MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEFSEC PROJECT ID:
COUNTRY: Mauritius
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of Mauritius
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES):
DURATION: 48 months
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: September 2005
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	427,800
PDF A*	
Sub-Total GEF	
CO-FINANCING**	
GEF Agency	
Government	207,900
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	
Total Project Financing:	635,700
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

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Letter of endorsement enclosed, dated 8/01/2003

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

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List of Acronyms

AIA	Advance Informed Agreement
AREU	Agricultural Research and Extension Unit
ASARECA	Agricultural research in East and central Africa
BCH	Biosafety Clearing House
BIOEARN	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy
CBD	Convention on Biological Diversity
CP	Cartagena Protocol
COP	Conference of the Parties
FARC	Food and Agricultural Research Council
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
LMO	Living Modified Organism
MOP	Meeting of the Parties to the Protocol
MSIRI	Mauritius Sugar Industry Research Institute
NBF	National Biosafety Framework
NCA	National Competent Authority
NCB	National Committee for Biosafety
NCC	National Coordinating Committee
NEA	National Executing Agency
NPC	National Project Coordinator
UNDP	United Nations Development Programme
WB	World Bank
SARB	Southern Africa Program on Biotechnology
SADC	Southern African Development Community

A. PROJECT SUMMARY

1. In the last decade, Mauritius has been involved in new biotechnologies and today, various institutions devoted to agricultural research as well as human and animal health have a Research and Development (R & D) programme in biotechnology. The research activities in biotechnology include projects in plant tissue culture, molecular diagnostics, genetic transformation and molecular mapping for breeding purposes. Government and private institutions intend to use biotechnology to solve problems in agriculture, food industry and the environment, and the creation of a Mauritius Agricultural Biotechnology Institute is going ahead. However, biosafety did not receive the same attention and is still lagging behind national biotechnology developments.

2. The preparation of a regulatory regime on biosafety started in 1997. In 1999, with the assistance of UNEP/GEF pilot project, Mauritius prepared its "National Biosafety Guidelines for the Safe Development and Introduction of Genetically Modified Organisms" (annex A). The guidelines outlined the administrative and institutional procedures necessary for the safe application of genetic modification.

   The guidelines recommend practices based on the precautionary approach to ensure the safe application of GMOs for different uses (contained conditions, field trials, import, exports, transport, etc) so as to protect the country from any adverse effect to human and animal health or the environment. The scope of the guidelines includes all use, development and release of GMOs.

3. Following this, the Ministry of Agriculture, Food, Technology and Natural Resources approved the Non-Sugar Sector Strategic Plan (Annex B). This is a five–year plan for the years 2003-2007 aimed at promoting the transition from traditional practices to a technology-based approach to agriculture. The focus of this plan is self-sufficiency, meeting product quality exigencies, developing the local agro-processing industry, promoting entrepreneurship, optimising export opportunities, conforming to international norms governing food safety and maximising on the potential benefits of regionalisation. The need for this reorientation process in agriculture has become essential at this juncture in Mauritius as 1) Government is actively promoting the adoption of new technology in all economic sectors and 2) the inherent constraints such as high vulnerability to climatic changes, depleting arable land in favour of more remunerative economic activities, and high cost of labour and agricultural inputs have posed severe impediments to agricultural development. Furthermore, the increasing internal and external challenges, with mounting competition at the market front, increasing food demand, higher customer exigencies, more stringent regulations governing food issues and trade in agriculture and enhanced pressure to attain a certain level of food security on the global scene, have altogether called for a review of the whole agricultural sector in Mauritius.

4. The Non-Sugar Sector Strategic Plan includes -among its main objectives- " the strengthening of administrative, infrastructural and legislative frameworks to achieve the targeted objective of a 'modern agriculture' whilst ensuring biosafety". The plan has therefore entailed the final approval of the specific legislation for biosafety and allowed Mauritius, Party as of April 2002, to meet the requirements of the Cartagena Protocol. The GMO Bill (Annex A) was passed and voted at the National Assembly on the 16 March 2004.

5. In this context, the project aims at strengthening capacity for the implementation of the Mauritius Biosafety Framework in relation to the Cartagena Protocol on biosafety. It is imperative that necessary human resources are trained in biosafety issues so as to allow them

to take appropriate and timely decisions regarding the transboundary movement of Genetically Modified Organisms (GMOs) and regulate all GMOs related activities in the island, ensuring adequate precautionary measures.

The Overall Goal of the project is that by 2009 Mauritius has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations.

The immediate objectives:

- To assist Mauritius to have a fully functional and responsive regulatory regime in line with CP, national needs and other international obligations**.**
- To assist Mauritius to have a functional national system for handling request, including risk assessment, decision-making and administrative processing;
- To assist Mauritius to have a functional national system for "follow-up" activities , especially monitoring of environmental effects and enforcement.
- To assist Mauritius to have a functional national system for public awareness, participation, education, and access to information

Project Outcomes

A. Mauritius has a fully functional and responsive regulatory regime in line with CP, national needs and other international obligations

- The implementing regulations and procedures are developed, adopted and in effect

B. Mauritius has a functional national system for handling request, performing risk assessment and management, decision-making, performing administrative tasks, handling, storing and exchanging information in line with the BCH requirements

- The technical guidelines and operational manuals for handling of application are produced and in use
- Personnel are educated and trained on handling of request, packaging and labelling

C. Mauritius has a functional national system for monitoring of environmental effects and inspections

- The methods and procedures for monitoring for environmental effects and inspections are set and in use
- The technical means and capacity for monitoring and inspections is in place and in use

D. Mauritius has a functional national system for public awareness and participation

- Increased Public awareness and education on biosafety

Indicators for outcomes**:** please refer to the attached log frame (Annex H)

12. Budget (in USD) :

GEF :	427,800
Co-financing *(in kind)* :	207,900
Total (USD) :	635,700

Information on Project proposer:

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The Ministry of Agriculture has been designated as the National Competent Authority for Biosafety and the Biosafety Clearing House to carry out administrative functions under the Cartagena Protocol. It has a defined Research and Development programme in all aspects of agriculture including biotechnology and is in the process of setting up a Mauritius Agricultural Biotechnology Institute which will bear a regional dimension. The Ministry of Agriculture has a keen interest in promoting Biosafety in the country.

B - COUNTRY OWNERSHIP

B1. Country eligibility

Mauritius was the first country in the world to ratify the CBD in 1992 and acceded the Cartagena Protocol on Biosafety on 11 April 2002.

B2. Country Driveness

In 1985, the Government of Mauritius published a White Paper for a National Conservation Strategy in which it defined the major objectives for the conservation of its natural resources, namely:

(i) To maintain and promote essential ecological processes and life support systems
(ii) To preserve the genetic diversity of cultivated plants and domesticated animals
(iii) To ensure the sustainable utilisation of species and ecosystems

In 1991, the government published a white paper for the Environment Policy that gave a commitment to attain sustainable development that would safeguard welfare, conservation, ecosystem preservation and environment

The government of Mauritius is signatory to a number of International Conventions that address the need to conserve biodiversity . These include.

1. Convention on Fishing and Conservation of Living resources of the High Seas- 1958
2. African Convention for the Protection of Nature and Natural Resources- 1968
3. Convention on Wetlands of International Importance Especially as Waterfowl Habitat (RAMSAR)-1971
4. Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES)- 1973
5. The Stockholm Convention on Persistent Organic Pollutants-2000.

The Government of Mauritius has ratified in April 2002 the Cartagena Protocol on Biosafety as called for under Article 19 of the CBD.

Mauritius has drafted its National Biodiversity Strategy and Action plan in June 2001, a project in

fulfilment of the government's obligations to the Conference of the Parties to the Convention on Biological Diversity.

In 1999 with the assistance of UNEP/GEF Mauritius prepared its National Biosafety Guidelines for the Safe Development and Introduction of Genetically Modified Organisms. Following this the Ministry of Agriculture, Food Technology and Natural Resources has requested the preparation of a National Genetically Modified Organisms Law (GMO Law).

The GMO Bill was read and approved in the National Assembly on 16 March 2004.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area. It is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private sector stakeholders."

It is therefore most relevant to the implementation of GEF Operational Programs (OPs) 1-4 and 13

C2. Project Design

C2.a Background and context

1. In 1997, responding to the third Conference of the Parties to the Convention which called for GEF to provide the necessary financial resources to developing countries for **Capacity Building in Biosafety**, the GEF Council approved a US$ 2.7 million Pilot Biosafety Enabling Activity Project.

   The Pilot Project involved 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia and Malawi) and consisted of the following two components:

   A *National Level Component* aimed at assisting the eighteen countries to prepare National Biosafety Frameworks (US$ 1.9 million), and

   A *Global Level Component* aimed at facilitating the exchange of experience at regional level through the organisation of regional workshops (2 workshops in each of four regions) which involved a very large number of countries (US$ 0.8 million).

   In order to design a **National Biosafety Framework**, each country that participated in the National Level Component was required to:

   - Assess the existing national capacity and roles in environmental release of LMOs and their products;
   - Develop the methods, techniques, standards, guidelines, indicators for assessing and monitoring the risks, and control and regulatory measures for those risks posed by LMOs;
   - Facilitate national capacity building needs for biosafety management;
   - Promote the establishment of institutional arrangements and operational mechanisms for biosafety management;
   - Develop human resources for biosafety management through a series of training programs;
   - Undertake activities at the national and local levels to increase the understanding of potential benefits and risks of biotechnology application among the public and decision makers;
   - Enhance international co-operation and communication in biosafety.

2. The Cartagena Protocol on Biosafety was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity in Montreal, Canada, on 29 January 2000. It was opened for signature in Nairobi, on 24 May 2000 and as of 1 November 2004, 110 countries have already ratified or acceded to the Protocol. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements of LMOs".

3. In November 2000 the GEF Council approved the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety" (GEF/C.16/4). The main objectives of the strategy are to a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and sub-regional level, and c) promote collaboration with other organizations to assist capacity-building for the Protocol.

4. In December 2001, the GEF Council approved 12 demonstration projects to support countries in the implementation of their national biosafety frameworks. Two projects (Malaysia and Mexico) are implemented by UNDP, eight projects are being implemented by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and World Bank is implementing two projects (India and Colombia).

5. Mauritius is a Party to the Cartagena Protocol on Biosafety, which entered into force on September 11, 2003, on the 90th day after the date of deposit of the fiftieth instrument of ratification or accession.

6. Parties at the seventh Conference of the Parties to the Convention, serving as the first Meeting of the Parties to the Cartagena Protocol (COP7/MOP1), which was held in Kuala Lumpur, (Malaysia) in February 2004 focused on setting up an operational framework for the effective implementation of the Protocol. They approved Decision VII/20 on Further Guidance to the financial mechanism. The decision invites the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.

   The COP/MOP decision specifically calls upon the GEF to "provide additional support for the development and/or strengthening of existing national and regional centres for training; regulatory institutions; risk assessment and risk management; infrastructure for LMO detection, testing, identification and long-term monitoring; legal advice; decision-making; handling of socio-economic considerations; awareness-raising and technology transfer for biosafety." This project fulfils these criteria.

7. Further endorsement of the above is reflected in the decision on *Agenda Item 9, at* the Joint Summary of the Chairs of the GEF Council, held from 19-21 May 2004, which states "*The Council welcomes the guidance of the Conference of the Parties to the CBD inviting the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.*"

C2.B Current situation (in the country with respect to the NBF)

The Government of Mauritius has ratified in April 2002 the Cartagena Protocol on Biosafety as called for under Article 19 of the CBD.

Biosafety Policy

The policy of the Government of Mauritius as spelt out in the Non Sugar Sector Strategic Plan 2003-2007 (Annex B, executive summary) is to promote Biotechnology through the setting up of the Mauritius Agricultural Biotechnology Institute.

The policy ensures that the uptake of biotechnology is fostered within a sound environment and that all dealings with GMOs are efficiently regulated with adequate biosafety precautionary measures (policy document available on the following website http://agriculture.gov.mu/nsssplan.htm). This has entailed the development of appropriate legislation for biosafety. In this context, the Government of Mauritius has recently passed and voted the GMO Bill at the National Assembly as mentioned below under regulatory regime.

Regulatory Regime for Biosafety

In 1999, Mauritius prepared its 'National Biosafety Guidelines for the safe development and introduction of Genetically Modified Organisms' (Annex A) with the assistance of UNEP/GEF. The guidelines provide a common framework recommending practices and procedures for the safe application of genetic modification in Mauritius.
A GMO Act (Annex C) was approved on the 16th March and promulgated on the 15th of April 2004.The GMO Act provides measures for:

- Ensuring responsible development, production, use, importation and exportation, marketing and application of GMOs

- Ensuring that all importation, production and release of GMOs are carried out in such a way as to limit possible harmful consequences to human and animal health and to the environment
- Preventing accidents regarding use of GMOs
- Evaluating and reducing potential risks associated with GMOs
- Laying down necessary requirements and criteria for risk assessments
- Establishing a National Biosafety Committee
- Ensuring that GMOs do not present a hazard to human health and to the environment
- Establishing appropriate procedures for the application of specific activities involving use of GMOs
- Providing means to inform the public on GMOs

The GMO Law establishes a National Biosafety Committee to advise the Minister of Agriculture on :

- All aspects concerning the importation, exportation, transit, development, research, production, use, application, marketing, sale and release of genetically modified organisms; or
- Any other matter concerning genetically modified organisms that may be referred to it.

The National Biosafety Committee is composed as follows:

- A Chairperson, with expertise in biotechnology and related fields, appointed by the Minister of Agriculture;
- A representative of the Ministry of Agriculture;
- A representative of the Ministry responsible for environment;
- A representative of the Ministry responsible for health;
- A representative of the Ministry responsible for international trade;
- A representative of the Mauritius Sugar Industry research institute;
- A representative of the University of Mauritius;
- A representative of the Food and Agricultural Council;
- A representative of the Mauritius Research Council;
- A law officer designated by the Attorney General;
- A representative of the consumer associations, appointed by the Minister of Agriculture.

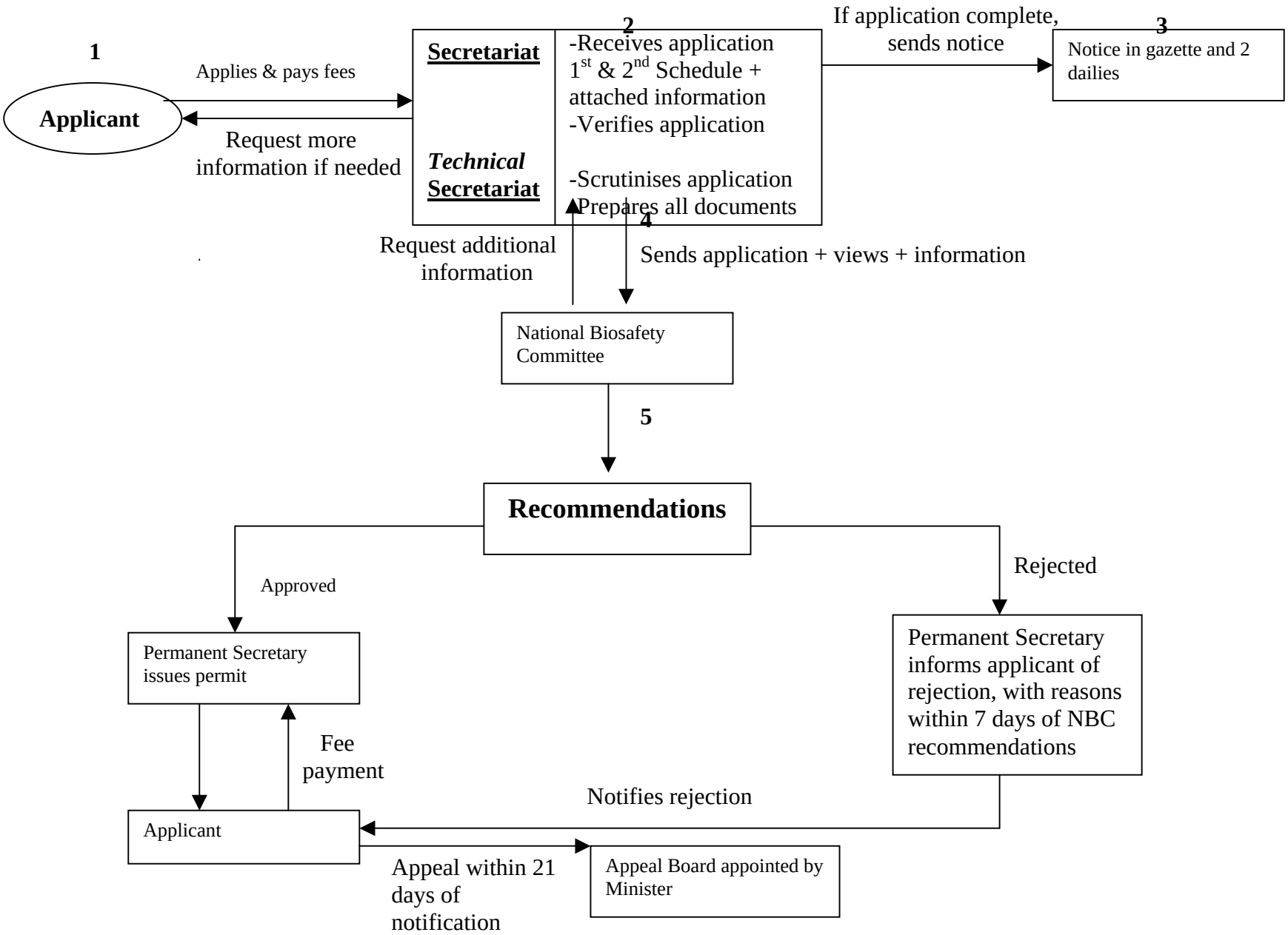
Regulations as per art.24 of the GMO Act have yet to be established.

System for handling requests for permits

A technical committee has been set up and is presently working on the procedures involved in the processing of application for GMO permit in Mauritius.

Based on article 7 of the GMO Law, an application shall be made in the form set out in the First Schedule (Annex C.1) and on payment of a prescribed application fee. The application shall submit a risk assessment report and contingency plan in the form set out in the Second Schedule (Annex C.2).
A draft flowchart of the steps for handling the application for a GMO permit is shown below.

Processing of application for GMO Permit



Systems for "follow-up" activities (monitoring and enforcement)

Art. 19 of the GMOs Act establishes the monitoring powers. However, procedures and indicators for monitoring as well as for enforcement have yet to be established. The Mauritius Agricultural Biotechnology Institute (MABI) will be in charge of testing the GMO and GMOs products.

Public Awareness and Participation

Public participation in decision-making on planned release proposals is recognised as significant issue. Applicants are required to draft a press release concerning any application for a permit to undertake field trials, clinical trials, placing on the market or general release with GMOs. Applicants should indicate the area, time period of release or district where release will occur.

After the submission of an application for GMO permit, the GMO Act requires that a notice on the application be published in the Government gazette and two daily newspapers.

In addition, the GMO Act establishes that a representative of the consumer associations be a permanent of the National Biosafety Committee.

C.2c Status of other ongoing biosafety efforts in the region

In Southern and Eastern Africa, a sub-regional biosafety program dates back to 1991, when the two sub-regions initiated a biosafety programme housed in Zimbabwe. This initiative helped to create awareness on biosafety in the region.

Several initiatives have been launched at both regional and sub-regional levels to enhance activities in biosafety: The Southern Africa Program on Biotechnology (SARB) program aims to create awareness and provide training on biotechnology and biosafety issues in the SADC (Southern African Development Community) countries. The Association to strengthen Agricultural Research in East and Central Africa (ASARECA) has initiated a program to develop and harmonise biosafety regulations at the regional level. The East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) founded in 1998, has been focussing on capacity building in biotechnology policy development also at sub-regional level.

C2.d Rationale

Mauritius is presently planning to set up a Mauritius Agricultural Biotechnology Institute. This means that further research in biotechnology will be carried out in the country. Work on genetic transformation is already in place in the sugar sector, and transgenic sugar cane with herbicide resistance has been already produced. Application of genetic engineering will be extended to the non-sugar sector with the coming into operation of the Mauritius Agricultural Biotechnology Institute. Therefore, the need to fully implement the National Biosafety framework is extremely urgent.

Training is therefore a crucial part of the project. Human resource capacity has been identified as a major constraint to the progress in biosafety in Mauritius. In order to set up the various mechanisms as required by the Cartagena Protocol on Biosafety, it is imperative that capacity building is acquired in various aspects at different levels for the smooth implementation of the requirements of the protocol. It is also important that members belonging to different institutions and background be trained so that expertise and knowledge are broadened in the Mauritian Community

GEF funding is therefore needed to enable such developments and link up with other countries in the region.

The present project will build on the experiences, achievements and lessons learned from the current demonstration projects on implementation. This project will be among the first ones to test the replicability of some aspects of the current demonstration projects. It will yield further experience and best practices which can be incorporated into future similar projects in other parts of the world.

The present project will complement the BCH project, which aims to meet the needs of countries for access and management of information from the Biosafety Clearing House. The MoU of the BCH project for Mauritius is currently under negotiation. Under the BCH project, which will be run in parallel, a website will be established to facilitate the rapid exchange of information between stakeholders and to provide regular updates on significant developments in biosafety. The BCH project will also assist the country in:

a. Purchasing and setting up of the equipment required for the national BCH;
b. National-level training workshop(s) on the use, maintenance and access of the national BCH, and fulfilment of national obligations in relation to the Cartagena Protocol on Biosafety;
c. Access to regional advisers to assist in the design and development of the national participation in the BCH. The regional advisers could assist in several ways:
    - Assist in making the country's choice for national participation in the BCH;
    - Conducting training workshop(s) with national counterparts to train up to 20 participants in the use and access of the BCH;
    - Assist in setting-up and making the national BCH components operational.

a. Implementation of Protocol

The GEF intervention is crucial for the implementation of the National Biosafety Framework (NBF) in Mauritius. The pilot project carried out in 1999 for the development of the NBF in Mauritius created awareness amongst scientists, stakeholders, politicians, NGOs and the public on biosafety with regard to the development and application of biotechnology in Mauritius and elsewhere and has assisted with the drafting of the Framework.

However, the formulation of an appropriate national law on biosafety, finally approved by the National Assembly in March 2004, has been strongly delayed due to poor human resource capacity available in the country.

A GEF intervention would therefore complement these baseline activities and will ensure that key capacities needed for implementation of the GMO Act and in line with the Cartagena Protocol are addressed and further strengthened.

b. Economic, Environmental and Development Viewpoint

The Government of Mauritius is promoting a transition from the traditional practices, towards a more sophisticated, technology-based approach to agriculture with focus on attaining a certain degree of self-sufficiency, meeting quality exigencies, developing the local agro-processing industry, promoting entrepreneurship, optimising export opportunities, conforming to international norms governing food safety and maximising on the potential benefits of regionalisation. In doing so, it is pushing towards the development of agricultural biotechnology and a feasibility study has already been completed on the setting up of a Mauritius Agricultural Biotechnology Institute to promote research and application of Biotechnology with a view to giving a technological boost to agriculture in Mauritius.

In light of the difficulties being encountered within the sugar sector, the Mauritian non-sugar sector will be called upon to assume an even more important role in the agricultural economy.

The recently enacted Genetically Modified Organisms (GMO) Act and amendments to the Plants Act are the two major legislative measures that would have significant impact in the implementation of the plan. The GMO Act ensures that the uptake of biotechnology is fostered within a sound environment

and that all dealings with GMOs are efficiently regulated with adequate biosafety precautionary measures, in line with the Cartagena Protocol.

GEF assistance at this stage is considered crucial, as it would be:

- Timely, as it would be run in parallel to the already mentioned reorientation strategy;
- Appropriate, as it would help in speeding up the implementation of the legislative framework and empowering institutions to efficiently carrying out their tasks

Without GEF support, this positive trend would be hampered by inadequate expertise, limited financial resources and regional/international cooperation.

C2.E Expected project outcomes, with underlying assumptions and context

A key issue in Mauritius is the strengthening and the development of human resources in biosafety issues and the setting up of appropriate facilities to implement the Cartagena Protocol on Biosafety. Therefore, the expected outcomes of this project can be summarised as follows:

Component A	Mauritius has a fully functional and responsive regulatory regime in line with CP and national needs
Outputs	*Implementing regulations needed to make the GMO Law fully operational drafted and submitted to concerned Ministries; 35 policy makers, lawyers, Senior Government Officers, scientists, National Biosafety Committee members, University of Mauritius staff trained on the implementation of GMO Law and the Cartagena Protocol*
Component B	Mauritius has a functional national system for handling request, performing risk assessment, decision-making, performing administrative tasks, handling, storing and exchanging information in line with the BCH requirements
Outputs	*Technical guidelines on handling of requests, transport, labelling of GMOs are finalised; 35 persons from the Ministry of Agriculture, Food Technology and Natural Resources, Ministry of Environment, Ministry of Health and Quality of Life, Ministry of International Trade, State Law Office, Custom Departments, Research Organizations and University staff Workshop trained on procedures for handling of applications for release of GMOs into the environment; 10 officers/technical staff trained on risk assessment/risk management (two one-week training courses for 10 officers/technical staff); 10 officers/technical staff trained on handling, transport and packaging of GMOs; Application forms for LMOs permit available on the website; Operational manuals for regulators on handling requests, namely written procedures on administrative processing, risk assessment and decision making prepared;*
Component C	Mauritius has a functional national system for "follow-up", namely monitoring of environmental effects and inspections
Outputs	*Guidelines/Procedures on monitoring prepared; 10 officers /inspectors/technical staff trained in LMOs testing and monitoring carried out (two one-week training courses) ; Laboratory facilities adequately equipped for detection of GMOs.*
Component D	Mauritius has a functional national system for public awareness and participation
Outputs	*50 persons from the general public, media, NGOs, journalists, policy makers, and scientists, NGO representatives trained on "Public awareness and participation in the NBF of Mauritius; Outreach material for main users developed and published; Lessons learnt and best practices documented and shared*

C2.F Activities and Financial inputs needed to enable changes

The estimated additional cost of the substitution scenario as compared to the baseline scenario, mentioned in paragraph C, will allow the acceleration of the implementation of the **Cartagena Protocol on Biosafety** , and the supply of legal and technical elements that are essential for that are essential for managing and evaluating risks.

Activities needed to enable substantial changes are planned as follows:

Component A: Regulatory Regime (TOT: USD 30,000; GEF : USD 18,000)

Implementing regulations are needed to make the GMO Act fully operational. In this respect a one-day workshop will be organised for the main stakeholders including scientists, policy makers, lawyers, Senior Government Officers, National Biosafety Committee members, University of Mauritius staff. It will cover the issues related to the implementation of the recently approved GMO Law in relation to the obligations of the Cartagena Protocol.

Implementing regulations as required by article 24 of the GMO Act (specifications for containment facilities for GMOs, labeling and identification of GMOs, etc) will be drafted, shared and commented by other stakeholders according to national consultation procedures. The regulations will be then finalised for submission to the relevant Ministers. National/international consultancy may be required.

Activity A.1 Draft implementing regulations in accordance with the GMO Act and in compliance with CP

Activity A.2 Hold a one-day workshop for about 35 participants including scientists, policy makers, lawyers, Senior Government Officers, National Biosafety Committee members, University of Mauritius staff on the Implementation of National Biosafety Legislation-GMO Law and the Cartagena Protocol

Component B: Handling of requests (TOT: 90,100USD; GEF: 63,000USD)

As already mentioned, a technical committee has been set up and is presently working on the procedures involved in the processing of application for GMO permit in Mauritius. A draft flowchart of the steps for handling a request is attached at page 10 .

In order to have an operational system for handling request, performing risk assessment, decision-making, carrying out administrative tasks, handling, storing and exchanging information in line with the BCH requirements, Mauritius has to finalise the procedures involved with handling of application for release of GMOs into the environment, and make sure that adequate training courses and tools are provided as follows:

Activity B.1 Organise a two-day workshop for about 35 participants from the Ministry of Agriculture, Food Technology and Natural Resources, Ministry of Environment, Ministry of Health and Quality of Life, Ministry of International Trade, State Law Office, Custom Departments, Research Organizations and University staff on 'Procedures involved with handling of applications for release of GMOs into the environment'.

During the two days workshop, participants will learn relevant aspects that need to be considered on examining applications for the entry or export of GMOs. Risk assessment procedures and risk management strategies as well as transboundary movement will be covered.

Activity B. 2 Prepare technical guidelines on handling of request , transport, labelling of LMOs

Activity B.3 Organise two one-week training courses for 10 officers/technical staff to specialise on risk assessment/risk management

Activity B.4 Organise a three-day training of 10 officers/technical staff to specialise on handling, transport and packaging of LMOs

Activity B.5 Make "application forms for LMOs permit" available on the website

Activity B.6 Prepare operational manuals for regulators on handling requests, namely written procedures on administrative processing, risk assessment and decision making procedures

Component C Systems for follow-up, namely monitoring of environmental effects and enforcement (TOT: 132,000 USD; GEF: 95,000 USD)

Article 25 of the Cartagena protocol requires parties to adopt appropriate measures to prevent GMOs entering the country without permission. The main activities include adequately training people to monitor the environmental effects as well as equipping the laboratory of the Ministry of Agriculture to test for the presence and composition of GMOs (Annex D, provisional list of equipment).

Activity C.1 Prepare technical guidelines on systems for follow-up, namely monitoring and enforcement

Activity C. 2 Provide the laboratory of the Ministry of Agriculture with adequate equipment for LMOs testing (see provisional list)

Activity C.3 Hold two one-week training of 10 custom officers/inspectors/technical staff on LMOs testing, monitoring and investigation

Component D Public awareness and participation (TOT: 36,500 USD; GEF: 27,000 USD)

The Mauritian society at large is not aware of the development of biotechnology and the related biosafety. This one-day workshop will aim at exchanging information on biosafety amongst the general public, media, NGOs, journalists, policy makers, teachers, and scientists. Decisions on the best method to disseminate information to the general public will be discussed. Risks associated with GMOs as well as the benefits of biotechnology will be the key discussion.

Awareness material will be prepared and disseminated across the country among the main users

Activity D.1 Organise two one-day workshops for 25 participants/workshop representing the general public, media, NGOs, journalists, policy makers and scientists on 'Public information and participation in the GMO Act'.

Activity D.2 Develop awareness material (brochures) and disseminate it to main users, i.e. politicians, community leaders private sector, consumer protection association, chambers of commerce and general public

Activity D.3 Produce, share and incorporate lessons learned from project activities

C3. SUSTAINABILITY

This project is of national importance. The effort to establish biosafety legislation in Mauritius is part of the effort to comply with CBD and the Cartagena protocol on Biosafety, that Mauritius has acceded on 11 April 2002. As the law is enacted and the national Biosafety Committee constituted, sustainability of the process beyond the life of the project is guaranteed.

The project builds on the baseline activities carried out in the Pilot Phase. Feedback, lessons learnt and best practices from the current demonstration projects are and will be considered in the project during its execution and further explored so as to provide tools and experience for further use in other areas of the world .

Institutional and operational sustainability

The recently approved GMO Law defines the institutional set-up and procedures needed to regulate the development, production, use, marketing and application of genetically modified organisms. The national Biosafety Committee, which comprises the main categories of domestic stakeholders, plays a key role in supporting the decision-making process of the Competent Authority, the Ministry of Agriculture.

The involvement of an institutionalised multi-sectoral Committee in decision-making will ensure ownership. In addition, the project focuses on building human capacity in the key areas of biosafety.

These two elements will ensure institutional and operational sustainability of the process beyond the life of the project.

Financial sustainability

The GMOs Law determines specific financial allocation for biosafety activities and, under article 24, refer to a specific regulation (to be drafted) “to provide for the levying of fees and charges”

Environmental sustainability

The structure of the committee-, which is multi sectoral – will ensure that the decisions taken will be the result of attentive evaluations and different points of view, so guaranteeing that the adverse risks to the environment and human health are minimised.

The main anticipated risks under this project would be inherent to the quality of the decisions taken in relation to the implementation of the protocol. In particular this will include:

- Limited information exchange between stakeholders;
- Limited scientific capacity on risk assessment ;
- Lack of clarity in the distinction of roles and responsibilities between the administrative, technical and juridical personnel;

Mitigation measures: These risks could be reduced when a comprehensive regulatory regime is completed and fully operational. This will establish

- An institutionalised process that would engage all stakeholders in the decision-making process;
- Wide involvement of the scientific community in scientific and technical matters and increased national capacity in biosafety;
- Improved information flow among stakeholders and regulators;

C4. Replicability

The project benefits of a « replicability » effect generated by the experience gained through the demonstration projects and will produce a similar effect (by for example further developing training material and methodologies, producing risk assessments or environmental reviews of LMOs

generated by regulatory processes, taking final decisions on import or release of LMOs, etc.) so as to be used in other areas of the world and different contexts.

So as to guarantee sharing and dissemination of information and amplify the replicability potential of national projects to other countries in the world, documents, reports, findings of the demonstration projects will be posted and regularly updated on the web. Contacts between National project Coordinators will be facilitated by UNEP.

C5. Stakeholder Involvement

C5.a Project Preparation

During the Pilot Enabling Activity Project, NGOs participated in the various activities undertaken by the Task Force. This has allowed preliminary public awareness on biosafety. Throughout this project, NGOs will be consulted before any decision is taken regarding the introduction of GMOs in the country. With the creation of the Website on Biosafety, relevant information on various aspects (importation and exportation of GMOs, risk assessment, trials, etc) will be made available to the general public.

C5.b Stakeholder identification

The main stakeholders are the government organizations such as the Ministry of Agriculture, Food Technology and Natural Resources, the Ministry of Environment, the Ministry of International Trade, the Ministry of Health and the Customs Department. The scientific community from various organizations such as the Agricultural Services of the Ministry of Agriculture, Mauritius Sugar Industry Research Institute (MSIRI), the Food and Agricultural Research Council (FARC), the Agricultural Research and Extension Unit (AREU), the State Law Office have provided the expertise for reviewing the GMO Bill and in the preparation of the various regulations and guidelines to implement the act. They will also play a key role in risk assessments and management.

C5.C Stakeholder participation (including the public)

The Ministry of Agriculture, Food Technology and Natural Resources is the main stakeholder within the Government. This Ministry will be responsible for issuing permits for working and introducing GMOs into the country. The risk assessment procedure will be also co-ordinated by this Ministry.

The Ministry of Environment will play an important role for environmental impact assessment (if and when required) .
Scientists will be trained in risk assessment and risk management and will participate in workshops and public awareness campaign.
NGOs, consumers' protection association, teachers, farmers and students will be made informed of the progress in biotechnology and biosafety. They will attend the planned workshops and their role will be to disseminate the acquired information.
Media will play an important role in diffusing precise information to the public. They will attend the workshops and be responsible to summarize information generated during the activities for newspapers, magazines and television broadcast.

As per activity D, information will be compiled and disseminated to the public.

Table 1

STAKEHOLDERS	TYPE OF INVOLVEMENT
Ministry of Agriculture, Food Technology and Natural Resources	Issuing permits for working and introducing LMOs into the environment; coordinating the risk assessment and management

	procedure.
Ministry of Environment	Contributing to environment impact assessment, if and when required
Ministry of Health	Monitoring food commodities; monitoring of LMOs related to Health
Ministry responsible for international trade	Involved in the consultation for the formulation of advise to the Minister of Agriculture on all aspects concerning the importation, exportation, transit, development, research, production, use, application, marketing, sale and release of genetically modified organisms; or Any other matter concerning genetically modified organisms that may be referred to it
Customs Department	To provide Customs clearance of GMO product subject to availability of permit
Scientific community: *AREU (Agricultural Research & Extension Unit), FARC (Food and Agricultural Research Council), UoM (University of Mauritius), Mauritius Research Council, Mauritius Sugar Industry Research Institute (MSIRI)*	Contributing to risk assessment and risk management
Non Government Organizations: *ICP (Institute for Consumer Protection), ACIM (Association des consommateurs de l'Ile Maurice)*	Consultation before any decision regarding the introduction of GMOs in the country is taken
Media	Summarising and diffusing precise information to the public.
Industry & Commerce: The Mauritius Chamber of Agriculture, The Mauritius Chamber of Commerce & Industry	Consultation before any decision regarding the introduction of GMO is taken; To disseminate information to private sector regarding information on decision taken for trading in GMO and GMO-related products

C5.d Information dissemination and consultation

Activity D.1 is specifically aimed at developing capacity by illustrating the tools and processes envisaged in the GMO law for public participation and information, and activities D.2 and D.3 aimed at disseminating information about biosafety and the project to ensure maximum outreach of the project results.

C.6 MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This process will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs (Annex E, C.6 a) and project impact (Annex E, C6.b) will be measured according to the indicators developed in the project log frame (Annex H), and using this specific Monitoring and Evaluation Plan. The general and specific objectives of the project, and the list of its planned outcomes, provide the basis for this monitoring and evaluation plan. The project co-ordinator, with the assistance of the NCC, will be in charge of the monitoring and evaluation component of the project and will take action whenever needed so as to guarantee that the M&E activities of the project and related indicators adequately reflect the needs of the project.

The Monitoring and Evaluation plan is detailed in Annex E. The monitoring and Evaluation plan includes Table 2 Indicators and Means of Verification, Table 3 reporting and monitoring responsibilities, Table 4 information on reporting requirements.

The Log frame is attached in Annex H. The matrix on key indicators, baseline and methods of data collection is attached in Annex I.

D – FINANCING

D1. Incremental cost assessment

Table 5 provides a summary of baseline and incremental costs by project component as well as information on GEF financing and national Co-funding. A detailed incremental cost analysis is attached in Annex F. The total baseline expenditure amounts to US$131,000 . The increment has been estimated at US$ 635,700. The country will cover the 33% of the cost of the increment. The remaining total cost of US$427, 800, which includes 70,000USD for technical support, is requested from GEF.

Table 5- Incremental Cost (US $)

PROJECT COMPONENTS	Baseline	Alternative	Increment	Cost to GEF	National Co financing
Biosafety regulatory regime	15,000	45,000	30,000	18,000	12,000
Handling requests for permits, monitoring and inspections of LMOs	5,000	95,100	90,100	63,000	27,100
Monitoring for environmental effects and inspections	105,000	237,000	132,000	95,000	37,000
Public awareness/education/involvement	6,000	42,500	36,500	27,000	9,500
Project coordination	-	227,100	227,100	124,800	102,300
Project Consultancies	-	50,000	50,000	30,000	20,000
Technical support	-	70,000	70,000	70,000	-
Total	131,000	766,700	*635,700*	*427,800*	*207,900*

D2. BUDGET (including national co-financing)

The detailed budget of the project is shown in Annex G. A summary of the budget by components with co-financing details and the staff costs are shown in Tables 7 and 8 respectively (below).

Table 6: Project Budget by Components.

Component	GEF (US $)	Government (US $)	Total (UD $)
Regulatory regime	18,000	12,000	30,000
Handling applications	63,000	27,100	90,100
Monitoring for environmental effects and Inspection	95,000	37,000	132,000
Public awareness and participation	27,000	9,500	36,500
Project coordination and management	124,800	102,300	227,100
Consultancy (regulations, operational manuals guidelines, etc)	30,000	20,000	50,000
Technical support	70,000		70,000
TOTAL	427,800	207,900	635,700

Table 7: Staff costs – not directly linked to a specific activity

Personnel	GEF	National co-financing	TOTAL (USD)
National coordinator of the project	48,000	38,400	86,400
One project assistant (full time)	16,800	26,400	43,200
National Coordination Committee Meetings	10,000	10,000	20,000
Travel for NPC, Staff and NCC members	30,000	10,000	40,000
TOTAL	104,800	84,800	189,600

The total personnel cost for the project is therefore 189,600USD, of which 104,800USD is requested from GEF and 84,800USD provided in-kind by the government of Mauritius.

Equipment and operating costs amount to a total of 27,500USD, of which 12,500USD by GEF . They include maintenance, stationery and communications costs.

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out over four years. The implementation plan will be associated to the budget provided in Annex G.

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on an UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the CP-carried out through the development and implementation of National Biosafety Frameworks projects respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will

benefit from UNEP's experience and expertise to develop a fully operational NBF in Mauritius where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

E2. CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IMPLEMENTING AGENCIES, EXECUTING AGENCIES, AND THE GEF SECRETARIAT (WHERE APPROPRIATE)

E2.a National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA), namely the Ministry of Agriculture, Food Technology and Natural Resources, to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex J.

E2.b National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, namely the Ministry of Agriculture, Food Technology and Natural Resources , after consultation with UNEP, for the duration of the National Project. The National Project Coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex J.

E2.c UNEP Steering Committee

The Steering Committee provides guidance and direction to the implementation of the project. It is chaired by UNEP, and comprises representatives of the National Executing Agency, namely the Ministry of Agriculture, Food Technology and Natural Resources , two other implementing agencies as well as the GEF Secretariat. However, *whenever technical and scientific issues related to the implementation of the MSP are to be addressed*, the representative of STAP as well as experts selected in their personal capacity *will be* invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

ANNEXES

ANNEX A	National Biosafety Guidelines for the Safe Development and introduction of Genetically Modified Organisms
ANNEX B	Executive summary of the Non-sugar sector strategic plan
ANNEX C, C.1,C.2	(Approved) GMO Act
ANNEX D	Provisional list of equipment for testing GMOs
ANNEX E	Monitoring and Evaluation plan
ANNEX F	Incremental Cost Assessment
ANNEX G	Detailed Project Budget and Implementation plan
ANNEX H	Project Log Frame
ANNEX I	Key Indicators, Baselines and Data Collection
ANNEX J	Draft TOR for the National Executing Agency, National Project Committee, National Project Coordinator

TABLES

ANNEX A

"UNEP/GEF Pilot Biosafety Enabling Activity Project"

Preparation of National Biosafety Framework in Mauritius

National Biosafety Guidelines for the Safe Development and Introduction of Genetically Modified Organisms in Mauritius

Prepared by:
Mauritius Sugar Industry Research Institute
Réduit
Mauritius

Editors: A Dookun, L J C Autrey and M Koch

September 1999

NATIONAL BIOSAFETY GUIDELINES FOR THE SAFE DEVELOPMENT AND INTRODUCTION OF GENETICALLY MODIFIED ORGANISMS IN MAURITIUS

CONTENTS *PAGE*

1. INTRODUCTION

With the growing development of biotechnology in industrialized countries, it is inevitable that genetic modification technology will become more and more accessible to developing countries. While such development will add to the economic well-being of many countries by increasing their food supply and health status, it should not be ignored that adverse effects may result from the use and application of modern biotechnology. Mauritius has recently introduced biotechnology in its research programme. So far, most of the biotechnology is in relation to agriculture, and Mauritian sugarcane varieties have already been modified for herbicide resistance trait. In the coming years there will be an increase in the application of genetic modification technology to other sectors such as human and animal health, aquaculture, marine biology, pharmaceutical and environmental protection.

It is important that the introduction of genetic modification technology is undertaken in a manner that is harmonized with existing policy in Mauritius, e.g. Freeport status. For this reason it is necessary to implement a strong biosafety framework in Mauritius. These guidelines have been developed to provide a common framework recommending practices and procedures for the safe use of biotechnology in Mauritius. Application of the guidelines will ensure that the new technology is implemented in a responsible manner that will not harm people or the environment.

The guidelines introduce the concept of a National Committee for Biosafety Regulation (NCBR) and give an outline of the procedures needed to implement safe work with Genetically Modified Organisms (GMOs). It will be necessary to form an interim NCBR structure until legislation or regulations enable an official biosafety structure to be formed. These guidelines include guidance on containment, risk assessment and risk management, inspection and monitoring, reporting accidents and approval, or withdrawal of approval for work with GMOs.

2. OBJECTIVES

The guidelines outline the procedures necessary for the safe application of genetic modification in Mauritius. They recommend practices and precautionary approaches to ensure the safe application of GMOs so as to protect the country from any adverse effect to human and animal health or the environment. The scope of the guidelines includes all use, development and release of GMOs.

The guidelines will be reviewed and modified as required. Applicants must ensure that they have the most recent edition of the document.

3. PROCEDURES FOR INITIATING WORK WITH GENETICALLY MODIFIED ORGANISMS

Institutions commencing work with GMOs should familiarize themselves with the national guidelines and undertake to implement a policy that ensures the safe use of genetic modification technology and that abides by the national guidelines. Permission and permits for working with GMOs must be obtained from the NCBR.

3.1. National committee for biosafety regulation

The NCBR will be established as defined by the Genetically Modified Organisms Act for Mauritius (under preparation). The objectives of the NCBR, its powers and duties will be defined in the Act. The Committee shall provide advice on all aspects concerning the development, production, use, application, marketing and release of GMOs and ensure that all activities in Mauritius with regard to the development, production, use, application, marketing and release of GMOs are performed in accordance with the provision of the Genetically Modified Organisms Act.

3.2. Permission and permits for working with genetically modified organisms

Research and teaching with GMOs in contained laboratory facilities falls under the jurisdiction of the NCBR, and will require a permit on first use of the technology. These groups must undertake and keep copies of risk assessments that adequately identify

potential risks and the contained conditions to be implemented to maximize human and environment safety. Groups wishing to undertake work in the following categories must also apply to the NCBR for a permit:

- Greenhouse trials with GMOs
- Field trials with GMOs
- Clinical trials with GMOs
- General release of GMOs.

3.3 Applications

Applications, containing answers to the relevant questionnaire and a covering letter, should be delivered to:

The Secretariat
National Committee for Biosafety Regulation

3.4 Time frame

Applicants must ensure that adequate time is allocated for a full review of their application. The time required to assess an application will depend on the nature of the proposal and the quantity and quality of the information supplied. The NCBR should be contacted for information regarding the time required for the review of specific applications.

3.5 Confidentiality

The regulators are conscious of the need to protect information that may have commercial significance. Applicants must indicate which information in the applications is to be withheld from the public domain and should mark this as "commercial-in-confidence". Care will be taken to nominate reviewers who have no direct or indirect interest in, or any other conflict of interest with an application. The NCBR members and all reviewers will sign confidentiality agreements stating that they will not divulge or use "commercial-in-confidence" information contained in applications.

A person shall immediately remove himself or herself as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest. It also applies if there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

3.6 Cost of review of an application

The NCBR will charge a fee to cover the cost of reviewing an application. These fees will be set according to the nature of the application and updated as and when required. Applicants should contact the NCBR to ascertain the fee and the number of copies of documentation needed for a review.

3.7 Press release and public awareness

The NCBR recognises that public participation in decision-making on planned release proposals can be a significant issue. The NCBR together with the responsible Government Department will take the lead role in any public participation programme. The NCBR will encourage public participation by allowing access to information on which decisions are based, whilst respecting confidential commercial information. Information to the public will be communicated through meetings, local newspapers, radio, television, Internet and any other means appropriate within Mauritius.

Applicants are required to draft a press release concerning any application for a permit to undertake field trials, clinical trials or general release with GMOs and to submit this to local papers. Applicants should indicate the area or district in which the release is likely to take place.

3.8 Inspection and reporting

One or more members of the NCBR together with the responsible Government Department and the applicant should monitor the progress of a release and immediately report any significant unforeseen occurrences to the Chairman of the NCBR. All data collected on the field trials and the procedures carried out must be provided to the NCBR. At the end of a permitted programme, the inspectorate and the applicant should each

submit a report to the NCBR. The inspectorate’s report should detail compliance with containment conditions and any changes that were necessary during the project. The applicant's report should summarize the outcome of the work and give details of compliance with containment conditions and any changes that were necessary during the project.

3.9 Risk Assessment

Risk assessment aims to identify any possible problem that might arise by a GMO. Generally the risk assessment will have to be carried out by the applicant.

The NCBR will consider whether the proposed genetic modification will directly affect the distribution and abundance of the modified organism or cause changes to it physical, or biological environment. The essential questions will be:

- Will the GMO survive and multiply, or interbreed with a pre-existing population?
- Will the GMO disperse from the release area?
- Will the GMO have a direct adverse effect on human beings, other species or the physical environment?
- Will any indirect adverse effect arise from the release, multiplication and dispersal of the GMO (e.g. build-up of a toxic metabolite in the food chain, undesirable genetic reaction in populations of other species, etc.)?
- Are the benefits that are suggested likely to be achieved from the release?
- What will be the extent of the possible consequences of an adverse event?
- Will it be possible to contain, control or eliminate the GMO after release if an adverse effect becomes apparent?
- Will there be any social and economic impact on the introduction of the GMO?

Applicants must ensure that answers to the relevant points raised on risk assessment in Annex 4 are provided.

In reaching its decision, the NCBR will balance perceived benefits against perceived risks.

4. GUIDELINES FOR THE SAFE USE OF GENETICALLY MODIFIED ORGANISMS

4.1. Laboratory and contained conditions

The first principle of containment is a strict adherence to good laboratory practices. The following standard practices, not necessarily in order of importance must be followed in all laboratories undertaking work with GMOs:

1. The laboratory door should be closed when work is in progress
2. The laboratory should be kept clean and free of materials not required for the work
3. Smoking, drinking, eating and storage of food in the laboratories should be prohibited
4. Laboratory coats should be worn in the laboratory and removed when leaving the laboratory premises
5. Disposable gloves should be worn when dealing with toxic and infectious agents. The gloves should be autoclaved before disposal
6. Hands should be disinfected and washed as soon as contamination is suspected, after handling viable microorganisms and before leaving the laboratory
7. Mouth pipetting is prohibited. Automatic pipetting devices should be used
8. Safety glasses, face shields or other protective devices should be worn when necessary
9. Bench tops and laboratory equipment should be cleaned and disinfected as appropriate after use
10. Effective disinfectants should be available for immediate use in the event of spillage
11. All contaminated liquids and solid waste should be decontaminated before disposal and reuse. Contaminated materials that require autoclaving or incineration at a site away from the laboratory, need to be placed in well sealed leak-proof bags before removal from the laboratory

12. All waste material containing viable microorganisms should be disposed of in a safe manner
13. All chemicals and bottles should be labelled
14. All work with fume producing chemicals must be carried out under a fume hood
15. All accidents and incidents should be recorded and reported to the health and safety officer
16. Emergency plants must be elaborated for the elimination and rapid destruction of GMOs in case of unforeseen circumstances.

Groups are encouraged to contact the NCBR when progressing from research to product development for an assessment of the containment conditions, accident protocols and risk management procedures needed to safely implement any proposed scale up.

A number of guidelines that deal with good laboratory practices are available:

- MSIRI Guidelines: Biotechnology and Biosafety at MSIRI - Internal Guidelines, 1996.
- World Bank Report: Doyle, JJ, 1996. Enabling the Safe Use of Biotechnology: Principles and Practice. ESD Monograph Series No. 10, The World Bank, Washington, DC.
- ACGM Compendium of Guidance from the Health and Safety Commission's Advisory Committee on Genetic Modification, 1997. Health and Safety Executive, UK.

A transcript of the relevant chapters on contained use of GMOs from the World Bank report (Doyle, 1996) are appended in Annex 1 for quick reference.

Annex 1 includes guidance to the following:

- Contained use of GMOs
- Introduction of GMOs for academic research and teaching
- Microbiological safety cabinets

- Classification of Etiological agents and oncogenic viruses on the basis of hazard (US list).

4.2 Classification of Etiological Agents and Oncogenic Viruses on the Basis of Hazard-Consideration for Mauritius

For Mauritius, the US list on the classification of etiological agents and oncogenic viruses provided in Annex 1 (Section 4) can serve as a guide with the following considerations:

The listed organisms below (provided by the Ministry of Health and Quality of Life), are to be categorized in risk class 3 instead of risk class 2 when it applies to Mauritius.

Bacteria
Neisseria meningitidis
Salmonella enterica ser. typhi and paratyphi A, B and C
Shigella dysenteriae type 1
Vibrio cholera (inc. EI Tor)

Parasites
Leishmania spp. (mammalian)
Trypanosoma brucei, T cruzi

The following organisms should also be included in risk group 3:
Bacteria
Erlichia- all species
Escherichia coli, shiga-like toxin producing (verocytotoxin-producing *E coli*)

Viruses
Paramyxoviredae, genus paramyxovirus; Hendra virus, Nipah virus

Parasites
Plasmodium spp. (human and simian)

It should be noted that this is not a complete list and before assuming that an unlisted organism is classified in risk class 1, its characteristics and pathogenicity must be verified in consultation with the Ministry of Health and Quality of Life.

Categories of pathogens

Risk class 1: This class includes microorganisms, bacteria, fungi, viruses and parasites which are unlikely to cause diseases in healthy workers or animals.

Risk class 2: A pathogen that can cause human and animal disease but under normal circumstances is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease, effective treatment and preventive measures are available and the risk of spread is limited.

Risk class 3: A pathogen that usually causes serious human or animal diseases, or which can result in serious economic consequences, but does not ordinarily spread by casual contact from one individual to another, or that can be treated by antimicrobial or antiparasitic agents.

Risk class 4: A pathogen that usually produces very serious human, animal diseases often untreatable and may be readily transmitted from one individual to another or from animal to human or vice-versa directly or indirectly, or by casual contact.

4.3 List of animal disease organisms and vectors that are forbidden entry in Mauritius (List provided by the Ministry of Agriculture, Food Technology and Natural Resources).

1. African horse sickness virus
2. African swine fever virus
3. *Bacillus anthracis*
4. Aujeszky's disease virus
5. Avian influenza virus
6. Avian mycoplasma
7. *Bestoitia besnoiti*
8. Borna Disease virus
9. Bovine infectious petechial fever
10. *Babesia bigemina, B. bovis, B. argentinum*
11. *Brucella abortus*
12. BSE prion
13. *Cowdria ruminanatium* (Heartwater)
14. Classical swine fever virus
15. *Dermatophilus congolensis* (Dermatophyllosis)
16. Blue Tongue virus
17. Dourine virus
18. Ephemeral fever virus
19. Epizootic lymphangytis fungus
20. Equine infectious anaemia virus
21. Equine influenza virus
22. *Echinococci* and *Cystercerci*
23. Fowl plague virus
24. Foot and mouth disease virus
25. Fowl pox virus
26. Goat pox virus

27. Glanders virus
28. Hog cholera virus
29. Horse pox virus
30. Infectious bovine rhinotracheitis virus
31. Infectious bronchitis virus
32. Infectious laryngotracheitis virus
33. Infectious bursal disease virus
34. Louping ill virus
35. Lumpy skin disease virus
36. *Leptospira*
37. *Mycoplasma mycoides* – contagious bovine pleuropneumonia
38. *Mycoplasma agalactiae* – contagious agalactia of sheep
39. Marek's disease virus
40. Malignant catarrhal fever (bovine) virus
41. Nairobi sheep disease virus
42. Newcastle disease virus – Asiatic strains
43. *Nocardia*
44. *Paratuberculosis bacillus*
45. *Pasteurella*
46. Q fever virus
47. Rinderpest virus
48. Rabies virus
49. Rift valley fever virus
50. Sheep pox virus
51. Swine vesicular disease virus
52. *Salmonella*
53. Scrapie/Maedi-visna virus
54. Teschen disease virus
55. *Theileria annulata*
56. *Theileria bovis*
57. *Theileria hirci*

58. *Theileria lawrencie*
59. *Theileria parva* – East Coast fever
60. *Trypanosoma evansi*
61. *Trypanosama vivax* – Nagana
62. *Trichmonas*
63. Transmissible gastro enteritis virus
64. *Trichinella*
65. Vesicular exanthema virus
66. Wesselsbron disease virus
67. Zyonema

4.4 Trials in greenhouse facilities

Only greenhouses with appropriate safety conditions that enable full containment can be used for work with GMOs.

All proposed experiments involving transgenic organisms in greenhouse containment must have the approval of the NCBR and an application form (Annex 2) must be submitted with a covering letter for biosafety review. Transfer of GMOs to a greenhouse should not occur before written permission has been received from the NCBR.

The following regulations will have to be followed:

1. Greenhouses must be locked at all times, and have their biosafety categories and safety regulations posted at their entrances
2. Only personnel with specific clearance are allowed access and all entries in the greenhouse must be recorded
3. Plant material or plant parts may leave the greenhouses only under the following circumstances:
    1) For disposal, in which case they must be autoclaved and/or incinerated before disposal; or,
    2) For storage, in other laboratory or containment facilities, in which case the living organisms must undergo adequate containment before and during transport to avoid accidental dissemination. Such materials stored outside the greenhouses must be appropriately tagged
4. Precaution must be taken so as not to allow foreign gene dispersal from the GMOs
5. Hand washing is required prior to exiting the greenhouse if materials have been handled
6. Work implements must not be taken out of the greenhouse unless decontaminated
7. Laboratory coats must not be taken out of the greenhouse.

4.5 Field trials with genetically modified organisms

This section provides guidance for small-scale field testing of transgenic organisms. All proposed field-testing with transgenic plants must be carried out at suitably secured trial sites or experiment stations. The applicant should provide a map of the location of the

field trial to the NCBR. The NCBR should keep an integrated map of all sites of field trials and this should be constantly updated. For field trials with transgenic plants, animals or microorganisms, an application must be submitted to the NCBR for biosafety review, environment analysis, and/or risk assessment. For trial release, applicants should provide answers to the relevant questions in the questionnaire in Annex 3. Trials may only proceed once written permission and a permit have been received from the NCBR.

General guidelines require that transgenic plants may be used in field experiments only under the following experimental conditions:

1. Plants should be grown in confinement
2. Plants must be prevented from spreading pollen, seed or vegetative material. (This may require that flowers be removed or bagged)
3. If flowers, fruit or seed are needed for testing and further experimentation, the material must be carefully transported to the laboratory
4. Other protective measures should be taken (i.e. bagging, labeling, confinement to restricted storage areas), as needed, to ensure the isolation of harvested plant parts
5. Entry to plots by unauthorized personnel must be prohibited
6. Provisions must be made to eliminate the GMOs from the test site upon completion of the trial. Plots may need to lie fallow to detect and destroy volunteers for one or more seasons after the trial.

During biosafety reviews, other parameters may be identified as necessary for adequate containment and risk management of a trial. A more detailed guideline for field trials with transgenic plants is given in Annex 4.

Useful isolation distances for certain crops are given in Annex 5.

4.6 Clinical trials with genetically modified organisms

Applicants wishing to carry out clinical trials with GMOs must obtain clearance from the NCBR. Applicants should provide answers to the relevant questions and matters contained in Annex 3. Applications must comply with existing Regislations such as the

Pharmacy Act (1983), The Dangerous Drugs Act (1996) and the Psychotropic Act (1994), etc.

4.7 Release of genetically modified organisms into the environment

Release of a living genetically modified organism may not occur without the approval of the NCBR. Approval will only be given following a thorough risk assessment, carried out by applicants, that adequately determines the safety of the GMO for the national environment. Approval may be withheld until sufficient safety information is presented to enable an adequate assessment.

Applicants for general release of GMOs must ensure that answers to the relevant questions for trial release of the GMO (Annex 3) are also submitted.

Applicants wishing to release a GMO without any containment conditions for commercialization or any other reason must apply to the NCBR for a deregulation permit. The application should contain answers to relevant questions from both the trial release and general release questionnaires (Annex 3 and Annex 6). Having reviewed the application and carried out a risk assessment of the proposed release, the review panel may wish to meet with the applicant to clarify certain issues. Annex 7 contains guidance from the World Bank on the safe release of GMOs into the environment.

The GMO risk assessment will take the place of an environment impact assessment (EIA).

4.8 Import of genetically modified organisms

Applicants wishing to import GMOs should obtain an import permit prior to the material being shipped. The application for import must declare the genetically modified nature of the living organism. The importation must comply with existing legislation on the import of living material into Mauritius. This is covered by the other existing legislation, e.g. the Plants Act.

4.9 Export of genetically modified organisms

Applicants wishing to export GMOs must determine whether adequate biosafety measures are active in the country of destination and whether the receiving party has fulfilled local biosafety requirements to import GMOs. The exportation of GMOs must comply with existing regulations e.g. the Freeport Legislation.

4.10 Transport of genetically modified organisms for contained use

In all instances GMOs must be transported in a manner that minimizes the risk of accidental release into the environment. Care should be given to ensure the following basic requirements:

- Package the GMOs in several secure packages to minimize the risk of spillage in case of an accident during transport.
- Label the package clearly indicating:
    - The contents (e.g. genetically modified bacteria),
    - That it must not be opened by untrained personnel under any circumstances,
    - That it must not be opened outside a contained facility,
    - Contact details for a responsible agent, (i.e. the recipient or the sender) should the package be mislaid.
- Transport must be by trained personnel or professional transporters.
- Storage must be in a locked facility.

Annex 8 gives the World Bank guidance on the safe transport of GMOs.

5. TERMINOLOGY

Accident - Any incident involving an unintended general release of genetically modified organisms which could have an immediate or delayed adverse impact on the environment.

Applicant - Any person in control of facilities and activities involving genetic modification of organisms and includes "user".

Biosafety - The assessment of the safety of genetically modified organisms and their products to humans, animals and the environment.

Biotechnology - Applied biological science, including techniques that use living organisms or substances from these organisms to make or modify a biological product or to improve plants or animals, or microorganisms for specific uses.

Committee - The National Committee for Biosafety Regulation.

Confined use - Experiments with plants, animals and microorganisms that are confined within a designated indoor or outdoor environmental zone of control with designated borders and limits. Confinement is appropriate to field experimentation with genetically modified organisms.

Contained use - Any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment.

Containment - A term used to describe physical barriers that severely limit release of an organism to the environment.

Control - To examine, regulate, manage or direct any activity within a person's jurisdiction.

Environment - The aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms.

Gene - The fundamental physical and functional unit of heredity; a portion of a DNA molecule made up of an ordered sequence of nucleotides that produces a specific product or has an assigned function.

General release - The introduction of genetically modified organisms into the environment by whatever means, or in confinement where the organisms are no longer contained by any system of barriers and are no longer under any person's control, so that the organisms are likely to survive and be disseminated.

Gene therapy - A technique for delivering functional genes (to replace aberrant ones) into living cells by means of a genetically modified vector or by physical means in order to genetically alter the living cell.

Genetically modified organism - An organism that contains genes or genetic material not normally found in it. The genetic material will have been transferred into the organism using genetic modification technology.

Hazard - An intrinsic biological, chemical or physical characteristic of a genetically modified organism, which could lead to an adverse impact on the environment.

Monitoring - Maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process.

Notification - Presentation to the Committee of documents containing the information required by the Committee.

Organism - A biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a microorganism.

Permit - A written authority from the NCBR or from any other appropriate body.

Recombinant DNA - DNA formed by combining segments of DNA from different organisms.

Regulation - A regulation made under an Act.

Risk - The probability of causing or incurring a loss or damage or an adverse impact or a misfortune.

Risk assessment - The analytical evaluation of criteria to predict the potential effect of a process, event, or product on the environment.

Transformation - The process of genome modification of an organism through the incorporation and assimilation of foreign DNA using recombinant DNA technology.

Transgenic plant - Plants whose hereditary DNA has been transformed through the addition of DNA from a source other than its normal gene pool using recombinant DNA techniques.

Trial release - The deliberate release of genetically modified organisms in confinement i.e. into the open environment under conditions where the degree of dissemination of the

genetically modified organisms is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment.

User - Any natural or legal person or institution responsible for the use or development of genetically modified organisms and includes an end-user or consumer.

Waste - Any matter, whether gaseous, liquid or solid or any combination thereof, which is, in the opinion of the person in whose possession or under whose control it is, an undesirable or superfluous by-product, emission, residue or remainder of any process or activity.

ANNEX 1

WORLD BANK GUIDELINES FOR SAFE LABORATORY USE OF GENETICALLY MODIFIED ORGANISMS

This guidance is modified from Chapter 6 (Guide to the Contained Use of Organisms with Novel Traits) and Chapter 7 (Guide to Good Laboratory Practice and Industrial Large-scale Production) of the World Bank report: Doyle, JJ, 1996, Enabling the Safe Use of Biotechnology: Principles and Practice. ESD Monograph Series No. 10, The World Bank, Washington, DC.

The annex uses terms and systems not necessarily found in the national guidelines but is being included for additional reference and information.

1. Guide to the Contained Use of Genetically Modified Organisms

One of the first tasks of implementing safe GMO development is establishing a national regulatory framework to develop, publish, and ensure compliance with guidelines for work with GMOs from the laboratory to field or clinical trials and then to general release. These guidelines will need to be continually revised to take into account current knowledge and practices in relation to the existing regulatory systems and GMOs.

In general, all work with GMOs must be undertaken in a contained laboratory environment that ensures:

- the safety of all laboratory personnel
- practices to prevent GMO release into the environment
- established measures to manage risk, should accidental release of GMOs occur
- good record maintenance to quickly identify GMOs and experiments.

2. Introduction of GMOs for Academic Research and Teaching

Any introduction of GMOs for academic research and teaching should be carried out responsibly with full consideration of any adverse effect the accidental release of these could have on the environment. Containment facilities must be adequately managed to

minimize accidental release. Risk management procedures must be defined to deal effectively with accidental release, should it occur.

The NCBR should monitor the safe use of GMOs in contained facilities and be able to insist on improved containment and management where necessary.

Approval or denial of academic research and teaching with GMOs shall be based on the following guidelines for evaluation.

Materials being used:

- Quantity of the GMO, proposed schedule and number of introductions
- All scientific, common, and trade names and all designations necessary to identify the GMO
- Country and locality in which the GMO was developed and produced
- Known potential to cause an epidemic (survival, reproduction, and dispersal rates)
- Known potential hosts or alternative hosts
- Known ability to evolve
- Known vector or organisms
- Known mode of spread and conditions for epidemic
- History of epidemics
- Nomenclature and characteristics of donor, recipient, and vector organisms
- Molecular biology of the systems (for example, donor-recipient-vector) that is used or will be used to produce GMOs
- Anticipated or actual expression of the altered genetic material; an explanation of how that expression differs from the expression in the non-modified parental organism, such as morphological or structural characteristics, physiological activities and processes, and number of copies inserted in the genetic material; the physical state of this material inside the recipient organism (integrated or extra-chromosomal), products and secretions, and growth characteristics

- Processes, procedures, and safeguards that have been used or will be used to prevent contamination, release, and dissemination of the GMO and products derived from it
- The uses and the purpose for introducing the regulated material, including a description of the proposed experimental or production design
- History of similar introductions
- Transport of the GMO to, from and within the facility (for example, mail, common carrier, baggage, or hand carried).

3. Microbiological Safety Cabinets

A microbiological safety cabinet is a device intended to offer protection to the user and the environment from airborne droplets or particles generated in handling infected and other hazardous biological material. Microbiological safety cabinets must be adequate to protect personnel from any exposure to GMOs. The level of protection must relate to the potential harm GMOs or GMO experimental methods could impose.

Reference could be made to British Standard 5726: 1992 Microbiological safety Cabinets, for a full description of the three types of safety cabinets, Class I, Class II and Class III. Guidance on the technical issues and the use of safety cabinets can be requested from the:

Health and Safety Executive
Dangerous pathogen Unit
Magdalen House
Stanley, Precinct
Bootle
Merseyside, L20 3QZ
United Kingdom

4. Classification of Etiological Agents and Oncogenic Viruses on the Basis of Hazard- US list

An understanding of the risk organisms have with regard to the hazard they pose, facilitates risk assessment of GMO activity. The list given below can serve as a starting point for the compilation of such a classification. This list is derived from the U.S. Government Department of Health and Human Services: Guidelines for Research

Involving Recombinant DNA Molecules (NIH Guidelines). Rockville, Md. National Institutes of Health, 1994.

Appendix B-I. Class 1 Agents

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes shall be considered Class 1 agents.

Appendix B-II. Class 2 Agents

APPENDIX B-II-A. CLASS 2 BACTERIAL AGENTS

Acinetobacter calcoaceticus

Actinobacillus - all species

Aeromonas hydrophila

Amycolata autotrophica

Arizona hinshawii - all serotypes

Bacillus anthracis

Bordetella - all species

Borrelia recurrentis, B. vincenti

Campylobacter fetus

Campylobacter jejuni

Chlamydia psittaci

Chlamydia trachomatis

Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani

Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale

Dermatophilus congolensis

Edwardsiella tarda

Erysipelothrix insidiosa

Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strians bearing K1 antigen

Haemophilus ducreyi, H. influenzae

Klebsiella - all species except oxytoca

Legionella pneumophila

Leptospira interrogans - all serotypes

Listeria - all species

Moraxella - all species

Mycobacteria - all species except those listed in Class 3

Mycobacterium avium

Mycoplasma - all species except Mycoplasma mycoides and Mycoplasma agalactiae, which are in Class 5

Neisseria gonorrhoea, N. meningitides

Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis

Pasteurella - all species except those listed in Class 3

Rhodococcus equi

Salmonella - all species and all serotypes

Shigella - all species and all serotypes

Sphaerophorus necrophorus

Staphylococcus aureus

Streptobacillus moniliformis

Streptococcus pneumoniae, S. pyogenes

Treponema carateum, T. pallidum, and T. pertenue

Vibrio cholerae, V. parahemolyticus

Yersinia enterocolitica

APPENDIX B-II-B. CLASS 2 FUNGAL AGENTS

Blastomyces dermatitidis

Cryptococcus neoformans

Paracoccidioides braziliensis

APPENDIX B-II-C. CLASS 2 PARASITIC AGENTS

Endamoeba histolytica

Leishmania sp.

Naegleria gruberi

Schistosoma mansoni

Toxocara canis

Toxoplasma gondii

Trichinella spiralis

Trypanosoma cruzi

APPENDIX B-II-D. CLASS 2 VIRAL, RICKETTSIAL, AND CHLAMYDIAL AGENTS

Adenoviruses - human, all types

Cache Valley virus

Coronaviruses

Coxsackie A and B viruses

Cytomegaloviruses

Echoviruses - all types

Encephalomyocarditis virus (EMC)

Flanders virus

Hart Park virus

Hepatitis viruses - associated antigen material

Herpes viruses - except Herpesvirus simiae (Monkey B virus), which is in Class 4

Influenza viruses - all types except A/PR8/34, which is in Class 1

Langat virus

Lymphogranuloma venereum agent

Measles virus

Mumps virus

Parainfluenza virus - all types except Parainfluenza virus 3, SF4 strain, which is in Class1

Polioviruses - all types, wild and attenuated

Pox viruses - all types except Alastrim, Smallpox, and Whitepox, which are Class 5, and Monkey pox, which depending on experiments is in Class 3 or Class 4

Rabies virus - all strains except Rabies street virus, which should be classified in Class 3.

Reoviruses - all types

Respiratory syncytial virus

Rhinoviruses - all types

Rubella virus

Simian viruses - all types except Herpesvirus simiae (Monkey B virus) and Marburg virus, which are in Class 4

Sindbis virus

Tensaw virus

Turlock virus

Vaccinia virus

Varicella virus

Vesicular stomatitis virus

Vole rickettsia

Yellow fever virus, 17D vaccine strain

APPENDIX B-II-E. CLASS 2 ONCOGENIC VIRUSES (SEE APPENDIX B-VI-C)

APPENDIX B-II-E-1. LOW-RISK ONCOGENIC VIRUSES

Adenovirus 7-Simian virus 40 (Ad7-SV40)

Adenovirus

Avian leukosis virus

Bovine leukemia virus

Bovine papilloma virus

Chick-embryo-lethal orphan (CELO) virus or fowl adenovirus 1

Dog sarcoma virus

Guinea pig herpes virus

Lucke (frog) virus

Hamster leukemia virus

Marek's disease virus

Mason-Pfizer monkey virus

Mouse mammary tumor virus

Murine leukemia virus

Murine sarcoma virus

Polyoma virus

Rat leukemia virus

Rous sarcoma virus

Shope fibroma virus

Shope papilloma virus

Simian virus 40 (SV-40)

APPENDIX B-II-E-2. MODERATE-RISK ONCOGENIC VIRUSES

Adenovirus 2-Simian virus 40 (Ad2-SV40)

Epstein-Barr virus (EBV)

Feline leukemia virus (FeLV)

Feline sarcoma virus (FeSV)

Gibbon leukemia virus (GaLV)

Herpesvirus (HV) ateles

Herpesvirus (HV) saimiri

Simian sarcoma virus (SSV)-1

Yaba

Appendix B-III. Class 3 Agents

APPENDIX B-III-A. CLASS 3 BACTERIAL AGENTS

Bartonella - all species

Brucella - all species

Francisella tularensis

Mycobacterium bovis, M. tuberculosis

Pasteurella multocide type B - "buffalo" and other foreign virulent strains (see appendix B-VI-B)

Pseudomonas mallei (see appendix B-VI-B)

Pseudomonas pseudomallei (see appendix B-VI-B)

Yersinia pestis

APPENDIX B-III-B. CLASS 3 FUNGAL AGENTS

Coccidioides immitis

Histoplasma capsulatum

Histoplasma capsulatum var. duboisii

APPENDIX B-III-C. CLASS 3 PARASITIC AGENTS

None

APPENDIX B-III-D. CLASS 3 VIRAL, RICKETTSIAL, AND CHLAMYDIAL AGENTS

Monkey pox virus - when used *in vitro* (see appendix B-VI-D)

Arboviruses - all strains except those in Class 2 and 4. (Arboviruses indigenous to the United States are in Class 3 except those listed in Class 2. West Nile and Semliki Forest viruses may be classified up or down, depending on the conditions of use and geographical on the conditions of use and geographical location of the laboratory.)

Dengue virus - when used for transmission or animal inoculation experiments

Lymphocytic choriomeningitis virus (LCM)

Rickettsia - all species except Vole rickettsia when used for transmission or animal inoculation experiments.

Yellow fever virus - wild, when used *in vitro*.

Appendix B-IV. Class 4 Agents

APPENDIX B-IV-A. CLASS 4 BACTERIAL AGENTS

None

APPENDIX B-IV-B. CLASS 4 FUNGAL AGENTS

None

APPENDIX B-IV-C. CLASS 4 PARASITIC AGENTS

None

APPENDIX B-IV-D. CLASS 4 VIRAL, RICKETTSIAL, AND CHLAMYDIAL AGENTS

Ebola fever virus

Hemorrhagic fever agents - including Crimean hemorrhagic fever, (Congo), Junin, and Machupo viruses, and others as yet undefined

Herpesvirus simiae (Monkey B virus)

Lassa virus

Marburg virus

Monkey pox virus - when used for transmission or animal inoculation experiments (see appendix B-VI-D)

Tick-borne encephalitis virus complex - including Russian spring-summer encephalitis, Kyasnur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.

Venezuelan equine encephalitis virus, epidemic strains - when used for transmission or animal inoculation experiments

Yellow fever virus-wild - when used for transmission or animal inoculation experiments.

Appendix B-V. Class 5 Agents (see appendix B-VI-E)

APPENDIX B-V-A. ANIMAL DISEASE ORGANISMS THAT ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY LAW

Foot and mouth disease virus

APPENDIX B-V-B. ANIMAL DISEASE ORGANISMS AND VECTORS THAT ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY THE US DEPARTMENT OF AGRICULTURE POLICY

African horse sickness virus

African swine fever virus

Bestoitia besnoiti

Borna disease virus

Bovine infectious petechial fever

Camel pox virus

Ephemeral fever virus

Fowl plague virus

Goat pox virus

Hog cholera virus

Louping ill virus

Lumpy skin disease virus

Mycoplasma mycoides - contagious bovine pleuropneumonia

Mycoplasma agalactiae - contagious agalactia of sheep

Nairobi sheep disease virus

Newcastle disease virus - Asiatic strains

Rhinderpest virus

Rickettsia ruminatium - heart water

Rift valley fever virus

Sheep pox virus

Swine vesicular disease virus

Teschen disease virus

Theileria annulata

Theileria bovis

Theileria hirci

Theileria lawrencie

Theileria parva - East Coast fever

Trypanosoma evansi

Trypanosoma vivax - Nagana

Vesicular exanthema virus

Wesselsbron disease virus

Zyonema

APPENDIX B-V-C. ORGANISMS THAT MAY NOT BE STUDIED IN THE UNITED STATES EXCEPT AT SPECIFIED FACILITIES

Alastrim (see appendix B-VI-D)
Smallpox (see appendix B-VI-D)
Whitepox (see appendix B-VI-D)

Appendix B-VI. Footnotes and References for above listing

APPENDIX B-VI-A

The original reference for this classification was the publication *Classification of Etiologic Agents on the Basis of Hazard*, 4th edition, July 1974, U.S. DHHS, Public Health Service, Centers for Disease Control and Prevention, Office of Biosafety, Atlanta, Georgia 30333. For the purposes of these *NIH Guidelines*, this list has been revised by the National Institutes of Health.

APPENDIX B-VI-B

A U.S. Department of Agriculture permit, required for import and interstate transport of pathogens, may be obtained from the U.S. Department of Agriculture, ATTN: Animal and Plant Health Inspection Service, Import-Export Products Office, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

APPENDIX B-VI-C

National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses, U.S. Department of Health, Education, and Welfare Publication No. (NIH) 75-790, October 1974.

APPENDIX B-VI-D

All activities, including storage of variola and whitepox, are restricted to the single national facility (World Health Organization Collaborating Center for Smallpox Research, Centers for Disease Control and prevention, Atlanta, Georgia).

APPENDIX B-VI-E

U.S. Department of Agriculture, Animal, and Plant Health Inspection Service.

5. Guide to Good Laboratory Practice and Industrial Large-Scale Production

The following examples of guidelines for good laboratory practice and good industrial large-scale practice are taken from the Organization for Economic Co-operation and Development (OECD) study: OECD, Safety Considerations in Biotechnology (1993).

i. Good Laboratory Practice

Human error, poor laboratory practice, and misuse of equipment cause the majority of laboratory accidents and related infections. This section provides a compendium of techniques designed to correct or minimize the most commonly reported accidents caused by these factors.

Techniques in the Use of Pipettes and Pipetting Aids

- Cotton-wool-plugged pipettes will reduce the possibility of contaminating the pipetting aid.
- Air should never be blown through a liquid containing infectious agents.
- Infectious material should not be mixed by alternate suction and expulsion through a pipette.
- No infectious material should be expelled forcibly from a pipette.
- To avoid the hazards of accidentally dropping infectious cultures from pipettes, a disinfectant-soaked cloth should be placed on the working surface and autoclaved after use.
- Mark-to-mark pipettes are preferable to other types because they do not require expulsion of the last drop.
- Fluids should be discharged down the inner wall of the tube or bottle or beneath the surface of the liquid in the container.
- Contaminated pipettes should be completely immersed in a suitable disinfectant before being autoclaved.
- A discard pan for pipettes should be placed within the biological safety cabinet, not outside it.
- A syringe fitted with a sharp hypodermic needle must not be used as a pipetting device. Blunt cannulas should be substituted for needles.

Techniques to Avoid Dispersal of Infectious Material

- A pipetting aid should always be used. Mouth pipetting should be prohibited.
- The circle of a microbiological loop should be completely closed and the arm not more than 6 centimeters long.
- When there is risk of spatter of infected material in a Bunsen flame, a micro-incinerator should be used. Plastic disposal loops are a safe alternative.
- Catalase tests should not be done on slides. Tube methods should be used or cover-glass methods used in an exhaust protective cabinet. Catalase tests may also conveniently be performed by touching a microhematocrit capillary tube loaded with hydrogen peroxide on to the surface of a colony.
- Discarded specimens and cultures should be placed in leak-proof containers for disposal.
- Working areas must be cleaned with a suitable disinfectant when each work period is finished.
- Horizontal outflow cabinets (clean air workstations) are not microbiological safety cabinets and should not be used as such.

Techniques in the Use of Biological Safety Cabinets

- The use and limitations of cabinets must be explained to all potential users.
- The cabinet must never be used unless the fan is switched on and the airflow indicator is in the safe position.
- If it has an openable glass-viewing panel, this must be raised when the cabinet is in use.
- Apparatus and materials must be kept to a minimum during operation.
- A Bunsen burner must not be used in the cabinet. The heat produced might distort the air flow and the filters might be burnt. A micro-incinerator is permissible, but disposable plastic loops are preferable.
- All work must be done in the middle to the rear of the cabinet and be visible through the glass window.

- It must be understood that the cabinet will protect neither the hands nor the worker from gross spillage, breakage, or poor technique.
- The cabinet fan should be run for at least fifteen minutes after completion of work in the cabinet.

Techniques to Avoid Ingestion of Infectious Material

- Larger particles and droplets (>5 micrometers) released during microbiological manipulations settle rapidly on the bench surfaces and the hands of the operator. Hands should be washed frequently. Workers should avoid touching their mouth and eyes.
- Food and drink should not be stored or consumed in the laboratory.
- There should be no smoking or gum-chewing in the laboratory.
- Cosmetics should not be applied in the laboratory.

Techniques to Avoid Injection of Infectious Material

- Injection may result from accidents with hypodermic needles, Pasteur pipettes, and broken glass.
- Accidents with hypodermic needles can be reduced only by greater care and making less use of syringes and needles. If syringes must be used for measurement, blunt cannulas should be substituted for needles.
- Accidental inoculation with Pasteur pipettes and broken glass may be avoided only by greater personal care.

Techniques for the Separation of Serum

- Only properly instructed laboratory staff should be employed for this work.
- To prevent splashes and aerosols, good microbiological technique should be observed. Potentially infected fluids, including blood, should be pipetted carefully, not poured. Mouth pipetting must be forbidden.
- Pipettes should be discarded and completely submerged in hypochlorite or some other suitable disinfectant. They must remain in the disinfectant at least overnight before disposal.

- Discarded specimen tubes containing blood clots and the like should be put in suitable leak-proof containers (with the caps replaced) for autoclaving or incineration.
- A solution of sodium hypochlorite should be provided for cleaning splashes and spillage of blood and serum.

Techniques for the Use of the Centrifuge

GENERAL.

The following precautions should be observed:

- Mechanical safety is a prerequisite in the use of clinical centrifuges.
- Infectious airborne particles may be ejected when centrifuges are used improperly. These particles travel at speeds too high to be captured and retained if a centrifuge is placed in a safety cabinet.
- The centrifuge should be operated according to the manufacturer's instructions.
- Good centrifuge technique and sealed centrifuge buckets offer adequate protection from microorganisms and agents of moderate risk. All residue and spillage should be cleaned and the surfaces of the centrifuge disinfected after each run.

CENTRIFUGATION OF LOW RISK MICROORGANISMS, AGENTS AND MATERIALS.

The following precautions should be observed:

- Centrifuge buckets and trunions should be paired by weight and should be properly balanced with tubes in place.
- To avoid dislodging trunions and spilling the contents of the tubes, the motor should be paired by weight and should be properly balanced with tubes in place.
- Centrifuges should be placed at such a level that workers of less than average height can see into the bowl to place the trunions correctly on the rotor.
- Centrifuge tubes and specimen containers to be used in the centrifuge should be made of thick-walled glass or plastic and should be inspected for defects before use.

- The interior of centrifuge bowls should be inspected daily for evidence of bad techniques, indicated by staining or soiling at the level of the rotor, and should be cleaned if necessary.
- Angle head should be used for microbiological work except in special high-speed centrifuges. With ordinary angle heads some fluid, even from capped tubes, may be ejected because of the geometry of the machine.
- Except in ultracentrifuges and with small pro-thrombin tubes, a space of at least 2 centimeters should be left between the level of fluid and the rim of each centrifuge tube. Tubes containing infectious material should be capped.
- All residue and spillage should be cleaned and the surfaces of the centrifuge disinfected after each run.

CENTRIFUGATION OF MODERATE TO HIGH RISK MICROORGANISMS, AGENTS AND MATERIALS.

The following precautions should be observed, in addition to those above:

- Centrifugation should be done in batches separate from other material.
- Centrifuge tubes or bottles should have screw caps and should be marked in a way agreed locally to indicate that the contents include moderate to high risk organisms.
- Sealed centrifuge buckets (safety cups) should be used.
- The sealed buckets should be loaded, sealed and opened in a biological safety cabinet.

Techniques for the Use of Homogenizers and Shakers

- Caps and cups or bottles should be sound and free from flaws or distortion. Caps should be well-fitting and gaskets must be in good condition.
- Aerosols containing infectious particles may escape from shakers and homogenizers between the cap and the vessel. A pressure builds up in the vessel during the operation. Teflon homogenizers are recommended because glass homogenizers may break releasing infectious material and possibly wounding the operator.

- Machines should be covered when in use by a transparent, plastic housing of strong construction. This should be disinfected after use. When possible, these machines, under their plastic covers, should be operated in a biological safety cabinet.
- After shaking or homogenization, all containers should be opened in a biological safety cabinet.
- Sonicators should be used inside biological safety cabinets. Hearing protection should be provided.

Techniques for the Use of Tissue Grinders

- Grinders should be held in a wad of absorbent material in a gloved hand when tissues are ground.
- They should be operated in a biological safety cabinet.

Techniques for Opening Ampoules that Contain Lyophilized Infectious Materials

Care should be taken when ampoules of freeze-dried materials are opened as the contents are in a vacuum and the sudden inrush of air may disperse the contents into the atmosphere. Ampoules should always be opened in safety cabinets.

The following procedure is recommended for opening ampoules:

- The outside of the ampoules should be decontaminated before use.
- A file mark is made on the tube near the middle of the cotton-wool plug.
- A red-hot glass rod is applied to the file mark to crack the glass.
- The top is removed gently and treated as contaminated material.
- The cottonwool plug, if still above the contents of the ampoule is removed with sterile forceps.
- Liquid for resuspension is added slowly to the ampoule to avoid frothing.

Storage of Ampoules that Contain Infectious Material

- Ampoules containing infectious material must never be immersed in the liquid phase of liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal.

- If very low temperatures are required, ampoules may be stored in the vapour phase only (that is, above the level of the liquid nitrogen). Whenever possible, infectious agents should be stored in mechanical deep freeze cabinets or on dry ice rather than in liquid nitrogen.
- The outside of ampoules stored in these ways should be decontaminated when they are removed from storage.

Techniques for Care, Use and Operation of Refrigerators and Freezers

- Refrigerators, deep freeze and dry-ice chests should be checked, cleaned out and defrosted periodically to remove any ampoules or tubes containing hazardous materials that may have broken during storage. Rubber gloves should be worn during cleaning.
- All materials, especially infectious or toxic materials, stored in refrigerators or deep freeze should be labelled with the scientific name of the material, the date stored and the name of the individual storing the material.
- Do not store flammable solutions in non-explosion-proof refrigerators.

ii. Good Industrial Large-Scale Practice

The OECD study on safety considerations for biotechnology worked out the principles for handling organisms with novel traits in industrial use. This report sets out the principles and criteria recommended for the safe use of such organisms in industry and is an appropriate basis for regulating this sector.

An important general point made in the 1993 OECD report is that hazards associated with recombinant DNA (rDNA) organisms can be assessed and managed like those associated with any other organisms. It is expected that the vast majority of rDNA organisms to be used in industrial large-scale production can be handled using good industrial large-scale practice (GILSP).

Irrespective of the intrinsic safety of the organisms concerned, zero risk is not realistic even for GILSP organisms.

Central to the concept of GILSP are:

- The assessment of the recombinant organism according to identified criteria to determine that it is as safe as the low-risk host organism.
- The identification and adoption of practices ensuring the safety of the operation.

Recombinant DNA organisms that meet the GILSP criteria and are therefore of low risk can thus be handled under conditions already found to be appropriate for the relevant hosts. GILSP applies to organisms considered to be of low risk and classified in the lowest-risk class. In order to ensure that, for each individual case, a rDNA organism merits the designation of GILSP, the criteria elaborated by the OECD must be taken into consideration in an integrated way. Two clear examples of other classes of organisms that warrant the GILSP designation, provided they are non-pathogenic and without adverse consequences for the environment, are:

- Those constructed entirely from a single prokaryotic host (including its indigenous plasmids and viruses) or from a single eukaryotic host (including its chloroplasts, mitochondria or plasmids but excluding viruses).
- Those consisting entirely of DNA segments from different species that exchange DNA by known physiological processes.

Organisms that do not meet all the criteria for GILSP are not GILSP organisms. However, after the case-by-case evaluation, they may be found to be of low risk. In such circumstances these organisms may be handled using GILSP. Care must be taken when extrapolating GILSP to other organisms to evaluate whether specific practices in addition to GILSP are required to mitigate a specific concern.

Organisms that can be handled on a large scale under conditions of minimal controls and containment procedures will be:

- Those meeting the criteria of GILSP organisms.
- Those other classes of organisms described above.

- Other organisms not meeting either of these sets of criteria but which have been demonstrated to be of low risk, as described above.

When handling GILSP and other low-risk organisms, established principles of good occupational and environmental safety must be followed.

ANNEX 2

APPLICATION FOR GREENHOUSE EXPERIMENTATION WITH GENETICALLY MODIFIED ORGANISMS

Submit to the Secretariat, National Committee for Biosafety Regulation

---

Organisation:……

Department : ..... **Applicant's Name:** .....

Project Title : .....……...

Plant, Microorganism or Animal Species : …..……..

Identification (variety or description) :

.....

.....

.....

Reason for greenhouse experiment: …….....

.....…….....

Potential benefit of the GMO to the country:

.....…….....

.....

Brief experimental plan:

.....

.....

.....

.....

Outline of DNA construct used to transform plants:

.....

.....

Method of transformation:

.....

.....

Is it known whether the unmodified form(s) have any adverse effect on:

(i) Humans, animals or plants θ Yes θ No

(ii) Agricultural production θ Yes θ No

(iii) Any other aspect of the environment? θ Yes θ No

If so, provide full details of those effects, including applicable reports

……

……

……..

Is the transgenic plant phenotypically equivalent to a product of classical breeding?

θ Yes θ No

If not, explain:

.....

.....

.....

.....

.....

Are any of the likely gains directly linked to losses in other characteristics of the species?

……

……

……..

Ease of spread of the gene by natural means:

.....

.....

Does the plant produce viable pollen? θ Yes θ No

Is vegetative propagation of the GMO planned? θ Yes θ No

Can the GMO affect plants, animals or microorganisms? θ Yes θ No

Could any toxic product concentrate in the natural or human food chain?

……

……

Has a risk assessment been undertaken for this work according to Annex 4 of these guidelines?

θ Yes θ No

Other information:

.....

.....

.....

.....

_____

Applicant **Date**

Application number: ..... **Date received: .....**

NCBR action taken: θ **Approved** θ **Rejected** **Date action taken : .....**

θ **More information required**

_____

Chairman National Biosafety Regulation Committee

If rejected, reason why :

.....

.....

.....

.....

.....

Other comments :

.....

.....

.....

.....

ANNEX 3

QUESTIONNAIRE FOR TRIAL RELEASE OF GENETICALLY MODIFIED ORGANISMS, INCLUDING CLINICAL TRIALS.

This questionnaire is a guideline to indicate the scope of information required. Applicants need only answer the questions relevant to their proposed trial. Additional questions may be asked by the review panel during the review process.

1. BRIEF DESCRIPTION OF PROPOSED TRIAL RELEASE

2. OBJECTIVE

2.1 What is the aim of the proposed trial release of the GMO? What are the benefits of this approach compared with other possible methods, especially those not involving planned release?

2.2 Should the trial release prove to be successful, is it intended that a general release of the GMO be proposed? If so:

2.2.1 When is it proposed that the general release will take place?

2.2.2 Where is it proposed that the general release will take place?

2.2.3 By whom is it proposed that the GMO be released?

2.3 Is it intended that the GMO be marketed as a product in the Republic of Mauritius?

3. NATURE OF ORGANISM AND GENETIC MATERIAL

3.1 What is the species of the GMO to be released?

3.2 Is it known whether the unmodified form(s) have any adverse effect on:

3.2.1 humans, animals or plants

3.2.2 agricultural production

3.2.3 any other aspect of the environment

If so, furnish full details of those effects, including any applicable reports.

3.3 Furnish a description of the genetic and resultant phenotypic modifications of the GMO. This should include the origin of the inserted DNA, the procedure used to induce the genetic modification and the extent to which it has been characterised.

3.4 What is the frequency of reversion, i.e. loss of genetic modification?

3.5 How do you verify that you have the desired GMO?

3.6 What methods are to be used to test for batch to batch consistency?

3.7 On the basis of existing knowledge and contained experiments (please describe) indicate:

3.7.1 the survival rates of the GMO in the spectrum of conditions which are likely to be found in the proposed release area(s) and surrounding environment(s);

3.7.2 the capability of the GMO to disperse from the release area and the dispersal mechanisms;

3.7.3 any other relevant information.

(Where reports or publications are available for any of the above information, please furnish copies or references.)

3.8. Should the NCBR at any stage in the future need to ascertain whether the GMO is the same as the GMO specified here? How can this be done?

3.9 Provide a protocol and materials to enable detection of foreign gene(s) in surrounding microbial, plant and animal life.

4. TRIAL RELEASE: GENERAL

4.1 Full details are required as to the manner in which the trial release of the GMO is to be undertaken. The following aspects, at least, should be addressed:

4.1.1 the location of the site for the proposed release (e.g. ordnance survey map of appropriate scale with site marked)

4.1.2 description of the test site in terms of

* size
* soil
* groundwater level
* topography
* flora and fauna
* climate, especially prevailing winds
* former use
* distance from the nearest human settlements, along with the size of such settlements
* distance from surface waters
* distance from environmentally and otherwise protected areas

4.1.3 description of the environment immediately surrounding the release site

4.1.4 the barriers planned in order to segregate the experiments comprising the trial release from the surrounding environment

4.1.5 the supervision and monitoring of the trial release

4.1.6 the contingency plans to deal with extreme conditions such as storms, floods and bushfires during the course of the trial release;

4.1.7 the provisions to remove or eliminate the GMO from the test site or any other place where it may be found upon completion of the trial release and to restore the test site and any such other place to its *status quo*.

4.1.8 the arrangements for producing the GMO in quantity

4.1.9 the arrangements for transporting the GMO to the release site

4.1.10 the quantity of the GMO to be released.

4.2 What potential hazardous or deleterious effects resulting from the trial release of the GMO can be postulated?

4.2.1 Which of these effects are to be monitored and evaluated during the trial?

4.2.2 How are these effects to be monitored and evaluated during the trial?

4.2.3 If some effects are not going to be monitored, why not?

4.3 Have similar releases of similar GMOs been made before, either within or outside Mauritius? If so:

4.3.1 What were the beneficial consequences?

4.3.2 What were the adverse consequences?

4.3.3 What factors might suggest a greater, or a lesser, risk for adverse consequences for the now-proposed trial release?

(Provide references or reports to support your statements.)

4.4 Have similar requests or applications for the release of this particular GMO been made before in Mauritius or elsewhere?

4.4.1 Where was the application made?

4.4.2 What was the result?

4.5 What evidence is there concerning the transferability of the inserted genetic trait to other organisms in the release site and surrounding environment? If transferable:

4.5.1 to which organisms, and

4.5.2 at what frequencies is it transferable?

4.6 What data are available to suggest that the introduced genetic trait have no deleterious effect in the long term upon the species into which it has been introduced or allied species or any other organisms or the environment in general?

4.7 Is the GMO intended to modify the characteristics or abundance of other species? If so, what are:

4.7.1 the target species, and

4.7.2 the intended consequences?

4.8 What experimental results or information are there to show the probable consequences (positive and negative), of the release of such a modified organism, including impacts on:

4.8.1 human, animal or plant health;

4.8.2 agricultural production;

4.8.3 the target and non-target organisms in the area;

4.8.4 the general ecology, environmental quality and pollution in the area; and

4.8.5 genetic resources (e.g. susceptibility of economically important species to herbicides, pesticides, etc)?

What is your assessment of the possible effects?

4.9 Are there any unlikely but possible impacts due to the trial release? If so:

4.9.1 Would any of these have substantial impacts if they actually occurred?

4.9.2 Does the release protocol monitor these low probability risks?

4.9.3 How will these risks be monitored?

4.10 What are the consequences of the organism remaining in the environment beyond the planned period? (Cover the same range of issues as set out in 4.7 and 4.10 above.)

4.11 Has a trial release been carried out in the country of origin of the GMO?

4.11.1 If so, what was the outcome? (Provide documentation from the body controlling the release.)

4.11.2 If not, provide reasons why the trial release was not carried out.

4.12 Provide a draft copy of a press release informing the public of the trial or general release of the GMO.

5. TRIAL RELEASE: VACCINES

5.1 For human clinical trials, what arrangements are proposed to dispose of waste containing any vaccine organisms?

5.2 Will the subjects carry live vaccine organisms at the end of the trial? If so,

5.2.1 Will they be likely to disseminate the live vaccine organisms to the general population?

5.3 Based on data obtained in contained experiments (please supply), what are the effects expected when the vaccine organism interacts with target and non-target species in the test area and surrounding environment?

5.4 What is the existing evidence regarding level and duration of immunity produced in the target species?

5.5 What challenge or other tests using virulent field strains are to be carried out on vaccinated animals?

5.6 What is the likelihood that the host vaccine organism would be used in other human or animal vaccines?

5.7 Would the use of this vaccine preclude the future use of the host vaccine organism for immunisation purposes?

6. TRIAL RELEASE: MICROORGANISMS ASSOCIATED WITH PLANTS

6.1 What is the target species of plant?

6.2 Is the organism able to establish itself on/in non-target species in the surrounding environment?

6.3 To what extent does the organism survive and reproduce on/in:

6.3.1 the target plant

6.3.2 the rhizosphere of the target plant species

6.3.3 other plant species in the test site

6.3.4 and surrounding environment?

6.4 What characteristics do you intend to impart to the target plant species?

6.5 Can these characteristics be imparted to non-target plant species, especially those in the surrounding environment? If so:

6.5.1 Is the distribution and abundance of any non-target plant species likely to be affected by the acquisition of these characteristics?

6.6 In the case of soil organisms, what are the effects on organisms likely to be in the test area which are known to be beneficial to plants (e.g. *Rhizobium*, *Frankia* and *mycorrhizal* fungi)?

6.7 In the case of soil organisms, what are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?

7. TRIAL RELEASE: MICROORGANISMS ASSOCIATED WITH ANIMALS (e.g. ruminants)

7.1 What is the target species of animal?

7.2 What is known about the organism's ability to survive and reproduce?

7.3 Is the organism able to establish itself in non-target species?

7.4 What characteristics do you intend to impart to the target species of animal (e.g. ability to degrade pasture toxins)?

7.5 Can these characteristics be imparted to non-target animal species? If so:

7.5.1 Are the distribution and abundance of non-target species likely to be affected by the acquisition of these characteristics?

7.6 In the case of farmed target species, can these characteristics be imparted to feral populations of the target species? If so:

7.6.1 Are the distribution and abundance of such feral populations of the target species likely to be affected by the acquisition of these characteristics?

8. TRIAL RELEASE: MICROORGANISMS TO BE USED FOR MODIFYING THE ENVIRONMENT (e.g. biological control, pollution control)

8.1 In the case of biological control organisms, what is the biological control target species?

8.2 What direct effects do the unmodified and modified organisms have on:

8.2.1 The target species

8.2.2 Non-target species (including humans)

8.2.3 Any plant or animal species being protected from the target species?

8.3 What is known about the organism's ability to survive and reproduce in association with the target species or substance?

8.4 Can the organism establish itself in association with non-target species or substances?

8.5 Does the organism produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain?

8.6 Can the modified genetic traits be transmitted to other microorganisms which are likely to be in the environment? If so:

8.6.1 Are these likely to affect non-target species or substances?

8.7 What genetic response might be invoked in populations of the target organism as a result of the use of the modified organism (e.g. increased resistance to the modified organism)?

9. MICROORGANISMS TO BE USED IN FOOD

9.1 What relationship does the microorganism or the introduced DNA have to known human pathogens?

9.2 What is the possibility that the microorganism will produce metabolites, which may have deleterious effects?

10. DOMESTICATED OR FARM ANIMALS

10.1 Will the animals in this experiment be allowed to breed? If not:

10.1.1 Is breeding planned for later experiments? If so:

10.1.2 Are the arrangements for handling any offspring the same as those for the experimental animals? If not:

10.1.3 Please specify the arrangements.

10.2 What are the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, disease resistance, production gains, etc)?

10.3 What undesirable effects may result from the release (e.g. difficult birth, reduced fertility, increased disease prevalence, tumourgenicity and production losses, etc)?

10.4 Are any of the likely gains directly linked to losses in other characteristics of the species (e.g. an increased growth rate being accompanied by a decrease in wool or milk production)?

10.5 Can the genetic trait be transmitted by means other than normal reproduction?

10.6 Do feral populations of the species exist in Mauritius? If so:

10.6.1 Do the feral populations cause agricultural, environmental or disease-control problems? If so:

10.6.2 Specify the problems.

10.7 Has any experimental work been done on the phenotypic expression of the novel genetic material in feral genomes (e.g. cross-breeding of modified animals with captive feral animals)? If so:

10.7.1 What were the results?

10.8 What is the likelihood of the novel genetic material entering the feral gene pool (e.g. by interbreeding with modified farm animals)?

10.9 Would the entry of the novel genetic material into a feral gene pool have any effect on:

10.9.1 The distribution and abundance of the feral population

10.9.2 Its ability to cause agricultural, environmental or disease-control problems?

10.10 If no feral populations exist in Mauritius, would the imparted characteristics enhance the ability of the species to establish feral populations?

11. CROP OR PASTURE PLANTS

11.1 Will the plants in this experiment be allowed to set seed? If not:

11.1.2 Is this planned for later experiments?

11.2 Is vegetative propagation planned?

11.3 What are the desirable effects expected to result from the use of the modified plant (e.g. increased production, improved quality of product, new product, disease, insect or herbicide resistance, etc)?

11.4 What undesirable effects may result from the release (e.g. reduced fertility, increased disease prevalence, production losses, etc)?

11.5 Are any of the likely gains directly linked to losses in other characteristics of the species?

11.6 Are any members of the genus of modified plants known to be weeds?

11.7 Can the genetic trait be transmitted by means other than by normal reproduction?

11.8 Does the imparted characteristic have the potential to add or subtract substances from the soil (e.g. nitrogen)?

11.9 Has the modified plant been shown to be non-toxic to animals and humans?

11.10 Could any toxic products concentrate in the natural or human food chain?

11.11 Having regard to the pollination characteristics of the species, do wild populations of the species, or related species with which it can interbreed, exist in the vicinity of the field trial or agricultural site? If so:

11.11.1 Have any experiments been conducted to test the phenotypic expression of the novel genetic material in the wild form or the related species?

11.12 Having regard to the pollination characteristics of the plant, what is the likelihood of the novel genetic material entering a pre-existing gene pool? Provide information on the pollinators specific to the crop and the measures to be taken to prevent pollen spread to unmodified plants.

11.13 Should the imparted characteristic (e.g. insect, herbicide or disease resistance) "escape" into a wild population, would it have the potential to affect the distribution and abundance of that population?

11.14 Would there be any consequent problems with respect to:

11.14.1 Agriculture

11.14.2 The environment

11.14.3 Disease control?

11.15 If there is any possibility of 11.12 and/or 11.13 occurring, has any attempt been made to minimise the risk (e.g. by imparting male sterility)?

11.16 Could the imparted characteristic (either in the cultivated population or in a wild population) provoke a genetic response in populations of other species (e.g. increase the resistance of an insect population to an insecticide)?

ANNEX 4

GUIDELINES FOR TRIAL RELEASE OF GENETICALLY MODIFIED PLANTS

CONTENTS

1. INTRODUCTION

These guidelines are concerned with the trial releases of genetically modified (GM) plants into the environment. The majority of GM plants released into the environment to date have been common crop plants, which have been modified to alter and/or improve their agronomic performance. Such releases of GM plants are thought unlikely to present a significant risk to the environment. However, with a view to protecting the environment, such releases must initially be assessed for risks and then monitored during and after the releases.

These guidelines are specifically aimed at trial releases of plants with genomic modifications, i.e. plants with genetic material incorporated into the plant chromosome. The guidelines accordingly focus on recommendations for:

* the risk assessment process, and
* the design and development of a *monitoring programme* during such releases.

In undertaking the risk assessment, for the duration and monitoring of the trial release of the GM plants and in terminating such release, all applicants **must adhere to the**:

* requirements of the relevant sections of any **environmental protection legislation**, including any relevant regulations promulgated in terms thereof; and any other relevant legislation;
* principles and requirements of any **integrated environmental management procedure** published by the Department of the Environment.

For the purpose of these guidelines "**the environment**" means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms. This is taken to include human and animal health and safety.

2. RISK ASSESSMENT

Before any release is carried out, an identification and evaluation of risks posed to the environment by the release and of both the adverse and the positive impacts should be undertaken. A properly conducted risk assessment should reveal:

i. if there are any *hazards* posed by the GM plants to the environment;
ii. a comprehensive *description* of such hazards;
iii. *how* such hazards could be realized;
iv. the *likelihood* of the hazards being realized;
v. the *type, significance* and *magnitude* of *adverse impacts (*"*harm*") should the hazards be realized;
vi. the *likelihood* and *frequency* that *harm* will result should the hazards be realised;
vii. an overall evaluation of the risk of harm; and
viii. the type, significance and magnitude of positive impacts ("benefits") should the hazards be realized.

It is emphasized that the movement of the inserted gene may not result in harm. However, if harm may result from continued persistence in the environment of the released plant and/or introduced genes, it will be necessary to:

i. determine whether released plants persist in the environment or lead to the establishment of feral populations;
ii. determine the likelihood of transfer of introduced genes to other, non-transgenic plants; and
iii. measure any other impact of the released plant on the environment.

One of the steps of the risk assessment involves identification of the particular locale in the environment where the release is to occur. This is achieved during a pre-release survey.

The pre-release survey is an essential part of the risk assessment, providing biological and physical data appropriate to the site. Questions raised during the assessment will help to determine the rigour of the pre-release survey.

The risk assessment should identify all significant hazards and their attendant risks of occurrence, for example, killing of non-target insects by an insect-resistant plant.

Where the release involves integrated viral satellite nucleic acid or coat protein, or the transmission of viruses, virus satellite nucleic acids or virus-like particles from modified plants, then other environmental factors may have to be considered. Such releases may have specific risks, such as:

- the creation of novel types of virus by recombination between superinfecting viruses and viral nucleic acids;
- hazards, which might arise from human exposure to or consumption of the crop.

Dispersal of the plant (or its propagules) is relevant if there is a potential harm to the environment. In such cases an essential feature of the pre-release survey is to identify the potential dispersal area, and, if appropriate, within this area:

i. the habitats (biotopes);
ii. potential pollen recipients;
iii. any other relevant biological and physical factors which may have a bearing on the risk of the release.

The size of the potential dispersal area will depend on the type of plant and the scale of the proposed release: a large number of transgenic plants, and/or a large area used for the release could increase the potential for spread.

It may also be appropriate to take account of the procedures to be used for harvesting of the crops and/or termination of the release.

Estimates of the size of the dispersal area should be based both on practical and on theoretical considerations. They should include the spatial distribution (over which there is a significant probability of the spread of plant propagules occurring), and the probability of detecting spread at that distance. Factors which should be taken into account include:

i. known facts about the life history and breeding system of the plant (e.g. male sterility);
ii. the potential for seed dormancy;
iii. the role of specialised propagules (e.g. tubers, rhizomes, stolons) in dispersal and
iv. the scale of the proposed release.

It may also be relevant to consider mechanisms of pollen and seed dispersal such as by:

i. physical means (wind pollination, etc.) or
ii. *via* vectors - which may be :
    a. biological, (e.g. insects, birds and other animals), or

b. man-made (e.g. vehicles).

Spread will depend on factors such as the dispersal mechanism(s) of the species, the longevity of the pollen and seed, selection pressures on the new trait, and the invasiveness of the plant.

The presence of the same or related crops within the dispersal area may also increase the potential for spread.

Where possible, the estimate of dispersal area should be based on published data or previous releases, taking into account the scale of the proposed release. The estimate should be reviewed if new data become available.

The types of habitat (biotopes) within the dispersal area will be important considerations when estimating whether there are any risks arising from a release. For most releases, these will be managed agricultural or horticultural habitats, plus adjacent (non-cultivated) areas such as field boundaries, ditches, open vegetation, etc.

Possible future crop rotation plans and agronomic practices for the release site should be taken into account: these may affect the ability to monitor for the presence of the GM plant. If appropriate, also consider the consequences of the incorporation of a release site into rotational set-aside procedures.

If there is a risk of harm to the environment associated with the dispersal of the organism or gene concerned, then any pollen-compatible species in the dispersal area should be noted. Risk management in such cases could involve, for example, the removal of pollen-compatible species from the dispersal area. It may also be necessary to analyse the seed-bank if seed persistence is likely to be a problem.

Other factors may affect the dispersal and/or establishment of the organism, or the ability to detect and monitor these events.

Biological factors may include the presence of one or more of the following groups:

i. pollinators : availability of various insects which transfer pollen between plants will be of key importance for insect-pollinated plants;
ii. herbivores : mammals, birds or insects might move seed/pollen or other propagules, or facilitate transfer of inserted elements;
iii. antagonists : pathogens, parasites and other organisms may affect plant fitness, for example, the ability of a plant to produce its propagules or for these to mature;
iv. mutualists : nitrogen-fixing microorganisms and mycorrhizal fungi, for example, may affect plant performance.

Physical factors may include:

i. soil drainage characteristics;
ii. micro-climate, including shelter or exposure;
iii. prevailing wind direction (important for wind pollinated plants such as maize);
iv. macro-climate, and
v. site security and access.

Comparison of the results of pre-release survey and the initial risk assessment may lead to the review of the experimental design of the release.

Ultimately the risk assessment should identify all significant hazards and their attendant risks, for example, the risk (if any) created by dispersal of transgenic pollen, seed or vegetative propagules from the trial plots.

If safeguards are required to minimize the risk of harm, the isolation of the experimental plots from other hybridisable species will be an essential element of risk management.

The isolation distance should be based on the estimated dispersal area. Plant breeders isolation distances may be useful in estimating dispersal areas. However, it should be

noted that these are designed to prevent gene flow into (introgression), rather than out of, experimental plots.

Any further risk management procedures (applied to prevent possible harm) will depend on the individual release. They will be required when the risks cannot be properly assessed, due to uncertainty in the risk assessment.

Once the risks, harm and benefits have been identified and estimated as set out above, the assessment should reveal:

i. what risk management procedures ("safeguards") are required to control the risk and to prevent, minimize or manage any harm to the environment;
ii. what monitoring is required to ensure that any safeguards are effective.
iii. contingency plans of known efficacy which should be available to enable emergency control (including termination) at any stage of the release. Such plans should include any monitoring necessary to confirm that the controls are effective;
iv. the extent to which, and how, the benefits can be optimally utilized before, during and after the release.

There may be occasions however, where even a thorough risk assessment may not be able to provide definitive answers to all the questions considered, i.e. there is a high degree of uncertainty of the extent of risk as identified in the risk assessment. This may arise for example, due to lack of data relevant to the risk assessment.

Where there is such a degree of uncertainty, safeguards will be required in order to prevent any risk of harm; if the uncertainty is removed by the acquisition of appropriate data, then the need for the safeguards may be either confirmed or removed.

The safeguards applied to a release may thus be either:

i. to control an identified risk and to manage any harm to the environment;

or

ii. to address any degree of uncertainty of the extent of environmental risk.

3. MONITORING

Types of monitoring

There are two different types of monitoring which may be associated with a release of a GM plant. These are monitoring which may be required by the Government Department of Agriculture or any other government department; and voluntary monitoring. Each has its own distinct objectives:

Monitoring required by government is undertaken to confirm any assumptions made in the risk assessment procedures. It may also be required to ensure that products of plants, for example, potato tubers or maize cobs, do not enter the human or animal food chains where approval has not been granted by government acting on the advice of the NCBR. The precise design of the monitoring programme will thus depend on the details of the risk assessment (see Appendix B).

By contrast, voluntary monitoring is undertaken by the applicants in order to provide further information for their own purposes. Such purposes might include:

i. the further development of a programme of release proposals, for example, by accumulation of data on survival of the plant in the environment;
ii. obtaining data in order to address any uncertainty in the risk assessment, and thus allow relaxation of unnecessary safeguards in future releases.

All subsequent references to monitoring in these guidelines should be interpreted as monitoring required by government. This does not preclude the adoption of part or all of the guidelines for any other purpose.

It should be noted however that the above guidance does not alter the requirement to comply with the general duty of care to prevent any harm to the environment which may arise as a result of a release (refer to any local environmental protection legislation).

Most releases which do not pose effectively zero risks to the environment will require appropriate monitoring to ensure that no harm results from the release.

Monitoring during release

The primary purpose of monitoring during the release is to assess the practical efficacy of adopted safeguards.

The risk assessment should have identified the safeguards (and as a consequence, the management procedures) required to reduce any risks to an acceptable level. The frequency and extent of monitoring during the release should be adequate to ensure that any safeguards applied are effective.

Monitoring can, where appropriate, be carried out during the course of site visits made for other purposes, such as ensuring that there is satisfactory agronomic management of the crop. It is essential, however, that sampling regimes are realistic.

It is possible that, despite a thorough risk assessment, unforeseen events will still occur. The monitoring regime may or may not be able to detect whether this is the case. If an unforeseen effect is detected, its significance should be assessed. If there is a significant adverse impact on the environment, pre-planned emergency control will be required.

Monitoring post-release

Post-release monitoring is carried out after the release has been completed and the plants harvested. After harvest, the released organism and/or the inserted gene may or may not be present in the release area as residual ungerminated seeds, shed seeds (from the

released plants, or from pollen-compatible species), or other plant material capable of regeneration. The risk assessment should have identified the most likely possibilities. The monitoring will vary with the type of plant used in the release, the novel trait(s) expressed, and the conditions of the release experiment.

The requirement for post-release monitoring depends on the possibility that continued presence of the plant (or the inserted gene, if transferred into new plants) after harvest could cause harm. If the risk assessment identifies the possibility, the monitoring programme should be designed to:

i. confirm that the experiment has been terminated, (the released organism is absent after the end of the trial);

and, if required,

ii. monitor for any further dispersal of the plant, its propagules, pollen or the inserted gene, indicating any necessary control measures.

After a release has been terminated, applicants have a continuing obligation to comply with the general duty of care to prevent any harm to the environment.

Appendix A to these guidelines contains general guidelines for a typical release, and includes hypothetical worked examples of releases.

4. PROGRAMMES OF WORK

The release might form part of a series of experiments in a single programme of work submitted for approval. In such cases, the proposed monitoring programme should reflect any changes in the safeguards, which the applicant expects to apply to different experiments during the programme.

Any uncertainties in regard to risks or other elements of the work programme are best addressed at an early stage in the programme of work. This is likely to have the effect that many safeguards can quickly be relaxed. Some risks may be scale-dependent (for

example, effective dispersal area), and may require scale-dependent safeguards such as increased isolation distance. If risks greater than “low” or “effectively zero” remain, the need for safeguards may increase.

A carefully designed monitoring scheme should provide data to support a further release and/or commercialization by demonstrating the safety of the genetically modified plants in the environment.

Thus, by the time a project neared a further release or commercialisation, the risks would have been confirmed as low or negligible, even if the hazard is not zero.

5. APPENDIX A: RELEASES IN PRACTICE

Part One:

(i) General Guidelines for a Typical Release

This general outline of a typical release is particularly relevant to releases in the managed environments characteristic of agriculture and horticulture.

The monitoring methods will vary from release to release depending primarily upon the assessed risks and the management of an individual release.

Part one of this Appendix sets out general guidelines for a typical release. By contrast, Part two presents hypothetical worked examples of releases with differing hazard potential, and therefore differing requirements indicated by the risk assessment.

(ii) Risk assessment and pre-release survey

The first step of assessment is to identify any hazards associated with the proposed release, for example:

i. an insect resistant plant harming non-target organisms such as bees or leading to a population of insects with resistance to an insecticide; or
ii. the formation of a herbicide-tolerant weed population by introgression and subsequent dispersal of the inserted (herbicide tolerance) character(s) in wild or feral relatives.

Once any hazards and any methods of realization are identified, a qualitative assessment must be made of the magnitude of possible harm, and the likelihood that these hazards may result in damage to the environment. The likelihood may be “high”, “medium”, “low” or “negligible” and the risk of damage “high”, “medium”, “low” or “effectively zero” .

Any identified hazards that may arise from the release should be addressed. These are predominantly related to the risk that the GM plant can cause harm, for example that availability of potential recipients might cause damage by allowing introgression and subsequent dispersal of the inserted character(s) - such as promoting the spread of a population of insect resistant plants.

A key element of the risk assessment is to examine the environment where the release is to occur to identify which (if any) of the hazards are likely to be realised. The pre-release survey is an essential part of this examination.

The extent and depth of the survey should aim to provide enough data to satisfy all the concerns that are addressed in the risk assessment. Where this is not the case, risk management safeguards will be required, whether the risk is high, medium or uncertain.

If dispersal is a cause for concern, then isolation of the release plot from compatible crops or species should be considered. Isolation could be physical - i.e. by distance, or biological, for example by avoiding (or preventing) the genetically modified plant flowering simultaneously with compatible species.

Other factors which, may need to be considered include:

i. Species: The plant released; volunteers and feral populations; related crops; compatible wild relatives. Visits by pollinators or other fauna may also be relevant.

ii. Area: The release plot and the designated dispersal area around it. If relevant, include all plants that can be expected to be recipients of pollen.

The estimated dispersal area might include nearby fields or plots of the plant to be released. If appropriate, it may also include nearby gardens. For example:

i. for wind-pollinated plants, the potential dispersal area for pollen may depend on the size of the release plot, i.e. the number of plants contributing to the pool of pollen;
ii. for insect-pollinated plants, the availability of pollinators (e.g. honey bees) may be relevant.

Surrounding a release by non-transgenic (trap) plants could help ensure that any pollen from the transgenic plants is trapped and does not travel great distances.

If there is a high population of receptive plants in the area surrounding the trial site (including crops grown for seed and wild relatives), this is likely to affect the dispersal area.

It remains possible that the pre-release survey does not provide sufficient data to address any uncertainty identified by the risk assessment. In such cases, management may be required to ensure that harm does not arise. Monitoring would be required to ensure that any management procedures are effective.

For example, there may be a degree of uncertainty about the persistence and spread of the GM plant in the environment.

i. If spread (but not persistence) was judged likely to result in harm to human health or the environment, management safeguards would be needed to prevent spread occurring. Monitoring would thus need to concentrate on showing that such spread had not occurred.

ii. In addition, voluntary monitoring undertaken during the release stage might address any uncertainty regarding the survival of the GM plant. Such monitoring could concentrate on collecting data on survival of the GM plant on the release plot.

(iii) Monitoring during release

Monitoring during release aims to assess the efficacy of any risk management safeguards applied to the release. This should detect whether there is any risk of harm, caused for example by introgression with potential recipients.

For example, if the presence of available pollen recipients within the dispersal area is assessed to be a risk, their number should be kept below the level at which harm might occur.

The frequency of monitoring should take account of the growth rate and stage of maturity of relevant plants.

Monitoring data obtained during and after the release from such voluntary experiments to test survival could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal, and consequently, could allow risk management safeguards to be reduced.

(iv) Post-release monitoring

Where the risk assessment identifies that continued presence of the released GM plant or gene presents a risk of harm, post-release monitoring will need to concentrate on confirming the removal of the released plants.

Where appropriate, monitoring should concentrate on detecting and controlling any volunteer plants arising from the release.

In some cases there may be uncertainty regarding the risk of harm from continued presence of an organism, especially over the long term. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved.

Factors to be taken into account include:

i. seasonal effects, such as flowering and likely germination times, and
ii. post-trial treatment of the release site.
iii. Longevity of seed or tubers in soil may be particularly relevant for some releases. Post-release monitoring of a trial site may give basic data on, for example, the longevity of propagules.

In general, where flowering creates a risk of harm, e.g. by gene spread, monitoring visits should be planned to coincide with potential flowering times of volunteer plants. If volunteer plants do occur and subsequently flower, the dispersal area should be monitored for potential pollen recipients, or their offspring. Any such plants found should be destroyed.

Monitoring information could indicate how long transgenic plants could continue to appear, (and hence indicate the likely duration of post-release monitoring, see below).

Estimates of survival times for volunteers should take into account the effects of the volunteer control practices applied to the site.

In all cases, the extent and duration of the monitoring should be sufficient to prevent or minimize damage to the environment over the longer term as a consequence of the release.

Part Two:

(i) Examples of releases

This appendix gives examples of two hypothetical releases:

i. potato with modifications to carbohydrate metabolism, and
ii. oil-seed rape with inserted genes for a pharmaceutical protein.

They must not be regarded as definitive; real releases which appear to be similar may require different risk management elements, depending on the risk assessment. This may be affected by the local environment of the release. Procedures for other types of release may vary markedly.

Identification of hazards:

Release a) Potato

- Potatoes altered in carbohydrate metabolism. Not considered to be a hazard to human health; low hazard to the environment, genetic modification does not affect tuber survival or weediness. The magnitude of potential harm to the environment is negligible. Risk of harm, effectively zero.
- Management safeguards required :

(i) Prevention of entry of GM potatoes into the food chain.

Identification of hazards:

Release b) “pharmaceutical” oil-seed rape.

- Genes known NOT to be expressed in pollen, but are expressed in seeds and leaves. Protein known to be immunogenic.
- Identified hazards:
  (i) considered to be a hazard to human or animal health if exposure to large amounts of the protein occurs;
  (ii) possible spread of the gene to weedy relatives. The magnitude and significance of potential harm to the environment is moderate. The likelihood of harmful effects being realized depends on (a) exposure to GM plant material, and (b) availability of pollen recipients in dispersal area and numbers of transgenic plants remaining in the release area. Overall risk of harm, medium.
- Management safeguards required:
  (i) Prevention of exposure to growing plants - site security and control of access, netting of crop. Control essential during and after harvest (including seed and straw). Other factors: security of harvested seed; prevention of dispersal of seed during harvest, confirmation of elimination of released plants after harvest.
  (ii) Control of potential pollen recipients in the dispersal area.

(ii) Pre-release survey

A. Dispersal area

For release (a), the dispersal area might be within 10 m of the plot boundary.

For release (b), both of the identified hazards would need to be addressed.

For (i) - hazard to human or animal health - the pre-release survey should enable confirmation of the security of the proposed release site.

For (ii) - possible spread of the gene - the dispersal area could be up to 100 m or more away from the plot boundary, depending on the scale of release. A large block

of flowering rape could allow pollen dispersal by wind over a large area, and also be more attractive to pollinating insects.

B. Relevant species

For release (a), the pre-release survey should concentrate on the presence of other (mainly volunteer) potatoes within the potential dispersal area. The likely presence of adjacent potato crops or other trials within or near to the dispersal area would be particularly relevant.

For release (b), species survey should concentrate on (i) the presence of possible predators which might graze on the crop; and (ii) on the presence of compatible *Brassicaceae* (such as rape crops, grown for seed, volunteer and feral rape, other *Brassica* spp., etc.) within the potential dispersal area. It is considered unlikely that distance relatives would act as effective pollen recipients, even though they may overlap in flowering with rape. Some other Brassicas may be effective pollen recipients.

(iii) Monitoring during release

Monitoring should concentrate on ascertaining and demonstrating that the safeguards put into place are effective. Monitoring should concentrate on the release plot, plus the dispersal area identified in the pre-release survey, and relevant species within the area.
For release (a), only consideration of other potatoes (mainly volunteers and groundkeepers) would be relevant. If the GM potato berries freely, this may create a potential problem of high numbers of transgenic seed in the area of the plot. If other potatoes are present in the dispersal area, cross-pollination could occur, possibly giving rise to transgenic volunteers with different varietal characteristics from the GM parent plant (see below).

For release (b), (oil seed rape) - relevant species to be considered are as identified in the pre-release survey. Particular attention would need to be paid to possible effects on

grazing animals. Potential pollen recipients would be compatible species likely to overlap in flowering with the transgenic rape. Monitoring would also need to confirm that access to the site - either by people or potential grazing animals - is properly controlled.

(iv) Post-release monitoring

Example (a):

Post-release monitoring would not be required if there is negligible potential to cause harm. It should, however be noted that:

i. volunteer potatoes have been shown to survive in the managed agricultural environment for one or more years, despite the routine application of selective herbicides during crop rotations;

ii. Genetically modified potato tubers are not at present cleared for entry into the human or animal food chains. Management safeguards are required to prevent this happening. These safeguards would include sufficient post-release monitoring to ensure that the risk of tubers from volunteer transgenic potatoes entering the human or animal food chains was negligible.

Example (b):

The assessment indicates that continued presence of “pharmaceutical” rape poses a risk of harm to the environment. In addition, if sufficient numbers survive, they pose a risk of spread of the gene to compatible species and thereby increase the potential for harm.

Monitoring in such cases should therefore concentrate on the efficacy of the management safeguards put in place during and after the harvest of the crop.

i. Procedures employed during and after harvest would need to be carefully controlled and monitored: for example, harvest and collection of seed; transport to a secure store; cleaning of equipment used for harvesting; destruction of residual plant

material by ploughing in (or alternate techniques such as desiccation and burning, or collection for autoclaving). See also below.

ii. In the identified dispersal area, post-release monitoring would concentrate on the presence of:

a. volunteers arising from ungerminated seed on the plot. These may be either from the original sowing, or from seed shed prior to or during harvest; and on

b. possible descendants of compatible plants fertilised by pollen from the transgenic plants.

It is known that ungerminated rapeseed can survive in the soil for several years. As a consequence, risk management procedures should include the avoidance of any procedures that could lead to deep burial of seed on or around the plot.

6. APPENDIX B: MONITORING METHODS

This appendix summarizes some of the monitoring methods, which can be used and amplifies some of the points made in the main text to these guidelines.

Many methods can be used to monitor plants released into the field. These vary from simple, traditional methods to the most modern and complex.

The choice of monitoring methods will depend upon the purpose for which the monitoring is done. If the monitoring is done to demonstrate that there is zero or minimal risk of harm to the environment during the execution of the release experiment, then methods of appropriate scope and sensitivity should be used.

The validity of any one method, or combination of methods, depends partially upon the ease and accuracy of identification of the introduced plants, and their propagules or pollen.

Identification should ideally be by means of easily recognizable phenotypic or genetic characteristics.

The choice of monitoring method(s) should be appropriate to the degree of sensitivity of detection required: monitoring methods should be accurate, reliable and operable. There should be a balance between sensitivity and practicality.

Ideally, marker characteristics that are cheap and easy to identify would be the most suitable for assessing the spread of the organism or introgression of genetic markers.

Direct observation of the trial site forms the basis of all monitoring methods. Regular and methodical inspection of the site, and data recording will often provide much useful monitoring information. The frequency of inspection of the site before, during and after the completion (termination) of the experiment will depend on the estimated risk.

For monitoring by direction observation, the released plant should, where possible, be easily and unequivocally identifiable. Any identifying character should be stably inherited and expressed, and clearly different from the equivalent characters displayed by local crops and feral populations of the same species.

Sampling of the atmosphere (for pollen), or of soil (for seeds or vegetative organs) can be used to monitor dispersal. Physical sampling methods are most useful if the pollen or seed are morphologically quite uniform, and distinct from those produced by non-transgenic varieties. For example, a marker that produced a distinctive seed coat colour could be easily detectable.

There may be a risk that one or more of the inserted genes can spread to either nearby crop plants, volunteers, or pollen-compatible weed relatives. If so, the choice of monitoring method should enable detection of events of this type.

Detection of the presence of the inserted gene in a recipient plant may be by means of various biological methods.

One such method may assess the presence of a gene by examining potential recipients for signs of the presence of the gene, for example, herbicide tolerance.

An example of another method would be if possibly unrelated (i.e. non-transgenic) morphological characteristics of the transgenic plant (such as flower colour, leaf morphology, seed shape and colour) are transmitted to recipients. Such events can be interpreted to presume flow of the inserted gene.

Trap plants (of the same species as the plant to be released) can be used to detect the spread of pollen from the experimental plants. Transfer can be inferred from analysis of seeds or progeny of the trap plants. Male-sterile varieties may be particularly useful for this purpose.

Other characteristics that may be suitable for monitoring purposes include pest susceptibility, biochemical characteristics or end products of the gene product (for example, allozyme analysis, carbohydrate analysis), and DNA characteristics, including RFLP mapping and PCR* amplification.

* The polymerase chain reaction (PCR) process for amplifying nucleic acid. Patents assigned to Hoffmann LaRoche.

ANNEX 5

DETERMINING CROP ISOLATION DISTANCES FOR TRIALS WITH GENETICALLY MODIFIED CROPS

Crop isolation distances used for production of certified seed can be used as a guide to setting isolation distances for gene containment in field trials with GM crops. If in doubt, proceed with caution and extend the distance until local data are available to substantiate smaller distances.

RECOMMENDED CROP ISOLATION DISTANCES FOR PRODUCTION OF CERTIFIED SEED

(Souce: Doyle, JJ, 1996, Enabling the safe use of biotechnology: principles and practice. ESD Monograph Series No. 10, The World Bank, Washington, DC).

Crop	*Isolation distance (meters)*	*Crop*	*Isolation distance (meters)*
1. Maize	500	16. Courgettes (zucchini)	1 500
2. Beans	150	17. Watermelons	1 200
3. Irish potatoes	50	18. Lettuce	30
4. Wheat	150	19. Swiss chard	1 000
5. Rice	150	20. Radishes	1 000
6. Peas	100	21. Celery	500
7. Pigeon peas	1 000	22. Beet roots	500
8. Carrots	1 600	23. Cabbage	1 600
9. Onions	1 000	24. Kale	1 600
10. Spinach	500	25. Cauliflower	1 600
11. Tomatoes	50	26. Broccoli	1 600
12. Brinjal (eggplant)	50	27. Brussels sprouts	1 600
13. Cucumbers	1 500	28. Turnips	500
14. Melons	1 200	29. Chillies	1 000
15. Okra	500	30. Barley	150

ANNEX 6

QUESTIONNAIRE FOR GENERAL RELEASE OF GENETICALLY MODIFIED PLANTS

1. BRIEF DESCRIPTION OF THE GENETICALLY MODIFIED PLANT

2. GENERAL RELEASE

Detail why general release is required, whether the GMO will be marketed and how distribution will occur.

3. DESCRIPTION OF ANY PRODUCT DERIVED FROM THE PLANT

Detail the level of foreign protein and DNA in the plant and in products to be derived from the plant.

4. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

List the field trials carried out in Mauritius and in other countries. Summarize data that has been collected during these trials.

5. POLLEN SPREAD

Summarize the pollination biology of the plant paying special attention to local data.

6. SEED DISPERSAL

Summarize what is known about seed set and seed dispersal in local conditions.

7. VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS

Summarize what is known about vegetative spread of the plant under local conditions.

8. FOREIGN GENES AND GENE PRODUCTS

Provide diagrams of the foreign gene constructs, the method of transformation and the expression levels of foreign genes in the plant. List the foreign genes and control elements, indicating their origin and their role in the GMO or in its development.

9. RESISTANCE

Detail any resistance that may develop in the environment as a result of the GMO and methods to monitor and manage the risk.

10. HUMAN AND ANIMAL HEALTH

Detail data collected to identify the safety of ***all*** foreign gene products to human and animal consumers in the food chain. Address the levels of foreign protein in food and feed products derived from the GMO and all tests to determine the allergenicity of food and feed derived from the GMO.

11. ENVIRONMENTAL IMPACT AND PROTECTION

Detail any positive and negative impact the GMO may have on the local environment. Indicate the likelihood of the impact happening and whether monitoring is necessary. If applicable, indicate any risk management procedures that will be implemented to address potential negative impact.

12. SOCIO-ECONOMIC IMPACT

Detail any positive and negative socio-economic impact that the GMO is likely to have in Mauritius. Justify your response with relevant data.

13. WASTE DISPOSAL

Indicate what waste will be produced with the release of the GMO and how this waste will be managed.

ANNEX 7

GUIDANCE FROM THE WORLD BANK ON THE SAFE RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT

(Source: Doyle, JJ, 1996, Enabling the Safe use of biotechnology: Principles and Practice. ESD Monograph Series No. 10, The World Bank, Washington, DC.)

FOOD AND FEED ASSESSMENT

1. Food Safety Issues

The appropriate authorities will regulate the final products of biotechnology before they are released for human consumption or animal feed. There are, however, important food safety issues that pertain to the host plant, donor organisms, and new substances that will be introduced into the food that developers should address. Potential new substances considered in this safety assessment are proteins, carbohydrates, fats, and oils because these are the substances that will be introduced or modified in the first plant varieties developed by recombinant DNA (rDNA) techniques.

The principal investigators should consider the food safety issues mentioned in the following sections.

Host Plant

- Potential adverse effects of an altered metabolic pathway in the plant.
- The inheritance of the introduced genetic material as a single mendelian trait.
- Genetic stability of the new plant variety.
- Changes in the concentrations or bioavailalability of important nutrients for which a food is widely consumed.
- Monitor toxicant concentrations to ensure they are within an acceptable range.

Donor

- History and derivation of molecular constructs.
- Activities of any introduced regulatory sequences.
- Potential for inadvertently introducing undesirable substances (for example, as a result of the expression of extraneous open reading frames)
- Donor-derived toxicants that could potentially end up in food and feed products.

Proteins

- Safe history of use in food
- Similarity to proteins used as food components
- Toxicity, allergenicity and dietary exposure
- In the case of enzymes, ascertain that they are not involved in production of toxic substances.

Carbohydrates

- Elevated concentrations of an indigestible carbohydrate that normally occurs at low concentrations
- Conversions of normally digestible carbohydrate to an indigestible form.

Fats and Oils

- Presence of fatty acids of known toxicity (for example, erucic acid)
- Presence of fatty acids with chain lengths greater than C_{22}
- Alterations in the ratio of saturated to unsaturated fatty acids.

2. Genetically Engineered Pesticides

To ensure clarity, a pesticide is legally defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant or desiccant. Pesticides can be classified as either chemical pesticides or biological pesticides. Biological pesticides are subdivided into three groups: microbial pesticides, biochemical pesticides, and transgenic plant pesticides.

Pesticide regulation falls under the jurisdiction of the pest control products authorities who register new pesticides. The following guidelines are meant to assist developers of potential data requirements for toxicological evaluation of genetically engineered plant pesticides.

Transgenic Plant Pesticides

The following information will be required when registering new pesticides:

SOURCES OF PESTICIDAL GENETIC MATERIAL

- Identification of the donor organism(s)
- Identifications of the pesticidal genetic material.

PESTICIDE PRODUCTS

- Identification and characterization of the protein or peptides encoded by the inserted genetic material
- Identification and characterization of non-protein active pesticidal ingredients resulting directly from the introduction of the genetic material.

VECTOR SYSTEM

- A description of the vectors
- The identity of the organisms used for cloning of the vectors
- A description of methodologies used for assembling all vectors.

RECIPIENT PLANT

- Identity and taxonomy of recipient plant to cultivar, line or variety
- Life cycle, mode of reproduction, and dissemination
- Description of methods that are used to deliver the gene sequence(s) to the recipient plant.

GENE EXPRESSION IN THE PLANT

- Whether the inserted genes are expressed constitutively or if the genes are inducible
- Localization and expression in plant parts
- Estimation of the number of gene copies
- Gene expression during the plant's life cycle.

PRODUCTS ANALYSIS AND RESIDUE CHEMISTRY

- Mode of action of the pesticidal product
- Concentration of pesticidal product in the plant.

PHYSICAL AND CHEMICAL PROPERTIES

- Information required in the event that genetic manipulation is for the purpose of producing de novo non-protein products.

MAMMALIAN TOXICOLOGICAL REQUIREMENTS (PROTEIN PRODUCTS ONLY)

- *Food products*. Data on oral studies (acute, subchronic, chronic feeding, or other studies) are required as are reporting of observed dermal toxicology or irritation effects and pulmonary studies.
- *Nonfood*. Report any observed dermal toxicity or irritation effects; pulmonary studies in case of volatile pesticide products.

In general, for well-characterized proteins introduced by the rDNA techniques that do not exhibit unusual functions, safety testing will not be necessary. However, for certain groups of proteins known to be toxic to vertebrates – for example, bacterial and animal toxins, hemaglutinins, enzyme inhibitors, vitamin-binding proteins (avidin), vitamin-destroying proteins, enzymes that release toxic compounds, and selenium-containing proteins – testing is necessary to ensure safety.

Microbial Pesticides

The following information will be required:

- The potential for toxicity of the microbial ingredient together with the fermentation medium in laboratory animals
- Taxonomic characterization of the active microbial ingredient
- A description of the manufacturing (growth) process, including measures taken to minimize the presence of contaminating organisms
- Toxicological data from subcutaneous injection of rodents in the case *B. thuringiensis* products.

Under the pesticide act the pest control products authorities can exempt plant pesticides from the requirement of a tolerance if such tolerance is not necessary to protect public health. In the future, as more knowledge is obtained, the authorities may consider exempting some plant pesticides under the act.

ANNEX 8

GUIDANCE FROM THE WORLD BANK ON SAFE TRANSPORT OF GENETICALLY MODIFIED ORGANISMS

(Source: Doyle, JJ, 1996, Enabling the Safe Use of Biotechnology: Principles and Practice. ESD Monograph Series No. 10, The World Bank, Washington, DC).

1. Transport of microorganisms with Novel Traits

With regard to transportation arrangements for microorganisms with novel traits, measures must be taken to prevent dispersal into the environment. A number of recommendations are:

- Ensure that the receiving country has biosafety structures to oversee GMO work
- Where possible, transfer DNA rather than the living organism
- Package a living sample in at least three layers of air- and liquid-tight containers
- Ensure that at least one layer is puncture-resistant
- Add a disinfectant to one or more of the outer layers
- Label the package clearly and address to a trained person
- Open in a biological safety cabinet.

2. Transport of animals with Novel Traits

With regard to transportation arrangements for animals with novel traits, three principles must be paramount:

- The need to prevent the animals from escaping, especially with regard to reasonable contigencies such as accidents en route, so that they will not interbreed with feral populations.
- The need to ensure that they are properly identified and duly arrive at the intended destination and to ensure that a competent biologist with some experience in handling animals with novel traits takes delivery of them.
- Accounting procedures should be in place to ensure that the same number of animals sent is also delivered.

The national or institutional biosafety committee may institute whatever procedures or rules it considers appropriate to meet these conditions. It may be necessary for the biosafety committee to inspect the arrangements to satisfy itself that the above principles are adhered to and that any additional conditions that the biosafety committee considers appropriate are met.

It may be helpful to arrange for the purchase of animal boxes that are approved by international airlines for the transport of specific pathogen-free animals. These may be adapted for specific needs.

3. Transport of Insects with Novel Traits and Their Pathogens

With regard to transportation arrangements for insects with novel traits (including live insects and insect cell cultures infected with pathogens manipulated to contain novel traits):

- The insects should be in a clearly labelled, unbreakable holding container that is adequately sealed to prevent escape.
- The holding vessel should be placed in another, clearly labelled and well-sealed container for transport.
- Insects should be transferred from the holding vessel to a new container immediately upon arrival at their destination.
- All transport materials should be decontaminated by autoclaving after transfer of transported insects into new containers.
- Accounting procedures should be in place to ensure that the same number of containers sent is also delivered.
- Requirements are the same for insect pathogens with novel traits as for human and vertebrate pathogens.

4. Transport of Plants with Novel Traits

With regard to transportation arrangements for plants with novel traits:

- Vegetative plant material from plants with novel traits to be transported within and between institutions should be carried in a primary container (for example, a plastic

bag for cuttings and an envelope for seeds) that is packed in a secondary, unbreakable container.

- The outer container should be labelled to indicate that it contains propagative material from plants with novel traits, and the label should include the telephone number of a contact person, should the package be lost or damaged. Labels on seed packets should include the number of seeds being transported.
- Whole plants should be netted and deflowered before transport. They may be transported in pots, contained in boxes or crates.
- Plants should not be transported once they have set seed.
- Accounting procedures should be in place to ensure that the same number of plants or containers sent is also delivered.

ANNEX 9

USEFUL WEB SITES FOR INFORMATION ON BIOSAFTEY AND BIOTECHNOLOGY

Search on these acronyms for useful biosafety and biotechnology information:

UNIDO/BINAS - biosafety for developing countries

ACGM UK biosafety authority

IFIC - international food information service based in the USA

USDA/APHIS - US department of agriculture, animal and plant health inspection service

FDA - US food and drug administration

EPA - US Environmental protection agency

AgCanada - Canadian biosafety and agricultural biotechnology

Greenpeace - GM watchdog

World Bank ESD - biotechnology and environmentally sustainable development

UNEP - biosafety in developing countries

GEMAC - Australian biosafety

ANNEX 10

RESOURCE MATERIAL USED IN DEVELOPING THE NATIONAL GUIDELINES

Mauritius: Draft - Genetically Modified Organisms Bill for Republic of Mauritius, April 1997 (Proposed by Mauritius Sugar Industry Research Institute to Ministry of Agriculture, Food Technology and Natural Resources).

Biotechnology and Biosafety at MSIRI - Internal Guidelines, Mauritius Sugar Industry Research Institute, Mauritius, September 1996.

World Bank Report: Enabling the Safe Use of Biotechnology. Principles and Practice. ESD Monograph Series No. 10, The World Bank, Washington, DC, 1996.

UNEP International Technical Guidelines for Safety in Biotechnology.

Bulgaria, National Biosafety Framework. UNEP and Institute of Genetic Engineering.

Cameroon, Draft Bill on Safety in Biotechnology in Cameroon, Ministry of the Environment and Forestry.

Namibia, Technical Guidelines for Work with Genetically Modified Organisms in Namibia. Namibian Biotechnology Alliance.

Zimbabwe: Biosafety Guidelines.

South Africa: SAGENE Guidelines on the Safe Introduction of Genetically Modified Organisms. Includes new Advisory Committee on Genetic Modification (ACGM) guidelines for contained use.

ACKNOWLEDGEMENTS

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Annex B

NON-SUGAR SECTOR STRATEGIC PLAN

EXECUTIVE SUMMARY

1.1 With a view to achieving the objective of a 'modern agriculture', a reorientation of the non-sugar agricultural sector is imperative. The main component of this reorientation strategy is to promote a transition from the traditional practices, towards a more sophisticated, technology-based approach to agriculture with focus on attaining a certain degree of self-sufficiency, meeting quality exigencies, developing the local agro-processing industry, promoting entrepreneurship, optimising export opportunities, conforming to international norms governing food safety and maximising on the potential benefits of regionalisation.

1.2 The need for this reorientation process in agriculture has become essential at this juncture whereby Government is actively promoting the adoption of new technology in all economic sectors. This rethinking strategy for agriculture has also become critical owing to a number of constraining factors, which altogether have proven that the conventional agricultural practices are too obsolete to sustain in the present highly competitive environment. The inherent constraints such as high vulnerability to climatic offsets, depleting cultivable land resources in favour of more remunerative economic activities, and high cost of labour and agricultural inputs have always posed severe impediments to agricultural development in Mauritius. Furthermore, the increasing internal and external challenges, with mounting competition at the market front, increasing food demand, higher customer exigencies, more stringent regulations governing food issues and trade in agriculture and enhanced pressure to attain a certain level of food security on the global scene, have altogether called for a review of the whole agricultural sector in Mauritius.

1.3 Following the implementation of the Strategic Plan for the Sugar Sector, the inception of a 'Strategic Plan for the Non-Sugar Sector' comes to lay the foundation for restructuring all non-sugar sectors within agriculture. In fact, in light of the difficulties being encountered within the sugar sector, the Mauritian non-sugar sector will be called upon to assume an even more important role in the agricultural economy.

1.4 This plan has been conceived as a comprehensive document elaborating on all the measures to be adopted to bring about the forecasted transition towards a modern agriculture, with a view to rendering the sector more economically sustainable and viable.

The plan for the non-sugar sector has the following main objectives:

(i) addressing the main direct constraints within the sector;
(ii) optimising productivity by promoting transfer of technology;
(iii) enhancing quality and providing the appropriate framework through the setting up of a *Food Technology Laboratory* to ensure that all agricultural activities are done in strict conformity with international norms governing food safety and quality;
(iv) attaining a certain degree of self-sufficiency in sectors in which Mauritius is not already self-sufficient;
(v) diminishing imports in the sector, in view of the high Food Import Bill;
(vi) optimising utilisation of resources by fostering a concept of an organised agriculture;
(vii) reorganising marketing at the local and international market levels, with a view to optimising profitability to stakeholders, based on up-to-date market information through the setting up of a Market Information System that will be operated by a *Market Intelligence Unit;*
(vii) setting-up of a clustering framework to foster more productive interaction between agricultural stakeholders and a better public/private sector

participation in achieving common objectives and accordingly, establishing the necessary mechanism and incentives;

(viii) developing potential export avenues, with emphasis on promotion of value-addition to primary products and the promulgation of the local agro-processing industry;

(ix) strengthening infrastructural and human capacity to enhance research and development support to agriculture with *inter alia*, the setting up of the *Mauritius Agricultural Biotechnology Institute*;

(x) promoting capacity building and training of agricultural stakeholders in new technology with a view to encouraging entrepreneurship;

(xi) strengthening of administrative, infrastructural and legislative frameworks to achieve the targeted objective of a 'modern agriculture' whilst ensuring biosafety;

(xii) promoting conservation of natural biodiversity and fostering sustainable utilisation of natural resources;

(xiii) ensuring a better, demand-driven policy orientation by Government, to optimise utilisation of resources in addressing the needs of the agricultural community and meeting national priorities; and,

(xiv) revamping agriculture in *Rodrigues.*

1.5 It is an inevitable fact that Mauritius is confronted to several constraints that have posed severe impediments to agricultural development. Other than climatic constraints, which has often led to substantial losses to producers, there are many other emerging issues brought about by rapid development in other key economic sectors, which are further limiting the scope of agricultural progress. Nevertheless, despite these constraints, Mauritius is more or less self-sufficient in a number of foodcrops. However, agriculture still holds a lot of promises for Mauritius and it can grow into an even more active contributor to the country's economy. There is enormous scope for development within the limited

resources provided the right strategy is devised that would allow optimal benefits to be derived out of the numerous advantages that the country is endowed with.

1.6 In the first place, the strategic plan proposes to judiciously address the most pressing problems faced by the agricultural community. Some of the major measures are discussed below:

(i) Census for Agriculture

In view of major role of agriculture in the economy, it is proposed that the Central Statistics Office *conducts a census for the whole agricultural sector*. This census would greatly assist the Central Statistics Office in the preparation of the economic accounts for the sector, which it is called to do, and which has so far been based on *ad hoc* production cost surveys of planters and on technical coefficients provided by the Ministry and related parastatals. Data collected from the census would also provide more accurate and reliable benchmark data that would assist in the reviewing and readjustment of policies and national plans with a view to channeling resources and targeting priority areas in a more productive manner. This would also help policy decision makers in the productive planning of future development in the sector. It is also proposed to carry out a similar study in Rodrigues.

This census would thus provide a solid database on agriculture which was so far lacking and posed a major hindrance in the formulation of policies.

(ii) Planning of Production

The plan also fosters the concept of an organised production system. It is evident that production in Mauritius is self-regulated, and not based on any scientific data. Production in Mauritius at the planters level has been done mostly based on experience of planters accrued over the years, which somehow provide useful indications. However, a good

reflection of climatic, seasonal, geographical and market indexes is essential in the optimisation of agricultural production, which has however so far not been taken into consideration while planning production. The vision of a planned production within agriculture forms the basis of the proposed reform at the planters' level. The Ministry is accordingly proposing to set up the necessary logistics, which will be centred around a strong informative service coupled with a strengthened extension support, to optimise the accessibility of up-to-date, timely and accurate data to planters. To this end, the proposed Agricultural Information System will play a primordial role in reorganising agriculture by serving as a national database for the horticultural sector. The Land Data Bank which is proposed to be set up will also assist in the judicious planning and optimal utilisation of agricultural land resources.

(iii) Irrigation

Irrigation is an essential component in successful agriculture. A lot of emphasis is being laid in the plan through a series of measures with a view to ensuring a judicious utilisation of water resources in agriculture. The institution of an 'Irrigation Liaison Committee' for close monitoring of irrigation related issues island-wide, the sensitisation of planters on efficient irrigation techniques, the promotion of fertigation techniques in modern agricultural systems and the setting up of an 'Irrigation Association' as joint public/private sector forum to oversee the whole irrigation issue with a view to recommending appropriate policy measures, are a few proposals made along this line.

(iv) Reorganisation of Marketing

Marketing logistics for agriculture is poor in Mauritius. Profitability to planters has often been questionable in view of the poor marketing system under which they operate presently. A majority of planters still resort to auctioneers to market their produce at the

local level. However, a lack of transparency in this system has often been reported, and a price control, ensuring a decent margin of profit to producers, seems difficult. Marketing at market places is also being done under poor sanitary conditions, which affects the overall quality and marketability of the produce, as well as, puts at risk the safety of customers. In view of increasingly stringent norms governing trade in agriculture, it is imperative that quality and food safety issues are given due attention. To this end, it is proposed to review and restructure the present infrastructure at auctions in conformity with international norms. It is also proposed to introduce a grading system for fresh food items with a view to facilitating price setting and control. A proper price setting mechanism at auction is also anticipated, along this line.

Also, with a view to maximising profitability to all agricultural stakeholders, it is felt that the proposed planning of production should be contemplated within a proper market-driven approach. Poor marketability is often the major cause of substantial losses incurred by planters in a number of instances. Bad organisation of production is often linked to surpluses of commodities on the market at some times and severe seasonal gluts at others. To this effect, timely availability of market information is essential. Along this line, it is proposed to set up a Market Information System in conjunction with the Agricultural Information system. This will act as a readily accessible network that will allow speedy collection and dissemination of market information and thus would also potentially help in regulating prices at the national level and hence ensure a reasonable margin of profit to producers, resolving the present difficulty encountered due to intermediaries.

With a view to achieving the objective of a planned market-driven production system both for the local and for export markets, it is proposed to set up a Market Intelligence Unit. This Unit, which will fall under the purview of the Agricultural Marketing Board, will serve as a market regulator both at the local and export markets. By operating on the basis of reliable up-to-date database from the Agricultural Information System and the Market Information System, in fine-tuning local production according to the market demand and

exigencies, this Marketing Intelligence Unit will play a pivotal role in revitalising the marketing activity within agriculture as a whole and ensuring optimal profitability. It will also work in close collaboration with the MIDA and Mauritian embassies in identifying new potential market outlets with a view to boosting up exports.

(v) Quality

One of the fundamental objectives of this reorientation process is the inculcation of quality notion at all levels of agricultural practices, ranging from production, post harvest handling, processing and sale. With rising customer needs and exigencies, coupled with increasingly stringent norms regulating food and agricultural trade, quality has become a *sine-quanon* condition for the development of agriculture and for the expansion of export opportunities. The gradual shift towards organic food worldwide is a clear indication that food safety has become an essential parameter in determining market tendencies.

This situation has called for an urgent review of the norms and standards of the local horticultural sector in general, with a view to setting up the appropriate framework to ensure that the local agriculture is in conformity with international norms. To this effect, assistance is being sought from the European Union for the setting up of a Quality System for the Horticultural Export Sector and establishing a National Code of Practice, along with the necessary supporting services required to attain this objective at the human capacity, technological and information levels. Capacity building in quality related issues at the production, handling, processing and sales levels is also being given due attention in the plan.

Quality at the production level is being fostered through the promotion of modern techniques of production such as greenhouse cultivation and hydroponic system that allow more efficient monitoring of quality parameters. Emphasis is also being laid on

promoting biological control in integrated pest management systems with a view to cutting down on chemical control measures.

The efficient monitoring of food quality, however, calls for a series of logistics which so far has not been successfully implemented. At this juncture, with emphasis being laid in the expansion of export-oriented activities and the development of the local agro-industry, a suitable analytical facility for quality control has become essential. In this line, it is proposed to set up a Food Technology Laboratory, which will be equipped with the finest technologies for quality assurance and monitoring. This facility will also play a key role in ensuring consumer safety by performing a tight regulation over all food products, whether locally produced or imported, entering the local market outlets. Efficient monitoring of quality will also require a tight control mechanism based on a solid inspection service. In this line, it is proposed to review and strengthen inspection services with all authorities concerned at points of sales of all food products to ensure that quality and food safety parameters are duly respected.

The functions of this Food Technology Laboratory will in no way overlap those under the mandate of existing laboratories of other institutions including the Mauritius Standards Bureau.

(vi) One-Stop-Shop

The rapid accessibility to information and technical guidance is central to the development of agriculture. Agriculture being a very sensitive sector, often dealing with perishables, and involving problems that can have rapid devastating consequences such as unexpected disease outbreak, timely assistance is critical to its efficiency. Agricultural stakeholders have often experienced difficulty in obtaining assistance on time. This has either been attributed to the distance constraint to the existing service delivery point or to a lack of information on procedures to follow to accede to the required service. As a remedial

solution, it is proposed to set up a **'One-Stop-Shop'**, which will act as a facilitating, **rapid problem-solving body** to all stakeholders involved in agricultural activities. This 'One-Stop-Shop' will be centrally located to allow easy accessibility and will offer a range of specialist services encompassing all local agricultural activities with a view to offering directed, fast track service. It will also be endowed with an up-to-date information system and documentation center on agriculture, which will be open for consultation by agricultural stakeholders.

(vii) Scarcity of cultivable land

Scarcity of cultivable land has been a major constraint for foodcrop growers in sustaining their agricultural activities. In view of unprecedented changes within the sugar sector brought about by the recent reform process, lesser land is being rented out for foodcrop cultivation by sugar estates. With a view to addressing the issue of land scarcity, Government has recently, by way of legislation, increased the acreage of land to be rented out by sugar estates to foodcrop growers from 50% to 65%, i.e. an extra 345 hectares. Furthermore, it is proposed to reach an agreement with sugar estates in order to ensure that land is released to growers at appropriate crop plantation times and at a reasonable cost.

However, considering our geographical limitations as a small island, future agricultural development strategies within Mauritius cannot be based on expansion of cultivable land areas. Instead such strategies have to be in tune with national development plans, which commands the increasing commitment of land in favour of other economic activities. In this context, the adoption of **intensive cultivation techniques based on modern practices** has become essential in optimising our agricultural productivity within the limited land resources. Such a transition away from conventional practices will also assist in raising the standards of agricultural production and will allow better control over quality parameters. In

this regard, one of the fundamental aims of the plan is based on the vulgarisation of modern production techniques amongst the planting community. Planters will be encouraged to shift away from outdoor cultivation towards intensive cultivation techniques under protected environment. In this respect, planters will be sensitised to take advantage of greenhouse and hydroponic systems. Cultivation under greenhouses will allow the optimal utilisation of agricultural space and will also contribute in enhancing productivity through a better control over environmental parameters. Another main concern as regards the present production standard is the quality of our produce. In this regard, cultivation under greenhouse conditions based on modern fertigation techniques, by providing more precision in the application of agricultural inputs will play an important role in quality improvement. In addition to providing a certain degree of protection against the entry of pests and diseases, such a system will also assist in limiting the usage of chemicals in control programmes. It is also proposed to promote soil-less cultivation techniques in non-arable areas and marginal lands, which are otherwise unproductive. In this respect, planters will be sensitised on the numerous financial facilities that can be extended to them in meeting the initial investment costs. Necessary training will also be imparted to interested growers with a view to aiding this transition process and facilitating the efficient transfer of technology. In this new approach to agriculture, planters will be encouraged to adopt a more professional attitude in their activities.

The feasibility and application of new emerging technologies in the local context that are less land resource dependent is also being looked into. In this respect, it is proposed to investigate into the technical and financial feasibility of aeroponics culture on a commercial basis in Mauritius.

(viii) Regional possibilities to expand local agricultural production base

Regional possibilities as potential production bases will also be studied as a means of increasing our production capacity. The objective is to use the technological advantage in agriculture to take optimal benefits of the regional assets such as its high production capacity and cheap labour. Production in the region, if achieved, will greatly assist in cutting down on local imports within the food sector. This strategy will also be highly beneficial to the local agro-industry, which presently depends almost entirely on imports for its raw materials. The probability of producing seasonal commodities that can be cost effectively grown in the region such as potatoes and onions on a complementary basis could be contemplated. However, it is essential that the feasibility and the financial implications of such an endeavour be assessed, prior to encouraging Mauritian investors to explore regional opportunities. In view of the high costs involved in such evaluation studies, it is proposed to look for possible financing sources to support such feasibility studies aimed at identifying suitable areas.

(ix) Strengthening Research & Development support in Agriculture

Science and technology have made such significant breakthroughs in the field of agriculture, that it would be unwise not to take advantage of their benefits. In view of the new technological era that we are operating in, much emphasis is being laid in the plan onto the promotion of modern technology application in agricultural activities. Efficient application of science and technology requires to be supported by a strong research and development back up. It has been noted that the research and development initiatives in the non-sugar agricultural sector have not been efficiently tuned towards meeting national objectives.

To this effect, it is proposed to strengthen research and development support to agriculture and restructure existing R&D programmes in addressing national priorities. The plan proposes to direct much effort and resources in R&D programmes that

would assist in meeting the objectives of the plan of an enhanced agricultural productivity both in terms of quantity and quality. In this respect, emphasis would be laid, *inter alia*, on enhancing research and development support towards the provision of:

i. high-yielding planting materials to the planting community;
ii. precise and rapid disease diagnosis and treatment services to the horticultural and livestock sector;
iii. efficient biological control methods as an alternative to chemical pest methods;
iv. modern production systems, including greenhouses and hydroponic systems, specifically fined-tuned to suit the local context;
v. alternative growing substrates for soil-less cultures in view of shortage of bagasse;
vi. efficient post harvest techniques and handling methods to minimise losses;
vii. optimise techniques for food preservation and processing to support the development of the local agro-industry; and,
viii. protect the endemic biological diversity of Mauritius.

Research and development towards the judicious application of new emerging technologies to meet national goals is also being given paramount attention in the plan. In this context, Biotechnology in particular, in view of the enormous possibilities it offers as a potential tool in addressing emerging challenges in agriculture, is being placed at the centre of the agenda of the plan in catalysing this targeted technological reform. Much of the benefits of biotechnology are of great relevance in the local context in raising agricultural productivity, particularly taking into account the inherent constraints such as limited land availability for agricultural activities, high vulnerability to adverse climatic conditions and constant exposure to pest and disease infestations. The vision of the modern agriculture is in fact based on the adoption of new emerging technologies, one of which is biotechnology.

Convinced of the fact that the traditional conventional agricultural practices are too obsolete to sustain in the present highly competitive agricultural environment, much effort is being geared at imparting a new technological edge to the Mauritian agriculture through biotechnology. Biotechnology holds a lot of promise for Mauritius, and will play a key role in achieving its long-term objective of a regional hub and a regional nursery. One of the major assets that the country holds in this respect, is a rich pool of scientific human resource capacity, which confers to it a strong comparative advantage with its regional counterparts in this technological strive. In order to strengthen its technology base in the field of agriculture, it is proposed to set up a Mauritius Agricultural Biotechnology Institute. This institute will provide a sophisticated infrastructural and strong scientific skill-base, that will cater for high-caliber, applied research in agricultural biotechnology. It will focus on optimising agricultural productivity in the non-sugar agricultural sector, including livestock, through the efficient application of biotechnology. With its primary objectives being to address issues of national priority, the eventual aim is to make the Institute emerge as a 'Centre of Excellence' and assume a leading national and regional role as a service provider and know-how disseminator in the field of agricultural biotechnology.

(x) Capacity Building

Capacity building is a major focus in the proposed plan in order to ensure the judicious uptake of new technology. Transfer of technology will be a central tool in achieving the objective of a modern agriculture and, in this respect, it is important to ascertain that every party concerned is adequately technically prepared to deliver and/or to adopt these technologies appropriately. The issue of capacity building has been considered at two main levels: the service/technology providers and the technology users. Accordingly, at the level of the Ministry, it is proposed to enhance the scientific capability of technical staff through specialised training courses with a view to facilitating the efficient delivery of targeted services to stakeholders in the proposed agricultural reform process. Provision is also made to sensitise and train agricultural stakeholders including planters, farmers, agro-

industrial entrepreneurs, in the adoption of new technology and modern practices in their respective domains, with a view to promoting entrepreneurship and professionalism in the sector.

(xi) Legislative reforms

Considering that this new approach will require a major shift from the usual conventional practices, the plan has been conceived from all fronts, with a view to facilitating the proposed transition process. In addition to major reforms proposed at the institutional, infrastructural, technical and stakeholder levels, provisions have also been made at the legislative level to legally support this reorientation process. The proposed Genetically Modified Organisms (GMO) Bill and amendments to the Plants Act are the two major legislative measures that would have significant impact in the implementation of the plan. The GMO Bill is being proposed to ensure that the uptake of biotechnology is fostered within a sound environment and that all dealings with GMO's are efficiently regulated with adequate biosafety precautionary measures, in line with the Cartagena Protocol. The Plants Act is being amended with a view to providing for important measures that would, *inter alia*, ensure the protection of Plant Breeders Right in conformity with the WTO TRIPS agreement, strengthen phytosanitary measures and thus facilitate trade in agriculture and provide for adequate protection of the natural biodiversity. Additionally, a number of existing legislations would be strengthened with a view to legally empowering institutions to efficiently deliver their respective services.

(xii) Agro-Industry

The future of the Mauritian agriculture and expansion of its export opportunities rests largely on the development of its agro-industry, in view of the highly perishable nature of fresh food together with the distance of Mauritius from its traditional niche markets. In this plan, much emphasis is laid on strategies to give a new dimension to the local agro-

industry with a regional approach. Endowed with a strong technological back-up and know-how in the field of agriculture and agro-processing, as compared to its regional counterparts, coupled with its ideal strategic location and its efficient infrastructural and communication logistics, Mauritius has all the credentials to emerge as a potential agro-processing hub in the region. The objective is to open up the avenue for Mauritius to use advantageously the resources and facilities available in neighbouring countries for the mass production of primary products at competitive prices to support its local agro-industry. In this respect, it is proposed to take optimal advantage of opportunities arising from regional trade protocols and the AGOA. This strategy is also being supported with a number of measures that would facilitate the process including the training of potential agro-industrial entrepreneurs, provision of incentives to attract foreign investment in this sector as well as financial and marketing facilities.

The plan also aims at encouraging and strengthening private sector partnership in this agricultural reform process. Along the same line, the private sector will be called upon to assume a very active role in this agro-industrial development process, with the setting up of a permanent Government/private sector joint committee that will have the responsibility of mapping out an organised development strategy for this sector.

(xiii) Clustering

The plan also fosters a tighter collaborative approach between all agricultural stakeholders, with a view to achieving common objectives in a more productive manner. Interaction between agricultural players has so far been almost absent. The clustering mechanism, by providing an efficient interactive platform, and triggering a constructive synergy between various stakeholders within a system based on the sharing of resources, has made its proof as a catalyst to product development. Such an interplay is particularly vital for the agricultural sector which is frequently confronted to new challenges and relies heavily on

prompt responses to problems encountered. To this effect, it is proposed to set up two clusters within agriculture.

The Food and Agricultural Cluster will be an institutional cluster, grouping all public and private organisations involved in agricultural activities, including *inter alia*, research institutions, extension services, academia and the service users. Its role will be to promote a coordinated approach between them, in order to avoid duplication of activities and ensure a demand-oriented delivery of services and product development. This will allow public institutions to be in tune with the national priorities and accordingly ensure a more judicious channeling of resources.

The Agro-Industrial Cluster will be exclusively constituted to assist in the development of the local agro-industry. Whilst regrouping major local agro-industries, research and institutions and all other support organisations in agro-processing, it will foster an efficient sharing of resources, information and know-how to address the needs and weaknesses of the sector, and at the same time maintaining the specificity of each player. Such a mechanism, through an integrated national effort, will impart a better competitive advantage to local entrepreneurs at the export front to access bigger market shares.

(xiv) Livestock Sector

The plan also elaborates on a number of measures to revitalise the local livestock sector. Although, in general, the future prospects of the local livestock sector appear rather bleak, in the wake of the trade liberalisation process, due attention has nevertheless been given to specific subsectors that hold enormous potential in Mauritius. Also, on a social concern, measures have been proposed towards sustaining and reviving the activities of the small farmers who are experiencing difficulties.

It is proposed to encourage farmers to expand to larger-scale farming activities through a number of support measures, whilst respecting applicable environmental norms and regulations, which are getting increasingly stringent. Such measures *inter-alia* include a strengthened extension service and regular provision of high yielding breeds of certain farm animals at the livestock breeding stations of the Ministry of Agriculture. Along the same line, it is proposed to strengthen the Veterinary Services of the Ministry of Agriculture, with a view to providing a more reliable and timely service to avoid losses at the breeders' level. Training of farmers in modern farm management practices towards achieving quality is also provided for. The applicability of integrated farming systems in the local context will also be studied.

The plan also projects to strengthen research and development support to this sector. Focus is laid on the diagnosis and prevention of diseases including the production of vaccines locally, identification and breeding of promising high-yielding breeds of farm animals and conservation of fodder for periods of scarcity.

In view of the current high imports of live animals and recent disease outbreaks, it is proposed to strengthen quarantine measures in order to safeguard the country from foreign phytosanitary threats and maintaining its disease-free status. Strategic stocks of the local animal breeds will be permanently maintained at the national level to constitute a genetic pool.

The food safety aspect of locally disposed meat is presently a matter of great concern. Accordingly, means to ensure conformity to food hygiene and safety norms at the production, slaughtering, processing, and specifically at points of sales have been given paramount importance in the plan. It is also proposed to modernise the central abattoir to ensure that slaughtering is done under appropriate conditions in conformity with international norms. Activities at the central abattoir would also be rendered more transparent with a view to gaining customers' confidence.

Considering the high volume of dairy imports, and in view of the fact that the local milk production is not being optimised, it is proposed to revive the local dairy sector through a number of policy measures. In addition to maintaining the current milk marketing scheme that many small farmers benefit from, the main measures in this respect provide for a review of the current price of milk, investigating into the prospects of value addition of locally produced milk. The Agricultural Marketing Board will be called upon to assume a more dynamic role in enhancing the marketing potential of the local milk.

Venison is one of the few promising subsectors within the local livestock sector, that has been given a lot of consideration in the plan. Measures have been primarily centred around prospects of expansion of the deer rearing activity, in view of the high demand of venison. It is proposed to promote research into finding efficient means to increase production on feedlot systems through enhanced breeding efficiency and nutrition.

Export of venison has ceased as a result of the inability of Mauritius to conform to international food quality and safety norms. For Mauritius to be in a position to revamp its export activities, it is essential to ascertain that the appropriate slaughtering logistics are in place to ensure conformity with export norms. To this effect, it is proposed to carry out a feasibility study on the setting up of a modern slaughterhouse for deer. Meat quality as regards carcasses emanating from 'chassées', is also a matter of concern, where currently no control is being exercised on the quality of the meat that ultimately reach the consumers. To this effect, it is proposed to set up a Technical Committee that would study this issue and make necessary recommendations on actions to be initiated for inspection of meat produced on 'chassées' to ensure conformity with required norms. Strengthening legislative measures to address the acute problem of poaching is also proposed.

The plan aims at encouraging value addition of livestock derived products as a means to enhance export opportunities within the sector. The services of the proposed Food Technology Laboratory would also be extended to local meat agro-processing industries,

which will act as a catalyst to this sector, by providing timely, rapid, and cheaper analytical facilities. Research and development initiatives to devise efficient meat processing techniques are also being promoted to sustain the development of this industry.

(xv) Agriculture in Rodrigues

Agriculture in Rodrigues has its own specificities. The plan proposes measures to address its major hindrances to agricultural development as well as means to optimise on its assets. The 'Organic Status' of Rodrigues is a pivotal element in its agricultural development strategy that needs to be capitalised upon. The plan accordingly proposes means to preserve and harness the organic label of the Rodriguan agricultural produce, with emphasis on the development of its export opportunities. Means to revitalise the main typical Rodriguan endemics such as chilli, lemon, red beans etc, to commercial ends forms another important aspect of this strategy. The importance of inculcating a higher degree of professionalism and quality notion amongst agricultural stakeholders in Rodrigues has been highlighted. Promotion of value-addition and enhancing the marketability of the typical Rodriguan specialities and recipes have also been given due attention. Training of farmers and planters in Rodrigues in modern farm practices, the adoption of new technology and in agro-processing with a view to enhancing their agricultural productivity has also been elaborated. Other important issues that have been addressed include, *inter alia*, means of improving irrigation infrastructure, setting up of appropriate storage and mechanization facilities, strengthening research and development support and extension services to farmers and ensuring a regular supply of high yielding young animals to interested farmers. The development of the apicultural sector is another important arm of agricultural development strategy of Rodrigues. Provisions have been made to establish a sustainable development programme for this sector based on the appropriate research and development, technical and analytical supports. A major consideration has been given to the rehabilitation of Rodrigues with potential melliferous plants, which is currently a major hindrance to this sector.

(xvi) Institutional Reform

This reform process within the non-sugar agricultural sector, along with a major conceptual transition in the approach to agriculture, also involves significant changes at the level of the institutional framework within which services are currently being provided. In order to meet the objectives of the plan for an enhanced agricultural productivity, it is essential that support institutions fulfill their respective roles in an efficient and proactive manner, without duplication of activities. In this new vision of a 'modern agriculture', certain existing institutions will also be required to assume new responsibilities. To this effect, for the proper implementation of the plan, a reorganisation at the level of existing institutions will be essential. The objective is to restructure the whole agricultural set-up with a more productive, demand-driven and target-oriented approach ensuring a judicious utilisation of resources. This responsibility will be assigned to an 'Institutional Review Taskforce' which is proposed to be set up. In this context, the Agricultural Marketing Board and the Tobacco Board have been identified as the two institutions that need to be reviewed with utmost priority in view of the recent changes and new challenges emerging in the two respective sectors.

1.7 The Strategic Plan for the Non-Sugar Sector is a five–year plan projected for the years 2003-2007. In addition to the measures elaborated above, this plan constitutes several other essential elements that would be crucial in driving the proposed reorientation process towards a 'modern agriculture'. The implementation of this plan would no doubt bring about a turning point in the Mauritian agriculture, as well as major changes for Rodrigues. By the year 2007, Mauritius would have achieved its ultimate vision of a high-technology base in agriculture, and the way to

making it emerge as a leading regional nursery and regional agro-processing hub, would be paved.

Annex C.1

FIRST SCHEDULE

[Section 9(2)]

APPLICATION FOR GMO PERMIT

PART I - GENERAL INFORMATION

1. INFORMATION ON APPLICANT

Name of Applicant/Organisation:

…….…….

Official Registration Number of Organisation/Institute/Laboratory: ……..

Address:

……

Tel.: …….. Fax.:

……

Email address:

……..……...

2. NATURE OF REQUEST (*Please tick as appropriate)*

Permit Request

Category A	θ	Laboratory experimentation
	θ	Greenhouse trial
	θ	Small field testing
	θ	Large field trial
	θ	General release
Category B	θ	Food and feedstuffs
Category C	θ	Transit
Category D	θ	Importation
Category E	θ	Exportation
Category F	θ	Large scale production

NB Applicants of category A should fill in Part A of Second Schedule

Applicants of category B should fill in Part B of Second Schedule
Applicants of categories C, D, E and F should fill in applicable parts of Part A & Part B of Second Schedule

Have you applied for a similar permit before? θ Yes θ No

Give outcome of decision if Yes: θ Approved θ Rejected

Applicant for a GMO permit should not entitle applicant to circumvent any licence, permit or approval granted under any other enactment

Give previous permit number:
……

Has your proposal been given the clearance by your Institutional Biosafety Committee?
……
…….

3. NATURE OF GMO

θ Plant

θ Microorganism

θ Animal

θ Others, please specify ……

4. CONFIDENTIALITY

Can the decision be publicly released? θ Yes θ No

PART II - SPECIFIC INFORMATION

5. INFORMATION ON RESPONSIBLE PARTY/PRINCIPAL INVESTIGATOR OF PROPOSED PROJECT

Name of Responsible Person /Principal Investigator:
……
Name of Institution/Laboratory/Firm:
…….
Address:
…….
Tel.: …….. Fax.:
……

Email address:

……..……...

Name of other persons involved in the project

(i.)

……

……

(ii.)

……

……

(iii.)

……

……

Background and experience of persons involved:

……

……

…….

……

…….

Title of project:

…….

6. DESCRIPTION OF PROPOSED DEALING

……

……

……

……

……

7. DURATION OF PROPOSED DEALING

Expected date of commencement:

……

Expected date of completion:

……

8. PURPOSE AND AIMS OF PROPOSED DEALING

……

……

……

……

……

……

……

9. JUSTIFICATIONS AND BENEFITS OF THE PROPOSED DEALING

……

…….

……

…….

……

…….

10. SCALE OF PROJECT

Volume or area to occupy:

……

Will the material be destroyed after the experiment? θ Yes θ No

If yes, give details of proposed method to eliminate or remove the GMO from the test site upon completion of the experiment:

…….

……

…….

If no, give details of future plans:

…….

……

…….

……

…….

……

…….

11. DESCRIPTION OF INFRASTRUCTURE INVOLVED IN EXECUTION OF PROPOSED DEALING

Details on laboratory, greenhouse, storage and any other facilities involved

Location of site *(provide map of trial site)*:

……..

……

……

Facility type (laboratory, greenhouse, insectary, etc.): ……

……

……

Physical containment level:

……

……

……

Date of registration of facility:

……..

……

…….

Registration number:

……

……

…….

Date of recent inspection:

……

……

…….

12. DESCRIPTION OF PACKING CONDITIONS

Proposed method of packaging (*if applicable*):

……..……

Description of labelling *(attach label if available*):

……..

……

…….

PART III - INFORMATION ON PROPOSED DEALING

13. ORIGIN OF GMO

Country of origin: …….. Port of Departure:

…….

Port of Entry: …… Means of shipment: Air - θ Sea - θ

Proposed mode of transport inland:

…….

Final Destination (if transit):

……

Information on Exporter: Name of Company:

……..

Address:

……..

Contact Person:

…….

Tel.: …….. Fax:

……..

Email address:

……

Please attach evidence to certify that the Exporter is an authorised dealer of GMOs.

Information on Importer: Name:

……..

Address:

……..

Contact Person:

…….

Tel.: …….. Fax:

……..

Email address:

……

14. FULL DESCRIPTION OF THE GMO

PLANT *Family name:* ……..

Genus: ……..

Species: ……..

Sub-species: ……..

Cultivar/breeding line: ……..

Common name: ……..

Give information on the mode(s) of reproduction of the plant:

……..

MICROORGANISM : θ Bacterium θ Fungus θ Virus θ Mycoplasma

Name : ……..

Genus : ……..

Species : ……..

Sub species : ……..

Strain : ……..

ANIMAL

Family name : ……..

Genus : ……..

Species : ……..

Breeding line : ……..

OTHERS (Please specify)

……

……

15. AMOUNT OF GMO

Units, weight, volume :

……

16. DETAILS OF PRODUCT

Description of product:

……

What are the benefits of the proposed GMO?

…….

……

…….

Description of the gene introduced:

……..

Method used in introducing the gene:

…….

Has the product been tested/commercialized elsewhere?

…….

What are the results of the tests?

……

……

…….

Provide evidence of the results of the tests:

……

…….

……

…….

How do you verify for the GMO concerned?

……

……

…….

What potential hazardous or deleterious effects resulting from the trial release of the GMO can be anticipated?

…….

……..……

……

……

…….

……

…….

17. RELEVANT PUBLICATIONS ON THE GMO *(Provide a list)*

……

…….

……

…….

……

…….

……

…….

……

…….

18. GENERAL INFORMATION ON GMO OR PRODUCTS DERIVED THEREOF TO BE INTRODUCED

	Parent Organism	***Recipient***
Scientific name		
Common name		
Commercial name		
Other designation		

……. ……..

Signature of Applicant ***Date***

For official use only

Date received: …….

Application No: …….

Approved or Rejected: …….

If rejected, give reasons why

……

……

…….

…… ……..

Chairman, National Biosafety Committee ***Date***

Annex C.2

SECOND SCHEDULE

[Section 9(3)]

PART A

INFORMATION ON RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANMISMS FOR CONTAINED/CONFINED AND GENERAL RELEASE

1. IDENTITY OF GMO

……

…….

2. BENEFITS

Describe the benefits to be gained through the GMO, e.g, agronomic gains, improvement of nutritional quality or pest resistance, etc:

……

…….

……

…….

……

…….

……

…….

3. NATURE OF ORGANISM AND NOVEL GENETIC MATERIAL

3.1 Identity of organism:

…….

Scientific name of parent organism:

……..

Common name of parent organism:

……..

Modified trait:

…….

3.2 Is it known whether the unmodified form(s) have any adverse effect on

i. Humans, animals or plants?

……

…….

ii. Agricultural production?

……

…….

iii. Any other aspect of the environment?

……

…….

3.3 Give a description of the genetic and resultant phenotypic modification of the GMO. Provide information on (i) the source of inserted DNA, (ii) the outline of the DNA

construct, (iii) the nature and source of the vector and procedure used to introduce the gene and (iv) the extent to which it has been characterized:

……
…….
……
…….
……
…….
……
…….

3.4 Is the gene inserted a pathogenic determinant capable of causing disease in human beings, animals or plants?

……..
……
…….

3.5 Is the gene introduced stable?

…….
……
…….

3.6 What is the frequency of reversion, that is, loss of genetic modification?

……
…….

3.7 How do you verify for the presence of the gene?

……..
……
…….

3.8 Have similar tests/releases of similar GMOs been made before, either within or outside this country?

……..

……
…….

3.9 What data are available to suggest that the introduced genetic trait has no deleterious effect in the long term upon the species into which it has been introduced or allied species or any other organisms or the environment in general?

……
…….

3.10 Does the GMO differ from the parental or recipient organism (e.g mode of reproduction, dissemination, survivability)?

……
…….
……
…….

If so, please give details:

……

…….

……

…….

……

…….

3.11 What experimental results/information are available to show the probable consequences (positive or negative) of the release of the GMO?

……

…….

3.12 Does the GMO have any impact on

i. Human, animal, plant health?

……

…….

ii. Agricultural production?

……

…….

iii. Target and non-target organisms?

……

…….

iv. The general ecology, biodiversity?

……

…….

3.13 Has a trial release been carried out in the country of origin of the GMO?

……

…….

3.14 Can the genetic trait be transmitted by means other than by normal reproduction?

……

…….

……
…….
……
…….

3.15 Has the introduced gene been shown to be toxic to animals and humans?

……
…….
……
…….
……
…….

3.16 Is there a risk of harm to the environment associated with the dispersal of the organism or the gene concerned?

……
…….
……
…….
……
…….
……
…….

3.17 List details of action proposed to be taken in case of an accidental release of the GMO from containment/confinement:

……
…….
……
…….
……
…….
……
…….

4. DETAILS OF FIELD TRIALS AND GENERAL RELEASE

4.1 Give the location, size of field trial(s) or release site(s) *(provide map of site)* as well as isolation distances from other trials:

……
……
…….

4.2 Describe the ecosystem including slope, climate, flora and fauna, presence of endangered species, including information on natural predators and parasites surrounding the field trial or release site:

……..……..
……
…….

……
…….
……
…….

4.3 List any sexually compatible wild relatives or cultivated plant species present around the trial or release site:
……
……
…….

4.4 Describe the barriers planned in order to segregate the experiment/trial release from the surrounding environment:
……
……
…….

4.5 How will the supervision and monitoring be carried out during and after the trial release?

……

…….

……

…….

4.6 Provide details of how the plant materials including wastes will be eliminated after the trial (herbicidal treatment, incineration, etc): …….

……

…….

……

…….

4.7 Provide contingency plans to deal with unforeseen circumstances such as cyclone, flood etc. during the course of the trial:

……..

……

…….

……

…….

……

…….

4.8 Give the duration of the trial or release:

……..

……

…….

5. ADDITIONAL INFORMATION FOR GENETICALLY MODIFIED PLANT

You must also fill in this part if you are proposing to deal with a GMO that is a plant.

5.1 Information about the use of the parent plant

State whether the parent plant has an extended history of cultivation and safe use:

……

…….

……
…….

5.2 Information about any unintended pleiotropic effects

Give details of any undesirable effects on the parent plant that may result from expression of the transgene, or an associated insertion-related mutation, in the GMO (for example, reduced fertility, increased disease prevalence, production loss, grain shredding), including the likelihood of any such events: ……..

……
…….
……
…….
……
…….

5.3 Information about pollen and cross-pollination

5.3.1 Describe the mechanism of pollen spread (by insect vectors or by any other means) in the plant population:

…….
……
…….
……
…….
……
…….

5.3.2 Give details of pollen viability for the parent plant and the GMO:

……
……
…….
……
…….

5.3.3 Provide details of any potential pollinators for the parent plant and the GMO, and their range and distribution in Mauritius:

…….

……
…….
……
…….
……
…….

5.3.4 Are quantitative data available on successful cross-pollination between the parent plant, the GMO and its wild relatives?

……
…….

5.3.5 List only sexually compatible plants near the site of the proposed release and provide details of the quantity and the chances for cross-pollination with the GMO:

……
…….
……
…….

5.3.6 If cross-pollination with the GMO were to occur, provide details of the likely resulting plants and an assessment of whether they would survive and compete well with unaffected plants: ……
……
…….
……
…….

5.4 Information about weeds

5.4.1 List members of the family of unmodified parent plants that are known to be weeds in any environment:

……..

……

…….

……

…….

5.4.2 Give details of cross-pollination between the species to which the GMO belongs and relatives known to be weeds, including a copy of any peer-reviewed reports that support the information:

……

…….

……

…….

5.5 Information about the possible result of the imparted characteristics being integrated into other species

5.5.1 State whether the novel characteristics of the GMO could be integrated into other species and if so, provide details of its potential to affect:

1. the distribution and abundance of populations of the affected species; and
2. factors that normally control populations of the affected species in the environment (for example, pathogens, herbivory and physiological stress)

……

…….

……

…….

……

…….

……

…….

5.5.2 List any other possible adverse consequences:

……
…….
……
…….

5.5.3 Give details of proposed measures to minimise the risk (for example, by imparting male sterility or other means of reproductive isolation):
……
……
…….
……
…….
……
…….

PART B

INFORMATION ON RISK ASSESSMENT OF FOOD AND FEEDSTUFFS DERIVED FROM GENETICALLY MODIFIED ORGANISMS

1. DESCRIPTION OF THE GMO

1.1 Name of GMO from which the Food and Feedstuffs is derived:

……
……..

1.2 Give a description of the genetic and resultant phenotypic modification of the GMO:
……
…

……
…….

1.3 Describe (i.) the source of the inserted DNA, (ii.) the outline of the DNA construct, (iii.) the vector and procedure used to introduce the gene and (iv.) the extent to which it has been characterised: ……..

……
……..

……
……..

……
……..

1.4 Which of the following characteristics have been introduced in the GMO?

i. Pesticidal properties
……

ii. Resistance to Plant Pathogen
……

iii. Insect resistance
……

iv. Herbicide resistance
……

v. Antibiotic resistance
……

vi. Environmental stress resistance
……

vii. Nutritional improvement (e.g protein modification, carbohydrates, fatty acid)

viii. Others, please specify
……..

1.5 Is the GMO commercialised?

……
…….

If so, list the countries where it is marketed:
…….

……
…….

Provide name and address of the supplier: ……..

……

…….

……

…….

1.6 Does the GMO has any impact on:

i. Human, animal, plant health? ……

ii. Agricultural production? ……

iii. Target and non-target organism? …….

iv. The general ecology, diversity? ……

2 FOOD AND FEEDSTUFFS

2.1 Describe the product derived from the GMO: ……...

……

……..

2.2 What is the proportion of the GMO in the food/feedstuffs?

……

……..

2.3 What method can be used to verify that you have the desired GMO?

……

……..

2.4 What methods are to be used to test for batch to batch consistency?

……
……..

2.5 How does the food/feedstuff ingredient from the genetically modified plant differ from the same food/feedstuff ingredient derived from the unmodified host?

……
……..

2.6 Has the food/feedstuff derived from the GMO been shown to be substantially equivalent to an existing food or food component?

……
……..

3. HUMAN AND ANIMAL HEALTH

3.1 Has any adverse effect on health been demonstrated upon consumption of the food/feedstuffs derived from the GMO in humans and animals? Provide results of any trials carried out: ……

……
…….

……
…….

……
…….

3.2 Provide information of any toxic or allergenic effects observed from the consumption of the food/feedstuffs derived from the GMO: ……..

……
…….

3.3 Could any toxic products concentrate in natural and human food chain?

……
…….

4. ENVIRONMENTAL SAFETY

4.1 Has any adverse effect of the release of the GMO food/feed on environment been demonstrated?

……
……..

4.2 What are the precautionary measures forecast to prevent accidental propagation of the GMO (e.g GM maize seed, germination and growing)?

……
……..

5. LABELLING

5.1 Give the proposed commercial name of the product: ……

5.2 Describe the labelling details on packaging: ……..

6. ADDITIONAL RELEVANT INFORMATION

6.1 What are the measures to be taken in the event of the escape of the organisms in the product or misuse of the product:

……
…….

……
…….

6.2 Give details of specific instructions or recommendations for storage and handling of the product including transportation inland:

……
…….

……
…….

THE GENETICALLY MODIFIED ORGANISMS ACT 2004

Act No. 3 of 2004

I assent

A R BUNDHUN
Ag. President of the Republic

15th April 2004

ARRANGEMENT OF SECTIONS

Section

An Act

To provide for measures to regulate the responsible planning, development, production, use, marketing and application of genetically modified organisms

ENACTED by the Parliament of Mauritius, as follows -

1. Short title

The Act may be cited as the Genetically Modified Organisms Act 2003.

2. Interpretation

In this Act -

"accident" means an incident involving an unintended release of genetically modified organisms which could have an immediate or delayed adverse impact on the environment or human and animal health;

"applicant" means a person in control of a facility involving the genetic modification of organisms, or of activities involving genetically modified organisms, who applies for a GMO permit;

"authorised officer" means a public officer designated as such by the Permanent Secretary;

"Chairperson" means the Chairperson of the Committee;

"Committee" means the National Biosafety Committee set up under section 4

"contained use" means any operation undertaken within a facility which involves genetically modified organisms that are controlled by specific measures to effectively limit their contact with, and their impact on, the external environment;

"environment" has the same meaning as in the Environment Protection Act 2002;

"facility" includes, but is not limited to, the following:

(a) a building or part of a building;

(b) a laboratory;

(c) a green house;

(d) a glasshouse;

(e) an insectary;

(f) an animal house;

(g) a field;

(h) any other place,

where activities involving genetically modified organisms are carried on.

"general release" means the introduction of genetically modified organisms into the environment by whatever means where the organisms are no longer contained by any system of barriers or under any person's control, so that the organisms are likely to survive and be disseminated;

"genetically modified organism (GMO)" –

(a) means an organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination, or both; and

(b) includes any of its derivatives;

"GMO permit" means a permit issued by the Permanent Secretary under section 8;

"member" –

(a) means a member of the Committee; and

(b) includes the Chairperson;

"Minister" means the Minister to whom responsibility for agriculture is assigned;

"monitoring" means the maintaining of regular surveillance over, the checking of, the warning about, or the recording of, any activity involving genetically modified organisms;

"organism" –

(a) means a cellular or non-cellular biological entity, capable of metabolism, replication, reproduction or of transferring genetic material; and

(b) includes a microorganism;

"Permanent Secretary" means the Permanent Secretary of the Ministry;

"trial release" means the deliberate release of genetically modified organisms in confinement into the environment under conditions where the degree of dissemination of the genetically modified organisms is restricted by chemical, physical or built-in barriers which prevent the survival of such organisms outside the confined area;

"user" means a person responsible for the use of genetically modified organisms, and includes an end-user or a consumer.

3. Application of Act

(1) This Act shall apply to the genetic modification of organisms which occurs through –

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material;

(b) techniques involving the direct introduction into an organism of foreign nucleic acid molecules; or

(c) cell fusion, including protoplast fusion, beyond the same taxonomic family or hybridization techniques where live cells with new combination of genetic material are formed.

(2) This Act shall not apply –

(a) to techniques involving genetic manipulation of human cells; or

(b) in cases where recombinant nucleic acid molecules or genetically modified organisms are not employed.

4. National Biosafety Committee

(1) There is established for the purpose of this act a National Biosafety Committee, which shall consist of –

(a) a Chairperson, with expertise in biotechnology and related fields, appointed by the Minister;

(b) a representative of the Ministry;

(c) a representative of the Ministry responsible for environment;

(d) a representative of the Ministry responsible for health;

(e) a representative of the Ministry responsible for international trade;

(f) a representative of the Mauritius Sugar Industry Research Institute;

(g) a representative of the University of Mauritius;

(h) a representative of the Food and Agricultural Research Council;

(i) a representative of the Mauritius Research Council;

(j) a law officer designated by the Attorney-General;

(k) a representative of consumer associations, appointed by the Minister.

(2) (a) Every member, other than the ex-officio members, shall hold office for 2 years and shall be eligible for reappointment.

(b) The Minister may revoke the appointment of a member referred to in subsection 1(a) or 1(k)for any reason specified in section 37(3)(b) of the Interpretation and General Clauses Act or where he is of opinion that the person is no longer qualified to be a member.

(3) (a) The committee shall meet as and when required by the Chairperson, or upon request of not less than 3 members, but not less than 4 times a year.

(b) 6 members shall constitute a quorum.

(4) The Committee may, with the Minister's approval, co-opt any other person to attend its meetings for a specific purpose, or period of time, but without the right to vote.

(5) Where any matter is being or is to be, considered by the Committee and a member has a direct or indirect interest in it or there is likely to be a conflict of interest as a result of his participation in the debate, he shall forthwith declare his interest and abstain from participating in the debate.

(6) The Minister may, at the request of the Committee, appoint independent professionals or consultants to assist the Committee in the discharge of its functions under this Act.

5. Objects of the Committee

The objects of the Committee shall be to advise the Minister on –

(a) all aspects concerning the importation, exportation, transit, development, research, production, use, application, marketing, sale and release of genetically modified organisms; or

(b) any other matter concerning genetically modified organisms that may be referred to it.

6. Functions of the Committee

(1) The Committee shall have such functions as are necessary to further most effectively the objects of the Committee, and in particular to –

(a) publish guidelines and a code of practice, with the approval of the Minister, for all uses of genetically modified organisms;

(b) encourage public participation in decision-making while maintaining confidentiality of information;

(c) advise the Permanent Secretary, as and when required, on the appropriate strategy in cases of emergency;

(d) examine any application made pursuant to section 7, and make its recommendations to the Permanent Secretary.

(2) In examining an application under subsection 1(d), the Committee shall take account of the proposed activity of the GMO in respect of its likely –

(a) direct or indirect effects on the environment and human and animal health; and

(b) social and economic effects on people and society.

7. Application for GMO permit

(1) Notwithstanding any other enactment, no person shall develop, use, market, produce, release into the environment, transit, import or export genetically modified organisms unless he holds a GMO permit issued under this Act.

(2) An application shall be made to the Permanent Secretary in the form set out in the First Schedule and on payment of a prescribed application fee.

(3) (a) The applicant shall submit a risk assessment report and a contingency plan in the form set out in the Second Schedule.

(b) A risk assessment for the purpose of paragraph (a) shall be carried out in a scientifically sound manner.

(4) On receipt of an application under subsection (2) –

(a) the Permanent Secretary shall -

(i) cause a notice of any application for a GMO permit to be published in the Gazette and for 3 consecutive days, in not less than two daily newspapers;

(ii) invite all interested persons, who so wish, to lodge with the Permanent Secretary such objections as they may have against the application;

(b) the Minister shall make a statement in the National Assembly informing it of such application.

(5) Any person who wishes to object to an application shall, not later than 21 days after the last date of the publication specified in subsection (4), lodge his objection in writing with the Permanent Secretary.

(6) The Permanent Secretary -

(a) may, on receipt of an application, request the applicant to furnish such additional information as he may consider appropriate;

(b) may, if he deems necessary, seek the views of any public department, non-government organisation or any other person on the application; and

(c) shall refer the application, together with any additional information and views expressed thereon, to the Committee for its recommendations.

(7) The Committee shall endeavour to identify and evaluate the possible adverse effects of the genetically modified organisms on the environment and on human and animal health.

8. Grant or refusal of GMO permit

(1) The Permanent Secretary, after taking into consideration the recommendation of the Committee, may –

(a) subject to subsection (3), grant a GMO permit and issue such permit on payment of the prescribed fees and on such terms and conditions as he may deem appropriate;

(b) reject the application, giving his reasons for so doing, with a direction to communicate the decision together with the reasons to the applicant.

(2) The reasons on which a decision under subsection (1)(b) is made shall be communicated, by registered post, to the applicant, within 7 days of the decision.

(3) No GMO permit shall be issued under subsection (1)(a) except after the relevant particulars of the intended GMO permit holder shall have been specified in regulations made to that effect.

(4) Any regulationsmade under subsection (3) may be subject to a motion for disallowance under section 20 of the Interpretation and General Clauses Act.

9. Suspension or revocation of GMO permit

(1) Where –

(a) a permit holder changes the type of activity allowed by his permit or otherwise breaches any of the terms and conditions of his permit;

(b) a permit holder moves his activity from a facility specified in his application form to a facility which, in the opinion of the Permanent Secretary, is not a fit and proper facility;

(c) the activity of the permit holder impacts adversely on the environment or on human and animal health, the Permanent Secretary may by notice in writing require the GMO permit holder to show cause, within 7-days from date of service of the notice, why his permit ought not to be suspended or revoked.

(2) Where the Permanent Secretary is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, he may suspend the permit for such period as is reasonable in the circumstances, or revoke the permit.

(3) The Permanent Secretary shall communicate, by registered post, any decision under subsection (2) to the GMO permit holder within 7 days of the decision.

10. Prohibition notice

(1) Where he is of the opinion that a facility or the manner in which the facility is carrying on its activities involves a serious risk to environment or to human or animal health, the Permanent Secretary may serve, or cause to be served, a prohibition notice on the person owning, or managing, or in charge of, or in control of the facility.

(2) A prohibition notice may be served whether or not –

(a) the facility, or the manner in which the activity is carried on, constitutes a contravention of this Act;

(b) there is in force in relation to the facility a GMO permit issued under this Act;

(c) there is before any Court of law or before a Judge sitting in Chambers any case involving the subject matter in relation to which a notice is being issued, unless the Court or Judge has issued an order preventing the Permanent Secretary from issuing the prohibition notice.

(3) A prohibition notice shall –

(a) state the Permanent Secretary's opinion;

(b) specify the risk involved, as well as the way in which the facility, or the manner in which the activity is carried on, is suspected to give rise to the risk;

(c) specify the measures that shall be taken to eliminate the risk and the period within which they shall be implemented;

(d) specify –

(i) the facility, or any aspect of the facility, that is prohibited from operation or performance; or

(ii) any conditions subject to which the activity may be resumed.

(4) A prohibition notice shall not be a bar to a prosecution for any offence, even if there are consultations with the person served with the notice.

(5) Any person who fails to comply with a prohibition notice, shall commit an offence.

11. Stop order

(1) Where a person commences or carries on any development or activity without the relevant GMO permit issued under this Act, the Permanent Secretary may, where such development or activity contravenes this Act, serve, or cause to be served, on that person, or any person responsible for the giving of instructions for the carrying on of such development or activity, a stop order prohibiting the development or the activity.

(2) Any person who fails to comply with a stop order issued under subsection (1) shall commit an offence.

12. Consultation on notices

(1) Before or at any time after issuing a notice, the Permanent Secretary shall as far as he deems practicable, consult –

(a) the person affected;

(b) the Committee.

(2) The Permanent Secretary may consult a technical advisory committee set up by him, or any public department, on a notice.

13. Variation notice

(1) Any person affected by a notice, may apply to the Permanent secretary for an amendment of the notice.

(2) The Permanent Secretary, on his own initiative, or on application, may amend a notice by causing to be served on the person affected a variation notice.

(3) A variation notice shall –

(a) refer to the notice which is amended;

(b) specify the amendment to the notice;

(c) where necessary, vary the date specified in the notice.

(4) A variation notice shall supersede the notice to which it refers to the extent of the amendment.

14. Service of notice

(1) A notice issued under this Act shall be served –

(a) personally on the person affected, or in the case of a body corporate, at its registered address; or

(b) by registered post sent to, or by leaving a copy at, the last known address of the person affected.

(2) Where service could not be effected by the means referred to in subsection (1), the service shall be effected by affixing a copy of the notice –

(a) at the facility which is the subject matter of the notice;

(b) where a contravention is being committed, or has been committed, or is suspected to have been committed.

(3) A certificate of an authorised officer or any other officer of the Ministry as to service under subsection (1) shall be prima facie evidence of effective service of the notice on the person affected.

15. Revocation of notices

Where he is satisfied that –

(a) (i) the measures required to be taken in a notice have been implemented; and

(ii) there exists no further risk to the environment or to human or animal health caused by the activity or the manner in which the activity is carried on; or

(b) the notice is not, or will not be effectual,

the Permanent secretary may revoke a notice and shall inform the person affected in writing.

16. Appeals

(1) Any person who feels aggrieved by a decision taken by the Permanent Secretary may, within 21 days of the communication of the decision to him, and on payment of the prescribed fee, appeal against the decision to the Appeal Board appointed under subsection (2) by a written notice together with the grounds of appeal.

(2) The Minister shall appoint on an ad hoc basis an Appeal Board comprising a Chairperson, who shall be a barrister with at least 5 years standing at the bar, and 2 members, being persons with expert knowledge in the field of biotechnology or related fields.

(3) A person appointed under subsection (2) shall challenge himself if he has any direct or indirect interest in the subject matter of the appeal.

(4) Any appeal lodged before the Appeal Board shall be dealt with as expeditiously as possible and the Appeal Board shall endeavour to dispose of the appeal within 6 months from the date the appeal was lodged.

(5) The Appeal Board may, after giving the parties to the appeal an opportunity of being heard, pass such orders as it thinks fit, confirming, varying or setting aside the decision appeal against.

(6) The Appeal Board shall send, by registered post, a copy of every order made by it to the parties to the appeal within 7 days.

17. Confidentiality

(1) No person shall disclose any information acquired by him through the exercise of his powers or the performance of his duties under this Act other than –

(a) the description of any genetically modified organism, the name and address of any applicant, the purpose of the contained use or release and the place of use;

(b) the methods and plans for the monitoring of genetically modified organisms in case of accident;

(c) the evaluation of any foreseeable disruptive impacts on human or animal health or on the environment; or

(d) any other information as may be approved by the Permanent Secretary.

(2) Where an applicant withdraws an application, any person who has knowledge of the details of the application shall respect the confidentiality of the information supplied.

(3) Nothing in the subsection (1) or (2) shall prevent the disclosure of information –

(a) in so far as if is necessary for the proper application of this Act; or

(b) for the purpose of any legal proceedings under this Act.

18. Registration of facilities

(1) The Permanent Secretary shall keep a register of all facilities.

(2) Every GMO permit holder responsible for the management of any facility shall register the facility with the Permanent Secretary.

(3) The register shall contain the –

(a) name and address of the GMO permit holder;

(b) details of the activities carried on; and

(c) location and description of the facility.

19. Monitoring powers

(1) Subject to subsection (2), where an authorised officer reasonably believes that a facility is being used for any activity involving genetically modified organisms, including contained use, trial release or general release, he may enter and inspect the facility for the purpose of inspecting and monitoring the activities carried on therein and to ensure compliance with this Act, any regulations made thereunder and any GMO permit issued under this Act.

(2) Where the authorised officer reasonably believes that any activity specified in subsection (1) is being carried on in a dwelling house, he may enter and inspect either with the consent of the owner or occupier of the dwelling house, or in virtue of a warrant to that effect issued by a Magistrate.

(3) The authorised officer may, in the course of an inspection –

(a) secure copies of any relevant document kept in the facility;

(b) secure, on reasonable grounds, any material which he believes to be evidential material.

20. Accidents

(1) Every person who is informed or becomes aware of an accident shall immediately notify the Permanent Secretary.

(2) Where a GMO permit holder notifies an accident, he shall supply to the Permanent Secretary –

(a) all relevant information on the circumstances of the accident, the identity, quantity and quality of genetically modified organisms released and any other information necessary to assess the impact of the accident on the environment and on human and animal health; and

(b) the details of any emergency measures taken to avoid or mitigate any adverse impact on the environment and human and animal health.

(3) The Permanent Secretary shall appoint on an ad hoc basis a Special Committee comprising a Chairperson and 2 members, being persons having wide expertise in the field relating to the accident, to enquire into the circumstances of the accident and make a report with recommendations to the Permanent Secretary.

(4) The Permanent Secretary may, after taking into consideration the report and recommendations of the Special Committee, and where he considers that the accident has had an adverse impact on the environment or on human or animal health, take a decision under section 9(2).

(5) The Permanent Secretary shall inform as soon as reasonably practicable any other country of any accident which may have an impact on that country's environment or on human and animal health in that country.

21. Labelling and identification

(1) Every GMO permit holder shall ensure that any genetically modified organisms is clearly identified and labelled, specifying the relevant traits and characteristics of the product.

(2) The labelling of any genetically modified organisms shall comply with such requirements as may be prescribed.

22. Offences

(1) A person who –

(a) fails to comply with any condition, permit, or prohibition under this Act;

(b) obstructs or hinders an authorised officer in the exercise of his functions under this Act;

(c) provides information under this Act which is false or misleading in any material particular;

(d) otherwise contravenes this Act,

shall commit an offence and shall, on conviction, be liable –

(i) on a first conviction to a fine not exceeding Rs 50,000 and to imprisonment for a term not exceeding 2 years;

(ii) on a second or subsequent conviction, to a fine not exceeding Rs 100,000 and to imprisonment for a term not exceeding 4 years.

(2) In addition to any penalty under subsection (1), the Court may order the forfeiture of any animal, plant, organism or any article used in, or connected in any way with, the commission of an offence.

23. Jurisdiction

(1) An authorised officer may swear an information and conduct prosecution in respect of an offence under this Act before a Magistrate.

(2) Notwithstanding section 114 of the Courts Act and section 72 of the District and Intermediate Courts (Criminal Jurisdiction) Act, a magistrate –

(a) shall have jurisdiction to try an offence under this Act; and

(b) may impose any penalty and forfeiture provided by this Act.

24. Regulations

(1) The Minister may make such regulations as he thinks fit for the purposes of this Act.

(2) Any regulations made under subsection (1) may –

(a) provide for the levying of fees and charges;

(b) lay down requirements for laboratory development of genetically modified organisms;

(c) set out standards to which facilities for activities involving genetically modified organisms should conform;

(d) make provision for quarantine, transit, marketing, sale, transport, handling and packaging of genetically modified organisms;

(e) provide for liabilities of GMO permit holders in respect of prejudice caused by their activities to other persons;

(f) amend the Schedules.

(3) Regulations made under this Act may provide that any person who contravenes them shall commit an offence and shall, on conviction, be liable to a fine not exceeding 50,000 rupees and to imprisonment for a term not exceeding 2 years.

25. Commencement

(1) Subject to subsection (2), this Act shall come into operation on a date to be fixed by Proclamation.

(2) Different dates may be fixed for the coming into operation of different sections of this Act.

Passed by the National Assembly on the twenty-third day of March two thousand and four.

André Pompon

Clerk of the National Assembly

Annex D

Provisional list of equipment required for testing of GMOs

Equipment	Approximate cost US $
1. Laminar flow cabinet	8 000
2. Thermal cycler	7 000
3. Electrophoresis tanks + power pack	4 000
4. Ultra violet transilluminator	3 000
5. MP4 Camera system	8 000
6. Bench Centrifuge	7 000
7. Microcentrifuge	4 000
8. Hybridization oven	7 000
9. Precision balance	5 000
10. Transfer tank for Western blot	3 200
11. ELISA reader	8 000
12. Low temperature freezer	9 000
13. Micropipettes	3 800
Total	77 000

Annex E

Monitoring and Evaluation Plan

C.6 a Execution performance and delivered outputs

Monitoring of the project execution will assess whether the management and supervision of project activities is efficient and seek to improve efficiencies and overall effectiveness of project implementation. It is a continuous process, which will collect information about the execution of the planned activities, allow for improvements in method and performance, and compare accomplished with planned tasks . This activity will be under direct responsibility of the National Coordination Committee (NCC) . The UNEP Task manager will, in collaboration with the NCC, track these indicators (Table 2).

Table 2 Indicators and Means of verification

Indicator	**Means of Verification**
Half-yearly and annual activity and progress reports are prepared in a timely and satisfactory manner	Arrival of reports to UNEP
Half-yearly disbursement plans and half-year and annual financial reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Yearly GEF Project Implementation Review reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Performance targets, outputs, and outcomes are achieved as specified in the annual work plans.	Semi annual and Annual progress reports
Deviations from the annual work plans are corrected promptly and appropriately.	Work plans, minutes of SC meetings
Disbursements are made on a timely basis, and procurement is achieved according to the procurement plan.	IMIS system at UNEP and Bank Account statements of executing agency
Audit reports and other reviews show sound financial practices.	Audit statements
National Coordinating Committee is tracking implementation progress and project impact, and providing guidance.	Minutes of NCC meetings
National Coordinating Committee is providing policy guidance, especially on achievement of project impact.	Minutes of NCC meetings

Monitoring and evaluation of project execution will be conducted through constant interaction, namely exchange via email and technical support or supervision missions. Throughout the project, approaches will be integrated with feedbacks, lessons learnt and best practices gained. The task manager will facilitate exchange of experiences between countries in the process of implementing their NBF. A meeting of the NPCs of the ongoing implementation projects is expected to be held annually.

The monitoring plan also covers the risks associated to project management. In this respect, special attention will be devoted to:

Management structure	so as to monitor whether stability and responsibilities are clearly understood
Work Flow	so as to verify if the project is maintaining its planned work load (key role in this case is played by quarterly reports and constant contacts)
Co-financing	so as to ensure that disbursements are carried out in time and with ease
Implementation	To verify if work plan is progressing according to schedule
Budget	So as to ensure that the work plan is progressing according to budget plans

Fund management[1]	So as to ensure that funds are wisely spent and correctly and transparently accounted for
Reporting	So as to monitor that work progress is reported comprehensively and on time. Reports contains critical analysis
Stakeholder involvement	So as to ensure that a multi-stakeholder process is in place and active
Communication	So as to guarantee that communication between management team members is fluid
Leadership	So as to ensure that project has an active and committed management team
Short term/long term balance	So as to guarantee that project meets short term need without compromising on long term outlook
Political influence	So as to verify project is making politically motivated decisions

C6.b Project impact

Evaluation of the project's success in achieving its outcomes will be monitored continuously through the project progress reports, mid-term and final evaluation reports, all of which will use the **log-frame** presented in Annex H.The full implementation of all components of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main focus for assessing the success of the project.

The Project Management team is responsible for monitoring progress as well as ensuring evaluation of impact. These are described in Tables 3 and 4 (below).

Table 3 Responsibilities of the project management entities regarding monitoring and reporting

UNEP Task Manager	**National Executing Agency (NEA)**	**National Coordinating Committee (NCC)**
Monitor the agreed M&E plan in accordance with the terms of agreement with GEFSEC Receive quarterly and annual reports (progress and financial), and copies of all substantive reports from (National Executing Agency). Task manager to attend and participate fully in meetings of the NCC Task Manager to conduct supervision missions to selected project sites and identify implementation problems and suggest remedies to annual meeting of the NCC. Engage and prepare terms of reference for independent M&E consultants to conduct the mid-term and final	Prepare quarterly progress reports (operational and financial) annual summary progress reports for UNEP, and forward quarterly operational and financial reports, with supporting documentation as appropriate, in a timely manner to UNEP. Carry out a programme of regular visits to project sites to supervise activities, and pay special attention to those sites with serious implementation problems	Meet at least on a quarterly basis and receive quarterly progress and financial reports, annual summary progress reports and all substantive reports and outputs and use them to review the progress of work in the project as a whole Advise on implementation problems that emerge, and on desirable modifications to the work-plan Monitor progress of the project, and advise on steps to improve it

[1] The total expenditures incurred during each year ending 31 December, certified by a duly authorised official, will be reported in an opinion by a recognised firm of public accountants according to UNEP regulations

evaluations		

Table 4: The key content required in the quarterly progress reports and financial reports.

Report	Format and Content	Timing	Responsibility
Progress Reports			
Document the completion of planned activities, and describe progress in relation to the annual operating/work plan. Review any implementation problems that impact on performance Summary of problems and proposed action Provide adequate substantive data outcomes for inclusion in consolidated project half-yearly and annual progress reports Highlights of achievements	Reports will use standard UNEP Progress Report format. The project log frame (Annex H) will be attached to each report and progress reported against outcome and output indicators.	Quarterly, within 30 days of end of each reporting period,	NEA
The Project Implementation Review (PIR) reports	Per GEFSEC format	Yearly (after project has been under implementation for one year)	UNEP Task Manager
Consolidated Annual Summary Progress Reports			
Presents a consolidated summary review of progress in the project as a whole, in each of its activities and in each output Provides summary review and assessment of progress under each activity set out in the annual work plan-, highlighting significant results and progress toward achievement of the overall work programme	Reports will use a standard format to be developed following the UNEP Progress Report model The project log-frame will be attached to each report and progress reported against outcome and output indicators. A consolidated summary of the half-yearly reports Summary of progress and of all project activities Description of progress under each activity and in	Yearly, within 45 days of end of the reporting period	NEA

Provides a general source of information, used in all general project reporting	each output Review of delays and problems, and of action proposed to address with these Review of plans for the following period, with report on progress under each heading		
Financial reports			
Report on co-financing that has been provided to project as originally estimated in project proposal approved by GEF	Use Annex as found in project document with supporting documentation of realized co-financing	Six-monthly	NEA
Details project expenses and disbursements	Standardized UNEP format as found in project document Disbursements and expenses in categories and format as set out in standard UNEP format, together with supporting documents as necessary	Quarterly	NEA
Summary financial reports	(Standardized UNEP format as found in project document)		
Consolidates information on project expenses and disbursements	Disbursements and expenses by category. Requirement for coming period: request for cash advance.	Half-yearly, within 30 days of end of period	Project financial officer
Financial audits			
Annual audit	Audit of accounts for project management and expenditures	Annual	Recognised firm of public accountants according to UNEP regulations.

A summary of the project against key indicators, baseline and method of data collected is presented in Annex I.

Annex F

Incremental cost analysis

Project Components	Baseline	Alternative	Increment
Biosafety regulatory regime	A GMO Law was approved in march 2004; Executive Directive Regulations (EDRs) to be formulated	The implementation of the Cartagena Protocol is supported by a regulatory regime reflecting existing policies and defining all the elements of the NBF , in line with CP.	A legal regime , which includes a Biosafety Law and related implementing regulations, is in place. Decision-makers and personnel involved in the application of the regulatory regime are trained.
System for handling requests for permits	Mauritius needs to set up procedures for handling requests as per GMOs Law and provide tools and training to staff in charge of handling requests and making decisions	The implementation of the Cartagena Protocol is supported by an operational system for handling requests, which includes administrative processing, risk assessment and decision-making in line with national legislation and CP procedures	A system for handling requests for LMOs, including administrative processing, risk assessment and decision-making is in place. Personnel and decision-makers are duly trained and supported in carrying out their tasks by internal manuals and guidelines for risk assessment and risk management
System for follow-up, namely monitoring for environmental effects and enforcement	Mauritius has to elaborate guidelines for monitoring of environmental effects and procedures for enforcement. Technical means and training are needed so as to enable inspectors, custom clearance officers and technicians to carry out their tasks	The implementation of the Cartagena Protocol is supported by an operational system for monitoring for environmental effects and enforcement	Systems for monitoring of environmental effects and enforcement are in place. The reference laboratory at for GMO testing is upgraded
Public information, participation, awareness and education	Awareness and education on biosafety need to be further raised, involvement of the public need to be part of the system so as to reflect Article 23 of the Cartagena Protocol	The implementation of the Cartagena Protocol is supported by a strengthened system for public information, and participation	Outreach material is produced and disseminated for different target groups. Two workshops aiming at raising awareness on the established (by GMOs Act) mechanisms for public information and participation are carried out.

Broad development goals

GEF resources will be used to assist Mauritius to meet the objective of the Cartagena Protocol (to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into

account risks to human health, and specifically focusing on transboundary movements) and therefore will be directed to support the implementation of the NBF in Mauritius.

Baseline

Mauritius benefited from funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project and builds on its main result, namely the approved GMO Act. The project benefits as well of the experience gained up to date through the 8 demonstration projects for the implementation of the NBF and complements the activities carried out by the BCH project approved in January 2005.

Baseline activities at domestic level amount to 131,000 USD**. A**round 15,000 USD were spent for the preparation of the regulatory regime, 5,000USD for handling request, around 105,000USD for monitoring of environmental effects , and 6, 000USD for public awareness.

The country's commitment is also shown by the governmental in kind co-financing to the project, equal to 207,900USD, and distributed among the project components as shown in details in the budget attached in Annex G.

GEF alternative

Human resource capacity has been identified as a major constraint to the progress in biosafety, which is based on the GMO Act approved in March 2004. Under the GEF alternative, this type of support is thoroughly planned and training is a crucial part of the project**.**

Costs in total

The total baseline expenditure amounts to 131,000USD. The alternative has been costed at USD766,700. The incremental cost analysis shows that an amount of USD635, 700 is required to achieve the project's global environmental objectives. The country will cover the 33% of the cost of the increment as in kind contribution. The national contribution is mainly devoted to the costs of project management, handling of requests and monitoring for environmental effects. USD427,800 , including 70,000 for UNEP Technical support - is requested from GEF.

Annex G

D2: BUDGET (including National co-financing)

Project Component	Year 1	Year 2	Year 3	Year 4	Total GEF Contribution	In Kind by Mauritius	Total
Regulatory Regime							
A.1 Draft implementing regulations as per GMO Act	20,000				10,000	10,000	20,000
A.2 Workshop on the National Biosafety legislation and the Cartagena Protocol (35 participants) 1 day	10,000				8,000	2,000	10,000
Sub-total A	*30,000*				*18,000*	*12,000*	*30,000*
Handling of requests							
B.1 Workshop on handling of applications (35 participants/ 2 days)		15,000			10,000	5,000	15,000
B.2 Technical guidelines on handling of request, transport, labelling of LMOs	2,000	8,000			8,000	2,000	10,000
B.3 Two hands-on training courses on risk assessment and risk management (1 week/each training for 10 custom officers/inspectors/technical staff)		20,000	20,000		30,000	10,000	40,000
B.4 Training course on transport, handling and packaging of LMOs (three-day /10 officers-technical staff			15,000		10,000	5,000	15,000
B.5 Make the "application forms for LMOs permit" available on the website		100				100	

B.6 Prepare operational manuals for regulators on handling requests, namely written procedures on administrative processing, risk assessment and decision making procedures		5,000	5,000		5,000	5,000	10,000
Sub-total B	*2,000*	*48,100*	*40,000*		*63,000*	*27,100*	*90,100*
Cumulative sub-total	*32,000*	*48,100*	*40,000*		*81,000*	*39,100*	*120,100*
System for follow-up (monitoring for environmental effects and enforcement)							
C.1 Prepare technical guidelines on systems for follow-up on monitoring and enforcement	5,000	5,000	5,000		10,000	5,000	15,000
C.2 Laboratory and infrastructure for testing of GMOs	38 500	38 500			55 000	22 000	77 000
C.3 Two training courses on testing and monitoring of LMOs (1 week/each training for 10 custom officers/inspectors/technical staff)			20,000	20,000	*30,000*	*10,000*	*40,000*
Sub-total C	*43,500*	*43,500*	*25,000*	*20,000*	*95,000*	*37,000*	*132,000*
Cumulative sub-total	*75,500*	*91,600*	*65,000*	*20,000*	*176,000*	*76,100*	*252,100*
Public awareness and participation							
D.1 Two one-day workshops for 50 participants representing the general public, media, NGOs, journalists, policy makers and scientists on 'Public Information and Participation'	10,000			10,000	15,000	5,000	20,000
D.2 Develop awareness material (brochures) and disseminate it to main			15,000		11,000	4,000	15,000

users, i.e. politicians, community leaders private sector, consumer protection association, chambers of commerce and general public							
D.3 Produce share and incorporate lessons learned from project activities	500	500	500		1000	500	1500
Sub-totalD	*10,500*	*500*	15,500	*10,000*	*27,000*	*9,500*	*36,500*
Cumulative sub-total	*86,000*	*92,100*	80,500	*30,000*	*203,000*	*85,600*	*288,600*
E. Project co-ordination and management							
Project Co-ordinator	21,600	21,600	21,600	21,600	48,000	38,400	86,400
Project Assistant	10,800	10,800	10,800	10,800	16,800	26,400	43,200
Equipment and premises	10,000	2,500	2,500	2,500	7,500	10,000	17,500
Audits	2,500	2,500	2,500	2,500	7,500	2,500	10,000
Communication and reporting (under sundry)	2,500	2,500	2,500	2,500	5,000	5,000	10,000
Staff and National Coordination Committee member travel expenses	10,000	10,000	10,000	10,000	30,000	10,000	40,000
NCC meetings	5,000	5,000	5,000	5,000	10,000	10,000	20,000
Sub-total E	*62,400*	*54,900*	*54,900*	*54,900*	*124,800*	*102,300*	*227,100*
Consultancy (regulations, guidelines, operational manuals, etc)	15,000	15,000	10,000	10,000	30,000	20,000	50,000
Subtotal	*77,400*	*69,900*	*64,900*	*64,900*	*154,800*	*122,300*	*277,100*
Technical Support					*70,000*		*70,000*
Total (USD)	*163,400*	*162,000*	*145,400*	*94,900*	*427,800*	*207,900*	*635,700*

D3 Project implementation plan

The project will be carried out over a period of 4 years according to the following schedule:

Activity	Year 1												Year 2												Year 3												Year 4											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
A. REGULATORY REGIME																																																
Review of the national biosafety regulatory framework	X	X	X	X	X	X	X	X	X	X																																					
Workshop on Legislation and Cartagena Protocol									X																																						
B. HANDLING REQUESTS FOR PERMITS																																															
Technical guidelines on risk assessment, handling, transport, labelling of LMOs											X	X	X	X	X	X	X	X	X	X																												
Two days workshop on Handling of applications																		X																													
Two one-week training courses for technicians on risk assessment/management																				x																												
Three days training for 10 officers/technicians on handling, transport and packaging of LMOs																							X																							
Make the application forms available on the web													X	X																																		

Prepare operational manuals on handling requests, namely administrative procedures on administrative processing, risk assessment and management and decision making procedures																						X	X	X	X	X	X																					
C. MONITORING AND ENFORCEMNET																																																
Prepare technical guidelines on systems for follow-up, namely monitoring and enforcement							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																						
Equipment for LMOs testing					X	X	X						X	X	X																																	
Two one-week training courses for 10 officers/technicians on LMOs testing and monitoring																											X												X									
D. PUBLIC INFORMATION AND PARTICIPATION																																																
One day workshop for 50 participants on Information Exchange and biosafety (general public, media, NGOs, policy makers, etc.)									X																																	X						

Awareness material							X	X	X	X	X	X	X	X	X	X	X																															
Lessons learnt											X	X												X	X										X	X									X	X		
Project management and co-ordination	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Annex H: Project Log frame

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
Development Goal: **By 2009, Mauritius has a workable and transparent national biosafety framework that is in line with its international obligations and national development priorities**	**Operational Nbf in line with its international and national obligations (GMO Law) by 2009**	**Report on NBF**	**Lack of workable systems for implementing the NBF**	**Make a regulatory system operational through implementing regulations, technical guides, and operational manuals.**
Immediate Objective 1: **To have a fully operational regulatory regime on biosafety, in line with the recently adopted GMO law and CP by 2009**	**A regulatory regime in place and in line with CP and international obligations, by 2009**	➢ **Implementing regulations approved as per GMO Act,** ➢ **Technical guidelines available** ➢ **Internal manuals available**	➢ **Regulatory regime cannot be enforced because of lack of implementing regulations, guidelines and manuals** ➢ **Regulatory regime cannot be enforced because of inefficiency of existing administrative structures** ➢ **Regulatory regime cannot be enforced because of lack of capacity of personnel in charge** ➢ **Internal manuals not available so responsible staff does not know who is who and who does what**	➢ **Develop implementing regulations as per GMO Act,** ➢ **Develop tools and training for translation of legislation into practice** ➢ **Provide training for legal experts** ➢ **Promote cooperation and exchange of information throughout government structure**
OUTCOMES				
1.1 The implementing regulations and procedures are developed in line with the recently adopted GMO law, adopted and into effect	➢ Compliance with ICCP list ➢ Compliance with other related international obligations with the CP	➢ ICCP list filled in and available	Regulatory regime not adequately translated into practice	Promote training on regulatory instruments related to biosafety in the country and the requested minimum compliance with CP
ACTIVITIES a) Draft and finalise the implementing regulations in line with GMO Law	➢ Approved implementing regulations	➢ Approved regulations published in national gazette ➢ Posting (at least) of the summary of the regulations in a UN language on the BCH	➢ Regulations cannot be finalised because of lack of public and institutional support; ➢ Internal operational manuals not available so responsible staff does not know who is who and who does what	➢ Promote consultation with stakeholders during preparation of the regulations ➢ Prepare operational manuals
a) Hold two workshops for about 30 participants, including all the main stakeholders, on the obligations of the Cartagena Protocol, the newly adopted GMO Law and related implementation needs	➢ Minimum of 80% of invited participants attending	➢ Workshop documents and evaluations ➢ List of participants	➢ Quality of the workshop material is not satisfactory ➢ Participants are not accurately selected ➢ Resource persons are not appropriate ➢ Duration of the workshop is not adequate	➢ Careful planning of the workshop ➢ Careful identification of the resource persons and participants

Annex H: Project Log frame

Immediate Objective 2: **To put in place and fully implement by 2009, a system for handling of permits (including administrative processing, risk assessment and decision-making), transport, packaging and labelling of LMOs**	➢ **System for handling applications in place** ➢ **Number of decisions made as result of request** ➢ **NCA(s) in place with clear distinction of responsibilities**	➢ **Set of procedures for handling requests available** ➢ **Decisions are recorded on the BCH**	➢ **System for handling requests cannot be enforced because of lack of implementing guidelines and manuals** ➢ **System for handling requests cannot be enforced because of lack of capacity on how to handle the request and how to perform risk assessment**	➢ **Develop tools and training on handling request (including risk assessment), transport, packaging, and labelling** ➢ **Specify roles and responsibilities so as to minimise inefficiencies**
OUTCOMES				
2.1 Guidelines and tools for carrying out handling of application, transport, packaging and labeling of LMOs developed and operational	➢ Technical guidelines available to all those involved with handling of application (risk assessment included), transport, packaging, and labelling ➢ Application form available ➢ Finalised operational manual	➢ Technical guidelines available ➢ Reports, documents	➢ Technical guidelines are not clear and do not cover all the steps	➢ Experts provide comments on guidelines before finalisation and publication
ACTIVITIES Draft and finalise the technical guidelines on handling of application transport, packaging and labelling of LMOs	➢ Approved technical guidelines	➢ Technical guides available ➢ Number of copies printed ➢ List of person dispatched to	➢ Technical guidelines are not clear and do not cover all the steps	➢ Experts provide comments on guidelines before finalisation and publication
Make the "application forms for LMOs permit" available on the website	➢ Application form accessible from the web	➢ Number of hits to download the application form accessible from the web available on the from website	➢ Website not user-friendly ➢ Downloading very slow	➢ Experts are consulted to guarantee a user friendly national website
Prepare operational manuals for personnel in the Biosafety Office on handling of requests	➢ Manuals are developed	➢ Manuals are available ➢ Number of copies printed ➢ List of person dispatched to	➢ Manuals are not clear in defining who is who and who does what and do not cover all the steps	➢ Experts are consulted for a revision of the manual
OUTCOME				
2.2. Personnel trained on handling of request and labelling	➢ Increased knowledge and awareness on handling of request and labelling by target groups	➢ Documents, training material and end- of-training evaluations	Quality of the training material is not satisfactory Participants are not accurately selected Not enough motivated to learn	➢ Careful planning of the training activities and training tools ➢ Careful identification of the target persons ➢ Involvement of the personnel and sensitising on their crucial role in the functioning of the NBF
Organise a two-day training workshop for about 35 participants of the Ministry of Agriculture, Food Technology and Natural Resources, Ministry of Environment, Ministry of Health and Quality of Life, Ministry of	➢ Minimum of 80% of invited participants trained	➢ Workshop documents and post-training evaluation ➢ List of participants	➢ Quality of the workshop material is not satisfactory ➢ Participants are not accurately selected ➢ Resource persons are not appropriate	➢ Careful planning of the workshop ➢ Careful identification of the resource persons and participants

International Trade, State Law Office, Custom Departments, Research Organizations and University staff on procedures involved with handling of applications for release of GMOs into the environment' as per GMO law			➢ Duration of the workshop is not adequate	
Organise two one week hands-on training courses for 10 officers/technical staff to specialise on risk assessment and management	➢ Minimum of 80% of invited participants trained	➢ Workshop documents and post-training evaluation ➢ List of participants	➢ Quality of the workshop material is not satisfactory ➢ Participants are not accurately selected ➢ Resource persons are not appropriate ➢ Duration of the workshop is not adequate	➢ Careful planning of the workshop ➢ Careful identification of the resource persons and participants
Organise a three-day training of 10 officers/technical staff to specialise on handling, transport, packaging and labelling of LMOs	➢ Minimum of 80% of invited participants trained	➢ Workshop documents and post-training evaluation ➢ List of participants	➢ Quality of the workshop material is not satisfactory ➢ Participants are not accurately selected ➢ Resource persons are not appropriate ➢ Duration of the workshop is not adequate	➢ Careful planning of the workshop ➢ Careful identification of the resource persons and participants
Immediate Objective 3: **To set up a workable system for monitoring and enforcement on biosafety by 2009**	➢ **Roles and responsibilities for monitoring and enforcement in place** ➢ **Set of methodologies and procedures for monitoring of environmental effects established** ➢ **Procedures for enforcement established**	➢ **Written and approved division of roles and responsibilities available** ➢ **Methodologies and procedures for monitoring available** ➢ **Procedures for enforcement available**	➢ **Monitoring and enforcement activities cannot be carried out because of lack of capacity of personnel in charge** ➢ **Monitoring and enforcement activities cannot be carried out adequately because of lack of equipment** ➢ **Methodologies for monitoring activities are not clear and/or appropriate** ➢ **Procedures for enforcement measures are not clear and consistent**	➢ **Reinforcement of the certified labs in terms of equipment needed for monitoring purposes** ➢ **Develop tools and training on monitoring and enforcement activities on biosafety** ➢ **Experts are consulted for a revision of the methodologies** ➢ **Experts are consulted for a revision of the procedures**
OUTCOMES				
3.1 Technical guidelines for monitoring and enforcement are developed and in force	➢ Technical guidelines for monitoring and enforcement developed	➢ Technical guidelines for monitoring and enforcement available	➢ Technical guidelines are not clear and/or appropriate	➢ Experts are consulted for a revision of the technical guidelines
ACTIVITIES Prepare technical guidelines on monitoring for environmental releases and enforcement actions	➢ Methods and procedures of monitoring for environmental releases are established	➢ Methods and procedures established and related technical guidelines available ➢ Number of technical guidelines	➢ Methods and procedures are not clear (in defining who is who and who does what and do not cover all the steps	➢ Experts are consulted for a revision of the Methods and procedures to be included in the technical guidelines

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		printed ➢ List of person dispatched to		
OUTCOMES				
3.2 Technical means and capacity for monitoring are in place	➢ Technical means for monitoring in use	➢ Invoice and reports on use of technical means	➢ Technical means for monitoring activities do not match needs	➢ Identification of needs ➢ Consultation with Task Manager
ACTIVITIES Provide the laboratory of the Ministry of Agriculture with adequate equipment for detection of LMOs (see provisional list of equipment attached in Annex D)	➢ Number of monitoring activities carried out using equipment purchased	➢ Reports of monitoring activities	➢ Equipment does not match needs	➢ Identification of lab needs before purchase of the equipment ➢ Approval of the list of equipment by the Task manager
Organise two one-week training courses for 10 inspectors/custom officers/technical staff on LMO testing and investigation	➢ Minimum of 80% of invited participants trained	➢ Training documents and post-training evaluation ➢ List of participants	➢ Quality of the training material is not satisfactory ➢ Participants are not accurately selected ➢ Resource persons are not appropriate ➢ Duration of the training is not adequate	➢ Careful planning of the training ➢ Careful identification of the resource persons and participants
Immediate Objective 4: **To have an operational system for promoting public awareness and involvement in decision-making on GMOs by 2009**	➢ Mechanism for public information and participation in place	- Legislation and/or specific strategies	- Lack of capacity to address public participation and awareness issues - Control of media. - Media not willing to promote debate on biosafety.	Developing and implementing plans for public education and awareness, ensuring that the decision-making process includes specific entry points for public participation, etc.
Outcomes				
4.1 Increased Public awareness and education on biosafety	➢ **Public debate and discussion in media**	**Media coverage**	➢ Lack of capacity to address public participation and awareness issues ➢ Control of media. ➢ Media not willing to promote debate on biosafety	➢ Cooperate with UNEP and regional network to build capacity in public awareness, education and participation. ➢ Use every means of media to ensure information related to risk reach the public. ➢ Encourage NGOs and other local institutions to handle public awareness as they have done before
ACTIVITIES Organise two one-day workshops on public information and participation in the GMO Act	➢ Minimum of 80% of invited participants attending	➢ Workshop documents and post-training evaluation ➢ List of participants	➢ Quality of the workshop material is not satisfactory ➢ Participants are not accurately selected	➢ Careful planning of the workshop Careful identification of the resource persons and participants

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			➢ Resource persons are not appropriate ➢ Duration of the workshop is not adequate	
Prepare education materials on biosafety, also using mass media including TV, radio, news papers, gazettes, homepage on biosafety	Number of different outreach materials distributed to target groups	Published outreach material	Different categories of audience and related needs are not correctly identified	Identification of the audience and messages before preparation of the outreach material
Produce share and incorporate lessons learned and best practices	Lessons learnt and best practices are identified	Disseminated material	Lessons learnt are not identified	Consultative process for the identification of lessons learnt

ANNEX I

Key Performance Indicators, Baseline and Methods of Data Collection

Project Intervention Strategy	Key performance indicator	Baseline (if not known, please identify how and when will be established)	Method of data collection/data collection strategy (including frequency)
Development Goal: **Mauritius has a workable and transparent national biosafety framework that is in line with its international obligations and national development priorities**	Operational Nbf in line with its international and national obligations (GMO Law) by project completion	The country provides current baseline information, including the approved GMOs Law .It adds up to the information collected during the Project for the Development of the NBF completed in 1999. Formalised at project start to constitute baseline .	Information on the status of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly TM visit to the country. It will be collected in the final project report
Immediate Objective 1: **To finalise and by 2009, to make fully operational the regulatory regime on biosafety (in line with the recently adopted GMO law)**	A finalised regulatory regime reflecting existing policies and in line with GMOs Act, CP and international obligations	Existing GMO Law , in line with CP	Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project
Outcomes 1. The implementing regulations and procedures are developed in line with the recently adopted GMO law, adopted and into effect	Compliance with ICCP list	ICCP list	Data will be extracted from the reports from workshops held to develop a biosafety strategy during the first year and internal discussion papers
Immediate Objective 2: **To put in place and fully implement by 2009, a system for handling of permits (including administrative processing, risk assessment and decision-making), transport, packaging and labelling of LMOs**	➢ NCA(s) in place with clear distinction of responsibilities ➢ Set of procedures for handling requests developed	Procedures and competencies as defined in the GMOs Act	Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project
Outcomes	➢ Technical guidelines available to all	General procedures and competencies as	Reports from experts on technical guidelines on handling of application (risk

2.1 Guidelines and tools for carrying out handling of application, transport, packaging and labelling of LMOs developed and operational	those involved with handling of application (risk assessment included), transport, packaging, and labelling ➢ Application form available on the website ➢ Finalised operational manual	defined in the GMOs Act Current application form are available only in paper No operational manual available, details in operational procedures still to be defined in the secondary legislation	assessment included), transport, packaging, and labelling Report by the expert in charge of making the forms available electronically Progress in drafting the operational manual
2.2. Personnel trained on handling of request and labelling	➢ Increased expertise on handling of request and labelling by target groups	Collection of material used to date for training purposes	Collection of material further elaborated for training purposes Proceedings of each training activity, list of participants, post-training evaluation questionnaire Progress reports
Immediate Objective 3: **To set up a workable system for monitoring and enforcement on biosafety by 2009**	➢ **Roles and responsibilities for monitoring and enforcement in place** ➢ **Set of methodologies and procedures for monitoring developed** ➢ **Procedures for enforcement developed**	General procedures and related competencies are set in the approved GMOs Law	Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project
Outcomes **3.1 Technical guidelines for monitoring and enforcement are developed and in force**	➢ Technical guidelines for monitoring and enforcement established	No detailed methodology or procedure is currently defined, other than the general procedures set in the approved GMOs Law	Reports from experts involved Implementing regulations, related explanatory documents/notes
3.2 Technical means and capacity for monitoring are in place	➢ Equipment for monitoring and inspection in use ➢ Training activities carried out as planned	Part of the equipment to be used for monitoring and inspections purposes available in laboratory	• Invoice documenting purchase of the equipment, financial progress report • Proceedings of each training activity, list of participants, post-training evaluation questionnaire
Immediate Objective 4: **To establish a national system for promoting public awareness and involvement in decision-making on GMOs**	Mechanism for public information and participation in place	- Lack of political support - Biosafety is not a sustainable development issue - Lack of capacity to address public participation and awareness issues - Control of media. Media not willing to promote debate on biosafety	Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project

Outcomes **4.1 Increased Public awareness and education on biosafety**	➢ **Public debate and discussion in media** ➢ **Outreach material produced**	• Past media coverage of biosafety • Outreach material produced so far • Material used for previous awareness raising activities	• Progress reports and the final report of the project with indications of number and type of outreach material developed and distributed • Proceedings of each training activity, list of participants, post-training evaluation questionnaire

ANNEX J

Draft Terms of Reference (TOR)

Draft TOR for:

- National Executing Agency (NEA)
- National Project Coordinator (NPC)
- National Coordinating Committee (NCC)

a) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:

- Establish a National Co-ordinating Committee (NCC);
- Appoint a National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final version of the National Biosafety Framework no later than eighteen months from signature of this Memorandum of Understanding.

b) The National Coordinating Committee (NCC**)** will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

- Develop a common understanding of what is needed to expedite the implementation of the National Biosafety Framework;
- Oversee the implementation of the National Biosafety Framework
- Approve the detailed workplan and budget produced by the NPC;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project;
- Ensure that information on the implementation of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
- Assist in mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;
- Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;

c) The National Project Coordinator (NPC**)** will carry out the following tasks

- The National Project Coordinator (NPC) will act as the chair of the NCC

- Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Prepare detailed workplan and budget under the guidance of the NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP National Project Team;
- Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NCC, regular progress and financial reports

The Project Assistants (PA) will carry out the following tasks

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation detailed work plan and budget under the guidance of the NCC;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outp uts of the NBF;
- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports
- Assist with the preparation of a project monitoring and evaluation plan

- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact
- Assist with capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines
- Assisting in identifying problems in the implementation of the project and to alert the NPC and NCC.