

NATIONAL BIOSAFETY FRAMEWORK OF SRI LANKA



**Ministry of Environment and Natural Resources
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ACRONYMS AND ABBREVIATIONS USED IN THE FRAMEWORK

CBD	Convention on Biodiversity
CEA	Central Environmental Authority
DAPH	Department of Animal Production and Health
DF	Department of Fisheries
DOA	Department of Agriculture
DWLC	Department of Wildlife Conservation
FCD	Food Commissioner's Department
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
IBSC	Institutional Biosafety Committees
LMO	Living Modified Organism
MCC	Ministry of Commerce and Consumer Affairs
NCA	National Competent Authority
NCC	National Coordinating Committee
NGO	Non Governmental Organization
PAA	Project Approving Agency
SCA	Sectoral Competent Authorities
UNEP	United Nations Environment Program
WTO	World Trade Organization

IMPORTANT WEBSITES RELATED TO BIOSAFETY

<http://www.biodiversity.org/biosafety>
<http://www.biosafety.lk>

FORWARD

UNEP-GEF PROJECT ON DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK FOR SRI LANKA STARTED IN MAY 2003 AND ENDED IN MAY 2005.

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National Coordinating Committee (NCC) consisted of 22 members representing Ministry of Environment and Natural Resources (Chairman of the NCC); National Project Coordinator, National Biosafety Framework Development Project (Secretary of the NCC); Ministry of Justice; Ministry of Health; Ministry of Agriculture, Animal Production, Land and Irrigation; Ministry of Trade; Ministry of Fisheries and Aquatic Resources; Ministry of Science and Technology; Central Environmental Authority; Director General of Customs; Non Governmental Organizations and Civil Societies (see Annex 1 for details about NCC members).

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PART I

1.0 INTRODUCTION

1.1 National biosafety framework project development

Though small in size, Sri Lanka has a varied climate and topography, which has given rise to rich species diversity, believed to be the highest in Asia, in terms of unit land area. This is especially relevant for mammals, reptiles, amphibians and flowering plants. The biological wealth is distributed within a multitude of systems that have been broadly categorized as coastal and marine, forest, wetland and cultivated areas. Sri Lanka is also identified as one of the global biodiversity hotspots indicating its significance in biological wealth and threats to the biological wealth.

The Cartagena Protocol on Biosafety was adopted in Montreal on 29 January 2000 as a supplement to the Convention on Biological Diversity (CBD) to address the safe transfer, handling, and use of "Living Modified Organisms" (LMOs). This agreement entered into force on 11 September 2003. In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse impacts on the conservation and sustainable use of biological diversity, taking into accounts risks to human health and specifically focusing on transboundary movements.

Sri Lanka signed the Cartagena Protocol on Biosafety on 24 May 2000, during the fifth meeting of the Conference of Parties to the Convention on Biological Diversity in Nairobi, Kenya, when it was first open for signatories. The country ratified Cartagena Protocol on 28 April 2004 and consequently the Protocol has entered into force in the country on 28 July 2004. The Ministry of Environment and Natural Resources as the Focal Point for the CBD, also took upon itself the responsibility of National Focal Point for Cartagena Protocol on Biosafety and is also the Project Executing Agency for the UNEP/GEF funded National Biosafety Framework Development Project for Sri Lanka. The project commenced in May 2003 and is due to be completed in May 2005. The overall objective of Sri Lanka's national biosafety framework is to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected in a maximum way regulating the transboundary movements through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. The biosafety framework is based on the precautionary approach.

The Ministry recruited the National Project Coordinator as Prof. ALT Perera of Faculty of Agriculture, University of Peradeniya. The project also established the National Coordinating Committee (NCC), consisting of representatives of biosafety related sectors and institutions (See Annex 1 for members of the NCC). The project management was done by the NCC. For successful completion of the project and to include a wider participation in biosafety issues, the NCC appointed four national sub-committees to look after different areas of the biosafety, namely sub-committee 1 (to recommend national policy on Biosafety, see Annex 2a for members); sub-committee 2 (to recommend the

regulatory mechanism for genetically modified organisms (GMO)/genetically modified food (GMF), see Annex 2b for members); sub-committee 3 (to recommend an administrative system for risk assessment and management - institutional set up, see Annex 2c for members); and sub-committee 4 (to recommend techniques and technology on biosafety, see Annex 2d for members). Information on present scenario with respect to regulation of GMOs and institutional responsibilities and authority for import, release, marketing, and contained use of GMOs was also obtained through available reports, inputs from the committee members as well as other selected individuals. The policies, legal regimes and institutional arrangements in other countries obtained mainly through internet searches were also taken into consideration in making recommendations for a suitable system for Sri Lanka. The project also conducted an island wide survey to identify policy issues, experts, physical resources etc. on biotechnology and biosafety in Sri Lanka. This information was later used to develop a national database on biotechnology and biosafety. The project also appointed 56 Institutional Coordinators to form a valuable network as they engaged in all activities of the project bringing their institutions into active participation in the project. The project also conducted a number of awareness programs on GMOs/GMF to various stakeholders with respect to safety on environment and human health. The project also carried out a training program on risk assessment and management, laboratory safety procedures and GMO/GMF detection.

1.2 Objective

The objective of the National Biosafety Framework is two fold:

1. To provide an overview of current situation in the country that was assessed during the National Biosafety Development Project and identify what is currently in place in Sri Lanka (i.e. policies, legislation, administrative system etc.).
2. To identify what still needs to be done to complete the National Biosafety Framework (the missing legislation, which still needs to be drafted/adopted, gaps in the administrative or enforcement systems etc.).

It is strongly suggested that the National Biosafety Framework is an initial step towards a more permanent legislative framework for biosafety in Sri Lanka. As such, it will continue to have many gaps and inadequacies of the existing system. In particular, critical issues related to creation of new agencies, funding and legal remedies for liability and compensation are not addressed adequately in this draft as new legislation is required to deal with these issues. In the meantime, however, having an initial biosafety framework brings many advantages, particularly its flexibility. The framework should be revisited, reviewed and revised periodically to ensure that it is effective in meeting its stated objectives.

1.3 Organization of the Framework

The project has been developed according to the UNEP/GEF rules as to its content and timing of actions. The National Biosafety Framework report of the project is structured according to the UNEP/GEF proposed format into 6 main parts, namely Part I: Introduction with information on the project development, objectives and definitions used in the document; Part II: Description of the Government policy on biosafety; Part III: description of existing law and enforcement system of the country including principal acts

related to biosafety, institutions responsible for their implementation; Part IV: proposed administrative system for handling applications on request for authorization; Part V: system of risk management and follow up including monitoring and enforcement of impacts on the environment and human health, and responsible institutions; and Part VI: mechanisms for public education, awareness and participation, relation biosafety issues.

1.4 Definitions used

Advanced Informed Agreement - a formal agreement between two states or between a state and a group of states belonging to a regional economic integration organization, to transfer any GMO products thereof, based on information supplied by the exporting state, with the explicit understanding that the information is complete and accurate

Contained Use - means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment

Genetically Modified Organism (GMO) - any living organism or part thereof which is capable of regenerating itself on its own or in the body/cell of another organism, and whose genetic material has been modified by modern biotechnology in a way not occurring naturally by mating or natural recombination.

Living Modified Organism (LMO) - means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Or any living organism or part thereof which is capable of regenerating itself on its own or in the body/cell of another organism, and whose genetic material has been modified by modern biotechnology in a way not occurring naturally by mating or natural recombination.

Living Organism - means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Modern biotechnology - means application of:

- a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Precautionary Approach - a lack of scientific certainty of the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity, on the environment and human health may be due to insufficient relevant scientific information and knowledge. This shall not prevent a country from taking appropriate steps/precautions with regard to the import of LMOs, in order to avoid or minimize such potential adverse effects.

Risk assessment - the use of scientific and other appropriate methods to identify and characterize the nature, likelihood of occurrence, and potential magnitude of any hazards, with due regard to the precautionary principle.

Transboundary movement - any movement of GMOs or biotechnology products, intentional or unintentional, and by any means including gene transfer, across one or more national boundaries.

PART II

2.0 NATIONAL BIOSAFETY POLICY

2.1 Introduction

It is accepted that the Biosafety policy of Sri Lanka will be based on precautionary approach. In compliance with the Cartagena Protocol on biosafety, the main goals of the national biosafety policy will be to:

1. Ensure a highest possible level of biosafety in transfer, handling and use of genetically modified organisms on the basis of precautionary approach.
2. Develop national biosafety framework and all its components.

Biosafety policy for Sri Lanka was drafted by the sub-committee 1 (see Annex 2a for details of members of the sub-committee) in collaboration with other sub-committees. The sub-committee conducted several workshops with key stakeholders to gather relevant information before drafting the policy. The drafted policy was distributed among members of other sub-committees and NCC members. Comments of such members were incorporated and several drafts were prepared. In addition, several discussion sessions, seminars and workshop were held before making the final draft.

2.2 National biosafety policy

2.2.1 The need for a national policy on biosafety in Sri Lanka

Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. Biotechnology is not a new process in Sri Lanka. Traditional animal and plant breeding techniques (such as hybridization and the selection of plants and animals with specific characteristics) have for centuries been used to create, for example, higher yields or drought and disease-resistant varieties.

Over recent years, however, modern biotechnology has revolutionised our ability to alter life-forms through applying *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Modern biotechnology may have the potential to lead to considerable advances in medicine, agriculture, and other fields. At the same time, many of the risks of modern biotechnology (such as potential adverse effects on biological diversity, and risks to human health) are not yet known.

The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. It describes efforts to reduce and eliminate the potential risks resulting from modern biotechnology and its products.

There is an urgent need to establish biosafety measures for Sri Lanka, not only for genetically modified organisms (GMOs) and Food, Feed and Processed Products (FFP) that may be produced locally in the future, but also for those that may be imported into the country. There remains considerable uncertainty about potential risks associated with modern biotechnology. The possible costs of mitigating or reversing any harm that may occur as a result of the use of modern biotechnology may also prove to be immense, and far-reaching, especially to the government who are ultimately responsible for assuring the health status and food security of the Sri Lankan population.

It is therefore of prime importance to establish a National Policy on Biosafety, which will set the overall framework in which adequate safety measures will be developed and put into force, so that Sri Lanka can minimise possible risks to human health and the environment while extracting maximum benefit from any potential that modern biotechnology may offer. The National Policy on Biosafety is also an important tool to ensure that the knowledge, practices and benefits of Sri Lanka's traditional biotechnology techniques are safeguarded.

The National Policy on Biosafety is guided by the principle that if there is any perceived threat of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation and health impacts. It thus implies shifting the burden of proof, requiring that modern biotechnology applications used in Sri Lanka are first proved to be harmless, instead of waiting to take action once they have been proven harmful.

The establishment of a National Policy on Biosafety is an important step in meeting the obligations of the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CP), both of which Sri Lanka has ratified. As a Party to these International Conventions, Sri Lanka has thereby committed to take action to support the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources; as well as to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology.

2.2.2 Policy framework

The national policy on biosafety shall conform to National Development Objectives of the Government of Sri Lanka

2.2.3 Policy objectives

The Biosafety Policy renews the commitment of the government, in ensuring adequate levels of protection in the safe use of modern biotechnology based on the precautionary principle, within the framework of sustainable development for the benefit of present and future generations. This policy supports other related policies and is intended to be complementary and not to replace or undermine them.

The major policy objectives are as follows:

- Implementation of biosafety measures in order to ensure that there will be no significance adverse effects on human health, the environment and biodiversity.

- Ensure effective regulation and management of GMO/FFP that may be imported to Sri Lanka, based on the Advanced Informed Agreement.
- Regulate and manage any locally produced GMO/FFP.
- Promote dissemination of knowledge in the safe use and probable hazards of modern biotechnology.
- Emphasize biosafety and bioethical considerations in the development and application of modern biotechnology
- Provide an institutional framework for national decision-making, networking, monitoring research and development, and international cooperation in all matters relating to biosafety.
- Promote public participation in the decision making processes of all matters related to biosafety in order to maintain transparency in the process.

2.2.4 Policy principles

1. Sri Lanka shall ensure that biosafety measures are established based on the precautionary approach and the advanced informed agreement.
2. Sri Lanka shall place utmost importance on developing its own capabilities in all aspects of biosafety.
3. The manufacture, use, import, export, sale or trans-boundary movements of modern biotechnology applications, practices and products shall conform fully to all relevant national legislations.
4. Public awareness, education and participation in the decision-making processes shall be made essential for ensuring the judicious use of modern biotechnological applications, practices and products for socio-economic development, without jeopardizing the environment, biodiversity and human health.
5. Risk assessment and management of GMO/FFP shall be carried out according to national biosafety regulations. Where scientific risk evaluation of a biotechnology product, application or procedure gives rise to a negative recommendation, this shall not be overruled.
6. As a matter of public health protection and democratic governance, the industries involved in the use of modern biotechnology shall reveal information on organisms used and all other relevant data in order that consumers are aware of the products they are exposed to. Safety test data, especially for agricultural biotechnology and human genetic testing, manipulations and applications, shall be fully disclosed and made public in accordance with legitimate protection of commercially sensitive information.
7. Some international fora are structurally biased to favour commercial considerations over public health, environmental and safety interests. Decisions on biosafety issues shall be made in fora that do not suffer from this structural orientation.

2.2.5 Policy statements

- Recognizing the importance of protecting its people, environment and biodiversity while promoting a sustainable social and economic development through adopting biosafety measures,
- Recognizing the human and environmental health risks that may be incurred by careless or unscrupulous development of modern biotechnology and the use of its products for agriculture, health, waste management and other purposes,
- Realizing the need for developing our own capabilities in biosafety through research & development and training and
- Reaffirming the commitment to the obligations of the CBD and CP

2.2.5.1 There should be a National Focal Point for Biosafety at the Ministry of Environment and Natural Resources. It shall be the controlling authority for all issues relating to biosafety in Sri Lanka, including research and development, development of industry linkages, establishment of relevant legislations, protocols and guidelines.

2.2.5.2 Labelling of genetically modified products shall be made mandatory. Compulsory labelling will be required for all products resulting from modern biotechnology, at all stages of the production process, from raw material to final product, in order that the demands of consumers for a free and informed choice regarding food are fulfilled.

2.2.5.3 National safety guidelines and implementation practices shall be adopted by industries using modern biotechnology. The guidelines shall cover all related aspects, including material handling, equipment, storage, waste disposal, laboratory safety, etc.

2.2.5.4 GMO detection and analytical laboratories should be identified and duly accredited. Resources for risk assessment and management, shall also be identified, established and supported.

2.2.5.5 Priorities in Human Resource Development in Biosafety shall be assessed identified and developed.

2.2.5.6 Public awareness of modern biotechnology and potential risks/benefits, risk assessment and management techniques shall be enhanced, involving the community at large, including policy makers, legislators, administrators, the private sector and biotechnology industries. Special courses in natural sciences, technology and ethics shall be offered to personnel, who in their professional activities come into contact with biosafety issues and their ethical applications.

2.2.5.7 Research into the risks to the environment and human health that can be caused by modern biotechnology shall be supported. Adequate funds shall be allocated to implement such programmes.

- 2.2.5.8 Safety standards shall be reviewed and updated on a regular basis.
- 2.2.5.9 Appropriate knowledge bases and infrastructure for information exchange on biosafety shall be established and developed.
- 2.2.5.10 A Master Plan for Biosafety shall be established and used to implement the strategies and to develop the infrastructure and instruments outlined in this policy.
- 2.2.5.11 In the interim period, until the national biosafety measures are in place for implementation, existing legislation shall be enacted in order to regulate and manage GMO/FFP

PART III

3.0 LAW AND ENFORCEMENT SYSTEM

3.1 Introduction

Existing law and enforcement system in the forms of Acts and Ordinances relevance to biosafety in Sri Lanka was developed by the sub-committee 2 on regulatory regime (see Annex 2b for the committee members). The sub-committee conducted several workshops with key stakeholders to collect relevant information. The committee reviewed present legal documents relevant to biosafety and identified relevant areas and cross-cutting areas related to biosafety issues. The sub-committee reviewed the provisions of 18 different enactments of which 10 had relevant provisions to deal with different types of GMO's. In addition, the sub-committee reviewed the provisions in the Intellectual Property Act since all GM technologies and their products have been the subject of patents and also because Intellectual Property Act makes it possible to patent GM microbes. In addition, relevant multilateral agreements that have been referred to during the past were also looked in to find out how they will affect any of the proposed measures. After analyzing information, the committee identified relevant Ministries to implement biosafety measures. The sub-committee also prepared recommendations on legal base for establishing the National Biosafety Framework.

During the course of the deliberations, special attention was made as regards the Precautionary Approach and the possibility of regulating GMOs through existing legislation. Therefore, the review of existing enactments emphasizes the possible measures and a separate section that explains the application of the Precautionary Approach in relation to GMO's and products.

The sub-committee also considered that the analysis of recommendations should not be limited to LMOs as needed under the Cartagena Protocol on Biosafety, but should be expanded to cover all other GMOs and their products.

3.2 Existing Legislation and their Relevance to Biosafety

It is clear that Sri Lanka has not yet passed any laws to specifically deal with the issue of GMO's. The only law that has the terms "genetically modified" (GM) and "living modified" (LM) is the Plant Protection Act, and that too, only in the interpretations. At the same time, it is identify that some provisions in the existing laws could be successfully used to control, check and even ban the introduction of certain GMO's.

The discretionary powers provided for in the Fauna and Flora Protection Ordinance and the Animal Diseases Act to be made use of with immediate effect to control, regulate and when necessary to prohibit the entry of all GM-animals and animal products.

The provisions in the Animal Feed Act to be used to regulate, control and when necessary prevent any animal feed containing GM- materials and also to prevent any GMO or item brought in to Sri Lanka as animal feed being subsequently released for human consumption.

The bringing in of regulations to the (i) Plant Protection Act; (ii) Food Act, (iii) Consumer Affairs Authority Act; (iv) Control of Pesticides Act; and (v) Fisheries and Aquatic Resources Act. so that they could be used to regulate, control and when necessary to prevent the entry of GMOs relevant to their respective sectors.

The provisions in the Consumer Affairs Authority Act (No 9 of 2003) are to be used in order to make regulations to provide for the compulsory labeling of all GMOs and products.

The draft regulations made by the Ministry of Health under the Food Act to be used as a basis to bring a new set of regulations to approve all food items containing GMO's and GM start-up cultures in food processing. Since the regulations brought in April 2001 were suspended in June 2001, there had been no regulation, monitoring, or approval of foods and food products with GMOs and ingredients. This is therefore to be considered as an immediate priority.

A Plant Breeders Rights Act (PBR Act) is being drafted at present in order to comply with the obligations under the Trade Related-aspects of Intellectual Property Rights Agreement (TRIPS) under the World Trade Organization (WTO). This act is intended to give Plant Breeders Rights on new plants varieties. If such variety is a GM-plant, it should first get approval under the provisions of the new law before it is given the Plant Breeders Rights. This could be implemented by the incorporation of suitable provisions to the PBR Act. Such provisions are found in the Plant Breeders Rights Acts of India (passed in 2001) and Thailand (passed in 1999), which can be referred to.

The Intellectual Property Act has provisions to deny patents to any inventions that are of such a nature that the exploitation of them would be detrimental order public and morality. This provision should be made use of to refuse patents to such bio-technologies such as Genetic Use Restriction Technologies (GURTS) that are intend to get corporate sector of developed countries to dominate the agricultural sector which may deny farmers rights and make the agriculture dependent on chemicals. There should be a mechanism to provide relevant information to the National Intellectual Property Office (NIPO). It could be done either by a committee of experts appointed by NIPO or preferably by the approving body.

The analysis of the laws and regulations pertaining to the importation and use of micro-organisms revealed that there is a need to have an enactment to deal with the import, storage and use of micro-organisms, some of which are pathogenic. Certain strains of micro-organisms are imported to be used as biological control agents of pests. There are covered by both the Plant Protection Act and the Animal Diseases Act. There are recent examples of microbes being used to control disease-vectors such as mosquitoes. These can be controlled under the Pesticide Control Act and the Malathion Control Act. In addition, it was noted that certain strains of micro-organisms are brought in for the purpose of being used as reference samples in determining the various types of a microbe. These are imported, not only by the government, but also by the private sector.

The other related area that need to be regulated is the certain and maintenance of type culture collections of various micro-organisms and the providing of samples for outside parties. There are no legal provisions at present to cover these aspects. It was also found out that there is no monitoring of such culture collections, nor the lists of different types

of micro-organisms deposited at them. This particular area, although beyond the immediate purview of the committee (except in the case of transgenic or transformed micro-organisms) needs the immediate attention of relevant authorities.

The advent of genetic engineering techniques has resulted in the manipulation of the genetic make-up of a number of living organisms. A large number of such technologies have been developed and patented by various institutes, research bodies and companies. They fall into two broad categories in relation to the manipulation process. One is the addition of one or more genes from another organism into the genetic make-up to get a desired trait expressed in the new organism and the other is to add one or more genes to stop the expression or inactivate one or more genes that are already found in the organism. In some, both these approaches are used together to silence one or more genes while adding a gene or more to express a new trait. Such organisms are generally referred to as GM-organisms, meaning Genetically-Modified or Genetically-Manipulated.

The creation of such GM-organisms and the release of such to the environment (both deliberately and by accidental releases) have created a lot of controversy in USA and Europe, where much of these research work is being carried out. Another controversial aspect is the food items made by or with the help of GM-organisms. These are a number of specific laws, regulations and guidelines in those countries to deal with various aspects of GMO's and related issues.

Table 1 gives a summary of existing legislation and their relevance to biosafety.

Table 1: Existing National Acts and Regulations and their Relevance to Biosafety.

Act, Ordinance or Regulation	Status (year of adaptation)	What does it regulate	Responsible institution	Relevance to Biosafety
Fauna and Flora Protection Ordinance No. 2 of 1937, amended by Act No. 49 of 1993	Adopted 1993	An ordinance to provide protection, conservation and preservation of the fauna and flora of Sri Lanka; for the prevention of the commercial exploitation of such fauna and flora.	DWLC	
Animals Act No. 29	Adopted 1958	An act to regulate the slaughter of animals; removal of animals from one administrative district to another; branding of animals, sale and transfer of such animals ; to provide for the seizure and detention of	DAPAH	

		animals which commit trespass; to provide for measures for the improvement of the breed of animals.		
Animal feed Act No. 15	Adopted 1986	An act to regulate, supervise and control the manufacture, sale and distribution of animal feed.	DWAP	
Animal Diseases Act No. 59	Adopted 1992	An act to provide for the control and prevention of contagious diseases in animals; for the control of the import and export of animals, animal products and veterinary drugs and veterinary biological products.	DWAP	
Fisheries and Aquatic Resources Act No.2	Adopted 1996	An act to provide for the management, regulation, conservation and development of fisheries and aquatic resources in Sri Lanka.	DF	
Plant protection Act No. 35	Adopted 1999	An act to make provision against the introduction into Sri Lanka and the spreading therein, of any organism harmful to or injurious to, or destructive of, plants, and for the sanitation of Plants Protection Ordinance (Chapter 417) and for matters connected therewith or incidental thereto.	DOA	
Food Act No.26	Adopted 1980	An act to regulate and control the manufacture, importation, sale and distribution of food, to establish a food advisory committee, to repeal the Food and	FCD	

		Drugs Act (Chapter 216) and to provide for matters connected therewith or incidental thereto.		
National Environmental Act, No. 47	Adopted 1980	An act to established a Central Environmental Authority to make provision with respect to the powers, functions and duties of that authority; and to make provision for the protection and management of the environment.	CEA	
Control of pesticides Act No. 33	Adopted 1980	An act to provide for the licensing of pesticides; to regulated the import, packing, labeling, storage, formulation, transport, sale and use thereof; for the appointment of a licensing authority for pesticides; for the establishment of a Pesticides Formulary Committee.	DOA	
Quarantine and Prevention of Diseases Ordinance No. 3	Adopted 1897	An ordinance to make provision for preventing the introduction into Sri Lanka of the Plague and all contagious or infectious diseases and for preventing the spread of such diseases in and outside Sri Lanka.	DOA DAPH	
Consumer Affairs Authority Act No. 9	Adopted 2003	An act to provide for the establishment of the Consumer Affairs Authority; for the promotion of effective competition and the protection of consumer; for the regulation of internal trade; for the establishment of A	MCCA	

		Consumer Affairs Council.		
Water Hyacinth Ordinance No. 9	Adopted 1909	To prevent the introduction of Water Hyacinth and other weed and invasive plants in Sri Lanka.	DOA	

Note: DWLC-Department of Wildlife Conservation; DAPH-Department of Animal Production and Health; DF-Department of Fisheries; DOA-Department of Agriculture; CEA-Central Environmental Authority; FCD-Food Commissioner's Department; MCC-Ministry of Commerce and Consumer Affairs.

3.3 Proposed Biosafety Law for GMOs

It is proposed that a new law to be drafted and enacted to regulate and monitor the applications of modern bio-technologies, including all, GMO's, LMO's and products: (a) All applications and uses, including applications and uses on human beings; (b) All development, research, productions and manufacture for commercial, research and other purposes; (c) Contained use; (d) Deliberate release; (e) All marketing and other commercial applications; (f) All imports and exports; and (g) All methods of disposal

This new enactment will details (i) The approving authority (its composition, powers and duties), (ii) The procedures for granting approval, (iii) Monitoring mechanisms and powers vested in it, (iv) Enforcement powers, (v) Emergency powers, (vi) Offences and related aspects, and (vii) Powers to make relevant regulations to enforce the provisions of the act.

It is suggested that the approving authority may be, an existing body such as the Central Environmental Authority that may be empowered as a Competent Authority to carry out the duties and functions needed under the new law or a newly created body with the structure and mechanism to enforce the provisions; or a regulatory committee with the necessary legal powers with the task of enforcement being provided by the concurrent government bodies or by a specially identified body or by both. This last is a mechanism similar to the Drug Regulatory Authority and the Telecommunications Regulatory Commission.

The authority of granting approval for any product, process, or living organism and part including all gene constructs and plasmid constructs, imports, exports, contained use, research and all related matters should be done by the approving authority with the concurrence of the line government body and the approval procedure has to give concurrent powers to both. This kind of system will help achieve more balanced decisions and help prevent any abuses, malpractices or political interferences.

There should be transparency and public-participation on decision-making. The material being forwarded to seek approval should be made available for public inspection and comment and mandatory period for public comments has to be given by law. The right of appeal from an aggrieved party should include the applicant and all those who have made comments, observations, reservations and objections.

The Precautionary Principle to be applied in the law and the regulations, especially in areas where there is uncertainty.

There should be no scope for confidential information. All relevant information should be made available for all the parties. The Biosafety Protocol allows certain information to be treated as confidential but it was decided that this should not be provided as a privilege as it would be used to hide relevant and even vital information.

All genetically modified organisms, their product and those products made by processes involving the use of a GMO or LMO should be labelled mandatory.

The issues of liability and redress for damages resulting from the release of GMOs to the environment have to be carefully considered and a suitable legal regime should be brought in to address the potential problems and implications. This law should not confine itself to LMOs but should include all types of GMOs and products.

This new law could even address the damages caused by the release of all other types of animals and plants such as alien invasive species, in addition to addressing the issue of GMOs, so that it covers damages caused by any introduced species.

3.4 Details of existing legislations and their relevance to biosafety

Details of existing legislations are discussed below.

3.4.1 Fauna and Flora Protection Ordinance No. 2 of 1937, amended by Act no 49 of 1993.

The purpose of this ordinance, as spelt out in the substituted long title is to provide for the protection, conservation and preservation of the fauna and flora of Sri Lanka, among others. The importation of animals to Sri Lanka has been dealt in part III.

1. The import of any animal, spawn, eggs, larvae of an animal can be done only under the authority of a permit issued by a prescribed officer of the Department of Wildlife Conservation (Section 37 (1)).
2. These provisions are applicable to all animals except those named under Section 37.
3. These are of two broad categories.
 - a) Tropical aquarium fish. This term is defined in Section 37 (3) to include those fresh water fishes specified in Schedule IV of the ordinance. This schedule (under section 31A) lists twelve species of freshwater fishes and seven species of marine fishes. Incidentally, this list of fresh water species has those that are endemic to Sri Lanka and threatened with extinction. The aim of the schedule is to give legal protection to these species and it is not clear why these same species have been treated as “tropical aquarium fishes” and some argue that it should have meant all those not listed in the schedule and that the wording is an error. However, according to the prevailing situation, the import of all species of fishes, barring these twelve endemics, can only be done under the authority of a permit.

b) Domestic animals. The term is defined under section 11 of the ordinance as follows. The term domestic animal means only the following, i. Cattle, sheep, goat, horse, ass, mule, ii. Dogs, iii. Cats, iv. Domesticated pigs, v. Domestic fowl reared by man as poultry.

Therefore, all fish are excluded from this part, including all forms that have been developed by men (e.g. ornamental Goldfish, ornamental Guppies). This is satisfactory because some GM-fishes that have been recently developed have been of improved varieties genetically-manipulated to serve a particular purpose. (e.g. GM-Goldfish that deposit real gold on scales) The permit to import animals is given at the discretion of the Department and the relevant officers can deny permits to any GM-animal.

3. According to section 37 (2), the provisions have the same effect as if it formed part of the Customs Ordinance. This means that the Customs Department has been given authority to deal with any offences regarding import of animals.

4. The Minister can make regulations (under section 38 (b)) to (a) Prohibit the release of any imported animal and (b) Prescribing areas where a release is permitted. The provisions under section 38 (b) apply to those imported under the authority of a permit, whose release to the environment should be either prevented or controlled.

5. The provisions under section 37 and section 38 (b) can be taken together to allow any import of any GM-animal that would be necessary only for research purposes and to prevent any releases subsequent to any import. (e.g. – GM-rats developed as medical research tools like the Harvard Oncomouse). There are still no regulations to give effect to section 38 (b), which could be to cover all “transgenic animals to be prohibited from being released in any part of Sri Lanka.”

6. These provisions could be used to prevent, control and check the import of any transgenic animal except transgenic domestic animals. An area of concern is GM-fishes, all of whom can be dealt with these provisions.

7. The Fauna and Flora Protection Ordinance does not have any provisions as regards the import of plants. Therefore, transgenic plants cannot be dealt with under this ordinance.

3.4.2 Animal Diseases Act, No. 59 of 1992

This act provides for, among other things for the import of animals and animal products, veterinary drugs and veterinary biological products. The term “animal” for the purposes of this act (defined under section 38) includes cattle, buffalo, sheep, goat, pig, fish, horse, mule, ass, dog, cat, bird and bees and includes any other domesticated animal or wild animals kept in captivity. This definition includes all the domestic animals defined under section 11 of the Fauna and Flora Protection Ordinance. Therefore this act can cover all those that cannot be dealt with under the FFPO.

1. The import of an animal, animal product, animal semen or embryos should only be done under a permit issued by the controller of Imports which has to be done upon the recommendation made by the Director of Animal Production and Health, (section 21 (1)) In making the recommendation to import any of these, the Director should also specify the port of entry (section 21 (2)). The process in this section has two steps. The most

important step is the recommendation to import made by the Director, who can use discretion in making it to ascertain whether the item should be allowed to be brought in. Therefore, this discretion can be used to prevent the introduction not only any GM-animal, but their sperm or embryos as well. The Controller of Imports and Exports has no discretizing power, but has to issue a permit once he receives the recommendation.

2. The discretion of the Director is restricted only in the respect that the permit to import can only be recommended if the importer produces a certificate from the Chief Veterinary Surgeon or an authorized veterinary surgeon of the country of origin. (sections 22, 26, 31 and 33)

3. These are intended to prove that the animals, products or semen and embryos are free from diseases and infective material. Since GM-animals cannot be termed as “infected” or “diseased”, it is not possible to make it mandatory for the Director to make an order to withdraw any semen or embryos and to get them destroyed as provided to by sections 9 and 33(4)

4. All imports of veterinary drugs and veterinary biological products should only be done under the authority of a permit issued by the controller of Imports and Exports upon the recommendation made by the Director of Animal Production and Health. The term veterinary biological product includes vaccines, sera, micro-organisms and their extracts and by-products that are intended for use in the diagnosis, treatment or prevention of diseases of animals. (Section 38). This could be used to prevent, control or regulate the import of vaccines and microbes produced through genetic engineering process or all products made by using such GM-microbes. The recommendation it self can be done only if the importer produces a certificate from the chief veterinary officer or an authorized veterinary surgeon of the country of import (section 31(1)).

5. The act also provides for the setting up of a Veterinary Drug Control Authority (section 32 (1)), whose functions powers and duties include (a) Exercise control over the manufacture, import of, sale and use of veterinary drugs and veterinary biological products (section 32 (8) (a)); (b) Determine whether to grant licenses for the manufacture and import of the same (section 32 (8) (c), (c) Promote research necessary to test the same (section 32 (8) (e)).

6. The powers and functions of the authority can be exercised not only to prohibit and control all veterinary biological material and drugs but the local production, sale or use of any veterinary biological material using genetic engineering within the country as well. A manufacturer of these in Sri Lanka can do only under a licence issued by the Director (section 17 (1)).

3.4.3 Animal Feed Act, No 15 of 1986

The aim of this act is to regulate, supervise and control the manufacture, sale and distribution of animal feed and to provide for related matters. The term animal feed is defined in section 32 to include simple and compound products. A simple feed means a feed containing only one ingredient of feedstuff and a compound feed has two or more ingredients and which contains essential nutritive elements.

1. A person who manufactures animal feed for sale has to do so under the authority of a licence issued by the Registrar (section 3). The application for manufacture should contain, among others, the composition of the animal feed (section 4 (2) (e)). The Registrar of Animal Feed has to declare any animal feed manufactured under a license or imported for sale under the Imports and Exports (Control) Act as an approved animal feed, which is then approved by the minister and publish the same in a gazette (section 6). A person can sell only such approved animal feed (section 7) which will have a number assigned by the registrar.

2. The minister can appoint an Animal Feed Advisory Committee (section 8 (1)). The functions of this committee include the setting of minimum standards as to the composition, strength, quality and purity of any approved animal feed. Therefore, this committee can under setting up minimum standards of composition, quality and purity, set standards to limit any GM-feed ingredient, or to ban the use of same. If an ingredient or feed has some unusual compound then the use of such could be even banned to maintain quality and purity. An example is the Star Link maize that has the endotoxin Cry 9 which is produced by a gene from *Bacillus thurengiensis*. This brand of maize is known to cause allergic reactions in human beings but has been recommended for animal feed in U. S. A. Such ingredients could be banned to maintain purity.

3. A person who has got approval for an animal feed could be prevented from adding GM-ingredients substantially. Regulations could be made to classify approved feed and to prescribe the composition, quality and character of any approved animal feed (section 31 (2) (a)). This could be used to control or prevent the inclusion of GM-ingredients as it could be deemed to affect the quality and character of feed.

4. An authorized animal feed manufacturer, adding a GM-ingredient without approval can be charged for adulterating (section 18 (b)). An approved animal feed is deemed to be adulterated if its composition, strength, quality and purity fails to conform to the standards prescribed under the act (section 19). These sections could only come into effect if regulations have been made under section 31.

5. In case of imports, the consignments can be examined by an officer authorized by the Director, who can take samples for the purpose of obtaining an examination report, (section 25 (1)) and kept without being delivered until the report arrives. If the report states that the feed does not confer to the minimum standards, the feed shall not be admitted into Sri Lanka for use as an animal feed. These provisions can be successfully used to prevent the import of any animal feed with unwanted or undeclared GM-material.

3.4.4 Plant Protection Act, No 35 of 1999

The purpose of this act is to make provisions to prevent the introduction and spread of any organism harmful or injurious to plants or destructive to plants found in Sri Lanka and connected matters. The definition of the term “organism” is broad and includes all active infective or dormant stages of life forms such as viroids, plasmids and all genetically-modified living entities. Therefore, these provisions can be used not only to prevent the entry of plants and animals, but to prevent the import of any genetically-modified plasmids that could be potentially harmful to plants. Similarly, all the other interpretations (section 15) are broad enough to include genetically modified material. It

is also the only enactment in Sri Lanka that has defined “Genetically modified” and “living modified”.

1. The Minister can make regulations (under Section 12) among other things to the providing for the import of organisms under special licences and conditions (Section 12(2)(d)) and in addition for the testing of organisms, plants and plant products at landing, before or after landing (Section 12(2)(e)) The term “organism” is defined (under Section 15) to include all active, infective or dormant stages of life form of an entity and includes not only plants, animals, bacteria, algae, fungi, protozoans but also viroids, plasmids or any living entity or related things which can be natural, genetically modified, living modified or otherwise. Thus, it is possible to make regulations under this act to control and manage the entry of any GMO, LMO, plasmid constructor any agricultural product containing GMO’S. In addition the regulations can provide necessary procedures for inspections and testing.

2. The Minister can make regulations to prohibit the entry of quarantine pests (section 7 (1)). The term “quarantine pest, according to the definition in section 15, means a pest of potential economic or environmental importance that is either not yet present, or present but not widely distributed and being officially controlled. It is important that this definition is not limited to those that are only potentially destructive or harmful, but include all those that can be economically or environmentally important. Therefore, it is necessary for the Minister to be aware of any potential adverse effects to decide a quarantine pest”. It is therefore possible to list all genetically modified plants, microbes used for plant genetic manipulation and plasmid constructs as quarantine pests, to prevent import.

3. When the Minister declared a quarantine pest under Section 7 (1), by a notification in the gazette, it is not lawful to knowingly keep, sell, plant, release, deliver to others, or dispose any such plant or plant material infested with a quarantine pest, unless under the specific written instructions of the Director General of Agriculture (Section 7 (3)). This will not only apply to all such genetically modified plants, but could be applied to any genetically modified plant or material (including plasmid constructs, viruses or bacteria) which have been included in the gazette notification.

4. The Director General of Agriculture can take necessary steps to control any quarantine pests if he receives information. (Section 7 (4)) and the Director General can destroy any quarantine pest or get them delivered to him (Section 7 (3)). These could be used to control any genetically modified plants that have been brought in without permission or made within the country using GM-material as breeding material.

5. The declaration of GM plants and GM-genetic constructs such as plasmid constructs would not prevent or hinder the importation of such material to Sri Lanka nor any research using such material by scientists. This is because provision had been made to meet such needs under Section 7 (b), which states that a quarantine pest declared by the Minister can be imported to Sri Lanka strictly for scientific studies by the Government of Sri Lanka under the authority of an import permit and under the conditions specified by the Director General. These conditions could include conditions as regards to the facilities needed to keep and use them and about the type of trained personnel needed to quarantine them. This Section controls and regulates the import of such GM-material. The first limitation is that these could only be imported by government institutions. Secondly, they

could be only imported for scientific purposes. Thirdly, and more importantly, it provides for the Director General to monitor and control them after such things have been imported and to ensure that they are handled with proper care and caution, and that too, only by properly qualified and trained personnel. These provisions, whilst promoting and regulating research, ensure unwanted and accidental releases and all unwanted or harmful use of such imported genetic material. These provisions could be made use of to import any plant material that had been genetically-modified using a negative trait technology (such as Terminator) so that the Government can get the scientists to determine ways to identify any planting material that have been created using the same technology by the development of probes.

3.4.5 Consumer Affairs Authority Act, No 9 of 2003

This act provides for, among other things, protection of consumers, for the regulation of internal trade and for the promotion of effective competition. This act intends to protect consumers. The term consumer is defined (Section 75-interpretations) to mean any actual or potential user of any goods or services made available for a consideration by any trader or manufacturer. The definition of goods, for the purpose of this act, means any food, drink, pharmaceuticals, fuel and all other merchandise. The Consumer Affairs Authority can issue general directions to manufacturers or traders to label the goods in respect of price marking, packaging, sale or manufacture of the goods. Since all genetic modifications relate to the manufacture of a good, this provision (Section 10(1) (a)) can be made use of to label all goods with any GM-ingredients. These directions have to be published in the gazette as regulations (Section 10(2)). Under this act, it is possible to mandatory label not only food, but also all other items such as pharmaceuticals, industrial products.

According to Section 12(1), the authority can ensure the quality of goods for the protection of consumers. These have to be published in gazettes (Section 12(2)). This can be made use of to regulate any GM-products that may contain unwanted byproducts in it (for example, the maximum level of endotoxins in a GM-plant produce) or the maximum level of contamination by GMO'S in a particular product.

3.4.6 Food Act, No 26 1980 amended by act No 20 of 1991.

This act intends to regulate and control the manufacture, importation, sales and distribution of food and the establishment of a Food Advisory Committee (FAC). According to Section 2, it is an offence to manufacture, import, expose for sale, sell, store or distribute any food that is injurious to health or has any novel or deleterious substances (Section 2(1) (a)) or food that is unfit for human consumption. These provisions give a wide range of powers to inspect and take necessary action against unfit food or a food with some unknown hazardous material. The enforcement of this can be done without any regulations, except in case of (Section 2(1) (e)). This paragraph pertains to this food containing any substance that has been included in violation of any of any regulations made under the Food Act. An authorized officer has the power to act in order to prevent any of the offences under Section 2, in accordance with the procedure laid out in the act. These provisions can be made use of to prevent the import or sales of any food containing a GM material that is known to be injurious (such as these with known toxins or allergens). It only covers these items whose deleterious effects have been previously known.

These provisions can be made use of to tackle any possibility of a person importing a GM-product approved only as animal feed and surreptitiously putting it in the market for human consumption. It is necessary to have proof that the item in question has been allowed to be imported and used as an animal feed and has not been authorized for human consumption. The provisions regarding the labeling, packaging, and the advertising of food are provided in Section 3 of the act. It is possible to make regulations under Section 3 to deem it mandatory to declare a particular fact or factors as regards to the food. This provision (Section 3(2)) can be made use of to bring mandatory labeling of all GM-foods or any food item containing a GM-ingredient. The minister is empowered, under Section 32(1), to make regulations in relation to any matter that is provided for in the act. However, Section 32(1) provides that the minister has to exercise the power of making regulations after consultation with the Food Advisory Committee.

The First attempt to regulate any GMO's and products has been through the Food Act. The gazette no 1178/18 of 06.04.2001 banned the import of 23 items containing GM-ingredients. This was comprised of six types of food (Soya, maize, tomato, potato, beet sugar and cheese) and starter cultures such as yeasts. These come into effect from 01.05.2001. This regulation was rescinded by a set of regulations published in the gazette no 1190/5 of 26.06.2001. These suspended the already enforced ban and declared that it would come in to effect from 01.09.2001. This was indefinitely suspended from coming into operation by a regulation published in gazette no 1199/23 of 30.08.2001.

3.4.7 Control of Pesticides Act, No. 33 of 1980, as amended by No. 6 of 1994

The purpose of this act is to, among other things, for the licensing of pesticides, to regulate the import, sale and use of them. According to the definitions in Section 27 the term pesticide means any substances intended for use or used for controlling a pest and shall include active ingredients, adjuvants and pesticide formations. The term active ingredient means any substance that gives a formulated product is pesticidal properties. This act and its provisions are important because the gene that produces endotoxins in the soil bacterium *Bacillus thuringiensis* has been isolated and inserted into other living organisms so that those make those endotoxins that are lethal to some kinds of insects. These compounds or often the organisms with the endotoxins are used as pesticides. The gene that produces these is commonly referred to as the Bt gene. Any organism with this gene and the corresponding endotoxins fell within the definition of a pesticide and could therefore be subjected to the provisions of this act.

1. A person who wants to manufacture, formulate, pack, distribute, sell or deliver a pesticide within Sri Lanka should do it only after registering it and obtaining a license is given in Sections 6,7,8 and 9. These could be used to control the entry of and sale of all novel organisms that have been genetically-engineered with Bt gene that could be used as a pesticide.

2. It is also seen that a number of crop plants have been genetically-engineered so that they contain the Bt gene. These plants produce the relevant endotoxin in their cells and cause the death of insect pests that feed on such plants. In this instance, the endotoxin producing plants do not fell under the definition of a pesticide since this gene is inserted to make a self-defense mechanism in the plant and not to be used in the control of pests. However, under Section 20, people are prohibited from harvesting or offer for sale any

food crop that contains pesticide residue over an acceptable level that can be prescribed. A genetically crop plant that produces Bt endotoxins in its tissues may get caught up as the pests may contain a certain amount of pesticide residues. The acceptable levels of pesticide residue in crops have to be prescribed by regulations published in a gazette.

3.4.8 Fisheries and Aquatic Resources Act, No. 2 of 1996

This act is to, provide, among other things, the management, regulation, conservation and development of fisheries and aquatic resources of Sri Lanka. For the purposes of this act, the term fish means any aquatic organism and includes everything from zooplankton to aquatic mammals. The definition of aquatic resources means Living aquatic organisms and covers phytoplankton, seaweed and other aquatic flora (section 66, " Interpretations")

1. According to section 30, the minister in charge of the subject of fisheries and aquatic resources may in consultation with the minister in charge of the subject of trade can prohibit or regulate the import of any fish or aquatic resources into Sri Lanka. This prohibition or restriction (which includes regulation and control) has to be done by an order published in the gazette.

2. An important feature in section 30 is that it can be used only to prohibit and regulate entry, or as a restrictive and controlling provision. It cannot be used to allow imports. (This can only be done under section 37 of the Fauna and Flora Protection Ordinance).

3. This section is wide enough to cover all transgenic aquatic animals and all transgenic aquatic plants by the issuing of relevant gazette notifications.

3.4.9 Intellectual Property Act, No36 of 2003

This act provides for the law relating to all the different types of intellectual property in Sri Lanka and provides the procedures of registration, control and administration of them. This act replaced the Code of Intellectual Property Act, No 52 of 1979(as amended). The part that deals with patents (Part iv) is relevant to the granting of intellectual property rights protection (by way of patents) to the genetic engineering techniques and their products.

A patent is granted to an invention that is new, which involves an inventive step and is industrially applicable (Section 63- patentable inventions). The invention can be or may relate to the product or a process (Section 63(2)) and the term invention means an idea of an inventor that permits in practice the solution to a specific problem in the field of technology (Section 63(1)). This first criteria in getting a patent is that the invention has to be new (or novel).It is not practicable to define what is novel and thus an invention is deemed to be new if it is not anticipated by art.(Section 64(1)) The term prior art is elaborated in Section 64(2) and 64(3).

The second criterion in granting of a patent is that the invention shall involve an inventive step. The term inventive step means any step that would not have been obvious to a person having ordinary skill in the art (Section 65).

The third criterion in getting a patent is the industrial application or the usefulness of the invention. According to the act (Section 66) an invention shall be considered as

industrially applicable if it can be made or used in any kind of industry (Section 66). This act allows the patenting of both a process and a product that could satisfy the three criteria. However, there are some inventions that cannot be patented although they may satisfy the criteria. These are given in Section 62(3). One such exclusion is an essentially biological process for the production of plants and animals (Section 62(3) (b)). Therefore it is seen that all genetic engineering technologies can be patented in Sri Lanka. It is not clear what is meant by the term “essentially biological process for the production of animal and plants” but is usually applied to the normal reproductory methods of the particular animal or plant. Thus, genetic engineering process does not get caught up in to this exclusion. The ultimate end of a genetic engineering technology may be either a compound or any nonliving material or a compound any non-living material or a modified, animal or microbe. According to Section 62(3) (b), no animal or plant, except a transgenic micro-organism can be patented in Sri Lanka. Thus, a) no transgenic animal can be patented, b) no transgenic plant can be patented, c) any transgenic micro-organism can be patented.

The act, under Section 62(3) (f) provides for the refusal of a patent for certain types of inventions. It is an optional exclusion (or an optional denial) as opposed to the compulsory exclusions in Section 62(3) (a) to 62(3) (e). This gives discretionary powers to the National Intellectual Property Office to decide whether to refuse a patent in order to protect public order or morality. The term public order, derived from the French term “Order public” broadly means well-being of the society in both material and moral contexts. The Section 62(3) (f) elaborates some of those areas such as the protection of human, animal and plant life or health, and the avoidance of serious prejudice to the environment.

This discretionary power can be made use of to deny a patent to an invention that could not only harmful but would hurt the sensitivities and those of the country. It is particularly helpful to deny patenting of all Genetic use Restriction Technologies (GURTS) that are intended to keep plants under the control of chemicals, to make plants that are debilitated or produce sterile seeds. Since such technologies are harmful to the plants and are against the interests of the farmers, they can be denied patents under this provision. According to Section 62(3) (b), the only living beings that can be patented in Sri Lanka are “transgenic micro-organisms”. However, the provisions of this act do cover a living plant or an animal made with the use of a genetic engineering process if the process is covered by a patent in Sri Lanka. It covers not only the making of the animal or plant, but also the import, export, use, sale and the offering for sale of them (Section 84(3)(a) and 84(3)(b)). Thus, a party can register import the plants or animals, instead of making them within Sri Lanka.

3.4.10 Animals Act, No. 29 of 1958

This act intends, among other things, the improvement of the breeds of animals and to restrict, control or regulate the removal of animals from one administrative district to another. The definition of animals for the purposes of this act includes oxen, buffaloes, sheep, goat and pigs (Section 38, Interpretations).

1. There are no provisions in this act to even prohibit or regulate the import of any GM-animals falling under the definition.

2. According to section 28 of the act, no person should be in possession of a male animal which is over one year and three months of age unless, (a) It had been castrated within three months after it has attained the age of one year, or, (b) Certified by a Veterinary Surgeon or an authorized officer to be fit for breeding. According to section 33, when a Veterinary Surgeon or an authorized officer is of the opinion that any male animal over an year of age is unfit for breeding, the owner or the person who possess such animal could be directed to castrate it. Regulations for these can be made under section 34. These provisions, taken together, would help prevent any transgenic, animal felling within the definition from breeding with native animals by ordering such males to be castrated.

A deficiency in implementing of these provisions in the control of transgenic animals cross-breeding with native breeds is that these provisions relate only to male animals. If the transgenic animal is a female, there is no provision to stop it being mated with native male animals and producing offspring which could be carrying any modified or alien genes.

3.4.11 Water Hyacinth Ordinance, No. 09 of 1909

This ordinance was enacted to prevent the introduction of Water Hyacinth to Sri Lanka and the spread of it in the country. Since both the short and long titles of this ordinance mentions only Water Hyacinth, which despite this act spread over throughout the country and is still a weed and invasive that has not been controlled, many consider it as a redundant piece of legislation. Although this act has been enacted to control Water Hyacinth, it can be used to control other plants as well.

1. Section 7 of this ordinance makes it possible for the Minister to make orders (by publishing in a gazette), to extend the provisions of this ordinance to any noxious weed or plant. This kind of an order makes it an offence to import any such plant, seed or other parts and the Minister can also impose penalties on an importer. When an order is made declaring a plant under this section, the Customs Department can destroy such plants when detected on importation. (Section 7 (1) (c)).

2. An order made under Section 7 (1) would make these other plants to come under all the other relevant provisions of this ordinance (Section 7 (2)) This means that it is unlawful to possess or keep such a plant or to grow them in any property that either belongs to a person or which is under the control or management of the person (Section 3). A person who finds that such a plant grows in the property belonging to or under his management it is the duty of the person who owns or control it to destroy the plants by burning them (Section 4)

3. This ordinance provides a simple yet effective means to prevent the entry into or keep in one's possession, any GM-plant or parts that can be named in a gazette regulation. However, in contrast to the Plant Protection Act, the scope of this ordinance does not extend to such entities as plasmid constructs. It also does not provide for the importation for research purposes. In case of a quarantine pest declared under the Plant Protection Act, the presence of such have to be notified to the Director General of Agriculture but under this ordinance the person has to destroy plants with fire.

3.5 The Precautionary Approach

The Precautionary Approach is used in law to deal with situations where there is no adequate scientific evidence to fully understand the potential effect of a technology or a products and cells for the withholding or preventing the technology or product until such facts are made available or can be analyzed.

The Cartagena Protocol on Biosafety to the convention on Biological Diversity has also reaffirmed the Precautionary Approach.

According to the preamble of the Cartagena Protocol on Biosafety, the Protocol reaffirms the Precautionary Approach contained in Principle 15 of the Rio Declaration. The Rio Declaration says, in order to protect the environment, the Precautionary Approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. There was an effort to get a consensual statement on the Precautionary Approach in order to have a consistent system in its application. The meeting for this effect was held in January 1998 in Wingspread in Wisconsin, USA and a consensus statement was issued at the conclusion of this meeting. It is known as the Wingspread Statement on the Precautionary Approach. Wingspread Statement on the Precautionary Approach The release and use of toxic substances, the exploitation of resources, and physical alterations of the environment have had substantial unintended consequences affecting human health and the environment. Some of these concerns are high rates of learning deficiencies, asthma, cancer, birth defects and species extinctions, along with global climatic change, stratospheric ozone depletion and worldwide contamination with toxic substances and nuclear materials.

The sub-committee believes there is compelling evidence that damage to humans and the worldwide environment is of such magnitude and seriousness that new principles for conducting human activities are necessary. While we realize that human activities may involve hazards people must proceed more carefully than has been the case in recent history. Co-operations, government entities, organizations, communities, scientists and other individuals must adopt a Precautionary Approach to all human endeavors. Therefore, it is necessary to implement the Precautionary Approach. When an activity raises threats of harm to human health or the environment, Precautionary measures must be taken even some causes and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.

The process of applying the Precautionary Approach must be open, informed and democratic and must include potentially affected groups. It must also involve an examination of the full range of alternatives, including on action.” The Widespread Statement shows that the Precautionary Approach has four main areas.

1. There is a duty to take anticipatory action to prevent harm.
2. The burden of proof of harmlessness of a new technology, process, activity or compound lies with the proponents, not with the general public.
3. There is an obligation to examine a full range of alternatives including the option of doing nothing, before using a new technology, activity, process or chemical.
4. Decisions in the application of the Precautionary Approach must be open, informed, democratic and must include affected parties.

This approach shifts the burden of proof from the potential user (or potential victim) to the producer of the product or the user of the technology. Thus, when there are reasons to believe that harmful effects might result from the use of a new technology, processor product, the industry has to scientifically establish that it is safe and fit to be used for the intended purposes.

The other important area is the transparency and participatory approach in decision-making that paves the way for the public to be aware of new developments and for them to give informed consent or to provide their reservations as regards to the use of a new technology or process or the release or use of a new compound. It means that the process should have necessary steps to accommodate the informing of public, getting public participation of the public and subsequent information released to the public for them to make informed choices.

3.6 The provisions of the SPS Agreement in relation to the Precautionary Approach

The agreement on the Application of Sanitary and Phytosanitary Measures or the SPS-Agreement is one of the fifteen multilateral agreements brought by the World Trade Organization (WTO). The intended purposes of this agreement, as set out in the preamble, are to improve human health, animal health and phytosanitary situation in all of the member states, to the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade and to ensure that these measures are not applied in a manner that would constitute a means of arbitrary and in justifiable discrimination between members that is a disguised restriction on international trade.

The Basic Rights and Obligations we set out in Article 2 of the SPS-Agreement. According to Article 2.1, members (which mean member states of WTO) have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, which have to be consistent with the provisions of the agreement. According to the definition of sanitary or phytosanitary measure as set out in Annex A (Definitions) in the convention, it means any measure applied as a law, regulation, procedures, testing, inspection, certification and approval procedures, quarantine measures, methods of risk assessments, packaging and labeling methods and requirements directly related to food safety that are used to

- a. Protect animal and plant life or health from risks arising from the entry, establishment or spread of pest, diseases, disease carrying organisms or disease-causing organisms,
 - b. To protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in foods beverages and foodstuffs.
 - c. To protect human life and animal life from risks arising from diseases carried by animals, plants or products or from the entry, establishment or spread of pests,
 - d. To prevent or limit other damages from the entry, establishment or spread of pests.
- The measures that a country could adopt to ensure sanitary and phytosanitary standards are subjected to certain limits and restrictions, which are set out in Articles 2.2 and 2.3.

These are

- a) such measures should be applied only to the extent necessary to protect human, animal or plant life and health (Article 2.2)
- b) has to be based on scientific principles (Article 2.2)
- c) is not mentioned without scientific evidence (Article 2.2)

- d) should not arbitrarily or unjustifiably discriminate between members (Article 2.3)
- e) should not be applied to constitute disguised restrictions on international trade (Article 2.3)

Therefore, it seems that although a country can adopt sanitary and phytosanitary measures, they have to be based on scientific principles and have to be maintained on scientific evidence. There are instances, such as in cases involving GMOs, LMOs and their products where there is enough scientific evidence there is enough reliability to take on informed decision on the measures that have to be adopted. There is because, according to Article 5, members have to ensure that their sanitary and phytosanitary measures are based on a risk assessment (Article 5.1). The SPS Agreement has provided for such situations.

Although Article 2.2 state that sanitary and phytosanitary measures should be based on scientific principles and maintained with sufficient scientific evidence, it gives an exception the end which says “except as provided for in paragraph 7 of Article 5. According to Article 5.7, a member can provisionally adopt sanitary and phytosanitary measures on the base of available scientific information in instances where relevant scientific evidence is insufficient. In such instances, the members shall seek additional scientific information within a reasonable period of time for a more objective assessment of risk and review the measures.” These provisions in Article 5.7 is the application of the Precautionary Approach in the cases where there is uncertainly in scientific material. It is evident that any measure to deal with a GMO, LMO or a product made from them made by country accordance with the Precautionary Approach does not run counter to nor contradict the provisions of Article 2 of the SPS-Agreement. Therefore, a country is not violating the SPC-Agreement unless such measures are enforced in a selective manner, such as them being applied only to the imports from certain countries.

3.7 The measures taken by the Ministry of Health regarding the GMOs and the proposed measures

The committee analyzed the measures adopted by the Ministry of Health regarding the import of GMOs and products in 2001, the report submitted to the ministry by the Special Committee of the Ministry of Health on genetically Modified Foods in Sri Lanka (May 2002), the regulations published in gazettes (No 1178/18 of 06.04.2001, No 1196/5 of 26.06.2001 and No 1199/23 of 30.08.2001) and the draft regulations of January 2003.

The initial regulations that brought in the ban on GM-foods “Food (Genetically Modified Foods) Regulations No 1 of 2001” are identical in their scope and contents, except the operational date. These regulations ban the import, manufacture for commercial purposes, transport, storage, distribution, sale and offering for sale any raw or processed food, food ingredient or food additive that has been subjected to any genetic modification or that contains any such ingredients. It also says that anyone who imports the items listed in the schedule should get a certificate from an accredited laboratory or Competent Authority to show that do not contain any material or ingredient containing GMOs.

These regulations, made under Section 2 of the Food Act with the approval of the Food Adversary Committee are based on the Precautionary Approach, since there are uncertainties about the safety of such foods. It is the duty of the government of Sri Lanka to ensure the safety and well-being of its citizens. This is enshrined in the Directive

Principles of State Policy under Article 27(2) of the Constitution of the Democratic Socialist Republic of Sri Lanka. This measure is a ban and is a provisional measure to ensure the safety of consumer. It is a provisional measure based on the Precautionary Approach that is consistent with the provisions of Article 2.2 of the SPS-Agreement read together with Article 2.1 and 5.7 of the same. The requirement of a certificate to the effect that certain food items are free from GMOs is also in conformity to the Precautionary Approach since it shifts the burden of proof to the producer importer. The draft regulations, made available in January 2003, have been done according to the recommendations made by the report of May 2002. This intends to bring a procedure of approval for all GM-foods to be done on a case by case basis and a system of compulsory labeling that informs the customer that it contains GMOs. This draft procedure and the labeling requirement are similar to that adopted by some countries and the European Unions Novel Food Regulations of 1997. Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (Official Journal L043.14.02.1979. pp0001-0007). According to the draft regulations (which were intended to be brought into force under Section 2 of the Food Act), a potential importer of any food item concerning or made from a GMO has to submit relevant information to the Food Advisory Committee. It is then evaluated by the committee and would be either approved to be used in Sri Lanka as a food or approval can be denied. If approval is granted, the item should carry a label to inform the consumers that it contains a GMO or an ingredient. If the information provided by the importer is not for all the parties. The Biosafety Protocol allows certain information to be treated as confidential but it was decided that this should not be provided as a privilege as it would be used to hide relevant and even vital information.

3.8 Priority Project:

The Framework suggested to draft and enacts a new biosafety law to regulate and monitor the applications of modern bio-technologies. This new law should consider all weakness in the existing legal framework as discussed and should compliance with national biosafety policy and regulatory framework (duration 8 months).

PART IV

4.0 SYSTEM TO HANDLE NOTIFICATIONS OR REQUESTS FOR AUTHORIZATIONS

4.1 Introduction

At present there is no single authority to handle GMOs and GMO products. The Ministry of Environment and Natural Resources is the National Focal Point designated to liaise with the Cartagena Protocol secretariat. The Protocol requires the designation of one or more competent national authorities who will be responsible to perform the administrative functions under the Cartagena Protocol; the functions the focal point and competent authority may be performed by a single entity. The existing status was analyzed by the sub-committee 3 institutional setup (see Annex 2c for the committee members). The sub-committee conducted several workshops with key stakeholders to collect relevant information. The committee reviewed present status relevant to biosafety issues and identified relevant areas and cross-cutting areas related to biosafety issues.

It is clear from Part III that Sri Lanka has not yet passed any laws to specifically deal with the issue of GMO's. The lack of a law specifically to deal with GMOs is a major drawback to implementation of a biosafety regulatory system in the country. There is a need to have a transparent procedure for receipt of application, evaluation and decision making, a mechanism for monitoring and inspections, and a system for providing information to stakeholders. The basic elements of a regulatory system are (i) procedure for receipt of applications, evaluation and taking a decision on GM; (ii) mechanism for monitoring and inspections; and (iii) a system to provide information to stakeholders.

Provisions in the relevant legislation can be applied to authorize certain government agencies to regulate GMOs. Two issues need to be addressed in this connection. Firstly, it appears that certain types of microorganisms in the category of bioremediation products does not fall clearly within the authority of any agency. Second, certain types of GMOs, can be regulated by more than one agency. Therefore cooperation and understanding between the agencies concerned is paramount importance. It is too important to be left to the good offices of the concerned individuals in agencies. There is a need for an institutionalized mechanism to ensure such cooperation and concurrence among relevant agencies in the handling of GMOs.

A typical procedure for handling applications for importation, release to environment, or placing on the market of GMOs and their products is outlined in Table 2.

Table 2: Stepwise Procedure for handling applications.

Application (or, request or notification) consists of a letter signed by the legal person who submits the request and an accompanying dossier. ↓	
Recorded and assigned a tracking number	Time period may start either at the time of

<p style="text-align: center;">↓</p> <p>Screening for completeness (administrative and technical information) If not complete – additional information requested from applicant</p> <p style="text-align: center;">↓</p> <p>Inform applicant that request complies with requirements.</p> <p style="text-align: center;">↓</p> <p>The Request and any accompanying information is sent to an expert/ advisory body/ies and/or other involved institutions for risk assessment of the proposed activity.</p> <p>Risk Assessment: Is the identified risk acceptable/ manageable? Risk management strategies</p> <p style="text-align: center;">↓</p> <p>Summary or conclusion ie, type of risks, risk management strategies proposed (if any), any potential beneficial effects on human health or environment.</p> <p style="text-align: center;">↓</p> <p>Competent authority for decision.</p> <p style="text-align: center;">↓</p> <p>Monitoring and inspections: After permit or consent is given and the activity has started usually a system of “monitoring and inspections” begins.</p>	<p>receipt ,or at time of acknowledgement of completeness</p> <p>Additional information can also be asked at any time during the process</p> <p>In some countries the request is publicly announced, and, made available to the public. In some countries requests are only made available together with the draft decision.</p> <p>Most decision documents contain the following elements – Summary of the application, description of the procedure followed, summary of the risk assessment and the final decision</p> <p>Monitoring is normally carried out by the person responsible for the activity, inspection is typically done by the government.</p> <p>Purpose of inspections is to ensure compliance with the conditions set in decision documents or permits.</p>
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4.2 Proposed System to Handle Notifications or Requests for Authorizations

In the Sri Lankan context, where established government departments and authorities have been functioning with defined powers and functions under specific legal enactments, it is proposed that these authorities be made use of in a coordinated way within the biosafety framework. This proposal is in harmony with the recommendation of the sub-committee 2 on Legal Issues. The recommended flow chart for receipt of applications, risk assessment, and decision making by the sub-committee 3 is shown in Figure 1.

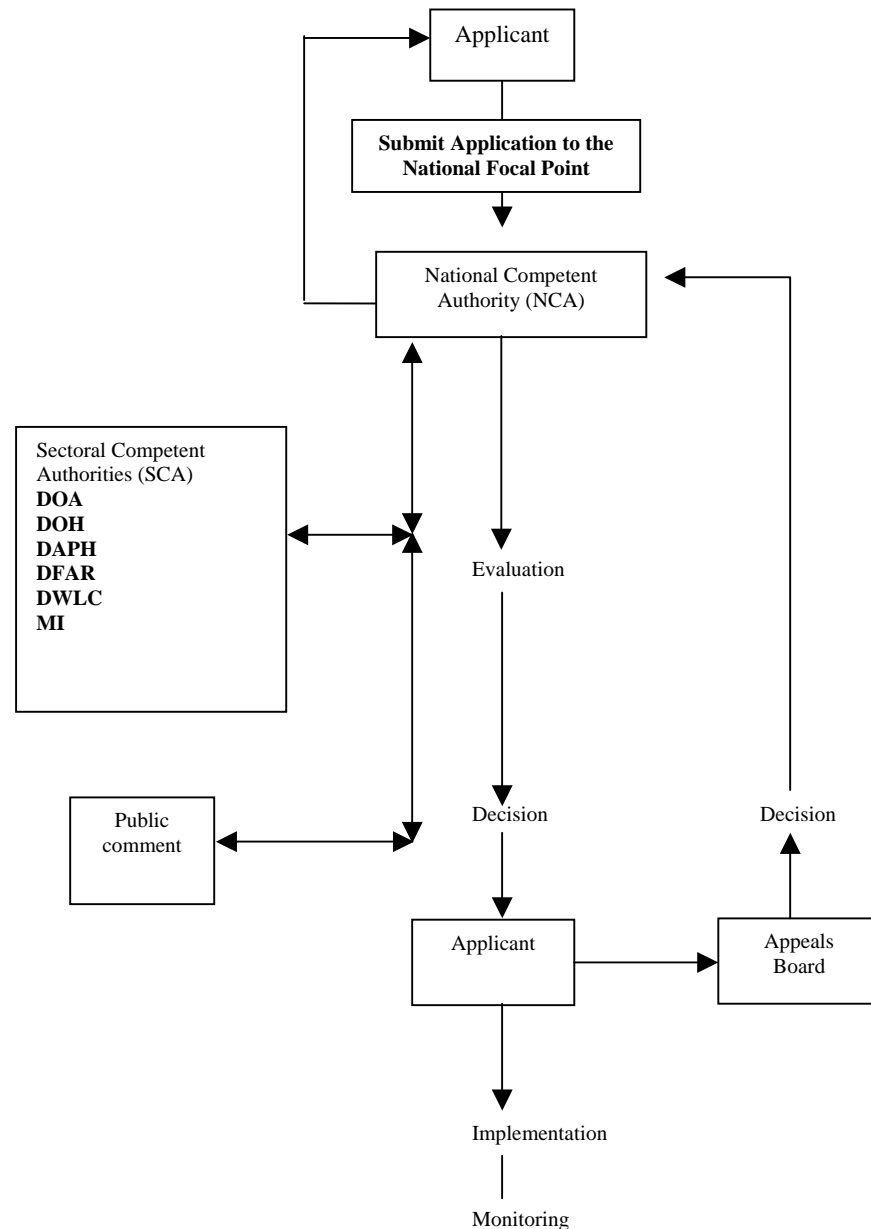


Figure 1: The Proposed Administrative System of Circulation and Assessment of the Notifications for the use of GMOs Applications.

Note: DWLC-Department of Wildlife Conservation; DAPH-Department of Animal Production and Health; DOA-Department of Agriculture; DH-Department of Health; MI-Ministry of Industries; DFAR-Department of Fisheries and Aquatic Resources.

Pre application process and country specific guidelines for import of genetically modified organisms and products are given in Appendix 3. Guidelines for internal transport and release of genetically modified organisms and products and production of genetically modified organisms are given in Annex 4 and 5, respectively. Necessary information to obtain import permits is shown in Annex 6 whilst Annex 7 showed standard application form to obtain permit for the production of genetically modified organisms.

4.2.1 National Competent Authority (NCA)

It is suggested to form the National Competent Authority (NCA) who will be responsible to perform the administrative functions under the Cartagena Protocol. It is proposed that the NCA for biosafety be established under the Ministry of Environment, and could be called the National Biosafety Board or Council (NBB or NBC). The national competent authority will have to be established by a framework law or Act of Parliament. In the National Biosafety Framework, it will be the responsibility of the National Competent Authority (NCA) - (a) to screen the application for completeness and forward the application to the relevant Sectoral Competent Authorities (SCA), and (b) to make the application available for public comment. The application will be sent to more than one agency where concurrent approval is required. The SCAs should have their own mechanism of carrying out the risk assessment and reporting to the NCA, as per agreed procedures. The NCA will specify the period for such assessment and feedback by SCAs and for public comment, within the overall time frame laid down for informing the applicant of the decision.

In order to ensure inter-agency coordination and to implement a system of concurrent approval in a transparent manner the National Competent Authority should be carefully constituted. Representation of the following would be desirable: Ministries in charge of the subjects of Agriculture, Forestry, Health, Livestock, Fisheries, Wildlife and Industries, Academics in relevant field, Business Community, Civil Society, Consumers, Farmer organizations. At present only six Institutes were identified as National Competent Authorities (see Annex 8).

4.3 Sectoral Competent Authorities (SCA)

Provisions in the relevant legislation may be made use of to authorize the following agencies to regulate GMOs as sectoral competent authorities.

Department of Agriculture	Agricultural and non agricultural (eg. Forest species, ornamentals) plants and planting material, microorganisms, and animals.
Department of Health Services	GM foods, pharmaceuticals
Department of Animal Production & Health Veterinary Drug Control Authority	Named domestic animals including fish, birds and bees, and any other domesticated or wild animals kept in captivity. Can cover GM-fish; all veterinary pharmaceuticals and vaccines [Animal Diseases Act]. Animal feed has to be approved by Registrar of Animal Feed [Animal Feed Act]. Minister can appoint an Animal Feed Advisory Committee to set minimum standards of composition, purity etc. of any approved animal feed. Can use for GM-feed ingredients. Director/DAPH can examine samples of consignments for minimum standards

Department of Wild Life Conservation	All animals except listed tropical aquarium fish and domestic animals (GM fish not in the excluded list). Can accommodate animals for research purposes eg, rats.
Department of Fisheries & Aquatic Resources	All aquatic animals and aquatic plants from zooplankton and phytoplankton to higher forms. Under the Fisheries and Aquatic Resources Act No. 2 of 1996 Minister can prohibit or regulate import. [But import can be allowed only under FFPO]

All categories of GMOs and their products can be regulated by the above agencies under existing laws, with the exception of certain types of microorganisms / microbial products in the category of bioremediation and other industrial products. It is recommended that this gap is filled by empowering the Ministry of Industries or an agency under its purview with the necessary regulations or legislation.

The SCAs will be considered as expert/technical bodies for risk assessment and management.

4.3 Biosafety at the Laboratory and Greenhouse level

The AIA procedure laid down in the Cartagena Protocol is not mandatory for contained use. Contained use is defined as any operation with GMOs, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment. It includes producing, growing, storing, using, destroying in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers. The National Science Foundation (NSF) of Sri Lanka has formulated guidelines for the safe use of Recombinant DNA technology under contained conditions. These guidelines include the risk categories and required containment levels for genetic manipulation of microorganisms, viruses/viral vectors of eukaryotes, plants, and animals (Annex 9). These requirements are based on international scientific standards. The recommended institutional arrangement is to establish Institutional Biosafety Committees (IBSC) at each institution where such work is carried out. It is the responsibility of the IBSC to ensure that the necessary safety protocols and physical structures are adhered to. Activities under Category I & II for microorganisms do not require approval of IBSC, but all other genetic manipulation activities require the approval of the IBSC.

It is also proposed that a Recombinant DNA Advisory Committee be established by the NSF under the Ministry of Science & Technology, to serve as a national advisory committee on DNA work and maintain records of all notified rDNA activities in the country. Its responsibilities include making recommendations on safety guidelines, monitoring activities of IBSCs and safety facilities.

4.4 Time Frame

The Cartagena Protocol has laid down the time frame for processing of applications for import, release to the environment and placing on the market of GMOs. These are the minimum periods within which a particular step in the procedure of receiving the application, risk assessment and evaluation, and decision making should be done based on case-by-case basis. The time allowed for the entire process from date of receipt of an application to notifying the decision to the applicant and to the Biosafety Clearing House is 270 working days. The application should be acknowledged within 90 working days of its receipt. Where a request is made by an applicant for review of the decision in the light of new scientific information, the NCA shall respond to the request within 90 working days.

4.5 Cost Recovery

The entire cost from application to risk assessment and management should be borne by the applicant.

4.6 Public Comment

The public as an important stakeholder should be fully informed with regard to consideration of any proposed introduction of GMOs to the environment or for consumption. Article 23 makes it obligatory for the public to be consulted in the decision making process. A process similar to the public notification of EIAs could be adopted for GMO applications.

Should all applications be opened for public comment, or only those which are deemed necessary according to certain pre-determined criteria, or, should it be only a notification after approval has been granted? In some countries applications are made available to the public only together with the draft decision. In the interest of having a fully transparent process it would be better to open all applications to the public, and also publish the decision once it has been conveyed to the applicant.

4.7 Provision to Appeal against the Decision

The decision of NCA on the requested activity may be to allow, allow with stipulated conditions, or to deny approval. There should be provision to entertain appeals by the applicant against any decision. The NCA must have authority to appoint an Appeals Board or Committee independent of the SCAs under the new law. Natural justice demands that the public or any party claiming adverse effects to them as a result of the approved activity should also have the right of appeal.

The Cartagena Protocol also allows for the review of decisions in the light of new scientific information that has become available or a change in circumstances that may affect the outcome of the risk assessment on which the decision was based (Article 12). Accordingly the applicant can request for a review of the decision; the party of import may also review and change its decision on a particular application for import of GMO.

4.8 Priority Projects:

4.8.1 Implementation of Biosafety Administrative/Management System.

4.8.2 Establish Local Biosafety clearing house.

PART V

5.0 Monitoring and Enforcement

5.0 Introduction

A mechanism for monitoring and inspection should form part of a national biosafety system. Activities ranging from general surveillance to a detailed monitoring plan including sampling, testing and analysis are included under “monitoring”.

A procedure for monitoring and reporting could be stipulated in the conditions under which an approval decision is given, and the person responsible for the activity could be required to comply with a specific monitoring plan. This will depend on the results of the risk assessment and therefore vary on a case-by-case basis. It is important that the requirement for monitoring by the person responsible (applicant) should be stipulated only if it is concluded that there is a reasonable chance that the monitoring can contribute to confirmation or dismissal of assumptions made in the risk assessment and decision making process.

Inspection is necessary to ensure compliance with the conditions set out in the decision documents or permits. This responsibility must therefore be performed by a government agency. It is recommended that the function of inspections should be with the relevant SCAs, with a system of reporting to the NCA.

New methods of genetic modification of plants, microorganisms and animals offer many possibilities for improvement of quality and services offered through biotechnology. Many new products in agriculture, aquaculture, health, industry and environmental remediation have emerged via these methods. Reports indicate that many genetically modified products have been approved in several countries of the world and are being used currently. The development of genetically modified products and their subsequent introduction to other countries before or after approval is inevitable with the prevailing conditions of international trade. **The approval of genetically modified products for import and use in Sri Lanka, if any must be given only after rigorous scientific testing and risk assessment procedures by qualified laboratories and institutions.**

At present, Sri Lanka has necessary expertise, laboratory facilities, technology and techniques to undertake the tertiary risk assessment and risk management of genetically modified organisms and products (Annex 11). Therefore it is proposed that these expertise and institutional facilities are properly and judiciously utilized to strictly regulate the production, import and use of genetically modified organisms and products according to a well formulated, legal procedure

The regular implementation of these procedures may require a mechanism to obtain the services of the recommended laboratories and institutions by nominating them as centers of excellence and providing them with necessary financial support. It is also anticipated that further improvement of the present methods of detecting genetically modified organisms will be reported in the future with development of molecular biology and biochemistry. Therefore it is regarded that the National Biosafety Framework maintain regularly updated data based on information of R&D activities related to genetically modified organisms by having a good library

The Cartagena Protocol recognizes the importance of socio-economic factors in risk assessment when considering import of LMOs, although it is not explicitly included in the risk assessment procedure. Article 26 specifies socioeconomic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities.

The following socio-economic aspects need to be considered in the risk assessment, in addition to other information required.

(a) Impact on food security – Any appreciable use of GM crops in a country like Sri Lanka where there are no locally produced GMOs could mean dependence for food production upon multinational companies, and consequent undermining of food security.

(b) Impact on livelihood of communities – The introduction of GMOs or their products can pose a threat to livelihoods of communities. For instance, GM technologies are being used to produce substitutes for substances derived from plants such as vanilla, chocolate and sugar. It is cautioned that the livelihood of sugar farmers in the South are threatened by genetically engineered sugars and sweeteners being grown and processed in the North.

The price of inputs required for GM crops could be beyond the means of small and medium farmers and lead them into bigger debt situations.

(c) Ethical issues and the right to choice - The right to choice could be addressed by having an effective labeling system. However where genes of certain animals or human genes have been inserted to produce GM crops, livestock or food, serious ethical issues arise. This aspect must be given due consideration.

It is necessary to identify and incorporate the relevant socio economic factors in the protocol for risk assessment. Socio-economic impact analysis will then become the responsibility of the applicant/notifier and the competent authority concerned.

Present status of risk assessment and risk management, country specific guidelines for import of genetically modified organisms and products, guidelines for internal transport and release of genetically modified organisms and products, guidelines for production of genetically modified organisms, and application to obtain import are discussed below.

5.2: Risk assessment and risk management

Risk assessment can be defined as “a process of evaluation, including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s)”.

A risk assessment comprises hazard identification, hazard characterization, exposure assessment and risk characterization. A hazard is the potential of an identified source to cause an adverse effect. Genetically Modified Organisms and products may cause some adverse effects to human health and the environment. The sequential steps in risk assessment of Genetically Modified Organisms identify characteristics which may cause adverse effects, evaluate their potential consequences, assess the likelihood of occurrence

and estimate the risk posed by each identified characteristic of the Genetically Modified Organisms.

5.2.1 Genetically Modified Plants

The potential hazards associated with Genetically Modified plants and products may be

- expression of toxic or allergenic compounds,
- effects on biogeochemistry,
- increased persistence in the environment and invasiveness,
- transfer of genetic material,
- instability of the genetic modification,
- unintended effects (the insertions may influence the expression of adjacent genes leading to unintended genetic modifications that may cause some adverse effects.)

5.2.2 Genetically Modified Microorganisms

The following have been considered as possible adverse effects caused by Genetically Modified Microorganisms.

- Diseases of human and animal including toxic or allergenic effects,
- Plant diseases and development of disease epidemics in agricultural and natural environments,
- adverse effects resulting from the inability to treat diseases or offer effective prophylaxis,
- adverse effects on natural bio-geo chemical cycles,
- adverse effects resulting from establishment or dissemination in the environment,
- adverse effects resulting from the natural transfer of inserted genetic materials to other organisms,

5.2.3 Genetically Modified Animals

The potential hazards associated with Genetically Modified animals and products may be

- adventitious infectious agent transfer,
- endogenous Retroviral activation (if the transformation is based on Retroviral mediated gene insertion),
- ectopic expression of transgenes (the presence of transgenes or their products in non targeted tissues can have adverse effects on human and animals exposed to these products.),
- excess production of transgene products or its metabolites,
- Pleiotropic effects of transgene expression (transgene insertion and expression can have unpredicted effects on the expression of other genes),
- prion disease susceptibility hazard (production of transgenic animals could produce a hazard through the accidental inclusion of genetic material with the transgene or alteration of the functioning of the genes related to prion susceptibility),
- leakage of expressed products from target tissues.

5.3 Risk assessment

5.3.1 General information required for risk assessment:

The risk assessment strategy for Genetically Modified Organisms and products seeks to deploy appropriate methodologies and approaches to compare the Genetically Modified Organisms and products with their non-Genetically Modified counterparts. The underlining assumption of this comparative assessment approach for Genetically Modified Organisms and products is that traditionally utilized organisms and products have gained a history of safe use for consumption by humans or animals and for the application in agricultural and environmental or industrial processes. These organisms and products can serve as a baseline for the environmental and food/feed safety assessment of Genetically Modified Organisms. **Based on that the concepts of familiarity and substantial** equivalence were developed and further elaborated by WHO/FAO for the assessment of the environmental and food safety of Genetically Modified Organisms respectively. This comparison is the starting point of the safety assessment which then focuses on the environmental or food/feed safety and nutritional impact of any intended or unintended differences identified.

The concept of familiarity is based on the fact that most Genetically Modified Organisms are developed from organisms the biology of which is well researched. In a risk assessment, it is appropriate to draw on this previous knowledge and experience and to use the Non-Genetically Modified Organisms and products as the comparators to the Genetically Modified Organisms and products in order to highlight differences associated with the transformation and the subsequent management of the Genetically Modified Organisms and products.

Risk assessment is a scientific process that makes use of the best up-to-date scientific knowledge and experience. Although details of risk assessment may vary from case to case, there are some common essential information to be considered during the risk assessment process which are indicated below.

5.3.2 Biology of the donor and recipient organisms

- Thorough knowledge, based on published literature, of the biology of the gene donor organism, especially history of safe use of the organism, and the presence and nature of any toxins, allergens or anti-nutritional substances.
- Thorough knowledge, based on published literature, of the biology of the recipient organism, especially; the presence of and nature of any toxic, allergenic or anti-nutritional substances, reproductive biology and potential, ability to out-cross and form fertile offspring with wild relatives.
- History of safe use of them and their products as food, feed and health care products.

5.3.3 Detailed Characterization of transgenes and proteins encoded by the transgenes

- complete nucleic acid sequence of the isolated gene(s) to be transferred,
- deduced amino acid sequence of expressed protein(s),
- biochemical function of expressed protein(s),
- any anticipated changes (e.g., change of substrate or altered end products) in the functioning of the biochemical pathway(s) in which the protein(s) function.

5.3.4 Description of “Gene Cassettes” used for transformation

- Genetic elements of the Gene Cassette(s) including control elements, structural genes, selectable marker genes,
- origin of control elements,
- function of control elements (e.g., tissue specific promoters, transcription enhancers and transcription terminators),
- complete nucleic acid sequence of all promoters, terminators, or other control elements (e.g., enhancers) and selectable marker genes,
- deduced amino acid sequence of protein(s) encoded by marker genes and their biochemical functions.

5.3.5 Methods used for transformation

- biological vectors (*Agrobacterium tumefaciens*, bacterial plasmids, viruses),
- physical methods (particle gun),
- chemical methods (using CaCl₂ or polyethylene glycol),
- electroporation
- Microinjection of cloned gene(s) into the pronucleus of a fertilized ovum.
- Injection of embryonic stem cells into embryos.
- Use of Retroviruses as the biological vectors to insert rDNA fragments into embryos.
- Any other methods.

5.3.6 Molecular characterization of any bacterial plasmids or viral vectors used for transformation

- Complete description of the gene vector system and the potential, if any, for incorporation of unwanted vector DNA into the recipient.
- Complete nucleic acid sequence of vector DNA.
- Vector map showing location of key restriction enzyme sites, all genes, control elements and other open reading frames together with table showing details of all genetic elements.

5.3.7 Toxicity and allergenicity

- Detailed review of any safety data concerning transgene(s), including screening for similarity at the protein sequence (amino acid) level against databases of sequences of toxins, food allergens.
- information of *in vitro* digestibility assay tests (digestible proteins have less potential to be food allergens),
- information of heat stability assay test (heat labile proteins have less potential to be food allergens in heat processed foods),
- information of acute oral toxicity testing in mice with maximum hazard dose.

Risk assessment for genetically modified plants and products, microorganisms and animals and products are given in Annex 11.

5.4 Risk Management

This is the process of measuring or evaluation of the risks and developing and implementation of strategies to manage the risk followed by monitoring and reviewing the risk mitigation measures.

- **Evaluation of risk:** This includes the processes of interpreting, comparing, judging the significance of and deciding the tolerability of the risks that are identified and estimated during the risk assessment.
- **Development and evaluation of risk mitigation process:** This is the process of identifying, evaluating the efficacy and feasibility and selecting appropriate measures in order to reduce the risk associated with Genetically Modified Organisms and products.
- **Implementation:** Proper actions are taken following the risk assessment decision on acceptance or refusal of the introduction of Genetically Modified Organisms and products.
- **Monitoring and review:** This is a process of observing the consequences of the introduction and conducting a review, if necessary of the risk assessment, risk mitigation measures and the risk management decision.

5.5 Priority Projects:

5.5.1 Establish Biosafety Monitoring System.

5.5.2 Development of Technical Guidelines for Risk Assessment and Management of GMOs including set up a system of environmental impact assessment.

5.5.3 Formulation of rules of risk management of GMOs.

5.5.4 Update biosafety database and upgrade to international standards and also contents of the websites

5.5.5 Capacity Building for National Biosafety Management (sectoral biosafety management, detection of GMO/GMF etc., strengthen National Laboratories, funding commitments).

5.5.6 Establishment of Local Clearing House for Biosafety Information

PART VI

6.0 Mechanisms for Promoting and Facilitating Public Awareness, Education and Participation

6.1 Introduction

The need to inform the public as an important stakeholder of biosafety issues is reflected in the Cartagena protocol. The Protocol also makes it obligatory for the public to be consulted in the decision making process regarding GMOs and to be informed of the results of the decision making process (Article 23). A process similar to the public notification of EIAs could be adopted for GMO applications.

Should all applications be opened for public comment, or only those which are deemed necessary according to certain pre-determined criteria, or, should it be only a notification after approval has been granted? In some countries applications are made available to the public only together with the draft decision. In the interest of having a fully transparent process it would be better to open all applications to the public, and also publish the decision once it has been conveyed to the applicant.

6.2 Public Awareness

A number of awareness programs were conducted to educate general public regarding risks and concerns of GMO/GMF. The stakeholders include school children and teachers, government institutes, Universities, media personals, non governmental organizations, research organizations representing almost all administrative districts of Sri Lanka except north province. Presentations made in awareness programs were distributed as handouts as well as in the project web site. The project also published o brochures (english and sinhala), Cartagena Protocol (english, sinhala and tamil), newsletter (english and sinhala), dockets for workshops, posters (english and sinhala), wall newspapers, books and produced exhibits, Calendars, stickers, caps and t-shirts. All these items carried a message on safety from GMOs. TV and radio programs and newspaper articles were conducted/published to deliver the message of safety requirements from GMOs.

A national database provides detailed information of biotechnology and biosafety related institutes, policies, laboratories etc for general public. The official website of the project also included majority of items produced by the project for public.

Sri Lanka has produced brochures and websites www.biosafety.lk with general information about the framework. Guidelines for making applications and application formats are also made available openly.

6.3 Public Participation

Information about requests that have been, or are being, processed is often made available through newspapers and websites. In many countries copies of the applications (without the confidential business information) are made available for interested people to refer, either in notified locations such as the library of a Ministry, or on request from the competent authority.

In Sri Lanka, a process of public notification and comments has been established in 1993 for EIA under the National Environmental Act of 1980 for prescribed projects. Once the Project Approving Agency (PAA) accepts the EIA report and adequate the EIA is opened for public comments for a period of 30 working days through notices in the press and the gazette. The comments received are forwarded to the developer by the PAA for response. After receiving the response the PAA makes a decision on the project. The developer has a right of appeal against the decision. The EIA report is made available in English, Sinhala and Tamil and is kept in the Divisional Secretary's office, Pradeshiya Sabha (local authority), Project Proponent's Office and at the CEA library. A similar process could be adopted for public notification of GMOs through Ministry of Environment and Natural Resources. For this purpose the ministry maintains the register of interested parties where any legal entity or individual may be included upon request. The list includes in particular, Environmental NGOs, consumers and their associations, media and their associations, scientific community, farmers and their associations, seed importants, local public administrative authorities, local communities and professional organizations.

6.4 Priority Projects:

6.4.1 Strengthen Publicity and Education on Biosafety

6.4.2 Strengthen public participation in decision making.

Annexes

Annex 1: National Coordinating Committee (NCC)

1. Ministry of Environment and Natural Resources (Chairman of the NCC)
2. Secretary, Additional Secretaries, Director (Biodiversity), Deputy Director (Biodiversity)
3. National Project Coordinator, National Biosafety Framework Development Project (Secretary of the NCC)
4. Ministry of Justice (Secretary or nominee)
5. Ministry of Health (Secretary or nominee)
6. Ministry of Agriculture, Animal Production, Land and Irrigation (Secretary or nominee and member from plant quarantine)
7. Ministry of Trade (Secretary or nominee and National Chambers of Commerce)
8. Ministry of Fisheries and Aquatic Resources (Secretary or nominee)
9. Ministry of Justice (Legal Draftsmen)
10. Central Environmental Authority
11. Director General of Customs (Director or nominee)
12. Department of Agriculture (Director or nominee)
13. Department of Animal Production and Health (Director or nominee)
14. Departments of Forests and Wildlife Conservation (Conservator General and Director or their nominees)
15. National Science Foundation (Director)
16. Non Governmental Organizations
17. Civil Societies

Annex 2: National Sub-Committees Appointed on Biosafety

Annex 2a: National Sub-Committee on Biosafety Policy

1. Dr. MCN Jayasooriya (Chairperson), National Science and Technology Commission
2. Mr. Jagath Gunawardene, Attorney at-Law, Member of the Steering Committee on Biosafety
3. Dr.(Mrs.) K.K.S. Fernando, Director, Seed Certification and Plant Protection Centre, Department of Agriculture
4. Mr. KG Piyasena, Director General, Department of Fisheries, Ministry of Fisheries and Aquatic Resources
5. Prof. Sirimali Fernando, Senior Lecturer, University of Sri Jayawardenapura
6. Dr. C.K. Shanmugarajah, Director, Ministry of Health Nutrition and Welfare
7. Mr. Gamini Gamage, Director, Bio-diversity Secretariat, Ministry of Environment and Natural Resources
8. Professor A.L.T. Perera, National Project Coordinator, National Bio-safety Framework of Sri Lanka
9. Miss JPD Rukshanthi, Research Associate, Agriculture Biotechnology Center, University of Peradeniya.
10. Ms. Gayathri Gunaruwan, The Ceylon Chambers of Commers.
11. Dr. Evarad Jayamanna, Coconut Research Institute, Lunuwila.
12. Prof. G. Widanapathirana, University of Kelaniya.

Annex 2b: National Sub-Committee on Legal Issues

1. Mr. Jagath Gunawardene (Chairperson), Attorney at-Law, Member of the Steering Committee on Bio-safety
2. Mrs. Punya Senevirathne, Deputy Legal Draftsmen, Legal Draftsmen's Department
3. Mr. H.D. Rathnayaka, Deputy Director, Department of Wildlife Conservation
4. Dr. (Mrs.) K.K.S. Fernando, Director, Seed Certification and Plant Protection Centre, Department of Agriculture
5. Mrs. M.A.S. Perera, Senior Manager, Board of Investment
6. Mrs. Lumbini Kirella, Legal Officer, Ministry of Environment and Natural Resources
7. Dr. C.K. Shanmugarajah, Director, Ministry of Health Nutrition and Welfare
8. Mr. Gamini Gamage, Director, Bio-diversity Secretariat, Ministry of Environment and Natural Resources
9. Professor A.L.T. Perera, National Project Co-ordinator, National Bio-safety Framework of Sri Lanka
10. Dr. M.C.N. Jayasuriya, Director, National Science and Technology Commission, (Chairman of the sub-committee on Biotechnology and Bio-safety Policy).

Annex 2c: National Sub-Committee on Institutional Aspects

1. Mr. M.Watson, Director, National Science Foundation (Chairperson)
2. Prof. Nimal Gunathilake, Department of Botany, Faculty of Science, University of Peradeniya

3. Dr. Gerry Jawardena, Former Chairman, Coconut Research Institute and the former Director General of Agriculture
4. Dr. (Ms) K.K.S. Fernando, Director, Seed Certification & Plant Protection, Department of Agriculture
5. Dr. C.K. Shanmugarajha, Director (E&OH), Ministry of Health
6. Dr. Ranjith Wickramasinghe, Department of Animal Production & Health
7. Mr. Sarath Fernando, Conservator General of Forest
8. Mr. Samantha Gunasekera, Superintendent of Customs
9. Mr. Gamini Gamage, Director Biodiversity, Ministry of Environment & Natural Resources;
10. Prof. A.L.T. Perera, National Project Co-ordinator, National Bio-safety Framework of Sri Lanka

Annex 2d: National Sub-Committee on Technical and Technological Aspects

1. Prof. G. Widanapathirana, Dean, Graduate Studies, University of Kelaniya (Chairperson)
2. Prof. Eric Karunanayake, Faculty of Medicine, University of Colombo
3. Prof. D.C.K. Illeperuma, Department of Food Science, Faculty of Agriculture, University of Peradeniya
4. Dr. Champa Bandaranayake, Research Officer, Coconut Research Institute, Lunuwila
5. Prof. Thilak Attanayake, University of Wayamba
6. Mr. Gamini Gamage, Director Biodiversity, Ministry of Environment & Natural Resources
7. Prof. A.L.T. Perera, National Project Co-ordinator, National Bio-safety Framework of Sri Lanka.

Annex 3: Country specific Guidelines for import of Genetically Modified Organisms and products:

1. All persons who desire to import Genetically Modified Organisms and products should apply for an import permit from pertinent regulatory agency as required by law.
2. Approval or denial of an import permit shall be based on the information provided for evaluation as formulated in Annex I.
3. A written application should respond to all items listed in Annex I for introduction of genetically modified organisms and products. Application should be submitted four (4) months before importation to National Focal Point (NFP). These applications will be then forwarded to the relevant Competent Authorities (Health, Agricultural, Veterinary, Environmental etc. identified by NFP to examine assess and to make recommendations.
4. After review of the application and with the recommendation of relevant agencies, NFP shall make the appropriate decision. If a permit is issued, it should specify applicable conditions for introduction of Genetically Modified Organisms and products. If the application is denied, the applicant shall be promptly informed of the reasons.
5. Any person whose application has been denied or whose permit has been withdrawn may appeal the decision in writing to the *appropriate authorities* within 30 days of receipt of the written notice. The appeal should clearly state all the facts and reasons to show that the permit was wrongfully withdrawn or denied. All appeals including application documents shall be referred back to NFP for final comments and suggestions.
6. Permit shall be issued in quadruplicate. The original shall be given to the applicant for presentation to the Authorized Officer at the port of entry; the duplicate shall be sent by the applicant to the shipper in the country of origin for their guidance relative to the terms and conditions; the triplicate shall be presented to the Collector of Customs at the port of entry, and the fourth copy shall be filed with the application.
7. A person who is issued a permit should comply with conditions specified in it. Non-compliance with the conditions shall be ground for suspension of permit. It will remain suspend until such time that the specified conditions are fully complied with.
8. All introductions of Genetically Modified Organisms and products shall be addressed to the Director/NFP.
9. Transport from the port of entry to a destination specified by Director/NFP shall be undertaken with the supervision of an Officer authorized by the Director/NFP at the importer's expense. No further movement of regulated material shall be made unless authorized by NFP.

Annex 4: Guidelines for internal transport and release of Genetically Modified Organisms and products:

- 1 Following information are required for the preliminary observation by an Officer appointed by the Director/NFP.
 - Name, address, and telephone number of consignee;
 - Name and address of shipper, owner, or person shipping or forwarding the consignment;
 - Identifying shipper's mark and number;
 - Written permit number authorizing the importation.
 - General nature and quantity of the content;
- 2 Detail inspection will be carried out in order to verify whether the consignment is fully complied with the import regulations. Depending on the recommendation made by the Officer appointed by the Director/NFP will grant permission to release the consignment if it is fully comply with conditions noted in the import permit, unless otherwise the consignment will be destroyed at the importer's expense.
- 3 No organisms or products other than the approved ones are allowed to transport and release.
- 4 All persons who are granted permission to import Genetically Modified Organisms and products shall be required to submit performance evaluation reports to the NFP as specified by the Director/NFP.
- 5 The relevant competent authorities of the NFP shall be responsible for monitoring the progress of the work and shall immediately report any significant outcome to the NFP for any malfunctions.

Annex 5: Guidelines for the production of Genetically Modified Organisms:

- 1 Before any experiment on organisms is undertaken, the principal investigator or project manager should prepare a proposal according to the format set by the NFP. The Proposal should respond to all items indicated in the Procedures for Evaluation.
- 2 The proposal should then be submitted to the NFP. The NFP should assess the project initially and then send the original proposal with its own evaluation, to the relevant competent authorities for assessment.
- 3 Genetic manipulation of organisms should be allowed only if the ultimate objective is for the welfare of humanity and the natural environment and only if it has been clearly demonstrated that there is no existing or foreseeable alternative approaches to servicing the welfare of humanity and the natural environment.
- 4 Assessment of risk should be based on the characteristics of the biological product and on the process by which it was obtained.
- 5 Upon receipt of proposal, the competent authority will form a working group, members of which may be from the authority itself, who will assess the proposal based on the Procedures for Evaluation. This working group may seek additional requirements either in elaboration of the proposal or on new issues that may arise from an examination of the proposal. The working group shall submit its recommendations to the NFP.
- 6 Approval or denial of an import permit shall be based on the information provided for evaluation as formulated in Annex II.

Annex 6: Application to obtain import permits should include the following information

1. Responsible person or persons involved
 - a. Name, title, address, telephone number, and signature;
 - b. Name, address, and telephone number of the person(s) who developed and/or supplied the regulated material;
2. Specify what Genetically Modified Organisms or products to be introduced;
 - 2.1 Country and locality where the Genetically Modified Organisms or products were, developed, and produced;
 - 2.2 Detail information of the Genetically Modified Organisms requested to be imported, or the Genetically Modified Organisms used to produce the products that to be imported.
 - 2.2.1 Nomenclature and characteristic of and history of safe use/adverse effects of the donor from which the genetic materials were obtained.
 - 2.2.2 Nomenclature, characteristic and history of safe use/adverse effects of the recipient in which the genome is altered.
 - 2.2.3 Nucleotide sequence and construction method of the recombinant molecule used as the transgene elements (Gene Cassettes) for transformation;
 - 2.2.4 Methods used to introduce transgenes into recipient cells.
 - 2.2.5 Specify the vectors if any, used in the transformation of recipient cells.
 - 2.2.6 Amino acid sequence of the proteins encoded by the inserted transgenes.
 - 2.2.7 Enzyme digestibility of the above proteins and susceptible sites react with respective enzymes.
 - 2.2.8 Heat and acid sensitivity of the proteins encoded by transgenes
 - 2.2.9 History of donor and recipient organisms as used in food production or eaten as food.
 - 2.2.10 Provide available data on toxicology, allergenicity, and other possible adverse effects of foods or any metabolites produced by Genetically Modified Organisms .
 - 2.2.11 Information about the products of Genetically Modified Organisms that can be concentrated in the food chain to levels which may become toxic.
 - 2.2.12. Provide data on potential hazards or deleterious effects specifically being evaluated.

Live Vaccines

 - Specify/give the identification characteristics or markers, the growth requirements, and the genetic modification of the vaccine strain of the organism.
 - Specify the proposed dose rate(s).
 - Give the period when the vaccine organism can be detected in the vaccinated animals and their excretions.
 - Indicate if the vaccine organisms spreads from vaccinated to in-contact, non-vaccinated animals of the same or other animal species. If so, state the mechanisms and frequency.
 - Give the vaccine strain's frequency of reversion to wild type characteristics.
 - For pen trials, specify arrangements proposed for disposal of waste containing any vaccine organisms and of the vaccinated animals at the conclusion of the trial.

- Give the clinical effects of the vaccine organism target and non-target species in the test area and surrounding environment.
- Specify the level and duration of immunity produced in the target species.
- State challenge or other tests using virulent field strains to be carried out on vaccinated animals.
- Indicate the probability of the host vaccine organism being used in other human or animal vaccines.
- Specify if the use of this vaccine precludes the future use of the host vaccine organism for immunization purposes.

Microorganisms to be used for biological control)

- State the effects that the unmodified and modified organisms have on the biological control target, the plant or animal being protected and non-target species (including humans) in the test area and surrounding environment. State, in particular, if there are any growth or quality reductions in the protected organism.
 - Specify the survival and reproduction characteristics of the organism in the rhizosphere of the plant species in the test site and surrounding environment.
 - Give 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).
- 2.3 Specify the arrangement for the transport of imported Genetically Modified Organisms and products within the country.
- 2.4 Indicate the Genetically Modified Organisms reproduction and survival rates under the natural environmental conditions.
- 2.5 Indicate the capability of the organism to disperse under the natural environment. Indicate the dispersal mechanisms.
- 2.6 Indicate if the inserted genetic trait could be transferred to other organisms in the release site and surrounding environment; if yes, specify with what organisms and at what frequencies.
- 2.7 Indicate data available which show that the introduced genetic trait has no unforeseen deleterious effect in the long term.
- 2.8 Indicate if the modified organism is intended to modify the characteristics or abundance of other species. If yes, specify these species and the intended changes.
- 2.9 Indicate the experimental results or information available which show the probable consequences (positive and negative) of the release of the modified organism, including impacts on:
- human and animal health;
 - agricultural production;
 - the target and non-target organisms in the area;
 - the general ecology, environmental quality in the area.
- 2.10 Specify the range of consequences which has been considered (e.g., what range of species was examined for non-target effects).
- 2.11 Give unlikely but possible impacts that have been postulated. Indicate if any of these would have substantial impacts if they actually occurred. Likewise, also

indicate if the release protocol minimizes or monitors these low probability risks. If so, indicate how.

- 2.12 Give the consequences of the organism remaining in the environment beyond the planned period.
- 2.13 Indicate the methods that will be used to control or eliminate the organism from the site and the surrounding environment should such action be required.
- 2.14 Provide data or any other information which the organization considers to be of assistance to the NFP's assessment.

Annex 7: Application to obtain permits for the production and introduction of Genetically Modified Organisms and products should include the following information

1. Title of the project
2. Program/Project/Study Leader(s)
3. Name of Institution
4. Cooperating Institution(s)
5. Objectives of the Genetic modification
6. Materials and Methods
 - 6.1 Degree of Genetic Manipulation
 - 6.2 Methodology/Protocol (including timetable of activities)
 - 6.3 Location of Experiment
 - 6.4 Characteristics of the Organisms: (Plants, Animals, Microorganisms)
(Local strains; Collected within the region (mention exact location); Collected from other regions - origin of strains; Imported strains (indicate point of origin); Not present in the country; Present but of restricted distribution in the country; Widely distributed in the country; Genetically modified strains; Ecological context)
 - 6.5 For Experiments Involving Genetically Modified Plants
 - Characteristics of the recipient organism
(nomenclature; the areas of cultivation or distribution in nature; reproductive cycle; possibility of natural crossing to related species; production of toxic substances, if any; weediness/effect on environment (soil, water, etc.)).
 - Characteristics of donor organism
(taxonomy; the areas of cultivation, distribution in nature; reproductive cycle; possibility of natural crossing to related species; production of toxic substances, if any; weediness/effect on environment; functions of the target gene)
 - Name, designation, origin and molecular characteristics of the vector
 - Construction method of the genetically modified organism
 - Structure and construction method of the recombinant molecule
 - Method to introduce target genes into recipient cells
 - Characteristics of genetically modified organism
 - Comparison with recipient organisms
 - Localization, copy number and stability of the target gene in recipient cell
 - Stability of the introduced gene expression
 - Any other important points obtained in the transformation experiment to develop the genetically modified plant
 - Specify if any member of the genus of the modified plant is known to be harboring pests or diseases
 - Indicate if the experimental plot is isolated from plants of the same species, with regard to the pollination characteristics of the plant
 - Provide data on any previous information on risk assessment of the organism
 - Provide data on any markers available to track the organism if it escapes.
 - 6.6 For Experiments Involving Genetically Microorganisms
 - Characteristics of the recipient organism
(Nomenclature (scientific name and strain); Genetic properties (Characteristics); History of prior genetic manipulation, if any; Factors which

might limit the reproduction, growth and survival of the recipient organisms; stability of genetic traits; Characteristics and stability of plasmids, phages, viruses, in the recipient organisms; Reproductive cycle (sexual or asexual); Pathogenicity (details and availability of appropriate prophylaxis and therapies, if any); Production of biological active compounds, if any; Adventitious agents; Previous reports of a history of industrial use, if any; Characteristics of the related strain of recipient organisms; Natural habitat and geographic distribution; Genetic traits; Characteristics and stability of plasmids, phages, viruses, in the recipient organisms)

- Characteristics of the donor organism
(Nomenclature (scientific name and strain); Pathogenicity, producibility of biological active compounds; Functions of the objective genes).
- Name, designation, origin, characteristics of the vector
- Construction method of genetically modified organism
(Structure and construction method of the recombinant molecules; Method used to introduce target genes into recipient cells).
- Characteristics of the genetically modified organisms
(Comparison with recipient organisms; Characteristics with respect to survival, growth and reproduction; Crossing possibility; Inserted genes; Localization, copy number and stability of the inserted gene in recipient cells; Stability of the introduced gene expression; Any previous genetic manipulations applied to already modified genetically modified organisms; Method to restrict the multiplication ability in open environment; Any other important remarks obtained in the transformation experiment or during the preliminary application in the controlled model environment).
- Other Considerations in Assessing Characteristic of Genetically Modified Microorganisms:
Known potential of natural variants to cause epidemics (survival rates, reproduction, dispersal, etc.); Known potential to cause losses; Known potential hosts and their economic or social importance; Known natural ability to evolve; Known carriers of organism and abundance
- Known epidemiological factors
(Host range; Pathogenicity, infectivity; Production of biological active compounds, if any; Mode of spread including vectors and other transport hosts; Environmental conditions needed for epidemics; History of epidemic, if any)
- Laboratory testing
(Required containment facilities of laboratory; Required biosafety equipments; Sterilization procedures; Personnel awareness of biosafety procedures; Labeling/designation of "risk" areas; Decontamination facilities)
- Field testing (Microorganisms on Soil/Water Associated with Plants).
(Specify the survival and reproduction characteristics of the organism in the rhizosphere of the plant species in the test site and surrounding environment; Give 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))
- Field testing (Microorganisms to be used for biological control).
(State the effects that the unmodified and modified organisms have on the biological control target, the plant or animal being protected and non-target species (including humans) in the test area and surrounding environment.

State, in particular, if there are any growth or quality reductions in the protected organism)

- Live Vaccines

(Specify/give the identification characteristics or markers, the growth requirements, and the genetic modification of the vaccine strain of the organism; Specify the proposed dose rate(s); Give the period when the vaccine organism can be detected in the vaccinated animals and their excretions; Indicate if the vaccine organisms spreads from vaccinated to in-contact, non-vaccinated animals of the same or other animal species. If so, state the mechanisms and frequency; Give the vaccine strain's frequency of reversion to wild type characteristics; For pen trials, specify arrangements proposed for disposal of waste containing any vaccine organisms and of the vaccinated animals at the conclusion of the trial; Give the clinical effects of the vaccine organism target and non-target species in the test area and surrounding environment; Specify the level and duration of immunity produced in the target species; State challenge or other tests using virulent field strains to be carried out on vaccinated animals; Indicate the probability of the host vaccine organism being used in other human or animal vaccines; Specify if the use of this vaccine precludes the future use of the host vaccine organism for immunization purposes)

6.7 For Experiments Involving Genetically Modified Animals

- Domesticated or farmed animals (terrestrial, aquatic)

Indicate the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, and disease resistance and production gains).

State the undesirable effects that may result from the release of the modified organism like alteration of nutritional quality (e.g. difficult birth, fertility reduction, and increased disease prevalence, tumorigenicity and production losses). Indicate if any of the likely gains are 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).

- Indicate if the genetic trait can be transmitted other than through their normal reproduction (e.g., from animal to animal via virus or insect transmission).

Annex 8: National Competent Authorities for Biosafety in Sri Lanka

The following will perform as National Competent Authorities in Sri Lanka.

Category	Competent Authority	Contact Details
1. Wildlife	1. Director General, Department of Wildlife Conservation	Department of Wildlife Conservation, 18, Gregory Road, Sri Lanka Tel: + 94 112 695043; 698086 Fax: + 94 112 698556
2. Domesticated Animal and Animal Medicines	2. Director General, Department of Animal Production and Health	Department of Animal Production and Health, 1120, Kandy Road, Peradeniya, Sri Lanka Tel: + 94 812 388195 Fax: + 94 812 388619
3. Fish and other Aquatic Organisms	3. Director General, Department of Fisheries and Aquatic Resources	Department of Fisheries and Aquatic Resources, New Secretariat, Maligawatta, Colombo 10, Sri Lanka Tel: + 94 112 449170; 442187 Fax: + 94 112 449170
4. Plants and Plant Materials	4. Director General of Agriculture, Department of Agriculture	Department of Agriculture, Peradeniya, Sri Lanka Tel: + 94 812 388157 Fax: + 94 812 388333
5. Food and Pharmaceuticals	5. Director General of Health Service, Department of Health Service	Department of Health Services, 385, Suwasiripaya, Colombo 10, Sri Lanka Tel: + 94 112 698543; 694860 Fax: + 94 112 693869
6. Industrial Products	6. Secretary, Ministry of Industries	Ministry of Industries, 356, NPC Building, Second Floor, Union Place, Colombo 2, Sri Lanka Tel: + 94 112 343937 Fax: + 94 112 432783

Annex 9: Research and Development Involving Recombinant DNA (Contained Use)

	Notification	Approval
1. Genetic manipulation of microorganisms Category I Category II Category III	Not required. IBSC IBSC	Not required. Not required. IBSC
2. Genetic manipulation of viruses and viral vectors of eukaryotes	IBSC	IBSC
3. Genetic manipulation of plants Containment level A Containment level B	} IBSC	} IBSC
4. Genetic manipulation of animals Containment level A Containment level B Containment level C	} IBSC	} IBSC

The Head of the Institution may notify or seek approval for the proposed rDNA work from the Recombinant DNA Advisory Committee (RAC) in the interim period of setting up the IBSCs.

IBSCs should send a list of all notified rDNA work performed within the institute to the RAC each year.

Details are given in "Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory, NSF, 2003. 99pp".

Annex 10: Facilities available for testing Genetically Modified Organisms and products in Sri Lanka

A survey was conducted by The National Biosafety Framework Development Project of the Ministry of Environment and Natural Resources in order to identify the Sri Lankan Institutes that are capable of undertaking testing and risk assessment of Genetically Modified Organisms and products. During this survey the information were collected as follows.

- Institutes that have basic equipment and laboratory facilities for detection of genetically modified organisms and for risk assessment and the techniques currently available in these Institutes.
- Expertise and Trained Technical staff capable of testing Genetically Modified Organisms and products, risk assessment and risk management.
- Current research activities in Biotechnology and Molecular Biology

These information compared with universally accepted modern techniques for the production, testing, risk assessment and risk management of genetically modified organisms described earlier in this report, make it possible to recommend the following Institutes listed for testing, risk assessment, and risk management of genetically modified organisms and products classified as safety category 1 and 2.

Institutes that have facilities for testing and risk assessment of Genetically Modified Organisms and Products are Coconut Research Institute; Horticulture Crop Research and Development Centre; Veterinary Research Institute; Sugarcane research institute; Tea research institute; National Plant Quarantine service; Agricultural Biotechnology Center; Gene tech; Department of Plant science- University of Colombo; National Aquatic Resources Research and Development Agency; Department of Agriculture Biology University of Peradeniya; Department of Microbiology -University of Sri Jayawardenapura; Institute of Fundamental Studies; Department of Botany -University of Sri Jayawardenapura; Molecular Science and Biomedical Unit -University of Ruhuna; Department of Botany-University of Ruhuna; Department of Molecular Biology and Biotechnology University of Peradeniya; Plant virus indexing centre, Department of Agriculture, Homagama; Department of Microbiology -University of Kelaniya; Institute of Biochemistry, Molecular biology and Biotechnology.

Annex 11: Risk Assessment Process

Annex 11.1: Risk Assessment for Genetically Modified Plants & Products

Specific information required for the risk assessment of Genetically Modified plants and products in addition to the general information listed above.

Herbicide metabolites and residues

For genetically enhanced plants that are known as tolerant to specific herbicides, metabolism and residue data must usually be generated with the tolerant crop in order to obtain a new label for use of the herbicide on that crop.

Plant growth

Observations based on multiple plantings over at least 2 growing seasons of the genetically enhanced plant growing in different environments confirming that new trait(s) are stable, express the expected phenotype, and have no detrimental effects on plant development (e.g., growth habit, fertility, disease susceptibility, predation by herbivores or tendency to increased weediness) that could be indicative of unexpected effects of the genetic modification.

Agronomic performance

At least one season of observations at multiple sites of agronomic performance (e.g., growth rate, maturity and yield).

Environmental risk

Environmental risk assessment is conducted to evaluate potential routes of exposure of new gene products, or their metabolites, to the environment and significance of those exposures. Some or all of the following hazard and risk considerations should be evaluated, depending on the nature of the modification.

- Weediness of the Genetically Modified plant
- Mode of distribution, seeds or vegetative propagules
- Transgene product released from any plant parts
- Possible ways of horizontal gene transfer
- Consequences of gene transfer
- Any adverse effects caused by the accumulation of transgene products in food web in the natural environment.

Tests for impacts on non-target organisms are designed based on this assessment. If the genetically enhanced plant can out-cross with wild or weedy species in the areas where it will be planted, additional field studies will be required to confirm that the fitness of the resulting crosses has not been significantly changed, which could potentially result in new weeds or invasion of natural habitats or species loss. These studies could involve screening collections of wild relatives to show that a trait (e.g., disease resistance) is already present in wild populations or the gene may have to be bred into wild relatives which can then be tested to see if they exhibit altered fitness (e.g., increased seed production on insect resistant plants due to reduced herbivore activity).

Annex 11.2: Risk assessment of products of Genetically Modified Microorganism

The risk assessment process requires the identification of any potentially harmful properties of the Genetically Modified microorganisms as a result of the genetic modification or any alteration of the recipient organisms' existing properties. Potentially harmful properties associated with the Genetically Modified Microorganisms must be determined. This should be done by consideration of the recipient organism, the donor organism, the characteristics and location of the inserted genetic material and any vector. Specific information required for the risk assessment of Genetically Modified M's and products in addition to the general information listed above in section 5.1.1, are given below.

The recipient organism

- nature of pathogenicity and virulence, infectivity, allergenicity, toxicity and vectors of disease transmission;
- nature of indigenous vectors and adventitious agents, where they could mobilise the inserted genetic material, and the frequency of mobilisation;
- nature and stability of disabling mutations, if any;
- any prior genetic modifications;
- host range (if relevant);
- any significant physiological traits which may be altered in the final Genetically Modified organisms and if relevant their stability;
- natural habitat and geographic distribution;
- significant involvement in environmental processes (such as nitrogen fixation or pH regulation);
- interaction with, and effects on, other organisms in the environment (including likely competitive pathogenic or symbiotic properties);
- ability to form survival structures (such as spores or sclerotia).

The donor organism

- nature of pathogenicity and virulence, infectivity, toxicity and vectors or disease transmission;
- nature of indigenous vectors: Sequence; Frequency of mobilization and specificity; Presence of genes which confer resistance to anti-microbial compounds including antibiotics.
- host range;
- other relevant physiological traits.

The insert

- specific identify and function of the insert (genes);
- level of expression of inserted genetic material;
- source of the genetic material, identity of the donor organism(s) and characteristics where appropriate;
- history of prior genetic modifications if appropriate;

- location of inserted genetic material (possibility of insertional activation/deactivation of host genes).

The Vector

- nature and source of the vector;
- structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified microorganism;
- if present in the final Genetically Modified organisms frequency of mobilization of inserted vector and/or capability of transfer of genetic material.

Genetically modified microorganisms

- expected toxic or allergenic affects of the Genetically Modified Organism and/or its metabolic products;
- comparison of the modified microorganism with the recipient or (where appropriate) parental organism regarding pathogenicity;
- expected capacity for colonization;
- if the microorganism is pathogenic to humans who are immunocompetent:
 - Diseases caused and mechanism of transmission including invasiveness and virulence;
 - infective dose;
 - possible alteration of route of infection or tissue specificity;
 - possibility of survival outside of human host;
 - biological stability;
 - antibiotic-resistance patterns;
 - allergenicity;
 - toxigenicity;
 - availability of appropriate therapies and prophylactic measures.
- expected survivability, multiplication and extent of dissemination of the modified microorganism in the identified ecosystems;
- anticipated result of interaction between the modified micro-organism and the organisms or microorganisms which might be exposed in case of unintentional release into the environment;
- known or predicted effects on plants and animals such as pathogenicity, toxicity, allergenicity, vector for a pathogen, altered antibiotic-resistance patterns, altered tropism or host specificity, colonisation;
- known or predicted involvement in biogeochemical processes.

Annex 11.3: Risk assessment for Genetically Modified animals and products

Specific information required for the risk assessment of Genetically Modified animals and products in addition to the general information listed above in section 5.3.1.

Prior to the production of transgenic animals, the pathogen status of the components (reagents, animals, semen, embryos, etc.) used in production should be evaluated. The information should be obtained as follows.

- Epidemiologic status of the country/ geographic region of origin

- Evaluation of the protocols of the production facility with respect to hygiene and animal health
- Health status evaluation of donor and recipient animals
- Evaluation of the sterility of reagents used in production
- Evaluation of the techniques for production of the biotechnology-derived animal

Endogenous Retroviral Activation

Endogenous retroviruses have been found in all vertebrate genomes investigated to date. Theoretically, the use of replication-incompetent retroviruses as transgene vectors could lead to the activation of endogenous retroviral sequences through a process of recombination. The activation of these replication-competent, recombined viruses could pose a hazard to both the host animal and others, including humans, if the retrovirus is transmissible. Another potential hazard posed by retroviral vectors is the possibility of recombination between transgenic retroviral sequences and wild-type retroviruses to which the animal may be subsequently exposed. The information is required therefore on the detection of the shedding of intact retrovirions from Genetically Modified animals.

The presence of transgene products in non-target tissues and leakage of expressed transgene products from target tissues into serum

The information on the mRNA based detection and protein based detection techniques are required to determine the presence of these transgene products in non-target tissues.

Susceptibility to prion disease

Increased susceptibility to prion disease can be assessed by characterization of the transgene and transgene product in the transgenic animal, and comparison with known nucleic acid and protein sequences related to prion disease susceptibility. Therefore, the reaction of the Genetically Modified animal to prion disease should be informed accordingly.