consulted the administration officials, and the elected representatives, the producers (of GMO), the consumers (of GMO), the tradesmen, the researchers and the scientists, the NGOs and the participants involved in communication. In addition, the public is encouraged to observe and give an account of the environmental impacts of any human activity. In return, they must be kept informed of the results of the risk assessment and the decisions related to the introduction, the use and the handling of GMO.

Awareness-raising – Education

- The activities of awareness-raising and education must take into account the short, the medium and the long term. The decision makers and elected representatives who change on a periodical basis will be considered in short and medium term programmes of awareness-raising . Long-term awareness-raising will include the introduction of topics on the GMO into the national education.
- The activities of awareness-raising and education must take into account sociocultural specificities of each area of Madagascar as well as ethics.
- The activities of awareness-raising and education must be adapted to the ages and educational levels of the targeted public.
- To avoid the harmful consequences of the nonintentional GMO movements, mechanisms or measures must be set up with all the actors concerned: the public, the supervising authorities of the transborder movements of plant and animal products ...

Information

- The information of the public as regards the importation of GMO will have to start from the reception of the notification.
- The transparency of the information must be the rule: the advantages and the disadvantages of the GMO product to be introduced must be clearly communicated to the public.
- The vocabularies used in information must be simple and comprehensible to any type of public. The use of scientific and technical terms will be reserved for a public which is particularly interested in it.
- According to the coming in GMO product, the confidentiality criteria must be clearly defined and communicated to the public with argued justifications.
- Any information regarding the GMO products imported by Madagascar or not, as well as the products that are already put on the market must be available at the focal point, the National Biosafety Framework and all the structures directly related to the product in question. These structures, according to their functions (national structure, regional or sectoral

associations...) must facilitate the access to information, first of all to the public with whom they work on a daily basis, then to other types of public.

- The collaboration with the center of exchanges will be requested to get further information on the use of GMO product in the process of being introduced or already put on the Malagasy market in other countries. This collaboration will be managed by the focal point.

- New information regarding an already introduced GMO product is mandatory if new scientific or sociocultural elements would indicate the existence of hazards for biological diversity and human health as regards the use of this product.

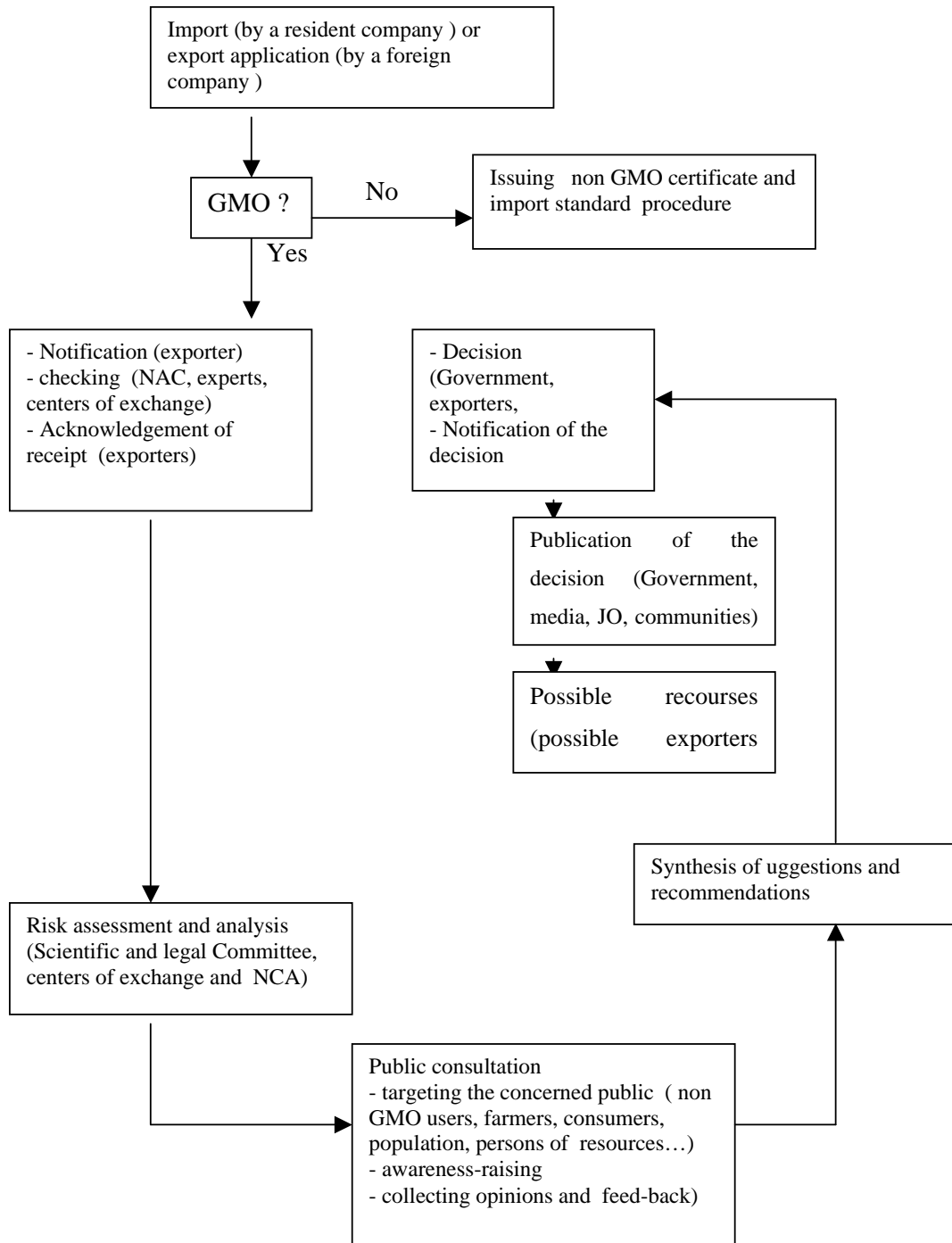
- To ensure a free choice of the consumer and to contribute to facilitate the expression of the public concerning the GMO products, marketing, labelling must be systematic. The labels will relate to the presence of GMO or not, the GMO percentage in the considered product if necessary, and the co-ordinates of the structures to be contacted in case additional information are necessary.

- Any use of GMO on the Malagasy territory must be in conformity with the biosecurity national policy and communicated to the public.

As the ONE has already a structure able to carry out this task through the procedures related to the MICE, its implication should be total. Its role as the leader should even be confirmed.

In short, the information must be controlled, accessible, comprehensible to the whole of the public, including the underprivileged strata , while adhering to the possible confidentiality of some data.

Diagram of the public participation process



4.3 – Decision-making

- **The National Authority Concerned (NAC)** discharges administrative duties such as the reception of the applications and the notification of the importing party;
- The NAC is linked with **the National Biosafety Committee (NBC)**;
- The NBC refers to **the Scientific and Technical Committee** on an individual basis the necessary qualifications for the analyses and/or the necessary follow-ups before and/or after the notification by the NAC of the GMO introduction or production ; after that the results are sent back to the NBC which informs **the Public** concerned and **the media** to collect their opinions.
- Following the public consultation, the NBC formulates the decision and forwards it to the NCA for action to be taken by the applicant.
- For a positive follow-up then authorizing the GMO introduction and release , the NBC refers to **the Official Service of Mixed Control** to carry out follow-up operations, control and inspection.

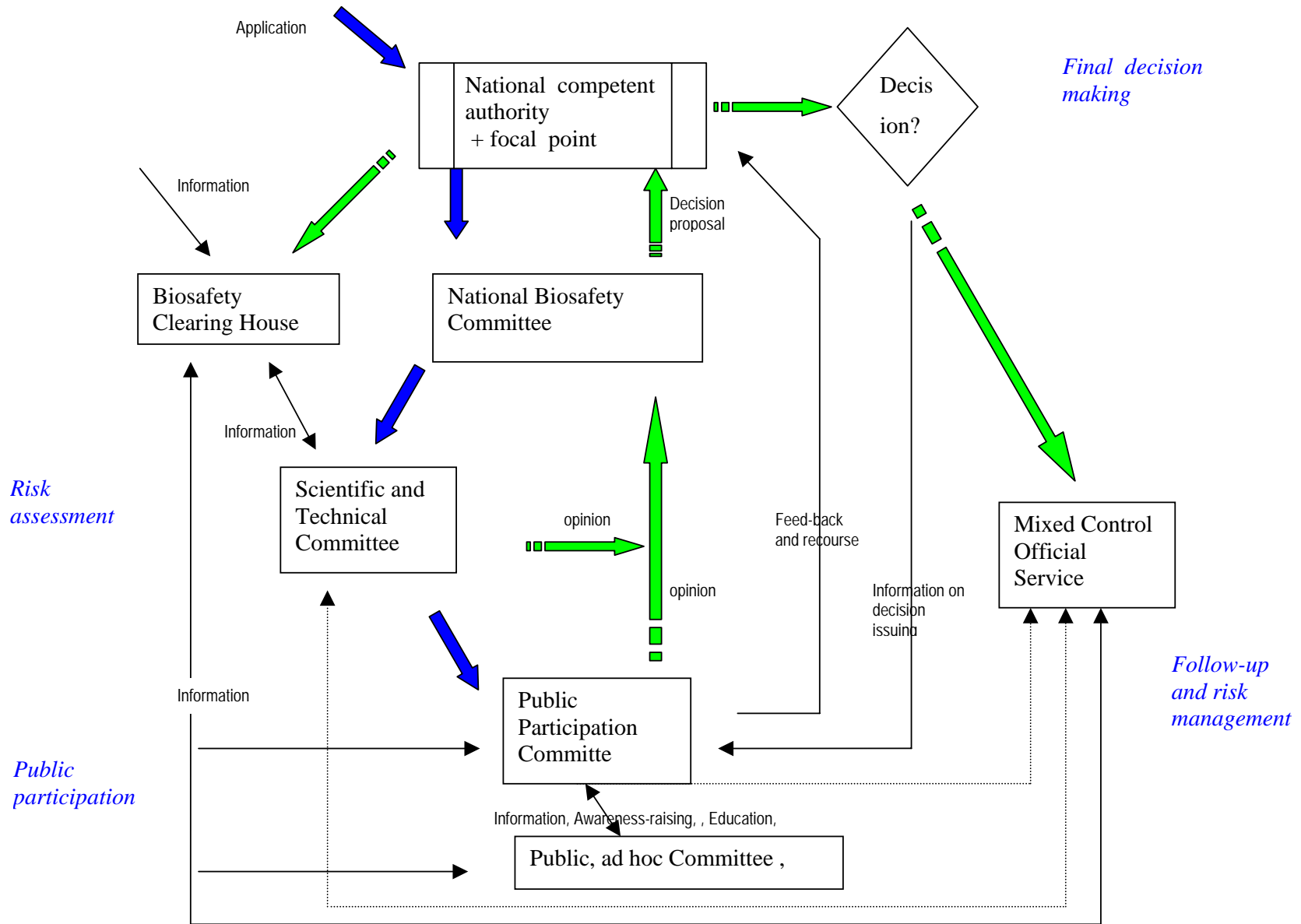
Composition of the BNC:

- representatives of the ministerial departments concerned with Biosecurity;
- scientists and technicians
- representatives of the private sector
- representatives of the public: associations of the consumers, promoters of products.....

Duties of the BNC:

- Ensuring the implementation of the Biosecurity national policy ;
- Guaranteeing adherence to the Biosafety national law;
- Following-up the process of making sectoral laws compatible with the national law on Biosecurity;
- Setting up the national and sectoral priorities in terms of Biotechnology development ;
- Establishing the contact and keeping in touch with other countries and organizations working on the issue of Biosafety.

PROCESS OF DECISION-MAKING



Appendix 2

PRESENTATION NOTE

DRAFT INTERMINISTERIAL ORDER

Dealing with the regulation of import and export, transit, marketing, handling and use of Genetically Modified Organisms (GMO) and/or derivatives .

The Conference of the Parties at the Convention on Biological Diversity adopted on January 29, 2000, an additional Protocol to the Convention, known by the name of Cartagena Protocole on the Prevention of biotechnological risks.

This Protocol is aimed at contributing to ensure an adequate degree of protection for the transfer, handling and use without any danger of modified living organisms resulting from modern Biotechnology which can have unfavourable effects on the conservation and the sustainable use of biological diversity, taking also into account the human health risks, by more precisely putting the emphasis on the transboundary movements.

Madagascar ratified the Cartagena Protocol in November 2003. To this end, in accordance with the provisions of article 2 of the Cartagena Protocol, each signatory State must take a couple of measures including drawing up a legal framework related to modern Biotechnology.

However, considering the complexity related to the slowness of the procedure leading to the adoption of a law on the one hand and the need for taking urgent transitional measures as regards biosafety on the other hand, it proves to be necessary to work out an interministerial decree with a view to manage and to control the risks associated with the use and the release of genetically modified organisms if necessary which are likely to have harmful impacts on the environment, taking also into account the risks for human health.

That is dear Messrs Ministers the purpose of this note of presentation.

The Minister of Environment, Water and Forest Service

Appendix 3

INTERMINISTERIAL DECREE N°

Pertaining to the regulation of import and export, transit, marketing, handling and use of genetically modified Organisms (GMO) and/or derivativ.

The MINISTER OF ENVIRONMENT, WATER AND FOREST SERVICE,
The MINISTER OF AGRICULTURE, LIVESTOCK AND FISHING ,
THE MINISTER OF INDUSTRIALIZATION, TRADE AND DEVELOPMENT OF THE
PRIVATE SECTOR,
THE MINISTER OF HEALTH AND FAMILY PLANNING,
THE MINISTER OF NATIONAL EDUCATION AND SCIENTIFIC RESEARCH

Considering the Constitution,

Considering the law n° 90-033 of December 21, 1990 on the Environment Charter and its amendments

Considering the law n°94-038 of January 3, 1995 relating to the seed legislation;

Considering the law n°95-013 of August 08, 1995 authorizing the ratification of the Convention on Biodiversity;

Considering the law n°2001-014 of September 11, 2001 relating to animal life ;

Considering the law n°2003-015 of April 23, 2003 authorizing the ratification of the Cartagena Protocol ;

Considering the order n°82-029 of November 6, 1982 relating to the National heritage ;

Considering the Order n°86-013 of September 17, 1986 relating to the phytosanitary legislation in Madagascar;

Considering the Decree n°99-798 of October 6, 1999 on the approval of the agents of biological fight and pesticides;

Considering the Decree n°99-954 of December 15, 1999 amended by the Decree n°2004 – 167 of February 03, 2004 relating to the MICE;

Considering the Decree n°2003-007 of January 12 ? 2003 on the appointment of the Prime Minister, Head of the Government;

Considering the Decree n° 2003-008 of January 13, 2003 amended by the Decree n°2004-001 of January 5, 2004 on reshuffling the composition of the members of the Government

DECIDE

General principles

Article one :

This decree is aimed at regulating the transboundary movements, the transit, marketing, the handling and the use of any genetically modified organism (GMO) and derivatives, which could have unfavourable effects on the conservation and the sustainable use of the biodiversity by taking into account the human health risks, the health of the animals and the plants.

Article 2:

Are excluded from the field of implementation of this decree, the genetically modified organisms and derivatives which are pharmaceutical products intended for man and coming under relevant international agreements, except for the agricultural GMO with a double medical function.

Article 3:

for the purpose of this decree one understands by:

Desoxyribonucleic Acid (DNA): molecule carrying the genetic information of the majority of the organisms, and made up of 4 nitrogenized bases and carrier of phosphatic sugar .

Modern biotechnology: the implementation of in vitro techniques to the nucleic acids, including the recombination of the desoxyribonucleic acid and the direct introduction of nucleic acids into cells or organisms.

Marketing: the sale and purchase of products containing genetically modified organisms and/or modified living organisms and derivatives.

Exporter: any natural person or legal entity coming under the jurisdiction of another State who makes provisions so that a genetically modified organism or its derivatives is exported.

Importer: any natural person or entity coming under the jurisdiction of another State which makes provisions so that a genetically modified organism or its derivatives is imported.

Transboundary movements: any movement of a modified living organism and/or modified Living organism or its derivatives coming from another State and bound for another State in accordance with the provisions of the Cartagena Protocol.

Handling: any research, development or operation of the Genetically Modified Organisms and/or derivatives which are carried out in laboratories or greenhouses (confined environment) in which physical barriers, or a combination of physical, chemical and/or biological barriers are used in order to limit the contact of these GMO with the environment.

GMO: any organism which, except for human beings, has a new combination of genetic material obtained by using modern biotechnology;

International Transit: the passage of goods on a State territory without being cleared.

National Transit: the passage of goods on a State territory waiting for clearance .

Use in confined environment : any operation utilizing genetically modified organisms or derivatives controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers and which limit the contact between the aforementioned organisms and the potential receiving environment, including human beings.

Setting in quarantine: Handling and/or culture of plants under specific conditions of insulation, immediately on their arrival, under official and special monitoring, so as to ensure the interception of any harmful organism that is likely to be introduced by these plants.

Precaution principle: the absence of scientific certitude due to the inadequacy of information and relevant scientific knowledge concerning the extent of the potential unfavourable effects of a modified living organism on the conservation and the sustainable use of biological diversity in the importing Party, taking also into account the human health

risks, does not prevent this party from taking a decision concerning the importation of modified living organism as it is appropriate, to avoid or reduce these potential unfavourable effects to a minimum .

Making up authorization request file for exploiting the activity of GMO or derivatives

Article 4:

Any GMO and derivatives movement which is likely to have or having the capacity to cause an environmental damage or an irreversible change in the ecological balance of the biological diversity, or whose dangerous nature for human, animal and plant health is scientifically proven, is prohibited.

Article 5:

Any import, export, transit, marketing, handling and use of GMO, whatever their harmful or non harmful effects require a preliminary authorization of the National Authority Concerned (NAC) and are subject to the strict control and follow-up of the of Mixed Control Official Service (MCOS).

Article 6:

Any natural person or legal entity wishing to be involved in any exploitation of activity relating to the GMO and derivatives must make an application for authorization made up of the following information:

- A registration certificate to the Register of Trade and Companies or a scientific certificate of research if necessary;
- A specification sheet of information,
- A risk assessment report,
- **A sworn statement certifying that the provided information, is exact, signed by the notifier, including, according to the case, a commitment on behalf of the information supplier guaranteeing that this information is exact and complete;**
- A certificate of origin of the GMO and/or derivatives concerned ;
- A clear and sequential description of the stages which will be followed during the implementation of the project, and the follow-up and assessment procedures which will be carried out at the end of each stage, as well as the waste disposal mode ;
- The place and the aim for which the GMO or the derivatives is to be used, preserved, or marketed, as well as the conditions of use and a

- labelling and packing procedure in accordance with the international standards;
- A reference to the information on the GMO which is at the Biosafety Clearing House (BCH);
- A prior agreement with knowledge of the facts.

The specification sheet of the information must report the information certifying the safety of the biotechnological products of the authority concerned of the origin country, the safety measures taken by the importer or the exporter in the event of transit, the mention of a ten (10) days period on the documents accompanying the containers escorted and certified by the Customs Department, and transport in a special primary container for any transgenic plant material.

The risk assessment report for any activity relating to the GMO and derivatives in confined environment or not is aimed at:

- defining the probable risks and the undesirable effects resulting from the GMO and derivatives,
- assessing the risk probability,
- defining the modes of risk management to be managed and the appropriate alternatives by taking into account the measures suggested by the applicant,
- analyzing the cost/profit ratio related to the risks to be managed.

This presentation of the prior agreement given with knowledge of the facts will not exempt the importer or the exporter under any circumstance of all other obligations provided for by the rules of the international trade.

Article 7:

The file thus made up is deposited to the NCA which, within two (2) months. and in accordance with the opinion of the technical department concerned (department of plant protection , department of Forest service, veterinary service) delivers an authorization or rejects the application. The decision of rejection must be justified.

The decision of rejection can be the subject of a recourse to the Administrative Chamber.

However, if a GMO or a GMO derivatives is the subject of a legal prohibition in the country of origin, its importation will not be authorized on any account.

Article 8:

At the time of the file deposit, the applicant is liable to pay a provision of an amount of Ar 1,000,000 to Ar 2,000,000 to cover the different expenditures of studies and/or analysis of samples. The aforementioned sum is paid into the Public Treasury account.

Prior agreement with knowledge of the facts

Article 9:

Any import/export of GMO or derivatives is subject to the prior agreement formality with knowledge of the facts

Article 10:

The importer or the exporter addresses the NAC a written notification of his intention to import or export GMO or derivatives and request prior agreement with full knowledge of the facts.

The request must be accompanied by:

- information relating to the project (objective, location, duration, partners...) and all other useful information,
- information relating to the GMO or by products concerned in accordance with the appendix from the Cartagena Protocol.

The NCA has a 90 days' deadline to take action pursuant to it.

The NAC, prior to its decision-making can request additional relevant information. The decision is communicated to the exporting party within a 270 days' deadline.

However, the fact of not communicating its decision in the 270 days does not mean that the NCA grants the transborder movement and this under the terms of the precaution principle.

Import, export, transit, transport, and marketing of the GMO and/or derivatives

Article 11:

Any introduction of genetically modified organisms (GMO) and/or derivatives on the national territory requires a risk assessment carried out in the country of origin in accordance with the provisions of appendix III of the Cartagena Protocol

Article 12:

Is subject to an environmental impact study any introduction of GMO or derivatives on the national territory before their scattering .

Article 13:

The import, export and transit of GMO and/or derivatives must be subject to a border controls by the NAC in collaboration with the customs

Article 14:

The GMO and/or derivatives in transit on the national territory must be kept and preserved in a good health state, and packed and transported under safety conditions in accordance with the international rules and standards.

Article 15:

The transport of GMO and/or derivatives in transit on the national territory bound for the other countries must be communicated to the NCA at least fifteen (15) days in advance , and to conform to the national requirements in terms of confinement and/or storage of transport.

Article 16:

Any GMO and/or derivatives intended for marketing must be identified by affixing the label of the producer and/or shipper and with the mention "GMO Prducts", and the identification must specifically mention its particular features and characteristics with sufficient details to ensure its traceability, and in order to indicate if it can possibly involve risks or reactions of the allergic types.

In addition, this labelling must comply with the standards defined by the NCA with the collaboration of the other administrations concerned.

Organ of evaluation, control and follow-up

Article 17:

The control and follow-up within the framework of this decree are carried out by a Mixed Control Official Service (MCOS) made up of Phytosanitary Police officers, inspectors of the technical departments of the Ministry of Agriculture, Livestock and Fishing , the Ministry of Health, inspectors of the industrial facilities, inspectors of the Customs and Trade commissioners, officials of the Department of the Environment, Forest Service.

The officials of these departments take the oath to the Court of first instance of their respective workplaces before taking up their duties.

Decision-making

Article 18:

The NCA is the decision-making organ within the framework of the Cartagena Protocol on the Prevention of the biotechnological risks relating to the Convention on biological diversity. The Managing Director of Environment, carries out the coordination of the duties falling to the NCA within the framework of this decree.

Article 19:

The NCA, made up of the representatives of the ministerial departments, institutions, civil society and NGO, is presided by the Minister of Environment who can delegate his power to the Managing Director of Environment.

Information and declaration commitment

Article 20:

Any person who, on some resources belonging to him or exploited by him, or on products or materials which he holds in stock will have noted the presence of GMO and/or derivatives will have to declare it to the local administrative authorities who will in their turn immediately inform the authority concerned by the fastest means of communication.

The technicians of the local public services, any citizen having suspected the quality of the GOM of a product are liable to inform the local administrative authorities immediately.

Article 21:

However, the NCA cannot reveal to third parties any confidential information if the applicant requires the written confidentiality.

But, it can decide that some information, in spite of their confidential nature, must be made available to the public, for reasons of general interest.

Sanctions

Article 22:

Any infringement of the provisions of this decree, besides the confiscation of the GMO and/or derivatives, stated by the MCOS, is prosecuted and repressed in accordance with the provisions of the laws and regulations governing the issue, in particular, the laws relating to the seed legislation, animal life, the ordinance relating to the plant health legislation and their laws of implementation, the legislation on trade and its laws of implementation.

Article 23:

The legal police Officers who have the required jurisdiction for that purpose immediately proceed to the seizure and the confiscation of GMO and/or derivatives for violation of the provisions of this decree.

Various and final provisions

Article 24:

For any import, use in confined environment or marketing of a GMO and/or GMO derivatives which already started before the enforcement of this decree, the promoter must make a statement to the NCA within 90 days from the publication of this decree for regularization purposes.

Article 25:

The Vice Prime Minister, Minister of Transport, the Minister of Environment, of Forest Service, the Minister of Agriculture, Livestock and Fishing, the Minister of Economy, of Finances and Budget, the Minister of Industrialization, Trade and Development of the Private Sector, the Minister of Scientific Research, the Minister of Health, the Minister of Public Security and the Minister of Justice are in charge, each one in what concerns him, of the enforcement of this decree.

Article 26:

This decree will be recorded and published in the Government Publication (Journal Officiel) of the Republic.

DRAFT BILL RELATING TO THE BIOSAFETY SYSTEM

EXPOSE OF THE REASONS

The Conference of the Parties at the Convention on Biological Diversity adopted on January 29, 2000, an additional Protocol to the Convention, known under the name of Cartagena Protocole on the Prevention of the biotechnological risks.

This Protocol aims is “to contribute to ensuring an adequate level of protection in the field of trhe safe transfer, handling and the use of living modified organisms resulting from modern Biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements”.

Madagascar ratified the Protocol of Cartagena in November 2003. The provisions of article 2 of the aforesaid Protocol invite the signatory States to take a couple of biosafety measures including drawing up the legal framework relating to modern Biotechnology.

Thus, this bill aims at implementing the rules and procedures of using, handling without any danger the Genetically Modified Organisms.

This bill also puts the emphasis on :

- ❑ The methods of risk assessment and risk management as regards genetically Modified Organisms,
- ❑ The institutional framework of the management of genetically Modified Organisms,
- ❑ The procedures relating to import, export, transit and marketing of the genetically Modified Organisms,
- ❑ The penal provisions as regards genetically Modified Organisms.

These procedures and requirements are conceived to provide to the Importing/Exporting Parties the necessary information enabling them to make decisions with knowledge of the facts as regards Genetically Modified Organisms.

That is the purpose of this draft bill.

Appendix 5

DRAFT BILL RELATING TO THE THE BIOSAFETY SYSTEM

TITLE ONE GENERAL PROVISIONS

CHAPTER ONE FIELD OF IMPLEMENTATION

Article one:

This law governs the transboundary movements, transit, marketing, handling and use of any genetically modified organism (GMO) and derivatives likely to have adverse effects on human, animal and plant health, and on biodiversity and environment.

Article 2:

Are excluded from the field of implementation of this law, the GMO and derivatives which are pharmaceutical products intended for man and concerning relevant international agreements, except for the agricultural GMO with a double medical function.

CHAPTER II DEFINITIONS

Article 3:

In the meaning of this law and of its implementation laws, one understands by:

Desoxyribonucleic Acid (DNA): molecule carrying the genetic information of the majority of the organisms, and made up of 4 nitrogenized bases and a carrier of phosphatic sugar.

Modern biotechnology: the implementation of in vitro techniques to the nucleic acids, including the recombination of the desoxyribonucleic acid and the direct introduction of nucleic acids into cells or organisms.

Marketing: the sale and purchase of products containing genetically modified organisms or derivatives.

Exporter: any natural person or legal entity coming under the jurisdiction of another State who makes provisions so that a genetically modified organism or its derivatives is exported

Importer: any natural person or legal entity coming under the jurisdiction of another State who makes provisions so that a genetically modified organism or its derivatives is imported.

Transboundary movements: any movement of a modified living organism or its derivatives coming from another State and bound for another State in accordance with the provisions of the Cartagena Protocol .

Handling: any research, development or operation of Genetically Modified or produced Organisms which are carried out in laboratories or greenhouses (confined environments) in which physical barriers, or a combination of physical, chemical and/or biological barriers are used in order to limit the contact of these GMO with the environment.

GMO: any organism which, except for the human beings, has a new combination of genetic material obtained by using modern biotechnology;

International Transit: the passage of goods on the territory of a State without being cleared.

National Transit: the passage of goods on the territory of a State waiting for clearance.

Use of GMO: any operation utilizing GMO and derivatives;

Use in confined environment: any operation utilizing genetically modified organisms or derivatives controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers and which limit the contact between the aforementioned organisms and the potential receiving environment, including the human beings.

Setting in quarantine: Handling and/or cultivation of plants under specific conditions of isolation, immediately on their arrival, under official and special monitoring, so as to ensure the interception of any harmful organism likely to be introduced by these plants.

Notifier: Any natural person or legal entity engaged in the export of GMO or derivatives.

Precaution principle: the absence of scientific certitude due to the inadequacy of information and relevant scientific knowledge concerning the extent of the potential unfavourable effects of a modified living organism on the sustainable conservation and the use of biological diversity in the importing Party, taking also into account the human health risks, does not prevent this party from taking a decision concerning the importation of modified living organism, to avoid or reduce these potential unfavourable effects to a minimum

CHAPTER III

SAFETY MEASURES

Article 4:

Is subject to the environmental impact study any introduction of new animal or plant species and any industrial facility related to the GMO and/or derivatives on the national territory.

This applies to any research relating to GMO and/or derivatives.

Any natural person or legal entity who imports genetically modified seeds and their derivatives must have a licence of importation delivered by the National Council of Seeds (CONASEM).

Any importer of GMO and/or derivatives of plant origin must adhere to the importation requirements in particular the plant health risk assessment.

Any GMO import of animal origin must adhere to the provisions provided for by articles 33 and 34 of the altered law n°91 008 of July 25, 1991 relative to the animal life.

Any activity relating to the GMO and/or derivatives must have the authorization of the National Competent Authority provided for for this purpose.

The National Competent Authority takes measures concerning the awareness increasing of the population relating to handling, the use, the industrial facilities or the movement of the GMO and/or derivatives .

CHAPTER IV

IDENTIFICATION, CLASSIFICATION OF THE LEVELS OF SECURITY AND RESPONSIBILITY

Article 5:

The classification and the identification of the security levels of biotechnological projects can be done at 3 levels

- a) level 1: biotechnology projects recognized as not presenting risk for human, animal and plant health, for biodiversity and environment
- b) level 2: biotechnology projects recognized as presenting slight risks for human, animal and plant health, for biodiversity and environment.
- c) Level 3: biotechnology projects recognized as presenting definite risks for human, animal and plant health , for biodiversity and environment.

Article 6:

The responsibility for any damage caused as a result of the introduction or the activities relating to the GMO and/or derivatives falls to the blamed importer or user .

Any person victim of introduction, use, marketing, research or industrial activities related to GMO and/or derivatives can claim for damagein reparation of his wrong to the court concerned against his authors.

Article 7:

The State can have certain responsibilities because of its decision relating to the GMO and/or derivatives or to non adherence to the regulations provided by this law. At the international level, the Malagasy State can take the various available mechanisms as regards the settlement of trade disputes on issues concerning the agricultural GMO and their derivatives.

Chapter V

CONFIDENTIALITY OF INFORMATION

Article 8:

The public must be informed of all the stages of the course of the GMO and/or derivatives: from the research, to thisation of products for human consumption or industrial activities. Such information is provided to the public on request and the provisions hereafter:

- *The National Competent Authority to which the request is addressed is not in possession of the required information.*
- *The request is obviously abusive or formulated in too general terms.*
- *The request relates to documents concerning the GMO and/or derivatives which are under development.*

Article 9:

The NAC makes the following information public:

- Those relating to any GMO and/or derivatives for which the importation, the confined use, the use in open environment or the marketing has been authorized or refused;
- Any assessment report of the risks concerning the GMO and/or derivatives .

The National Competent Authority cannot reveal to third parties any confidential information if the notifier requests the written confidentiality.

However, the NCA can decide that some information, in spite of their confidential nature, must be made available to the public, for reasons of general interest.

Article 10:

The importer must indicate in his request for GMO and/or derivatives s import the information which is dealt with like confidential trade information in accordance with the legal regulations and provisions in force.

TITLE II

USE OF THE GMO

CHAPTER ONE

USE IN CONFINED ENVIRONMENT

Article 11:

Any research, any handling and use of GMO and/or derivatives in confined environments must be made in accordance with the measures prescribed in articles 12 et 13 hereafter.

Article 12:

In order to ensure the maximum precaution as regards the use of GMO and/or derivatives, containment must be guaranteed by the use of appropriate barriers proposed by the user and approved by the NCA on the assent of conformity from the Scientific and Technical Council (STC)..

Article 13:

The containment measures are periodically revised every two (2) years by the user in order to allow to take into account the new scientific and technical knowledge as regards biosecurity. These revised measures are approved by the NCA on assent of conformity of the Scientific and Technical Council (STC).

Article 14:

The conditions and modes of implementation of this chapter are laid down by decree of the Minister of Environment.

**CHAPTER II
USE IN OPEN ENVIRONMENT**

Article 15:

Any use in open environment must be subject to a request submitted to a very large public consultation.

It must be carried out so as to ensure the security of human, animal and plant health, of biological diversity and of environment.

Article 16:

The NAC can carry out a risk assessment of any GMO development and research project in open environment independently of that achieved by the user or the promoter.

Article 17:

The NCA, in collaboration with the decentralized territorial Communities and the decentralized technical departments concerned watches over an appropriate awareness-increasing of the public dedicated to research, to the use, the scattering and the marketing of GMO and/or derivatives.

Article 18:

The NCA, with the STC support holds a national biosecurity register in which will be recorded all the information related to the use, the scattering and the marketing of any new substance resulting from biotechnology.

Article 19:

The procedures of test, implementation and plantations will be laid down through a decree of the Ministry of Environment and they must be revised on a periodical basis every two years or in a specific way in an emergency.

**CHAPTER III
INDUSTRIAL FACILITIES**

Article 20:

Any industrial facility related to the GMO and/or derivatives must meet the requirements of the industrial facility system defined by the law n° 99- 021 of August 19, 1999 on the policy of management and control of industrial pollution before submitting the request for authorization of operation to the NCA.

All the provisions provided for by this law are also applicable as regards industrial facility related to the GMO and/or derivatives.

**CHAPTER IV
RISK ASSESSMENT**

Article 21

The risk assessment for any activity relating to the GMO and/or derivatives aims at :

- defining the probable risks and the unfavourable effects resulting from the GMO and/or derivatives,
- assessing risk probability,
- defining the modes of risk management to be managed and appropriate alternatives by taking account the measures suggested by the notifier,
- analyzing the cost/profit ratio related to the risks to be managed.

Article 22:

Any activity related to the GMO and/or derivatives must be the subject of a risk assessment. It must take into account the precaution principle and be carried out

according to what is appropriate, in order to guarantee human, animal and plant security , as well as the protection of biological diversity and of the environment.

Article 23:

Any activity relating to the GMO and/or derivatives must be the subject of setting in quarantine according to the case.

Article 24:

Any GMO and/or derivatives which represents risks for human, animal and the plant health, for biological diversity and environment, is destroyed under the conditions laid down by the regulations.

Article 25:

The risk assessment carried out on an individual basis. The nature and the type, as well as the level of the details in terms of necessary information can vary according to the GMO and/or derivatives in question, its final use as well as the environment of potential reception.

Article 26:

Any risk assessment is carried out in accordance with the guidelines, steps and parameters worked out by the STC and approved by the NCA. It can call on the technical aid of an international institution.

It has be based on all information available on the GMO and/or derivatives in question, to be carried out according to tested scientific methods, in transparency and to take into account the risks posed by the receiving organisms or non modified relations in the probable potential receiving environment .

Article 27:

Necessary information for the risk assessmentof must be provided to the NCA and the STC by notifier .

Article 28:

Any movement of GMO and/or derivatives likely to have or having the capacity to cause an environmental pollution or an irreversible change in the ecological balance of the biological diversity, or whose dangerous character for human, animal and plant health is scientifically proven, is prohibited.

Article 29:

The scientific lack of knowledge should not be interpreted as an indicator of seriousness, of risk absence or existence of an acceptable risk.

Article 30:

All the costs and expenditures incurred by this assessment are supported by the notifier.

Article 31:

The conditions and procedures of implementation of this chapter are laid down through regulation channel.

**CHAPTER V
RISK MANAGEMENT**

Article 32:

The applicant is liable to suggest measures of risk management proportional to the actual or virtual risks inherent to any use of GMO and/or derivatives. These measures must be taken into account in the Environmental Impact Study.

Article 33:

In order to make sure of the stability in the environment of the genomes and the characteristics, the MCOS, in collaboration with the STC and the risk assessment specialists, is in charge of watching over that any GMO and/or derivatives, imported or of the local production, is submitted to a period of observation proportional to its life cycle or its reproduction period, according to the case before its passage to the intended use.

Article 34:

The waste management, gas emissions and other toxic emissions resulting from research, handling, industrialization and marketing of the GMO and/or derivatives must adhere to the provisions provided for by the legislations in force.

Waste and contaminated effluents containing viable GMO must be inactivated through means determined by the national legislation and allowed by the ratified international conventions before their destruction.

All the costs and expenditures incurred by the measures prescribed in this chapter are supported by the applicant in full.

The conditions and procedures of implementation of this chapter are laid down through regulation channel.

**TITLE III
INSTITUTIONAL FRAMEWORK OF GMO MANAGEMENT**

CHAPTER ONE ORGANS OF GMO MANAGEMENT

Article 35:

The management of the GMO and/or derivatives is carried out by:

- the National Competent Authority (NCA),
- The Scientific and Technical Committee (STC),
- The National Biosecurity Committee (NBC)
- The Mixed Coordination Official Service (MCOS),
- The Biosafety Clearing House (BCH),

Article 36:

The NCA is the decision-making organ within the framework of this law. It is at the same time the management organ and National Correspondent within the framework of the Cartagena Protocol related to the Secretariat of the Convention on biological diversity.

Article 37:

The NCA, made up of the representatives of the ministerial departments, civil institutions, civil society NGOs, is presided by the Minister of Environment who can delegate his power to the Managing Director of Environment.

Article 38:

The STC, composed of researchers and scientific and technical experts as regards biosecurity, lawyers, socio-economists, the CTE of MICE Decree, is consulted for any activity relating to the GMO and derived . It is also entrusted with:

- assessing the risks,
- supervising the risk management and
- expressing scientific and technical opinions before any decision-making
- providing information to be integrated in the CEBM.

Article 39:

The NBC is made up of the representatives of the ministerial departments, the NCA representative of the, the STC representative, the Committee of public participation representative, the representatives of the civil society.

The NBC is in charge of :

- watching over the implementation of the national Biosafety policy,
- drawing up the laws relating to Biosafety and ensuring their enforcement,
- ensuring to make sectoral laws compatible with the national law relating to Biosafety,
- establishing the national and sectoral priorities as regards development of Biotechnology,

- establishing and implementing a national programme of training as regards modern biotechnology and biosafety,
- calling upon the scientific and technical Committee and the public Committee of Biosafety on the requests forwarded by the NCA,
- collaborating with the media for any necessity to communicate to the public,
- coordinating the activities of the various units of the National Biosafety Framework,
- formulating the decisions to be taken on the basis of investigation of the Scientific and Technical Committee and the opinions collected by the public participation Committee and transmitting them to the NCA,
- establishing and commissioning a mixed coordination cell which will ensure the monitoring of the GMO release.

Article 40:

The MCOS, a mixed organ of inspection and control, is made up of, the Phytosanitary Police officers , Technical Departments inspectors of the Ministry of Agriculture, Livestock and Fishing, the Health Ministry, the inspectors of the industrial facilities, the inspectors of the Customs and Trade commissioners, officials of the Ministry of Environment and of the Forestry Service.

Article 41:

The CEBM, a tool at the disposal of the national management structures, is in charge of managing all scientific, technical, ecological and legal information, as well as the data of experiment relating to the GMO and/or derivatives .

Article 42:

The organization and the operation of the structures listed in the preceding articles are laid down through regulation channel.

**CHAPTER II
INSPECTION AND CONTROL**

Article 43:

The inspection and the control of the activities relating to the GMO and/or derivatives are carried out by the MCOS.

The civils servant appointed to the MCOS take an oath to the Court of First Instance of the localities where they are respectively in service before taking up their duties .

Article 44:

The MCOS carries out its duties under the control and the responsibility of the NCA. It reports to the latter by means of a report with each noted case. It is entitled to get its share of the fine defined in articles 71,72, 73 hereafter

TITLE IV

EDUCATION AND PUBLIC AWARENESS-RAISING

Article 45:

The NCA, in collaboration with the decentralized territorial communities and the decentralized technical departments concerned, must promote and facilitate the public awareness-raising, education and participation in terms of security in the use of the GMO and/or derivatives related to the conservation and the sustainable management of biological diversity, while taking into account the risks on human, animal and plant health, on biodiversity and environment.

Article 46:

Any natural person or legal entity implied in modern biotechnology has to raise the public awareness and educate it on the risks and advantages that the aforementioned organisms entail, and this, at all the stages planned for the project implementation.

Article 47:

From the reception of the importation implementation mentioned in article 10, the NAC must publish the relevant information and inform the ministries concerned.

To this end, an Environmental Impact Assessment (EIA) before any exploitation of activity related to the GMO and/or derivatives on the national territorial, allowing a significant reaction on behalf of the public, must be carried out in accordance with the provisions of the altered Decree n°99-954 of December 15, 1999 relating to Making Investments Compatible with Environment (MICE).

The EIA will be carried out at the expense and under the responsibility of the applicant.

Article 48:

The environmental licence constitutes only one mandatory precondition to any exploitation of activity related to the GMO and/or derivatives on the national territory.

TITLE V

STRATEGIES OF EMERGENCY INTERVENTION

Article 49:

In the event of accident, the user must inform the NCA and the local administrative authorities by all the fastest means within the forty eight (48) hours at latest, by providing the following information:

- The circumstances of the accident;
- The identity and the quantity of GMO and/or released derivatives;
- Any information allowing to evaluate the effects of the accident on the health of the whole of the population and on the environment;
- Emergency measures taken or having to be taken.

Informing the NCA does not release the user at all from any engagement which falls on him, in compliance with the common law rules or the duty to report to the likely affected people.

Article 50:

From the reception of the information mentioned in the preceding article, the NCA has:

- to make sure that all the suitable measures were taken to neutralize the risks for human, animal and plant health, for biological diversity and environment,
- to inform the governmental authorities and decentralized communities to be likely affected , as well as the CEBM.

Article 51:

Strategies of intervention and detailed emergency plans drawn up in accordance with the article 29 are implemented by those who are implied in handling, industrializing and marketing the GMO and/or derivatives under the MCOS control in order to effectively manage the emergency resulting from their intentional or accidental release.

Article 52:

In the event of disaster or of imminent danger resulting from voluntary or accidental release of the GMO and/or derivatives thus representing a threat to human, animal or plant security, to biodiversity or environment, the NCA informs the authorities in charge of disaster management as well as the administrations concerned and gives advice on the appropriate emergency strategies of intervention.

In such cases, the NCA must immediately suspend any exploitation of activity related to the GMO and/or derivatives . Its final decision must come up within four (4) months after reception of the results of the survey.

Article 53:

The people to be likely affected by an accident must be informed of it by the NCA, in particular on the security measures and the behavior to be adopted.

Article 54:

The victims of the accidents can take legal proceedings to make up for the wrong against their authors or against the State if this latter made a mistake.

**TITLE VI
IMPORT, EXPORT, TRANSIT, TRANSPORT, AND MARKETING OF THE GMO**

**CHAPTER I
NOTIFICATION OF PRIOR AGREEMENT**

Article 55:

The user is liable to notify the NCA in writing his intention of proceeding to import or export GMO and/or derivatives before undertaking any exploitation of activity.

The list of mandatory information that should appear in the written notification is laid down by regulation. The user is juridically held responsible for the correctness of the information provided.

If a GMO and/or a derivative were the subject of a legal prohibition in the country of origin, its export could not be authorized under no circumstances.

Article 56:

The exporter/importer sends to the NCA a written notification of his intention of exporting/importing GMO and/or derivatives and requests a prior agreement with knowledge of the facts. The NCA has a 90 days' deadline to take action pursuant of it.

However, the fact of not answering within the time allowed does not mean that it agrees to the transborder movement.

Article 57:

The NCA, before its decision-making can request additional relevant information. In such a case, the decision must be communicated to the exporting party within a period of 270 days.

However, the fact of not communicating its decision within the 270 days does not mean that it grants the transborder movement.

Article 58:

The presentation of prior agreement given with full knowledge of the facts will not exempt the exporter under no circumstances of all other duties provided for by international trade rules.

CHAPTER II
PROCEDURE

Article 59:

Any implementation for introducing GMO and/or derivatives on the national territory requires a risk assessment carried out in the country of origin.

Article 60:

Any natural person or legal entity who wishes to be engaged in importing , using or marketing GMO and/or derivatives must send a written implementation to the NCA with the following information:

- A registration certificate to the Register of Trade and Companies or a certificate of scientific research if necessary;
- The information specification sheet provided for in article 61 hereafter;
- The risk assessment report aforementioned in article 21 ;
- A sworn statement attesting the correctness of the information provided, signed by the notifier, including, according to the case, a commitment on behalf of this information supplier guaranteeing that this information is correct and complete;
- A certificate of origin;
- The STC recommendations if the implementation for authorization is intended for research or for scientific purpose;
- A clear and sequential description of the stages which will be followed during the project implementation, and the procedures of follow-up and assessment which will be carried out at the end of each stage, as well as the mode of waste disposal;
- the place and the aim for which the GMO and/or the derivatives must be developed, used, preserved, scattered or marketed, as well as the conditions of use and procedure of labelling and packing in accordance with the international standards;
- the reference to the information on the organization which is with the CEBM;
- A prior agreement with knowledge of the facts.

Article 61:

The GMO import, export and transit and/or derivatives must be submitted to a joint control done by the MCOS and the Customs at the borders.

Article 62:

The transport, the transit on the national territory, the import and export, the marketing of GMO and/or derivatives, must be the subject of an information specification sheet containing the information hereafter:

- Delivery of information attesting the safety of the biotechnological products by the authority concerned in the country of origin,

- Taking security measures by the importer or the exporter,

- In the event of transit, the mention of a ten (10) days period transit on the documents accompanying the containers escorted and certified by the Customs,

- Requires transport in a special primary container for any plant transgenetic material.

- Requires appropriate security measures in conformity with the international standards for the animal transgenetic transport .

Article 63:

The GMO and/or derivatives in transit on the national territory must be kept and preserved in a good health state, and packed and transported under security conditions in accordance with the national legislation and the international standards.

Article 64:

The transport of GMO and/or derivatives in transit on the national territory bound for the other countries must be communicated to the NCA fifteen (15) days in advance, and be in compliance with the national requirements in terms of confinement and transport.

Article 65:

Any GMO and/or derivatives intended for marketing and consumption must be identified by affixing the label by the producer and/or the shipper and being marked "GMO products", and the identification must specifically mention its traits and particular characteristics sufficiently in details to ensure its traceability, and in order to indicate if it can possibly involve risks or reactions of the allergic types.

This labelling must also comply with other additional standards defined by the NCA with the collaboration of the other administrations concerned.

TITLE VII PENAL PROVISIONS

Article 66:

Represent infringements of this law and its implementation regulation :

- The non-observance of one of the conditions, restrictions or guidelines provided for by this law,
- the refusal to provide information or any explanation to an inspector or to a controller in the discharge of his duties,
- the fact of providing false information or misrepresentations,
- the fact of pretending in all deceitfulness to be an inspector or a sworn controller,
- any infringement of the security measures,
- any use of GMO and/or hazardous derivatives .

CHAPTER ONE OBSERVATION OF THE INFRINGEMENTS

Article 67:

Without prejudice to the prerogatives acknowledged to the legal Police Officers provided for by the article 126 of the Code of penal procedure, the Inspectors and sworn Controllers of the administration in charge of biosecurity or other administrations concerned, are entrusted with assessing the infringements of this law, gathering the evidence to searching for the authors of these infringements

The Inspectors and Controllers of the MCOS take an oath in solemn court of the Court of First Instance in accordance with the provisions of article 132 of the Code of penal procedure at the request of the National Authority Concerned.

The oath does not have to be renewed in case these officials' posting places are changed.

Article 68:

In the discharge of their duties, in particular prior to any interrogation or examination of witness(es), or any visit of places or search, the sworn officials are liable to make their qualities known and, if they are requested, to show their badges or professional identity cards.

Article 69:

Any noted infringement must be the subject of regular official report according to the model laid down by decree of the Minister of Environment. The rules of common law notwithstanding, the official reports regularly drawn up by two agents are deemed authentic until challenge.

Article 70:

During the survey and in the process of drawing up the official reports, the senior officials are liable to observe, with the sentence of invalidity of the act, all the prescriptions of the article 53 of the Code of penal procedure in particular as regards respect for the defence right.

Article 71:

The National Competent Authority immediately notifies the copy of the official reports to the contravener who has a 20 days' time limit to be able to come to terms. In the absence of transaction, the National Competent Authority passes on the original of the official reports to the Public Prosecutor within the competence of the place of the infringement Commission or the arrest of the authors to institute the proceedings in accordance with the provisions of the rules of the common law.

**CHAPTER II
PENALTIES**

Article 72:

Is punished with a six-month to a two-year term of imprisonment and with a fine of Ar 1,000,000 at least or one of these two fines only, any person found guilty of the security measures infringement provided for in articles 4 subparagraphs 1, 11, 12, 13 of this law.

Article 73:

Is punished with a two to five-year term of imprisonment and with a fine of Ar 5,000,000 at least or only one of these two fines, any person who contravenes the measures of approval, authorization, notification and intervention urgently provided for in articles 4 subparagraphs 3, 48, 54 aforementioned.

Article 74:

Is punished with a five to ten-year term imprisonment and with a fine of Ar 10,000,000 at least or one of these two fines only, any person guilty of using GMO and/or hazardous derivatives.

Article 75:

In the event of repeat offense, the culprit incurs the double of the maximum provided fines, and the penalty of imprisonment is always delivered.

Article 76:

He who will have brought about a disease to others or personal disability due to the effect of imported, marketed GMO and/or derivatives in infringement of the provisions of this law and considering that the relations between cause and effect have been duly established, is punished with a five to ten year-term of imprisonment and of a fine of Ar 20,000,000 at least.

If these GMO and/or derivatives cause the death of one or several people and that if the relations between and effect have been duly established, the culprit is punished with a penalty for poisoning provided for by article 302 of the Penal code.

CHAPTER III TRANSACTION

Article 77:

All the infringements of this law as well as and its laws of implementation can be the subject of transaction prior to any legal procedure, except for the case of articles 74 and 75 aforementioned.

The transaction results in suspending the continuation of the infringements.

Article 78:

The National Competent Authority has full powers to come to terms. In order to do this, the author of the infringement must be duly referred to it through a request.

The contravener has a 20 day-term from the notification of the copy of the official reports. Once this period is over or in the absence of payment of the amount of the transaction within a time allowed by the decree of implementation, he has taken no notice of the transaction and the original of the official reports is transmitted to the Public Prosecutor concerned in accordance with the provisions of the Code of penal procedure.

The amount of the transaction is settled together with the National Competent Authority.. However, it cannot be lower than the minimum amount of the penal fine.

Article 79:

The overall product of the agreed transactions, or the final pecuniary sentences pronounced by the court, after deduction of the possible expenditures and taxes of any kind, is distributed according to the conditions provided for by the decree of implementation.

CHAPTER IV SEARCHES AND SEIZURES

Article 80:

The officials entitled to the observation of infringements provided for by this law and its texts of implementation can require with first requisition, for control, all the due documents. While complying with the provisions of the article 67 aforementioned and those of articles 135, 210, 211 and 212 of the Code of penal procedure, during their

rounds of control, they can freely get into the storerooms and salesrooms sale and, into the confined environments, into any place of industrial use and facility, proceed to the search and seizure of imported, exported, handled, scattered or marketed the GMO and/or derivatives in infringement of one of the provisions of this law.

The seized purposes are destroyed in the forms and under the conditions provided for by regulation channel.

TITLE IX VARIOUS AND FINAL PROVISIONS

Article 81:

The receipts coming from the taxes, the expenditures on the application for authorization, expenditures on seized GMO and/or derivatives seizure are allocated and shared out according to the procedures laid down through the regulatory channel.

Article 82:

The authorizations or scientific research licenses, movement or marketing of the GMO and/or derivatives which are valid and in the process of use, and also in order with regard to the protection of human and animal health, the conservation of the biodiversity and environmental protection, remain in force until their expiry.

However, their promoters are liable to declare their existence to the National Competent Authority and to comply with the prescriptions of this law within 3 months from the date of its enforcement. The non-observance of this obligation involves the implementation of the provisions of article 71 aforementioned to the contravenent.

Article 83:

The renewal of the authorizations is carried out in accordance with the provisions of this law and its texts of implementation.

Article 84:

All contrary provisions former to those of this law are and remain repealed.

Article 85:

This law will be published in the Official Publication (Journal Officiel) of the Republic of Madagascar. It will be enforced as a State law .