National Biosafety Framework
for
The Republic of Maldives
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## ACRONYMS AND ABBREVIATIONS USED IN THE FRAMEWORK

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIA</td>
<td>Advance Informed Agreement</td>
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<tr>
<td>BCH</td>
<td>Biosafety Clearing-House</td>
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<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<td>COP</td>
<td>Conference of the Parties</td>
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<td>DNA</td>
<td>Deoxyribonucleic acid</td>
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<td>EEZ</td>
<td>Exclusive Economic Zone</td>
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<td>EIA</td>
<td>Environmental Impact Assessment</td>
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<td>ERC</td>
<td>Environment Research Centre</td>
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<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GEF</td>
<td>Global Environmental Facility</td>
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<tr>
<td>GMO</td>
<td>Genetically Modified Organism</td>
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<tr>
<td>IPR</td>
<td>Intellectual Property Right</td>
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<tr>
<td>LMO</td>
<td>Living Modified Organism</td>
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<td>NBC</td>
<td>National Biosafety Commission</td>
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<td>NBSAC</td>
<td>National Biosafety Scientific Advisory Committee</td>
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<td>NBSAP</td>
<td>National Biodiversity Strategy and Action Plan</td>
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<td>NCA</td>
<td>National Competent Authority</td>
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<tr>
<td>NEAP</td>
<td>National Environment Action Plan</td>
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<tr>
<td>NGO</td>
<td>Non-governmental Organization</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
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<tr>
<td>SCAs</td>
<td>Sectoral Competent Authorities</td>
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<tr>
<td>STD</td>
<td>Sexually Transmitted Disease</td>
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<tr>
<td>UNCED</td>
<td>United Nations Conference on Environment and Development</td>
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<td>UNEP</td>
<td>United Nations Environment Programme</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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IMPORTANT WEBSITES RELATED TO BIOSAFETY

http://www.erc.gov.mv
http://www.unep.ch/biosafety
http://www.biodiv.org
http://www.biodiversity.org/biosafety
http://www.biodiversityasia.org
http://www.fao.org
http://www.who.int
http://www.twnside.org.sg/bio
http://www.iucn.org
Acknowledgements

The National Biosafety Framework is the result of a collaborative and comprehensive effort undertaken by the Environment Research Centre (ERC) of the Ministry of Environment, Energy and Water, with the extensive support of stakeholders representing the government, public and private sectors and also of NGOs. Appreciation is also due to the members of the National Experts Committee for their enthusiasm during their meetings in the development of this framework.

ERC acknowledges the support provided by the IUCN – The World Conservation Union, for the development of the NBF. ERC also gratefully acknowledges the technical assistance provided by Professor Athula Perera of Agricultural Biotechnology Center, University of Peradeniya, Sri Lanka.

Finally we wish to express our thanks to UNEP-GEF for providing financial and administrative support to accomplish this task. We are particularly indebted to Dr. Nizar Mohamed, Regional Coordinator for Asia-Pacific, UNEP-GEF Global Biosafety Project, for his guidance and advice.
Foreword

The Government of Maldives attaches great importance to the protection of its environment. As a result of the Government’s initiatives and efforts towards this important national objective, the Maldives has made significant achievements in environmental protection and conservation in recent years. The National Biodiversity Strategy and Action Plan have set the direction for the implementation of the Convention on Biological Diversity, which the Maldives signed and ratified in 1992. The firm commitment of the Maldives to the development and support of the biodiversity policy has paved way for the formulation of the National Biosafety Framework for the country.

The Framework, developed with financial assistance from the Global Environment Facility (GEF), is the result of collaborative efforts undertaken by the Environment Research Centre (ERC) and the United Nations Environment Programme (UNEP). The Framework will enable Maldives to fulfill its obligations as a Party to the Cartagena Protocol on Biosafety, which the Maldives joined on 2 September 2002. Notwithstanding the benefits of being a Party to the Biosafety Protocol, there was a need to develop our own national biosafety policy and regulations that not only gives force to the Protocol, but also focuses on individual national priorities related to food safety, protection of human health and environment.

The implementation of this Framework will play a vital role in increasing public awareness and understanding about Genetically Modified Organisms (GMOs), their impact and the system the Framework sets in place to manage these issues. The Framework covers key elements that include national policies on biosafety, regulatory regime, administrative and decision-making mechanisms, monitoring, mechanism for public awareness and participation.

Due to the capacity constraints, the policies on biosafety and regulations alone will not suffice the safe development and use of biotechnology. There must also be a national capacity to implement the regulations based on sound scientific principles with consistency. The capacity to regulate modern biotechnology through risk assessment and management is as important as are the regulations themselves. In this regard, the Maldives needs adequate and long-term assistance from external donor agencies in order to fulfill the country’s basic obligations and to build a strong infrastructure and technological foundation to ensure safe development of biotechnology.

GMOs can potentially revolutionise both the health and agriculture industries thereby improving the lives of billions around the world. However, there are growing concerns over the potential environmental and health risks associated with both medical and agricultural applications of biotechnology. I therefore, would like to take the opportunity to encourage our people to come together to strike a careful balance ensuring the health of people and environment are not sacrificed while we seek the benefits of biotechnology. Together we can overcome the challenges and obtain the maximum benefits that modern biotechnology brings.

I sincerely appreciate the UNEP-GEF, IUCN – The World Conservation Union, ERC and the National Coordinating Committee of the Biosafety Framework and various stakeholders for their efforts and guidance throughout the development of this Framework.

Ahmed Abdullah
Minister of Environment, Energy and Water
Republic of Maldives
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CHAPTER I

1.1 Introduction

Chapter 16 of Agenda 21 adopted at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro during June 1992 makes specific reference to ‘environmentally sound management of biotechnology’. It recognizes that biotechnology could contribute significantly to sustainable development by improvements in food and feed production, health care, and environmental protection. It also has recognized that the global community at large can only benefit maximally from biotechnology if it is developed and used with care and caution.

The Convention on Biological Diversity (CBD) that is now ratified by 188 countries including Maldives highlights the importance of the conservation and sustainable use of biological diversity and the equitable distribution of benefits of such use. The CBD addresses the issue of safety in biotechnology in Article 8(g) of the Convention, which stipulates that each Contracting Party shall, as far as possible and appropriate at the national level:

‘Establish or maintain means to regulate, manage, or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health’.

The Convention also emphasizes the need for safety in biotechnology at international level among Contracting Parties in Article 19(3) and (4) which stipulates:

19 (3): ‘The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement in the field of the safe transfer, handling and use of LMOs resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity’.

19 (4) ‘Each Contracting Party shall directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph (3) above, provide any available information about the use and safety regulations required by that Contracting Party in handling of such organisms, as well as any available information on the potential adverse impact of the specific organism concerned to the Contracting Party into which those organisms are to be introduced’.
The above Articles on safety in biotechnology were elaborated for action at the Second Conference of the Parties of the CBD (COP II, Decision II/5) which recommended the development of an International Protocol on Biosafety especially for transboundary movement of LMOs for which an Open Ended Ad-Hoc Working Group on Biosafety was established in 1995. After five years of negotiations, a legally-binding international Protocol – the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol) – was adopted in 2000 and came into effect on 11th September 2003.

In accordance with the Protocol (Article 1), each ratifying Party must make national provisions to adhere to the elements of the Protocol as well as implement decisions coming out of the Conference of Parties of the CBD serving as the Meeting of Parties (COP-MOP) to the Protocol. In order to comply with these responsibilities, countries need to establish the 5 main elements of the CP, viz.

1. National Policy on Biosafety
2. Regulatory Regime
3. Administrative structure, Decision Making and Risk Assessment
4. Risk Management, Monitoring & Enforcement
5. Mechanism for public participation

Many countries, especially in the developed world, already have national biosafety policies and regulatory frameworks governing the development and release of GMOs.

As a consequence of increasing trans-boundary trade coupled with norms established by the WTO, many countries are faced with the prospect of increased levels of introduction of GMOs and GMO products, some of which may have adverse effects on the environment and health in their countries. However, most developing countries including Maldives have neither safety guidelines for activities related to use and release of GMOs, nor mechanisms in place to evaluate the potential risks associated with the range of GMO products, nor plans for their management. As a country which has ratified the Convention on Biological Diversity and the Cartagena Protocol, Maldives is obliged to develop a national regulatory framework for safety in all aspects of GMOs and GMO products. Consequently, the Ministry of Environment, Energy and Water initiated a project to develop a National Biosafety Framework (NBF) for the Maldives. The project was funded by the Global Environment Facility (GEF) through the UNEP.

The Ministry recruited Mr. Ahmed Murthaza, Project Officer of Environment Research Centre as the National Project Coordinator (NPC). The Ministry also established the NEC, consisting of representatives of biosafety-related sectors and institutions (See Page 5 for members of the NEC). Project oversight was done by the NEC.

The NBF was developed after a series of consultations with relevant stakeholders in Maldives through questionnaire surveys, workshops and training programmes. Considering the national interests and priorities of Maldives the NBF provides the needed framework for regulating modern biotechnology, so that such technology can be used safely for future development of the country.
1.2 The National Biosafety Framework Development Project

Modern biotechnology or genetic engineering technology has resulted in several advances in agriculture, human health, environmental science and the processing industry. The modern genetic manipulative techniques can transfer genetic material between related and un-related species making novel genetic combinations that are new to existing environments. An organism altered by modern biotechnology is referred to in this document as a genetically modified organism (GMO).

The development of genetically modified plants, animals and microorganisms with novel genetic traits and their subsequent release into the environment could have potential risks that may affect biodiversity, human and animal health as well as the environment. The risk factors associated with introduction of novel genetic combinations into nature causes safety concerns in public health, agricultural production and environmental quality.

Maldives being a Party to the Convention on Biological Diversity and the Cartagena Protocol is obliged to develop its national regulatory framework for the safe transfer, handling, use and release of any genetically modified organism resulting from modern biotechnology to safeguard its environment including the biodiversity and the well-being of its people. There is an urgent need for developing regulations on biosafety at the national level, establishing administrative and monitoring procedures for activities related to all aspects of GMOs and providing advice to the Government on biosafety issues.

The Government of Maldives has designated the National Biosafety Commission (NBC) as the competent national authority, responsible for carrying out the requirements of the Regulations and Guidelines developed as part of the NBF to ensure that modern biotechnology and related products are appropriately assessed and managed in ways that will contribute to sustainable development and better use of modern science for human well-being in Maldives.

1.2.1 Objectives

The overall objective of the NBF 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 through regulating the transboundary movements by formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. The NBF is based on the precautionary principle and advanced informed agreement.

- The NBF provides an overview of current situation in the country that was assessed during the National Biosafety Development Project and identifies what is currently in place in Maldives (i.e., policies, legislation, administrative system, etc.). It also identifies the future needs of Maldives to implement the NBF through suitable policy and regulatory measures.

Information on the 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 using questionnaire surveys conducted during the initial stages of the project.

Information and experience on the policies, legal regimes and institutional arrangements in other countries obtained mainly through internet searches were also taken into consideration in making recommendations for developing the NBF for Maldives. Information collected during the course of the project was used to develop a national database on biotechnology and biosafety.

The project also conducted a limited number of awareness programs on GMOs for various stakeholders with respect to biosafety. The project also supported participation of national experts in training programmes on risk assessment and management and GMO detection methods.

While the development of the NBF is only the first step towards effective management of GMOs in the country; efforts are still needed to develop the scientific, administrative, management, financial and human resources of Maldives. In this regard it has been emphasized that the NBF in its current form is a preliminary step and further revisions and modifications for the NBF are foreseen.

The UNEP-GEF project to develop the National Biosafety Framework for Maldives started in April 2003 and ended in September 2005.

1.2.2 The National Focal Point and Executing Agency for Biosafety:

The Environment Research Centre
Ministry of Environment, Energy and Water
Jamaaludhdhin Complex, 4th floor
Nikagas magu

Tel: (960) 3335949
Fax: (960) 3335953
E-mail: admin@erc.gov.mv

1.2.3 National Project Coordinator (NPC):

Ahmed Murthaza
Project Officer
Environment Research Centre
Jamaaludhdhin Complex, 4th floor
Nikagas Magu
Tel: (960) 3335949
Fax: (960) 3335953
E-mail: murthaza@erc.gov.mv or, biosafety@erc.gov.mv
1.2.4 National Experts Committee (NEC)

Mr. Abdullahi Majeed, Deputy Minister, Ministry of Environment, Energy and Water (Chairman)
Mr. Hassan Moosa, Assistant Director General, Ministry of Health
Mr. Ahmed Shian, Desk Officer, Ministry of Foreign Affairs
Mr. Abdullah Shibau, Senior Planning Officer, Ministry of Planning and National Development
Ms. Aminath Shafia, Director, Ministry of Fisheries, Agriculture and Marine Resources
Ms. Hisaan Hussain, Assistant State Attorney, Attorney General’s Office
Mr. Mohamed Shiyam, Assistant Director, Ministry of Economic Development and Trade
Mr. Mohamed Anwar, Director, Maldives Customs Services
Mr. Hassan Shakeel, Assistant Director, Marine Research Centre
Captain Mohamed Ibrahim, Ministry of Defense and National Security
Dr. Mohamed Ali, Director General, Environment Research Centre
Mr. Ahmed Saleem, Assistant Environment Analyst, Environment Research Centre
Mr. Umaru Manik, Board Member, Maldives National Chamber of Commerce and Industry (NGO)
Mr. Mohamed Shujaaau, Director, Programmes, Blue Peace (an environmental NGO)
NPC (Secretary)

1.3 Organization of the Framework

The project has been developed according to the formats and guidance provided by UNEP/GEF. Thus, the National Biosafety Framework is structured according to the UNEP/GEF proposed format into 6 main parts:

Part I: Introduction, with information on the project development and objectives; and definitions used in the document;

Part II: Description of the Government policy on biosafety;

Part III: Description of existing laws related to biosafety and the 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 in relation biosafety issues.
1.4 Current Status of Biotechnology in Maldives

As a small island developing state, Maldives is heavily dependent on imports, especially food and agricultural products. This is due to ‘agricultural production is constraint by the low fertility of soil, the fragile relationship between land use and water supply, poor quality of plant material available, and the lack of effective quarantine and other regulatory structures to control pests and diseases’. In such respect strategies have been drawn up by the Government of the Maldives to ‘promote and facilitate the diversification of the varieties grown by providing support, targeting site specific species, as well as niche market crops such as fruits, vegetables and ornamental plants, to reduce vulnerability and increase income generating potential’. Moreover, promoting product diversification and value addition of agricultural products within the country through strengthening agricultural research by the Government and the private sector is also a policy provided in the Sixth National Development Plan.

Similar to most other developing countries, Maldives recognized the potential development gains from the use of modern biotechnology; however, the technology is still dormant in the Maldives. There are some efforts in Maldives to catch up in this rapidly developing area, especially in the fields of aquaculture and tissue culture. Therefore it is important to strike a careful balance to ensure that our people’s health and the environment are not damaged in the process. With the lack of capacity in terms of infrastructure and human resources, there is no work carried in the area of screening for organisms that have a potential biotechnological application.

1.4.1 Current status of agricultural biotechnology

More than 75 percent of 270,101 populations (as of March 2000) of the Maldives live in the rural parts of the country, where agriculture is the secondary source of income. Therefore, poverty alleviation and food security programs should address especially the rural sector. The potential, the rural sector has for agriculture, as a business venture is enormous.

The Sixth National Development Plan stated that the agriculture sector’s importance to the economy is greater than its contribution to GDP, considering its role in generating employment and income opportunities in the atolls, improving food security, and greater self-reliance in part through import substitution of certain agricultural produce. The lucrative market for agricultural produce, opened up by the growing tourism industry, has started to attract substantial investments to the sector. The sector has potential for expansion in the foreseeable future especially if the tourism industry continues to grow.

Difficulties in obtaining sufficient good quality farm input such as locally made compost continues to be a major constraint in increasing agricultural production.

The geographical distance between suppliers and markets acts as a barrier for the development of agriculture. Poorly organized marketing systems and poor market information available to growers, act as additional barriers for agriculture development. Appropriate storage, preservation technology, and processing facilities are very limited resulting in the wastage of unsold items. Only a very few types of agricultural produces are preserved in the country and traditional methods are used for such preservation.
Agro biotechnology must generate technology that will improve the economy of the user/grower/industry and food security of the country and provide consumers with more healthy and economical food. The contribution of agro biotechnology to develop agro products with improved efficiency in developing countries is enormous. It would contribute to sustainable economic growth and employment creation in the country. In developing the technology, the agriculture scientists have to consider and respond to the social, economic and political changes that take place in the country. This is important for the sustainable use of the technology.

Genetically Modified (GM) crops have been the subject of public debate in recent years both among the scientists and the general public, particularly in relation to their impact on human health and environment. There is still a greater apprehension regarding safety of genetically modified foods that need to be addressed by the scientists. This will also require application of available tests to study the probable toxicity of genetically modified food and feed, development of new methods of testing and means of continuous close monitoring.

1.4.2 Current status of medical biotechnology

People in Maldives have benefited from the global developments of this technology through diagnostics, therapeutics and vaccines produced by foreign and multi-national companies. However, all these items are imported from foreign manufacturers, draining large amounts of foreign exchange annually, for use by both government and private sector patients.

Every year hundreds of blood donors, clinic attendees of Sexually Transmitted Diseases (STD) and others are tested for the presence of syphilis, Hepatitis B and HIV infection in Government hospitals in Maldives, using commercial test kits based on biotechnology. Although blood donors should ideally be tested for Hepatitis C, this is not done in the Government hospitals at present due to financial constraints. Many more infectious diseases in Maldives need better diagnostics, majority of which are developed by biotechnology based industries.

Diabetes is a growing problem in Maldives. Those with Insulin dependent diabetes need treatment with insulin. The recombinant human insulin, which has hardly any side effects, is costly. This forces many patients to take animal insulin that has many undesirable side effects. If recombinant insulin could be produced in Maldives, the cost could be reduced making it available for many more patients.

At present, private sector has taken up the challenge of producing medicinal herbal products on a large scale, but these need better efficacy and toxicity studies, and quality control methods for which biotechnology could be easily applied. The undertaking of contract research for foreign pharmaceutical companies is likely to improve hospital infrastructure, provide valuable experience to medical staff and enable access to new drugs to local patients. A few small clinical trials based on personal contacts have been undertaken in the country but there is a need to take an overall view of this under a national organization.

It is now timely to plan how this technology and its potential clinical applications can be made available for the people of Maldives at an affordable price adhering to all safety and ethical norms.
1.4.3 Current status of microbial and environmental biotechnology

Maintaining an appropriate balance between environmental quality and long term sustainable economic development has been recognized as the basic environmental policy in Maldives. In Maldives there are few industries based on microbial technology. Basically the following categories of uses are recognized. The details given for each are not based on a large-scale survey.

Fermentation biotechnology

- Brewery industries (Vinegar)

In Maldives, brewery biotechnology involves cottage industries, small and medium scale industries. Generally productions of vinegar and coconut oil are a cottage industry, and release it to the retail market.

Environmental biotechnology

- Water and waste water treatment industries, solid waste management industries (re-cycling waste), biogas, and bioremediation.

Agricultural & Fisheries biotechnology

- Biofertilizers, biopesticides, bioherbicides, composting

Pharmaceuticals / health care products

- Detergents, confectionary
- Food supplement and fish processing

1.4.4 Current status of food biotechnology

Although food technology based industry is now gaining ground, better methods for assessment of quality of food, perhaps by molecular methods is needed. Although the market is flooded with various food imports there is no mechanism to test for genetically modified food or food items prepared with one or more genetically modified foods in Maldives, at present.

1.4.5 Current status of marine biotechnology

Aquaculture: In Maldives, the main marine biotechnology industry at present is aquaculture, which concentrates on shrimp farming and ornamental fish culture. Except for tissue culture based micropropagation of ornamental aquatic plants and detection of white spot disease in prawns very little is done in this area in Maldives at present. The shrimp industry has been affected due to a viral disease.
**Marine resources:** In 2000, Maldives ratified the United Nations Convention on the Law of the Sea declaring the 200-nautical-mile (370.4 km) Exclusive Economic Zone (EEZ). With this ratification, a large area of ocean came under the national jurisdiction of Maldives.

This has given Maldives a rather high water to land ratio of 300:1. In the EEZ, Maldives has sovereign rights with respect to natural resources, whether living or non-living, over the waters superjacent to the seabed and of the seabed and subsoil. However, Maldives is yet to utilize its massive ocean resource.

The country up to now has not harnessed the marine resources. Therefore, it is extremely important that efforts are made on research and development in other areas of marine biotechnology. A few potential areas that the country could start on research where inputs are low are: sea vegetables, food ingredients and nutraceuticals, (i.e., culturing in an open system of macroalgae with economic potential such as laminaria, prophyra, etc.); and culturing of microalgae (i.e., chlorella, spirulina) as a source of energy, biosorption and waste treatment (to remove heavy metals from polluted water). Initial investigation on the diversity of marine organisms for the above purposes needs to be carried out.

1.4.6 Current status of animal biotechnology

Biotechnology has the potential to play a significant role in animal productivity. Enhancing nutritional quality of animal products, animal welfare and disease diagnostics can be addressed from advances in biotechnology. Thus, most agree that investments on this area should be made alongside assessment of environmental risks, identifying research priorities and determining cost effectiveness.

**Current activities:** Activities related to Animal related biotechnology are mostly at teaching and research levels. The development of the livestock industry in Maldives falls within the purview of the Ministry of Fisheries, Agriculture and Marine Resources. It is directly responsible for the control of livestock diseases, livestock research, training of trainers in animal husbandry, preparation of project proposals for developing the industry and implementing special developmental programs covering the whole island. Important biotechnology areas are artificial insemination, vaccine productions, starter cultures and probiotics, and the use of exogenous enzymes in animal feed.

1.4.7 Current status of bioinformatics

There are at best a handful of scientists in the country knowledgeable on Bioinformatics. No central facility in the country has relevant international data or can provide access to the necessary software to potential researchers. There is a clear need to develop a central bioinformatics facility and the required expertise in this field.
CHAPTER II

NATIONAL BIOSAFETY POLICY

2.1. Introduction

UNCED recognized that the rapidly expanding world population exerting pressure on renewable and non-renewable resources would lead to an over-exploitation and degradation of some resources, and that the Convention on Biological Diversity would be an important international tool for the effective management and sustainable use of world’s biological resources by the present and future generations.

The CBD, whilst identifying modern biotechnology as a powerful tool for ensuring food security and for alleviating poverty, also recognizes the risks of genetically modified organisms, and therefore addressed the issue of biosafety in articles 8(g), 19.3 and 19.4. Article 19.3 specifically calls the Parties to the CBD to consider the need for and modalities of a protocol that sets out appropriate procedure, including in particular, advance informed agreement, in the field of safe transfer, handling and use of any living modified organism resulting from modern biotechnology that may have any adverse effects on conservation and sustainable use of biological diversity.

The expanding world population is increasingly using products of modern biotechnology to meet the demand for food, shelter and health. The commercialization of modern biotechnology has become a major industry worldwide even before the long-term effects of some of these technologies are fully evaluated and understood. Modern biotechnology may have both positive and negative impacts on socio-economic development and environment. The use of modern biotechnology often demands taking a stand on ethical issues, which the public clearly regards as important. Great potential exists in the opportunities afforded by the technology, with underlying responsibility for basic values in the society, health and environmental safety.

Recognizing the need for safety guidelines in use of modern biotechnology, Parties to the CBD began negotiating an international Protocol on biosafety in 1995. These efforts culminated in the development and adoption of the Cartagena Protocol on Biosafety that came into effect in 2003. Countries that are Parties to the CBD began developing national policy and regulatory regimes to implement the Protocol by developing National Biosafety Frameworks. This national policy reflects the interests, priorities and commitments of The Republic of Maldives on modern biotechnology.

2.2 The need for a National Policy on Biosafety in Maldives

Modern biotechnology has been identified by the global scientific community as well as international and regional organizations, as a new technology that can bring about improved health care, improved environmental management, advances in poverty alleviation, and maintenance of food security whilst also addressing the possible adverse effects on biodiversity, environment and human health.
In Maldives, the National Biodiversity Strategy and Action Plan (NBSAP) formulated by the Ministry of Home Affairs, Housing and Environment has identified biotechnology as a major thrust area in priority setting and strategic planning in crop improvement. It has also identified the need for regulatory mechanisms in areas of biosafety. Being a Party to the Cartagena Protocol on Biosafety Maldives has an obligation to implement the provisions as well as decisions under the Protocol. Thus, it becomes important that decisions on the use of biotechnologies are based on appropriate scientific, economic, social and ethical principles.

Biotechnology has received little state support so far, when compared to the support of the Maldivian Governments towards development of science and technology and of other Governments in the region towards biotechnology. Trade and exchange of products and derivatives from biotechnological interventions are at significant levels. However, such trade and all other activities related to modern biotechnology are not regulated at present and the responsibility for its component fields has been the uncoordinated tasks of several different departments and authorities. There is no unified regularity scheme, and Maldives at present lacks a cohesive and long-term policy on biotechnology and biosafety.

Recognizing the need to have resources, financial as well as human, Maldives is cognizant of the fact that limited resources will be available in the near future to develop biotechnology based industry and/or advanced research. Thus, it supports networks of co-operation and collaboration and sharing of information that exist, especially amongst regional bodies in the Indian sub-continent, which Maldives can make use of. However, decision making and priority setting in biotechnology R&D, product development and commercialization and access to and use of various technologies and products of biotechnology must be nationally driven and for the benefit of the country and priorities set by the people of Maldives. It must be recognized that while the use of some technologies may prove beneficial to the socio-economic development of the country, the application of certain others and the importation of biotechnology derived products, especially those of modern biotechnology, could jeopardize the development process, affect the environment and the biodiversity resources existing in the country and cause risks to human health as well.

These factors favour the development and adoption of a national policy on biotechnology and biosafety for Maldives. In addition, development of a national biosafety framework could strengthen the needs and priorities of the country as well as fulfill the country’s obligations to the Cartagena Protocol. This would however, require the immediate enhancement of the national institutional capacity and the human resource base, so that Maldives could make the correct decisions on modern biotechnology applications and adopt appropriate Biosafety measures on time.

Therefore, the National Biosafety Framework prepared by Environment Research Center of the Ministry of Environment, Energy and Water, has been set in place to address these issues. A National Policy on Biosafety would be a part of this framework, which will provide for the development, application and promotion of various forms of biotechnologies and ensure that no adverse impacts will be felt on environment and human health in Maldives.

It is imperative that Maldives’s National Policy on Biosafety strikes a balance between regulation and promotion of modern biotechnology. Risk analysis and cost-benefit
evaluation of individual applications should be undertaken in full consideration of Maldives’s biodiversity and physical and socio-economic environment.

2.3 Existing Policies and their relevance to Biosafety

2.3.1 National Biodiversity Strategy and Action Plan (NBSAP)


The NEAP provides the platform to work toward an integrated approach to environmental management and sustainable development. In such a manner, the NBSAP addresses biodiversity conservation as well as sustainable development issues strategically. Where, the NBSAP recognizes the importance of controlling and managing the exotic species for the conservation of the country’s marine and terrestrial biodiversity. Hence, NBSAP recommended establishing proper sanitary and phytosanitary measures necessary for conservation of biological diversity, animal and plant life and health. And more specifically NBSAP has recommended formulating quarantine laws and other regulations to control import of alien species, pests and disease and to adopt risk assessment techniques developed by international organizations for identification of potentially harmful species, their entry, establishment and control. Further, NBSAP called for establishment of suitable quarantine facilities at entry points and established appropriate measures for conservation of local biological diversity when transferring species from one locality to another within the country.

2.3.2 Sixth National Development Plan (6th NDP)

Ministry of Fisheries, Agriculture and Marine Resources developed policies to promote food production in the Maldives.

The policies defined below are given in the 6th NDP by the Ministry of Fisheries, Agriculture and Marine Resources;

- Policy 20: Develop infrastructure and provide institutional support to maximize economic and social benefits from ecologically sustainable agri-business
- Policy 21: Diversify the agricultural sector through research and transfer of appropriate technologies
- Policy 22: Encourage private sector participation in the expansion and growth of agriculture
2.4 POLICY FRAMEWORK

2.4.1 Scope of the Policy

This policy covers actions related to development and use of modern biotechnologies. The coverage includes living organisms, germplasm and all elements of genetic material used in genetic manipulation.

The national policy also considers:

a) Contained (laboratory and greenhouse) and field applications of modern biotechnology, both currently known and those to be developed in the future,

b) Application of modern biotechnology in sectors such as agriculture, fisheries, forestry, human, plant and animal health, food production, industry and environment,

c) Regulatory and deployment processes including import, sale, distribution, export and transboundary movement of modern biotechnologies and products thereof and commercial and non-commercial application of modified organisms

d) Research and development related to modern biotechnology as well as deployment of products generated through such research and development

e) Human resource needs, development and capacity building in biotechnology and to apply biosafety principles

f) Needs of finances and economic implications of adopting or promoting biotechnology

g) Occupational safety at workplaces where modern biotechnology procedures are used and/or products handled

h) All measures to ensure public health and environmental safety with regard to the application of modern biotechnology in the country

2.4.2 National Development Objectives

According to the Constitution of the Republic of Maldives, the government has identified the following national development objectives:

a) To enhance the environment and health care improvement

b) Sustainable development and poverty alleviation

c) Creation of employment opportunities

d) Developing the institutional capacity and human resource

e) Providing a quality of life to the people of Maldives

The areas in which biotechnology applications can be expected to make a significant contribution is in the promotion of environmentally friendly agriculture, livestock, fisheries, human and animal health and products for bioremediation. Population projections imply that demand for food will continue to grow and consequently the production needs to be increased if food security is to be ensured. The fragile environment of Maldives also demands the need for better and careful management of its resources as well as diversity so
that future supplies and demands of citizens of the country could be met without damaging the environment and associated resources.

2.4.3 Policy Objectives

The biosafety policy of a country should include the Government’s overall stance on biotechnology, areas where emphasis is to be placed, the kind of commitment, assistance and support that will be available from the government and how the responsibility for achieving the desired goals is intended to be assigned. The biosafety policy must also state in detail the mechanism of its implementation and risk assessment. For sustainable use of biotechnology, activities in R&D should be promoted and successful developments should be transferred to applications in agriculture, health, industry, fisheries, etc. Equally important is to identify mechanisms that would regularly monitor biosafety, the quality of biotechnology applications and address ethical issues.

The key objectives are:

a) To assess the uses and risks of all modern biotechnologies, for sustainable development, without jeopardizing human health, the environment and biodiversity
b) To safeguard the country’s biodiversity and fragile environment
c) To promote research and development in biotechnology and related human resource development in accordance with the needs and most appropriate biotechnologies and applications
d) To promote and regulate use of biotechnology in industrial and medical applications
e) To protect the country from unforeseen introductions of modified organisms or products, including for food, feed or processing
f) To ensure effective control of transboundary movements of modified organisms or the related products resulting from modern biotechnology
g) To enhance scientific, technical and technological skills and competence of stakeholders to make informed decisions
h) To promote safe and responsible use of modern biotechnology
i) To promote capacity building, ethics and equity on issues related to research, development and deployment of modern biotechnology
j) To understand, relate and link implications of trade, intellectual property rights and traditional practices with biotechnology and its products.

2.4.4 Principles of National Biosafety Policy

2.4.4.1 General Principles

This biosafety policy aims to promote the accumulation of knowledge and skills in the sector, to facilitate the conversion of results of research projects to practical applications, under ethically acceptable conditions. It is based on the following national policy principles for the safe use of modern biotechnology.
(i) Rights

Maldives reserves the sovereign right to protect its national heritage and property, and to exploit its own resources pursuant to its environmental and developmental policies. It also bears the responsibility to ensure that activities within its jurisdiction do not cause damage to its environment or to other states or areas beyond the limits of national jurisdiction. As a party to CBD Maldives is obliged to regulate modern biotechnology applications, which may harm its biological diversity, its environment and human health.

(ii) Research and development

In line with the national policy towards achieving sustainable socioeconomic development, Maldives will place due importance on developing capacities related to biotechnology and safe use of products and services arising out of modern biotechnology. Based on a careful assessment of national needs and priorities, suitable guidelines will be developed to support efficient use of resources, capacities and finances to develop biotechnology based initiatives.

(iii) Maintenance of biodiversity

Being a small island developing state, Maldives puts highest priority to safeguard its biodiversity. Any intervention related to modern biotechnology will be considered in line with protection of biodiversity for present and future needs of the country.

(iv) Safe use and regulation of modern biotechnology

The use, import, export, sale or transboundary movement of modern biotechnology applications, practices and products must conform fully to all existing national legislation. Maldives shall endeavor to strike a healthy balance between biotechnology promotion and regulation.

(v) Regional and International co-operation

Maldives shall endeavor to cooperate with its neighbors and Parties to the Cartagena Protocol on Biosafety to ensure the safe use of modern biotechnology within its national borders, legal jurisdictions and exclusive economic zones.

(vi) Public awareness and education

Maldives realizes the need for public awareness and education and participation in the decision-making processes for ensuring the judicious use of modern biotechnological applications, practices and products for development, without jeopardizing the environment, biodiversity and human health.

(vii) Ethics

Modern biotechnology has great potential for human well being if developed and used according to ethical norms of the society and with adequate safety measures for the environment and human health.
(viii) Import and Export

The import and export of Living Modified Organisms and their products will be according to National Biosafety Framework of Maldives

(ix) Transboundary Movements

Maldives retains its rights and obligations to regulate transboundary movement of Living Modified Organisms and their products. Guidance available through the Protocol and national biosafety framework will guide the decision making on such movements.

(x) Assessing and managing risks

Risk assessment and risk management will be according to the norms stipulated under the national biosafety framework. Though the precautionary principle will guide decision making, political and economic issues shall not influence such decision making.

(xi) Information, Transparency and Decision making

Since modern biotechnology has impacts on human and animal health, environment, socioeconomic aspects of the people, those involved in the use, development, deployment and decision making on issues of modern biotechnology should share full information on the process, product, impacts envisaged, responsible authority, relevant risk assessment and management information and other related issues. Information exchange, transparency and participatory decision making are critical to ensuring modern biotechnology and related products will help the people and the environment in a positive way.

(xii) Handling, Packaging and Labeling

Considering the potential impacts of modern biotechnology on human and animal health as well as the environment, handling, packaging and labeling of Living Modified Organisms and their products should receive utmost attention by all those involved in development, movement and trade of such organisms. The national biosafety framework should guide the process.

(xiii) International agreements

Some international agreements may be structurally biased to favour commercial considerations over public health, environmental and safety interests. Decisions on biosafety issues shall be made by considering the elements of such agreements but in ways that such decisions will not cause either economic, environmental or social disruptions to Maldives.

(xiv) Intellectual Property Rights (IPR)

Effective statutory expression shall be given to the moral and economic rights of the creators of their intellect and the application of such creations for the benefit of both the creator and the nation, while stimulating and promoting investment, transfer of technology and fair and competitive trade.
(xv) Socio-economic considerations

Considering the need and priorities of Maldives, careful socio economic assessments will be carried out in the risk assessment process before commercialization of Living Modified Organisms. Such assessments are also needed for import, sale and consumer rights related options.

(xvi) Legislation

Legislations to cover modern biotechnology and its applications will be developed and introduced to ensure safe use of the technology and its applications. Aspects of labeling, consumer rights and obligations under existing legal measures will be covered under such legislation.

(xvii) Regulatory Authority

The national biosafety framework provides for the establishment of a regulatory body to deal with issues of modern biotechnology and biosafety. The same body will be responsible for ensuring that the provisions of this policy are implemented. Suitable financial, institutional and human resource capacities should be provided for this Authority to fulfill its tasks and obligations.

(xviii) Research and funding

Prioritization of research areas in modern biotechnology and biosafety shall be carried out based on the national development policy and with the concurrence of public and private S&T institutions and agencies responsible for such fields of activity (eg. Universities, National Research and Development Institutions). Suitable funding for such actions should be made available through national budgets.

(xix) Monitoring and evaluation

Appropriate monitoring and evaluation methods and systems should be established to implement the provisions of the policy as well as the national biosafety regulations. Priority shall be given to the establishment of an efficient research management system and the development of research infrastructure such as biotechnology information centers, biotech parks and other institutions involved in research, design, consultancy and information, in order to strengthen the facilities for the smooth transfer of technology and development of new products.

It is accepted that the biosafety policy of Maldives will be based on the precautionary approach and the advanced informed agreement, in compliance with the Cartagena Protocol on biosafety.
2.4.4.2 Strategy

**Commitment from the Government of Maldives**

In Maldives, biotechnology-based activities have not received any significant state patronage so far, when compared with the direction and motivation of the Government shown towards development of science and technology in this country, and of the other governments in the region towards biotechnology. A strong commitment is essential from the present and all future governments, to establish a sustainable development plan for biotechnology in Maldives. This should be reflected in the political and financial commitments shown towards biotechnology by the Government. Some key areas that need attention include:

a) Financial and policy level support for the NBC;
b) Further development and implementation of the regulatory framework;
c) Research into socio-economic impacts of biotechnology and its products;
d) Review of legal and other measures related to environment, development and trade (including patents and IPR) and appropriate adjustment of policies and institutional mechanisms;
e) Human resource development; and
f) Public participation and awareness in governance of modern biotechnology.

The Government has designated the NBC as the national competent authority for biosafety. The NBC will be supported by the National Biosafety Scientific Advisory Committee (NBSAC). Its functions, among others, will be to advise the government on R&D and human resource development in relation to biotechnology and biosafety, inclusive of training and education. Its decision-making process will be transparent and will take full account of the environment, public health, socio-economic and cultural concerns of the community.
CHAPTER III

Regulatory Regime

3.1. Introduction

Existing regulatory instruments, including laws, regulations, and guidelines relevant to biosafety in Maldives, were reviewed during the development of NBF. National consultations and surveys were conducted with key stakeholders to collect relevant information.

3.2. Existing regulatory instruments and their relevance to biosafety

A review of regulatory instruments has shown that there is yet no single legal instrument that addresses biosafety concerns in the country. Rather there are various pieces of sectoral legislation and policies covering environmental conservation and management, animal and human health.

Regulating modern biotechnology during development, production and transport of GMOs, is evidently needed. Lack of such regulation could complicate importing or local production of such products. In compliance with the Cartagena Protocol on Biosafety, Maldives need to regulate modern biotechnology in terms of reducing risks to environment and human health. Such regulations could promote biotechnology by increasing public acceptance of new developments allowing companies to invest in the field of biotechnology in Maldives.

The following are some of the legal instruments that have been assessed in order to establish the extent to which they regulate the application of modern biotechnology in the country.

None of the reviewed legal instruments give a place to include GMOs and/or GMO products.

a) Environment Protection and Preservation Act of Maldives (Law 4/93)

It is obligatory to undertake Environmental Impact Assessment (EIA) studies prior to any development activities under the Environment Protection and Preservation Act of Maldives (Law 4/93). This is in order to assess the main environmental impacts associated with the development activities as well as to identify measures in which such impact is managed and mitigated. The Ministry of Environment is the responsible institution for implementation of this Act as well as designing of policies, regulations and guidelines under this Act, and plays a prominent role in the overall enforcement procedures.

The Ministry may levy fines of up to Rufiyaa 100 million for violations of the law. The Ministry also has the authority either to discontinue or to terminate any project that has an undesirable impact on the environment. A project thus terminated shall not receive any compensation.
b) **Fisheries Law (Law 5/87)**

The Ministry of Fisheries, Agriculture and Marine Resources is responsible for the protection, conservation and management of the coral reef environments in Maldives. Clause 9 articulates the fish catch for experimental purposes and Clause 10 describes the protection of the living marine organisms for specific uses.

Regulations under the Fisheries Law have been formulated by the Ministry of Fisheries, Agriculture and Marine Resources. These regulations prescribe rules and regulations and define general procedure such as prohibiting the activities involving fish catch (Article 1 and 2). The regulations also prescribe rules on migratory marine species (Article 10).

The Fisheries Law has been substantially revised and Regulations on Aquaculture developed, with the assistance of the Food and Agriculture Organization of the United Nations, and are expected to be adopted in 2006.

c) **Regulations for Food**

There is no law for food and food production in the Maldives, but regulations have been drafted by the Department of Public Health. The regulations define the general procedure for handling, transport and quality standards of food and food products and also describe rules and regulations for labeling food as well as for the import and sale of meat, fish products, fruits and vegetables.

d) **Regulation for Import and Sale of Drugs in the Maldives**

The Ministry of Health is the responsible institution for the implementation of this regulation.

Drugs and medicines which are allowed to be imported into Maldives are those in the Approved Drug List of the Board for Pharmaceuticals and discussed by the Ministry of Health. Drugs shall only be imported from suppliers or manufacturers approved by the Ministry of Health and certified to an approved quality standard.

c) **Import and Export Law of Maldives (Law 31/79)**

The enforcement authority of this law is the Maldives Customs Service. The law prescribes the regulations and rules of general procedure for the import and export of products including food and feed. Import and export licensing is by the Ministry of Trade and Industries.

h) **Quarantine**

Maldives does not have a quarantine law. However, the Port Health is empowered to quarantine any products that it may deem necessary. The procedure followed by the Port Health is to withhold any product shipment received from Maldives Customs Services, which is of concern for human and environmental health, and inform the concerned
Government authorities depending on the nature of the shipment withheld. The concerned authorities make the decision for permit entry or disposal.

Authorities that make decisions regarding quarantined products are:

1) The Ministry of Fisheries, Agriculture and Marine Resources for plants and plant materials, other living species, pesticides and herbicides.
   - A dossier from the exporting country is required for imports of animal species. The Ministry holds the species in quarantine and tests it on other beneficial insects. After that field releasing is done.
   - Imports of pesticides and herbicides in WHO classes 2 and 3 are permitted; Class 1 pesticides and herbicides are not permitted.
   - A Phytosanitary certificate from the country of export is required for importing plants.

2) The Department of Public Health for food, food products, poultry, meat, vegetables, fruits and other consumable products.

3) The Ministry of Health for pharmaceuticals.

4) The Ministry of Defense and National Security for any chemicals to be imported.
### 3.3 Proposed National Biosafety Regulations

#### Objectives
1. The objectives of these Regulations are to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to which the Republic of Maldives is a Party and to safeguard public health and the country's biodiversity and fragile environment.

#### Scope
2.1. These Regulations apply to all stages of research and development, import and export, contained use, deliberate release, direct use as food, feed or for processing, and any other type of use of GMOs and GMO products for any purpose.

2. These Regulations do not apply to:
   a) GMOs and GMO products that are pharmaceuticals for human use that are addressed by relevant international agreements and/or organizations;
   b) GMOs and GMO products in transit through but not destined for use in the Republic of Maldives; and
   c) Any other categories of GMOs and GMO products that may be exempted by the National Biosafety Commission (NBC).

#### Registration
3. All national public and private sector Operators must be registered with the NBC.

#### Prior Approval
4. Any Applicant intending to conduct any activity or operation involving GMOs and GMO products must get written approval from the NBC before seeking authorization by the concerned competent authority.

#### Confidential business information
5. An Applicant may identify information provided in accordance with the requirements of these Regulations that is to be treated as confidential.

#### Focal Point
6. Each Operator must, before commencing an activity or operation involving GMOs and/or GMO products, designate a Biosafety Focal Point and notify the NBC of the name, title, and all contact coordinates of that Focal Point.

#### Risk assessment
7. Risk assessment data/records must be submitted with applications for prior approval for import of GMOs and GMO
products and for domestic operations. Risk assessments must be carried out on a case-by-case basis and must be based on actual biophysical and socio-economic conditions in the Republic of Maldives at the time of assessment. At a minimum, the risk assessment must contain the information indicated in Annex 1, and must indicate specific risk management measures that may be applied. Risk assessment is the responsibility of the Applicant or Operator, who bears all costs.

| Risk management | 8. Risk management measures must be determined on a case-by-case basis, according to the characteristics of the GMO and/or GMO product and activities involved, and must be appropriate to the level of assessed risks. Risk management is the responsibility of the Operator, who bears all costs. |
| Administrative fees and costs | 9. All procedures are subject to payment of administrative fees. Public research institutions, colleges and universities, and any other public facilities designated by the NBC, may be exempted from payment of administrative fees. In the event of the need for additional information/data needed to make a decision on an application, such additional costs must be borne by the Applicant. |
| Security bond | 10. All activities and operations involving GMOs and GMO products are subject to payment of a security bond which amounts to 15% of the total value of the activity or operation must be deposited with the NBC at the time of prior approval of import or permission for domestic activities and operations. The amount of the bond will be returned to the Operator, without interest, on completion of the activity or operation for which prior approval or permission is granted. The security bond will be used, if needed, to recover any unforeseen costs associated with issues of non-compliance and/or for risk management actions. |
| Labeling | 11. All GMOs and GMO products imported into and used in Maldives, and also those exported from Maldives must be clearly labeled. |
| Public information | 12. 1. The NBC must ensure the meaningful participation of the public in the process of making decisions concerning the import and domestic use of GMOs and public access to non-confidential information related to GMOs in general and in particular to their presence and use in Maldives. 2. Each Applicant must, at its own cost, announce its
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<tr>
<th>Section</th>
<th>Description</th>
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<tr>
<td>Application procedure</td>
<td>The NBC must announce its final decisions on applications through print and/or broadcast media.</td>
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<tr>
<td>Conditions</td>
<td>In approving any application, the NBC may impose specific risk management measures, labeling or making requirements, and/or other conditions.</td>
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<tr>
<td>Notification of shipment</td>
<td>For any import of GMOs or GMO products the importer must, in writing, notify the NBC of the scheduled arrival of the shipment.</td>
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<td>Revocation</td>
<td>The NBC may at any time revoke approval to import a GMO or GMO product and registration of a domestic operation on the following grounds:</td>
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<td></td>
<td>a) Evidence of incomplete or false information in the documentation for the original application for prior approval;</td>
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<td>b) Non-compliance with or violation of any of the conditions of approval;</td>
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<td>c) Refusal to allow inspection of the facility or facilities where the GMO or GMO product will be stored, used and/or disposed;</td>
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<td>d) Suspension or revocation of the operating authorizations of the importer in the Republic of Maldives or the exporter in the country of origin;</td>
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<td>e) Availability of new technical information indicating that the GMO or GMO product, if allowed for its intended use, will result in significant risks to human health and the environment; and/or</td>
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<td>f) Other grounds as may be determined by the NBC.</td>
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<tr>
<td>Import of GMOs for deliberate release</td>
<td>Each import of GMOs into the Republic of Maldives for deliberate release into the environment is subject to risk assessment and approval by the NBC.</td>
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<td>Notification of intent and application for</td>
<td>The Applicant must notify the NBC of the intent to import and apply for prior approval. The notification and application for prior approval to import GMOs or GMO products for deliberate release must include all requirements specified in Annex 2 of the Biosafety Regulations.</td>
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<td>prior approval to import of GMOs for</td>
<td>Acknowledgement of</td>
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<td>deliberate release</td>
<td>Within ninety (90) days of receipt of notification, the NBC</td>
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| Notification | must acknowledge receipt:  
| a) Indicating the date of receipt of the notification;  
| b) Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and  
| c) Advising the Applicant whether it may proceed to the approval process.  
| Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application. |
| Approval of import of GMOs for deliberate release | 19. Within two hundred and seventy (270) days of the date of receipt of a notification and request for prior approval, the NBC shall communicate in writing to the Applicant its decision, indicating either:  
| a) its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or  
| b) Denying approval of the proposed import.  
| Failure by the NBC to communicate its decision within two hundred and seventy (270) days does not mean that the request for prior approval is approved. |
| Validity of approval to import GMOs for deliberate release | 20. Approval to import a GMO or GMO product for deliberate release is valid for a period of two (2) years from the date of approval, unless revoked for any reason specified in Section 13. The Applicant must include the original approval with the application for import permits. |
| Import of GMOs for direct use as food or feed or for processing | 21. The first import of a GMO or GMO product for direct use as food or feed or for processing is subject to risk assessment and approval by the NBC. |
| Notification and application for prior approval to import GMOs for direct use as food or feed or for processing | 22. The Applicant must notify the NBC of the intent to import and apply for prior approval. The notification and application for prior approval to import GMOs or GMO products for direct use as food or feed or for processing must include all requirements specified in Annex 2 of these Regulations. |
| Acknowledgement of notification | 23. Within ninety (90) days of receipt of notification, the NBC must acknowledge receipt: |
a) Indicating the date of receipt of the notification;
b) Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and
c) Advising the Applicant whether it may proceed to the approval process.

Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application.

| Approval of import of GMOs for direct use as food or feed or for processing | 24. Within two hundred and seventy (270) days of the date of receipt of a notification and request for prior approval, the NBC shall communicate in writing to the Applicant its decision, indicating either:
|-----------------------------|---------------------------------------------------------------|
| a) its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or
| b) Denying approval of the proposed import. |

Failure by the NBC to communicate its decision within two hundred and seventy (270) days does not mean that the request for prior approval is approved.

| Notification of Biosafety Clearing-House | 25. When the NBC approves a GMO or GMO product for direct use as food or feed or for processing, it must notify the Minister of Environment as National Focal Point for the Cartagena Protocol who must notify the Biosafety Clearing-House within fifteen (15) days of approval. |

| Validity of approval to import GMOs for direct use as food or feed or for processing | 26. Approval to import a GMO or GMO product for direct use as food or feed or for processing is valid for a period of five (5) years from the date of approval, unless revoked on any of the grounds set out in Section 13. Approval may be renewed for successive five-year periods upon showing by the Applicant/Operator that continued import of the GMO or GMO product as food, feed, or for processing, does not pose any significant risks to human health or biodiversity. |

| Import of GMOs for contained use | 27. The first import of a GMO or GMO product for contained use is subject to risk assessment and approval by the NBC. |

| Notification and application for prior | 28. The Applicant must notify the NBC of the intent to import and apply for prior approval. The notification and application |
| Approval to import GMOs for contained use | For prior approval to import GMOs or GMO products for contained use must include all requirements specified in Annex 2 of these Regulations. |
| Acknowledgement of notification | 29. Within ninety (90) days of receipt of notification, the NBC must acknowledge receipt:  
   - Indicating the date of receipt of the notification;  
   - Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information, including additional risk assessment, required. The costs of additional risk assessment must be borne by the Applicant; and  
   - Advising the Applicant whether it may proceed to the approval process.  
   Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application. |
| Approval of import of GMOs for contained use | 30. Within two hundred seventy (270) days of the date of receipt of a request for prior approval, the NBC shall communicate in writing to the Applicant its decision, indicating either:  
   - Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or  
   - Denying approval of the proposed import.  
   Failure by the NBC to communicate its decision within two hundred seventy (270) days of the date of receipt does not mean that the request for prior approval is approved. |
| Validity of approval to import GMOs for contained use | 31. Approval to import a GMO or GMO product for contained use is valid for a period of two (2) years from the date of approval, unless revoked for any reason specified in Section 13. The Applicant must include the original approval with the application for import permits. |
| Export of GMOs | 32. Any Applicant or Operator who intends to export GMOs and/or GMO products from the Republic of Maldives for any purpose must apply to the Competent National Authority of the proposed importing country according to the laws and regulations of that country, prior to applying to the concerned competent authority of the Republic of Maldives for an export permit. |
| Domestic research and development | 33. Domestic research and development activities and operations are subject to prior approval by the NBC. The NBC must |
establish and maintain a registry of GMOs and GMO products that have been approved for domestic research and development.

| Field testing | 34. No GMO or GMO product may be considered for deliberate release or placing on the market unless it has been field tested under contained conditions in Maldives, and has shown no harmful effects to the environment, biological diversity and animal and human health. Field testing must have prior approval of the NBC. |
| Revocation of permission for domestic research and development | 35. The NBC may revoke permission for domestic research and development on any of the following grounds:  
   a) Provision of false information in the application;  
   b) Violation of any conditions specified in the permit;  
   c) Failure to allow inspection of the field testing site;  
   d) Receipt by NBC of new information that the field testing of the GMO or GMO product being field tested poses significant risks to human health and the environment;  
   e) Such other grounds as NBC may deem reasonable to prevent significant risks to human health and the environment. |
| Inspection | 36. An authorized official of the Ministry of Environment may, at any time during normal business hours, enter and inspect the facilities where any activities or operations involving GMOs and/or GMO products are being, or have been, carried out. |
| Emergency response | 37. In the event of an emergency involving a GMO or GMO product, any person with knowledge of the emergency must immediately inform the NBC or local authorities who must immediately notify the NBC. |
| Penalty | 38. 1. Any Applicant who provides false information in an application for any purpose under these Regulations shall be fined no less than .......... Rufiyaa and no more than .......... Rufiyaa, in addition to revocation of approval and/or permit, and may, at the discretion of the NBC, be prosecuted according to the relevant laws.  
   2. Any Operator who violates one or more conditions of approval for import of GMOs and/or GMO products and/or one or more conditions of registration with the NBC shall be fined no less than .......... Rufiyaa and no more than .......... Rufiyaa, in addition to revocation of approval and/or permit and/or registration with the NBC, and may, |
at the discretion of the NBC, be prosecuted according to the relevant laws.

3. Any Operator that becomes aware of any significant new scientific information indicating that authorized activities involving GMOs and/or GMO products may adversely affect biodiversity and/or human health and fails to report to the NBC or intentionally hides this information shall be fined no less than .......... Rufiyaa and no more than .......... Rufiyaa, addition to revocation of its operating license and registration with the NBC, and may, at the discretion of the NBC, be prosecuted according to the relevant laws.

4. Any Operator who obstructs or causes the obstruction of an authorized official of the Ministry of Environment in the process of fulfilling his/her duties under Section 36 of these Regulations shall be fined no less than .......... Rufiyaa and no more than .......... Rufiyaa.

5. In the event of repeated violations, fines shall be progressively increased.

6. All evidence and equipment involved with activities and operations related to GMOs and GMO projects that are the subject of violations described in 38.1-38.4 may be confiscated on court order.

Applicability of other laws and regulations

39. The import of GMOs and GMO products for any purpose is also subject to all other relevant laws and regulations.

Interpretation

40. 1. “ Applicant” means a legal or natural person, national or non-national, that notifies its intent and/or applies for prior approval to carry out any activity or operation including but not limited to import, export, contained use, and deliberate release of any genetically modified organism for any purpose in the Republic of Maldives.

2. "Contained use" means any operation, including field testing, undertaken within a secure facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

3. “Deliberate release” means intentional introduction into the environment that is not contained use, including field
release, planting and release into water and/or air, of genetically modified organisms subject to these Regulations with the exception of those imported for direct use as food or feed, or for processing.

4. “Emergency” means any significant unintended release into the environment of genetically modified organisms or products of genetically modified organisms which could present an immediate or delayed hazard to human health or the environment.

5. “Genetically Modified Organism (GMO)” means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology and which does not occur naturally by mating and/or natural recombination.

6. “GMO product” means any commodity, other than pharmaceuticals for humans, which consists of or contains a GMO or a combination of GMOs.

7. “Organism” means any biological entity, including plants, animals and micro-organisms, capable of replication or of transferring generic material.

8. “Operator” means a legal or natural person, national or non-national, whether authorized or unauthorized, that undertakes any activity or operation including but not limited to import, export, contained use, and deliberate release of any genetically modified organism for any purpose in the Republic of Maldives.

9. “Risk assessment” means evaluating the potential risk to human health and the environment, including biological diversity, that is associated with a GMO or GMO product, estimating the likelihood that the risk will occur, and estimating how much damage would be caused if the risk does occur.

10. “Risk management” means adopting methods intended to reduce and/or mitigate the identified potential risk of a GMO or GMO product to an acceptable level and includes monitoring and subsequent modification, if necessary, of any methods used.
ANNEX 1

Risk Assessment
(Article 15 of CP)

1. Risk assessment must be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organizations.

2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk.

3. Risk associated with GMOs and GMO products must be considered in the context of the risks posed by the non-modified recipients or parent organisms in the likely potential receiving environment.

4. Risk assessment must be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case depending on the GMO or GMO product concerned its intended use and the likely potential receiving environment.

5. Risk assessment entails, as appropriate, the following steps:
   a) An identification of any novel genotypic and phenotypic characteristics associated with the GMO or GMO product that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risk to human health;
   b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO or GMO product;
   c) An evaluation of the consequences should these adverse effects be realized;
   d) An estimation of the overall risk posed by the GMO or GMO product based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
   e) A recommendation as to whether or not the risks are acceptable or manageable; and
   f) Recommendations for appropriate risk management strategies and for monitoring the genetically modified organism in the receiving environment.

6. Depending on the case, risk assessment must take into account the following:

   (a) **Recipient organism or parent organisms.** The biological characteristics of the recipient organism or parent organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

   (b) **Donor organism or organisms.** Taxonomic status and common name, source, and the relevant biological characteristics of the donor organism;

   (c) **Vector.** Characteristic of the vector, including its identity, if any, and its source or origin, and its host range;
(d) **Insert or inserts and/or characteristic of modification.** Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) **Genetically modified organism.** Identity of the genetically modified organism, and the differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parent organisms

(f) **Detection and identification of the genetically modified organism.** Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) **Information relating to the intended use.** Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) **Receiving environment.** Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment.
ANNEX 2

Information Required in Notifications and Requests for Prior Approval for Import

1. Name, address and contact details of the exporter

2. Name, address and contact details of the importer

3. Name and identity of the GMO or GMO product, as well as the domestic classification, if any, of the biosafety level of the GMO or GMO product in the State of export.

4. Intended date or dates of the transboundary movement, if known.

5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parent organisms.

6. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parent organisms and a description of the habitats where the organisms may persist or proliferate.

7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms.

8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO or GMO product.

9. Intended use of the GMO or GMO product.

10. Quantity or volume of the GMO or GMO product to be transferred.


12. Regulatory status of the GMO or GMO product within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions or whether it has been approved for general release) and, if the GMO or GMO product is banned in the State of export, the reason or reasons for the ban.

13. Written certification issued by the National Competent Authority of the State of export that attests to the accuracy of the information provided concerning the GMO to be imported.

14. Documented information on previous approvals or rejections by any other country of the GMO or GMO product proposed for import, including the result and purpose of any request for prior approval by the exporter to other States regarding the GMO or GMO product to be transferred.
15. Documented information describing a previous or current release in the Republic of Maldives or in any other country of the GMO or GMO product proposed for import.

16. A comprehensive description of the intended use of the GMO or GMO product proposed for import, including proposed monitoring and evaluation of that use, and the method of disposing of any waste.

17. The location and a comprehensive description of the facility or facilities where the GMO or GMO product proposed for import is to be stored and used.

18. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures.

19. A description of remedial measures to be undertaken in the event of any unintentional release into the environment caused by the activities to be undertaken.

20. Any additional information which the Applicant deems relevant to an assessment of the potential risk and/or benefit of the intended use of the GMO or GMO product.

21. Any other information as may be prescribed by the NBC.

22. A sworn declaration that all information contained in all documentation submitted is factually correct.
3.4 Guidelines for Implementing the National Biosafety Regulations

These Guidelines supplement the National Biosafety Regulations.

3.4.1. Objectives

The objectives of these Guidelines are to:

(a) Provide the basis for implementing an appropriate national regulatory framework for biosafety by supplementing existing laws, regulations and procedures related to agricultural, environmental, food and pharmaceutical products and the principles governing methods and standards of practice for research and development, risk assessment, import and export, deliberate release, and marketing of GMOs and GMO products;

(b) Promote the development and safe and responsible use of modern biotechnology, at the same time ensuring public health and environmental safety;

(c) Promote public awareness of and participation in decision-making related to the use of GMOs and GMO products in the Republic of Maldives; and

(d) Promote co-operation and consultation with international, regional and other national agencies to ensure safe and responsible use of modern biotechnology, GMOs and GMO products.

3.4.2. Scope

These Guidelines apply to:

(a) All stages of research and development, import and export, contained use, deliberate release, direct use as food, feed or for processing, and any other type of use of GMOs for any purpose; and

(b) All legal and natural persons within the jurisdiction of the Republic of Maldives and all applicants.

These Guidelines do not apply to:

(a) GMOs and GMO products that are pharmaceuticals for human use that are addressed by relevant international agreement and/or organizations;

(b) GMOs and GMO products in transit through but not destined for use in the Republic of Maldives; and

(c) Any other categories of GMOs and GMO products that may be exempted by the National Biosafety Commission (NBC).
3.4.3. General Principles

The Republic of Maldives reserves the sovereign right to protect its national heritage and property, and to exploit its resources pursuant to its own policies. It also bears the responsibility to ensure that activities within its jurisdiction do not cause damage to its environment or to other States or areas beyond the limits of national jurisdiction.

All import into, export from, and use of GMOs and GMO products in the Republic of Maldives are subject to the Regulations.

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a GMO or GMO product on human health and biological diversity, must not prevent the government from making a decision with regard to its import or use in order to avoid or minimize potential adverse effects.

Administration of GMOs and GMO products in all cases is subject to the process set out in the Regulations, which requires full disclosure to the public of all related information except confidential information and meaningful opportunity for the citizens of the Republic of Maldives to comment and to be heard.

3.4.4. Institutional Arrangements

The Minister of Environment, Energy and Water is the designated National Focal Point for the Cartagena Protocol to the Convention on Biological Diversity. It is the responsibility of the National Focal Point to provide timely notification to other States, the Biosafety Clearing-House, and relevant international organizations of any event in the Republic of Maldives that may result in the unintentional transboundary movement of a GMO.

The NBC is designated as the National Competent Authority for implementing the Regulations in collaboration with other concerned government institutions. The NBC comprises one representative from each of the following institutions:

(a) Ministry of Environment, Energy and Water, Chair
(b) Ministry of Environment, Energy and Water, Environment Section, Secretary
(c) Environment Research Centre
(d) Ministry of Fisheries, Agriculture and Marine Resources
(e) Ministry of Economic Development and Trade
(f) Ministry of Health
(g) Maldives Customs Services
(h) Maldives National Chamber of Commerce and Industry
(i) Attorney General’s Office
(j) One national non-governmental organization;
(k) One community-based organization.

The members representing the Maldives Customs Services and the ministries of Fisheries, Agriculture and Marine Resources, Economic Development and Trade, and Health also serve as the designated local Biosafety Focal Points for the institutions they represent.
The powers of the NBC are to consider notifications, applications, and the accompanying risk assessments and approve or deny approval for import, export and use of GMOs and GMO products.

The functions of the NBC are to:

(a) Oversee all activities involving GMOs and GMO products and ensure that any risks associated with them are identified and managed;

(b) Register all public and private sector Operators;

(c) Advise ministries, other government agencies, and the private sector on technical issues related to GMOs and GMO products and the implementation of the Regulations, ensuring that social, economic and ethical considerations are appropriately addressed;

(d) Review applications to import, export and use GMOs and GMO products and review the recommendations of the NSBAC before deciding whether a GMO or GMO product may be imported into, used in, or exported from the Republic of Maldives, and communicate approval or denial to the permitting authority;

(e) Review risk assessments and ensure that adequate testing of GMOs developed elsewhere has been performed in the country of origin before import into and use in the Republic of Maldives;

(f) Ensure the protection of all information identified as confidential in the prior approval process;

(g) Periodically review its prior decisions on import and export of GMOs and revise them at its discretion;

(h) Develop a Master Plan for biotechnology-based applications that, among other things, promotes technology transfer, national research and development in biotechnology, and collaborative research through grants and other incentives;

(i) Advise the government on policies and legal instruments governing biotechnology generally and GMOs and GMO products specifically;

(j) Identify national needs and demands for specialized skills in the biotechnology field and advise the government on the secondary and tertiary educational and research facilities required to develop them;

(k) Develop strong committed linkages with international organizations with a view to developing human resources, research collaboration and technology transfer;

(l) Ensure the full participation of the private sector and the general public in decision-making related to biotechnology, GMOs and GMO products;

(m) Propose mitigation measures to be undertaken in case of any accident;
(n) Review the Regulations and any subsequent legal instrument(s) governing biosafety from time to time as necessary; and

(o) Perform any other function as may be directed by the Office of the President.

The NBC must meet quarterly and may meet more frequently as required to consider applications and risk assessments.

The NBC must develop its own internal rules of procedure, in keeping with the requirements of the Regulations.

The Office of the President will designate the National Biosafety Scientific Advisory Committee (NBSAC), an autonomous body whose members must constitute a multidisciplinary team of experts in fields relevant to biotechnology and biosafety. Members of the NBSAC shall be paid an allowance for their work.

The functions of the NBSAC are to provide scientific and other technical advice to the NBC for:

(a) Reviewing notifications, applications, risk assessments and approvals; and

(b) Setting standards for facilities, operations and activities involving GMOs and GMO products.

The NBSAC may, as needed, request additional experts to assist in its work. Additional experts called on to assist the NBSAC must be compensated for their work.

Members of the NBC and NBSAC must not be involved in the review of applications in which their institutions or they personally, have an interest.

3.4.5. Obligations of Applicants and Operators

Any Applicant intending to conduct any activity or operation involving GMOs and GMO products, including import, export, contained use, deliberate release, and direct use as food or feed or for processing, must secure written approval from the NBC prior to seeking authorization by the concerned competent authority.

Each Operator must, prior to commencing an activity or operation involving GMOs and/or GMO products, designate a Biosafety Focal Point and notify the NBC of the name, title, and all contact coordinates of that Focal Point.

Any Operator responsible for an activity or operation involving GMOs and/or GMO products must comply with the provisions for managing the risks identified in the risk assessment process set out in Section 7 and with any subsequent risk management standards and measures that may be issued.
Any Operator responsible for any activity or operation involving GMOs and GMO products must ensure that such activity or operation is carried out in conformity with the Regulations and any subsequent legal instruments by, among other things:

(a) Keeping securely maintained records on all activities involving GMOs and GMO products. Documentation must include the description and location of each activity, the protocols involved, results, monitoring data and any other information that may be required by the NBC;

(b) Establishing mechanisms for internal monitoring of safety;

(c) Reporting immediately to the NBC when the Operator becomes aware of new scientific information indicating that these activities or operations and/or the GMOs and/or GMO products involved may adversely affect biodiversity and human health;

(d) Establishing measures to prevent an unintentional release of GMOs into the environment and to respond to and mitigate any harm to biodiversity and human health when unintentional introduction into the environment occurs;

(e) Establishing procedures for immediate response to an unintentional release of GMOs into the environment; and

(f) Facilitating and cooperating in authorized inspections of facilities where activities and operations involving GMOs and GMO products are carried out.

3.4.6. Risk Assessment

Risk assessments must be carried out in a scientifically sound manner, using internationally recognized risk assessment procedures. The Applicant or Operator must specify the procedure(s) used in conducting a risk assessment submitted with a notification and application for prior approval of import and/or an application for registering a domestic operation.

Risk assessments must be submitted with applications for prior approval for import of GMOs and GMO products and for domestic operations. Risk assessments must be carried out on a case-by-case basis and must be based on actual biophysical and socio-economic conditions in the Republic of Maldives at the time of assessment. At a minimum, the risk assessment must contain the information indicated in Annex 1.

Risk assessment is the responsibility of the applicant or operator, who bears all costs.

Risk management measures must be determined on a case-by-case basis, according to the characteristics of the GMO and/or GMO product and activities involved, and must be appropriate to the level of assessed risks. The risk assessment must indicate specific risk management measures that may be applied.

The NBC may, on the basis of new or additional information that becomes available, require
a new risk assessment of a GMO or GMO product already approved for import and/or domestic use.

3.4.7. Procedures for prior approval of imports,exports of GMOs and GMO products

All documentation specified in Sections 8, 9, 10, and 11 must be submitted in English or Dhivehi to the NBC. Documentation may be submitted by post or courier.

All requests for prior approval of imports of GMOs and GMO products must include the information specified in Annex 2 of the Regulations.

All procedures described in this Section and Sections 9, 10, 11 and 13 are subject to payment of administrative fees. Public research institutions, colleges and universities, laboratories, and any other public facilities designated by the NBC, may be exempted from payment of administrative fees. In the event of the need for additional information/data needed to make a decision on an application, such additional costs must be borne by the Applicant.

All activities and operations involving GMOs and GMO products are subject to payment of a security bond in the amount of 15% of the total value of the activity or operation must be deposited with the NBC at the time of prior approval of import or permission for domestic activities and operations. The amount of the bond will be returned to the Operator, without any interest, on completion of the activity or operation for prior approval or permission is granted. The security bond will be used, if needed, to recover any unforeseen costs associated with issues of non-compliance and/or for risk management actions.

The import of GMOs and GMO products for any purpose is also subject to all other relevant laws and regulations.

An Applicant may withdraw a request for prior approval at any time prior to the issuance of a final decision by the NBC. Administrative fees paid at the time of application will not be refunded in the event of withdrawal of an application.

The original written approval of the NBC must be attached to the import permit for any GMO or GMO product.

When an import permit for GMOs or GMO products is issued on the basis of prior approval by the NBC, the importer must, within fifteen (15) days from arrival of every shipment of the GMO or GMO product, notify the NBC, in writing, providing:

(a) The permit identification code/number;
(b) The name of the carrier on which the shipment arrived;
(c) Date of arrival;
(d) Country of origin;
(e) Name of shipper;
(f) Name and address of the importer; and

(g) Quantity of the GMO or GMO product imported.

The NBC may at any time revoke approval to import a GMO or GMO product on the following grounds:

(a) Evidence of incomplete or false information in the documentation for the original application for prior approval

(b) Non-compliance with or violation of any of the conditions of approval;

(c) Refusal to allow inspection of the facility or facilities where the GMO or GMO product will be stored, used and/or disposed;

(d) Suspension or revocation of the operating authorizations of the importer in the Republic of Maldives or the exporter in the country of origin;

(e) Availability of new technical information indicating that the GMO or GMO product, if allowed for its intended use, will result in significant risks to human health and the environment; and/or

(f) Other grounds as may be determined by the NBC.

3.4.8(a). Import of GMOs for deliberate release

Each import of GMOs into the Republic of Maldives for deliberate release into the environment is subject to risk assessment and approval by the NBC, in consultation with the concerned competent authority, prior to application to the concerned competent authority for the import permit.

The Applicant must notify the NBC of the intent to import and apply for prior approval. The notification and application for prior approval to import GMOs or GMO products for deliberate release must include all requirements specified in Annex 2 of the Regulations.

Within ninety (90) days of receipt of notification, the NBC must acknowledge receipt:

(a) Indicating the date of receipt of the notification;

(b) Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information required. Such additional information may, at the discretion of the NBC, include additional risk assessment. The NBC may require that additional risk assessment be carried out by the Applicant or by a designated independent expert. The costs of additional risk assessment must be borne by the Applicant; and

(c) Advising the Applicant whether it may proceed to the approval process.
Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application.

The Applicant must respond to a request for additional information within thirty (30) days of the date of the request, either by submitting the additional information required, or by making a justified request for up to ninety (90) additional days to respond.

If the Applicant does not respond to the request for additional information within the specified period, the NBC must notify the Applicant that its request for prior approval is denied.

If the Applicant submits the additional information requested within the prescribed period, the NBC must, within three (3) days, acknowledge receipt and transmit the additional information to the NBSAC.

Within fifteen (15) days from receipt of acknowledgement, the Applicant must cause to be published in two (2) newspapers of general national circulation a description of its application, inviting comments to the NBC within a period of thirty (30) days from the date of publication. The Applicant must submit to the NBC proof of publication within fifteen (15) days from the date of publication.

Within one hundred eighty (180) days of receipt of a request for prior approval, or with ninety (90) days of receipt of additional information, the NBSAC must submit to the NBC its report and recommendation for action on the request. Within three (3) days of receipt of the NBSAC report, the NBC must transmit the report to the Applicant. The Applicant may, within thirty (30) days of receipt of the NBSAC report, submit comments on it to the NBC. The NBC must take the Applicant’s comments into account in making its decision on prior approval.

Within two hundred and seventy (270) days of the date of receipt of a notification and request for prior approval, or of receipt of additional information if required, and/or comments on the NBSAC report, the NBC shall communicate in writing to the Applicant its decision, indicating either:

(a) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or

(b) Denying approval of the proposed import.

Failure by the NBC to communicate its decision within two hundred and seventy (270) days of the date of receipt of the request for prior approval or of the date of receipt of any required additional information does not mean that the request for prior approval is approved.

In approving a request, the NBC may impose specific risk management measures, labeling or marking requirements, and/or other conditions on the proposed intentional introduction. Conditions that may be imposed include, but are not limited to:
(a) The GMO or GMO product approved for import must enter the country only at the
port of entry designated in the approval;

(b) The GMO or GMO product approved for import must be identified with a label
showing the permit code/identification number, name of the GMO or GMO
product, and the name and contact information of the exporter and importer;

(c) All packing materials, shipping containers, and any other materials accompanying the
GMO or GMO product approved for import must be treated or disposed of in such
a manner as to prevent any significant risks to human health and the environment;

(d) The GMO or GMO product approved for import must be used exclusively for the
purpose stated in the notification and application for prior approval;

(e) The GMO or GMO product approved for import must be stored and used only in
specified physical containment facility or intermediate destinations;

(f) The GMO or GMO product approved for import must be stored and used in such a
manner as to prevent its accidental or unauthorized release;

(g) Disposal of the GMO or GMO product approved for import must be done is such a
manner as to prevent its accidental or unauthorized release;

(h) The facility or facilities where the GMO or GMO product is stored and used, and all
records related to its import, storage, use and disposal, must be accessible to
authorized inspectors during regular business hours;

(i) The operator must notify the NBC, within the time periods and in the manner
specified below, in the event of any of the following occurrences:
   1. Verbally immediately upon discovery and in writing within twenty-four (24)
hours, in the event of any accidental or unauthorized release of the GMO or
GMO product;
   2) In writing within three (3) days of discovery of new information that
becomes available after approval is granted indicating that the GMO or
GMO product approved for import could pose significant risks to human
health and the environment because it is found to have characteristics
substantially different from those listed in the application, unanticipated at
the time of the application, or for any other reason. In the event new
information becomes available indicating that the regulated article/product
could pose significant risks to human health and the environment, the
Applicant or Operator must on its own immediately take measures necessary
to protect human health and the environment;

and

(j) Such other conditions that the NBC may impose to prevent any significant risks to
human health and the environment.
If the request is denied, the NBC must state the reasons for denying approval. Within thirty (30) days of receipt of a denial of approval, an Applicant may request the NBC to review its decision on the basis of new and/or additional information not brought out during the decision-making process. The NBC shall acknowledge receipt of a request for review of denial within three (3) days and shall respond in writing to the Applicant within ninety (90) days of receipt, giving its reasons for either maintaining its original decision to deny approval or for revising its decision and approving the request.

Approval to import GMO or GMO product for deliberate release is valid for a period of two (2) years from the date of approval, unless revoked for any reason specified in Section 15 of the Regulations and Section 8.9 of these Guidelines. The Applicant must include the original approval with the application for the import permit.

**3.4.8(b). Import of GMOs for direct use as food or feed or for processing**

The first import into the Republic of Maldives of a GMO for direct use as food or feed or for processing is subject to risk assessment and approval by the NBC, in consultation with the concerned competent authority, prior to application for the import permit.

The application for prior approval to import GMOs or GMO products for direct use as food or feed or for processing must include all requirements specified in Annex 2 of the Regulations.

Within ninety (90) days of receipt of the application, the NBC must acknowledge receipt:

(a) Indicating the date of receipt of the notification;

(b) Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information required. Such additional information may, at the discretion of the NBC, include additional risk assessment. The NBC may require that additional risk assessment be carried out by the Applicant or by a designated independent expert. The costs of additional risk assessment must be borne by the Applicant; and

(c) Advising the Applicant whether it may proceed to the approval process.

Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application.

The Applicant must respond to a request for additional information within thirty (30) days of the date of the request, either by submitting the additional information required, or by making a justified request for up to ninety (90) additional days to respond.

If the Applicant does not respond within the specified period, the NBC will notify the Applicant that its request for prior approval is denied.
If the Applicant submits the additional information requested within the prescribed period, the NBC must, within three (3) days, acknowledge receipt and transmit the additional information to the NBSAC.

Within fifteen (15) working days from receipt of acknowledgement, the Applicant must cause to be published in two (2) newspapers of general national circulation a description of its application, inviting comments to the NBC within a period of thirty (30) days from the date of publication. The Applicant must submit to the NBC proof of publication within fifteen (15) days from the date of publication.

Within one hundred eighty (180) days of receipt of a request for prior approval, or within ninety (90) days of receipt of additional information, the NBSAC must submit to the NBC its report and recommendation for action on the request. Within three (3) days of receipt of the NBSAC report, the NBC must transmit the report to the Applicant. The Applicant may, within thirty (30) days of receipt of the NBSAC report, submit comments on it to the NBC. The NBC must take the Applicant’s comments into account in making its decision on prior approval.

Within two hundred and seventy (270) days of the date of receipt of a request for prior approval, or of receipt of additional information if required, and/or comments on the NBSAC report, the NBC must communicate in writing to the Applicant its decision, indicating either:

(a) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or

(b) Denying approval of the proposed import.

Failure by the NBC to communicate its decision within two hundred and seventy (270) days of the date of receipt of the request for prior approval or of the date of receipt of any required additional information shall not mean the request for prior approval is approved.

In approving a request, the NBC may impose specific risk management measures, labeling or marking requirements, and/or other conditions on the proposed intentional introduction. If the request is approved, the Applicant may proceed to apply for the import permit from the competent authority and must include the original approval with the application for the import permit.

If a request is denied, the NBC must state the reasons for denying approval. Within thirty (30) days of receipt of a denial of approval, an Applicant may request the NBC to review its decision on the basis of new and/or additional information not brought out during the decision-making process. The NBC must acknowledge receipt of a request for review of denial within three (3) days and shall respond in writing to the Applicant within ninety (90) days of receipt, giving its reasons for either maintaining its original decision to deny approval or for revising its decision and approving the request.
When the NBC approves a GMO for direct use as food or feed or for processing, it must within five (5) days notify the Minister of Environment as National Focal Point for the Cartagena Protocol who must then notify the Biosafety Clearing-House within ten (10) days.

Approval to import a GMO for direct use as food or feed or for processing is valid for a period of five (5) years from the date of approval, unless revoked on any of the grounds set out in Section 15 of the Regulations and Section 8.9 of these Guidelines. Approval may be renewed for successive five-year periods upon showing by the Applicant/Operator that continued import of the GMO or GMO product as food, feed, or for processing, does not pose any significant risks to human health and the environment.

3.4.8(c). Import of GMOs for contained use

The first import of a GMO into the Republic of Maldives for contained use is subject to risk assessment and approval by the NBC, in consultation with the concerned competent authority, prior to application to the concerned competent authority for the import permit.

The application for prior approval to import GMOs or GMO products for contained use must include all requirements specified in Annex 2 of the Regulations.

Within ninety (90) days of receipt of the application, the NBC must acknowledge receipt:
(a) Indicating the date of receipt of the notification;
(b) Stating whether the notification and application for prior approval are complete and if necessary, specifying any additional information required. Such additional information may, at the discretion of the NBC, include additional risk assessment. The NBC may require that additional risk assessment be carried out by the Applicant or by a designated independent expert. The costs of additional risk assessment must be borne by the Applicant; and
(c) Advising the Applicant whether it may proceed to the approval process.

Failure of the NBC to acknowledge receipt of a notification within ninety (90) days does not constitute acknowledgement of the notification or approval of the application.

The Applicant must respond to a request for additional information within thirty (30) days of the date of the request, either by submitting the additional information required, or by making a justified request for up to ninety (90) additional days to respond.

If the Applicant does not respond within the specified period, the NBC will notify the Applicant that its request for prior approval is denied.
If the Applicant submits the additional information requested within the prescribed period, the NBC must, within three (3) days of receipt, acknowledge receipt and transmit the additional information to the NBSAC.

Within fifteen (15) working days from receipt of acknowledgement, the Applicant must cause to be published in two (2) newspapers of general national circulation a description of
its application, inviting comments to the NBC within a period of thirty (30) days from the date of publication. The Applicant must submit to the NBC proof of publication within fifteen (15) days from the date of publication.

Within one hundred eighty (180) days of receipt of a request for prior approval, or within ninety (90) days of receipt of additional information, the NBSAC must submit to the NBC its report and recommendation for action on the request. Within three (3) days of receipt of the NBSAC report, the NBC must transmit the report to the Applicant. The Applicant may, within thirty (30) days of receipt of the NBSAC report, submit comments on it to the NBC. The NBC must take the Applicant’s comments into account in making its decision on prior approval.

Within two hundred and seventy (270) days of the date of receipt of a request for prior approval, or of receipt of additional information if required, and/or comments on the NBSAC report, the NBC must communicate in writing to the Applicant its decision, indicating either:

(a) Its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or

(b) Denying approval of the proposed import.

Failure by the NBC to communicate its decision within ninety (90) days of the date of receipt of a request for prior approval, or of receipt of additional information if required, and/or comments on the NBSAC report shall not mean the request for prior approval is approved.

In approving a request, the NBC any impose specific risk management measures, labeling or marking requirements, and/or other conditions on the proposed contained use activities. Conditions that may be imposed include, but are not limited to:

(a) The GMO or GMO product approved for import must enter the country only at the port of entry designated in the approval;

(b) The GMO or GMO product approved for import must be identified with a label showing the permit code/identification number, name of the GMO or GMO product, and the name and contact information of the exporter and importer;

(c) All packing materials, shipping containers, and any other materials accompanying the GMO or GMO product approved for import must be treated or disposed of in such a manner as to prevent any significant risks to human health and the environment;

(d) GMO or GMO product approved for import must be used exclusively for research and development under contained conditions;

(e) The GMO or GMO product approved for import must be stored and used only in the physical containment facility or intermediate destinations specified in the permit;
(f) The GMO or GMO product approved for import must be stored and used in such a manner as to prevent its accidental or unauthorized release;

(g) Disposal of the GMO or GMO product approved for import must be done in such a manner as to prevent its accidental or unauthorized release;

(h) The facility or facilities where the GMO or GMO product approved for import for contained use is stored and used, and all records related to its import, storage, use and disposal, must be accessible to authorized inspectors during regular business hours;

(i) The operator must notify the NBC, within the time periods and in the manner specified below, in the event of any of the following occurrences:

1. Verbal immediately upon discovery and in writing within twenty-four (24) hours, in the event of any accidental or unauthorized release of the GMO or GMO product;

2. In writing within three (3) days of discovery of new information that becomes available after approval is granted indicating that the GMO or GMO product approved for import could pose significant risks to human health and the environment because it is found to have characteristics substantially different from those listed in the application, unanticipated at the time of the application, or for any other reason. In the event new information becomes available indicating that the regulated article/product could pose significant risks to human health and the environment, the Applicant or Operator must on its own immediately take measures necessary to protect human health and the environment; and

(j) Such other conditions that the NBC may impose to prevent any significant risks to human health and the environment.

Approval to import GMO or GMO product for contained use is valid for a period of two (2) years from the date of approval, unless revoked for any reason specified in Section 15 of the Regulations and Section 8.9 of these Guidelines. If the request is approved, the Applicant must include the original approval with the application for the import permit.

If the request is denied, the NBC must state the reasons for denying approval. Within thirty (30) days of receipt of a denial of approval, an Applicant may request the NBC to review its decision on the basis of new and/or additional information not brought out during the decision-making process. The NBC shall acknowledge receipt of a request for review of denial within three (3) days and shall respond in writing to the Applicant within ninety (90) days of receipt, giving its reasons for either maintaining its original decision to deny approval or for revising its decision and approving the request.

3.4.8(d). Export of GMOs
Any Applicant or Operator who intends to export GMOs and/or GMO products from the Republic of Maldives for any purpose must apply to the Competent National Authority of the proposed importing country according to the laws and regulations of that country, prior to applying to the concerned competent authority of the Republic of Maldives for an export permit.

In order to obtain an export permit in the Republic of Maldives, the exporter must include with the application for the export permit either the original or a certified copy of the importing country’s authorization to import. The authorization of the importing country does not preclude the Republic of Maldives from taking into account other considerations in deciding whether or not to approve the export.

3.4.8(e). Domestic research and development

All national public and private sector research and development Operators must be registered with the NBC.

No GMO or GMO product may be considered for deliberate release or placing on the market unless it has been field tested under contained conditions in Maldives, and has shown no harmful effects to the environment, biological diversity and animal and human health. Field testing must have prior approval of the NBC.

The Applicant must submit to the NBC the application in Annex 2. The NBC may, at its discretion, require the Applicant to perform additional experiments under contained conditions and submit the results to the NBC, before the NBC makes a final decision on the application.

The Applicant must, at its own expense, notify and invite comments on the field testing proposal from local government agencies with jurisdiction over the field test site and from local communities in the area of the field test site. If the proposed release may pose significant risks to human health and the environment, the NBC must conduct public hearings within the vicinity of the proposed field test site.

An application for field testing must be approved by at least 50% of the NBC members, including at least one representative from an NGO or community-based organization. The NBC may impose conditions on the permit for field testing.

A permit for field testing must be issued for every approved field test site. A permit for field testing is valid for a period of two (2) years from date of issuance, unless revoked on any of the grounds set out in Section 15 of the Regulations and Section 8.9 of these Guidelines. It may be extended for such period as may be necessary to complete the field testing begun during the two-year period.

On completion of field testing, the Operator must submit to the NBC a comprehensive report on the results that includes a detailed description of potential risks to human health and the environment observed during the conduct of the field testing, the steps taken by the Operator to mitigate them, and the final disposition of the GMO or GMO product.
Domestic research and development activities and operations are subject to prior approval by the NBC. The NBC must establish and maintain a registry of GMOs and GMO products that have been approved for domestic research and development.

Domestic research and development facilities are subject to inspection by authorized officials of the Ministry of Environment.

The NBC may revoke permission for domestic research and development on any of the following grounds:

(a) Provisional of false information in the application;
(b) Violation of any conditions specified in the permit;
(c) Failure to allow inspection of the field testing site;
(d) Receipt by NBC of new information that the field testing of the GMO or GMO product being field tested poses significant risks to human health and the environment;
(e) Such other grounds as NBC may deem reasonable to prevent significant risks to human health and the environment.

3.4.8(f). Confidential Business Information

An Applicant may identify information provided in accordance with the requirements of the Regulations that is to be treated as confidential.

If an application does not contain any confidential information, the applicant must write “No Confidential Information” on the first page of all copies submitted.

The applicant must write “Confidential Information” on each page of documentation provided in accordance with the Regulations that contains trade secrets or confidential business information. The applicant must also submit one (1) copy of the documentation with all Confidential Information deleted and marked “Confidential Information Deleted” on each page containing deletions.

In no case, however, may the following information be considered confidential;

(a) Name and address of the applicant;
(b) Description of the GMO or GMO product;
(c) Description of the intended destination (including all intermediate and final destinations), uses, and distribution of the GMO or GMO product;
(d) Summary of the risk assessment of the effects of the GMO or GMO product on the environment and human health;
(e) Where appropriate, description of the proposed procedures, processes and safeguards which will be used by the applicant to prevent escape and dissemination of the GMO or GMO product at each of the intended destinations;

(f) Description of the methods and plans for emergency response in case of accidental release of the GMO or GMO product into the environment; and

(g) Description of the proposed method of final disposition of the GMO or GMO product.

In the event that the NBC rejects the claims of confidentiality of information, the NBC must immediately inform the applicant of its decision and the justification for its decision. In such a case, the applicant must, within thirty (30) days, notify the NBC whether it will proceed with or withdraw its application. In the event the applicant proceeds with the application, any information in the application may be released during the public consultation process. In the event the applicant withdraws the application, administrative fees are forfeited.

The NBC shall neither use nor permit the use of information accepted as confidential for any purpose without the written consent of the applicant and shall ensure that such information is protected by all persons involved in handling and reviewing applications. This commitment to confidentiality will be provided in writing to the applicant, if requested.

3.4.8(g). Emergency response

In the event of an unintentional release or transboundary movement of a GMO or in the event of an unforeseen consequence of deliberate release of a GMO, any person with knowledge of the emergency must immediately inform local authorities who must immediately notify the NBC.

On receiving notification of an emergency involving GMOs, the NBC must:

(a) Take immediate steps to inform the appropriate national and local authorities;

(b) Co-ordinate the actions of all relevant national and local authorities, according to an emergency response plan to be prepared;

(c) Inform the Minister of Environment, Energy and Water Resources as the national Focal Point for the Cartagena Protocol in order that s/he may inform the Biosafety Clearing-House and the competent national authorities in potentially affected States.
3.4.8(h). Public participation, information, and public awareness

The NBC must ensure the meaningful participation of the public in the process of making decisions concerning the import and domestic use of GMOs.

The NBC, in cooperation with the related authorities, must ensure public access to non-confidential information related to GMOs in general, and in particular to their presence and use in Maldives.

The NBC, in cooperation with the related authorities, must develop and implement strategies, programmes and activities designed to increase public awareness of GMOs in general, and in particular of their presence and use in Maldives.

3.5. Inspection

An authorized official of the Ministry of Environment may, at any time during normal business hours, enter and inspect the facilities where any activities or operations involving GMOs and/or GMO products are being, or have been, carried out.
CHAPTER IV

Administrative Structure for Receipt of Application, Decision Making & Risk Assessment

4.1. Administrative Structure and Decision Making

The Ministry of Environment, Energy and Water is the government’s designated Focal Point for the Cartagena Protocol. The Office of the President will designate the National Biosafety Commission (NBC) as the National Competent Authority responsible for implementing the NBF generally and the Regulations in particular to ensure that GMOs, GMO products and biotechnology are appropriately assessed and managed in ways that will contribute to sustainable development and better use of modern science for the well-being of the people of the Maldives.

The NBSAC, as indicated earlier, is the advisory body to the NBC. The Sectoral Competent Authorities/ Agencies (SCAs), which are expert/technical bodies, will carry out assessment of risks and concerns as well as risk management and monitoring.

The proposed administrative structure for receipt of applications, risk assessment and decision-making shown in Figure (1) is based on the precautionary principle and advanced informed agreement.

The applicant will make a request/notification/application with all relevant information to the NBC. In consultation with the NBSAC, the application will be screened for completeness, and if necessary, additional information can be requested.

A completed application and all relevant information will be sent to the relevant SCA for risk assessment. Depending on the material for import, several SCAs may be involved at this stage, in which case concurrent decision is required. The SCA, if necessary, can request applicant to carry out further assessment of risks. The decision of the SCA, based on the precautionary principle and the minimum requirements as per Article 15 of the CP, will be transmitted to the NBC. The NBC, in consultation with NBSAC, will make the final decision, which will be given to the applicant. The public will actively participate in this process as shown in the figure (1).
Figure 1. The proposed administrative structure for the National Biosafety Framework for the Republic of Maldives –2006.

1. **Application & Risk Assessment**
   - Applicant submits the application with Risk Assessment.

2. **Public Comments**
   - Public provides comments on the application.

3. **Decision**
   - NBC (National Competent Authority) makes the decision.

4. **Advice**
   - NBC provides advice to NBSAC (National Biosafety Strategic Advisory Committee).

5. **Sectoral Competent Authorities (SCAs)**

6. **Monitory**
   - Monitoring process continues.

7. **Implement**
   - Implement the decision if approved.

8. **Appeal**
   - If not approved, the applicant has the option to appeal.

This diagram outlines the proposed administrative structure for the National Biosafety Framework, including the flow of applications, assessments, decisions, and appeals.
4.2. Decision Making – Guidance Questions

4.2.1 Key Questions that Guide Decisions on GMO Plants

a) What are the primary and secondary centers of diversity of the parent plants?

b) Are any members of the genus of unmodified parent plants known to be weeds in any environment? Give details.

c) Is there any evidence as to the ability of the transgenic plant species to cross pollinate with other cultivated or weed species? Give details.

d) How is the pollination effected in this species? List species of pollinators

e) What is the natural seed dispersal mechanism?

f) If the transgenic plants are allowed to set seed, are there any methods adopted for control of seed dispersal? If not, why? Give details.

g) What are the effects of transgenic products on pollinators, fruit feeders and non-target organisms?

h) Can the transgenic plant species be propagated by vegetative propagation? Give details?

i) What are the effects of secondary transfer of transgenic to wild relatives and/or non-target species?

j) Is there any likelihood that the introduced gene could cause an increase in toxicity of the plant to animals and humans? If so give details.

k) Could any such products of the organism have a cumulative effect in food webs reaching toxic levels? Explain.

l) What secondary ecological effects could be anticipated from release of the GMO? (e.g. effect on threatened native species, resistance of insect populations to an insecticide, population dynamics of competitors, prey and predators).

m) If the construct involves resistance to a chemical agent,

n) Provide data on the degradability, selectivity and toxicity of the chemical concerned,

o) Give details of the biological activity, agronomic significance of the chemical and the rates of recommended application.

p) If the construct involves resistance to a herbicide, explain rates of recommended
application and their likely impacts on overall farming systems and Integrated Pest management strategies.

4.2.2 Key Questions for Organisms for Biological Control

a) What is the species targeted for biological control?

b) What direct effects does the GMO have on the target species?

c) What direct effects does the parent organism of the GMO have on the target species?

d) What is the rationale for the choice of the GMO?

e) Are the host ranges of the GMO and its parents different? Explain how and why?

f) What non-target organisms have been tested for susceptibility to the GMO and the rationale for the species tested?

g) What is the mechanism of transfer of the GMO among the target individuals and what are the factors that influence the transfer?

h) What are the host range specificities and the likelihood of the GMO affecting non-target species?

i) What secondary effects can be envisaged on predators, prey or parasites of the target species?

j) What are the effects of secondary metabolites produced by the GMO on other organisms in the food webs?

4.2.3 Key Questions related to Organisms for Bioremediation

a) What is the target substrate for bioremediation?

b) What is the effect of GMOs on target substrate?

c) What is the effect of the parent organism of the GMO on its target substrate?

d) What are the effects of secondary metabolites produced by a GMO on other organisms in the community/site of release?

e) What are the effects of GMO on water, air, or soil quality?
f) What are the likely toxicity effects to other organisms that ingest the GMO?

g) What information is available on population dynamics of the GMO?

h) What is the likelihood of dispersal of GMO from the site of application and its consequences?

4.3. Risk Assessment

The recommended administrative structure for receipt of applications, risk assessment and decision-making is shown in Figure (1).

The existing relevant legal instruments indicated in Chapter III identify agencies that can assess risks as shown below. They can function as Sectoral Competent Authorities/Authorities.

The Sectoral Competent Authorities shall assess risks and concerns involved with an application and convey the decision to the NBC. The NBC will make the final decision in consultation with NBSAC. Concurrent approval is recommended.

**Sectoral Competent Authorities**

Ministry of Fisheries, Agriculture and Marine Resources: Plants, Plant materials, other living species, Pesticides & Herbicides

Department of Public Health: Food, Food products, Poultry, Meat, Vegetables, Fruits and other consumable products,

Ministry of Health: Pharmaceuticals

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 committees.

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 Maldives 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 GMO products can pose a threat to livelihoods of communities.

(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. Socio-economic impact analysis will then become the responsibility of the applicant/notifier and the competent authority concerned.

### 4.3.1 Principles of Risk Assessment

Considering the impacts of Living Modified Organisms and their products release, import or commercialization of such organisms or their products can be allowed only in accordance with the following guidelines.

1. The risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information, including from sources outside the country, if needed.

2. Though precautionary principle will guide decision making lack of scientific knowledge shall not be interpreted as indicating potential risk, or an absence of risk, or an acceptable level of risk.

3. Risks – potential and perceived - posed by the GMO or its product and their use shall be compared to those presented by unmodified organism from which it is derived and its use under similar conditions of use. Such comparisons will consider the impacts of ecosystems in which these organisms will function, the environmental conditions where they will be used and the socioeconomic aspects of their release.

4. In all cases the assessment of risks shall be carried out on a case-by-case basis

5. In case new information on the GMO or its product and its effects on human health and the environment becomes available, the risk assessment shall be redone to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly. The National Biosafety Clearing House should be updated and used for this purpose on a regular basis.

### 4.3.2 Risk Assessment Guidelines

The conduct of the risk assessment shall be in accordance with the policies and guidelines on risk assessment issued by NBC.

#### 4.3.2(a). Genetically Modified Plants

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

a) expression of toxic or allergenic compounds,
b) effects on biogeochemistry,

c) increased persistence in the environment and invasiveness,

d) transfer of genetic material,

e) instability of the genetic modification,

f) Unintended effects (the insertions may influence the expression of adjacent genes leading to unintended genetic modifications that may cause some adverse effects.)

4.3.2(b). Genetically Modified Microorganisms

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

a) Diseases of human and animal including toxic or allergenic effects,

b) Plant diseases and development of disease epidemics in agricultural and natural environments,

c) Adverse effects resulting from the inability to treat diseases or offer effective prophylaxis,

d) Adverse effects on natural bio-geo chemical cycles,

e) Adverse effects resulting from establishment or dissemination in the environment,

f) Adverse effects resulting from the natural transfer of inserted genetic materials to other organisms.

4.3.2(c). Genetically Modified Animals

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

a) Adventitious infectious agent transfer,

b) Endogenous Retroviral activation (if the transformation is based on Retroviral mediated gene insertion),

c) 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.),

d) Excess production of transgene products or its metabolites,

e) Pleiotropic effects of transgene expression (transgene insertion and expression can have unpredicted effects on the expression of other genes),
f) Prion disease susceptibility hazard (production of transgenic animals could produce a hazard through the accidental inclusion of genetic material with the

g) Transgene or alteration of the functioning of the genes related to prion susceptibility),

h) Leakage of expressed products from target tissues.
CHAPTER V

Risk Management, Monitoring and Enforcement

5.1. Introduction

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.

5.2. Risk Management

5.2.1 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.

5.2.2. 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 Living Modified Organisms and products.

5.2.3. Implementation:

Proper actions are taken following the risk assessment decision on acceptance or refusal of the introduction of Living Modified Organisms and products.

5.2.4. 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.

5.2.5. Accidental release / escape due to natural disasters:

All precautions needed to stop possible escape of GMOs into the environment due to the accidental release and/or escape due to natural disasters should be undertaken by the applicant. The NBC shall suggest such actions as deemed necessary on a case by case basis.
5.3. General Principles of Risk Management

Risk management involves the steps that have to be taken to manage identified harm to an acceptable level. It is used systematically to reduce risks to low levels (using controls, containment measures etc.), especially when familiarity is low.

Risk management methods for field release vary from case to case. It is determined by risk assessment, type of organism used and method of release, location of release. Risk management has to involve the control of gene flow (e.g. removal of flowers and ‘volunteer’ plants) and, planting distance (related to pollen travel) and even abort the release if necessary.

Risk management should be built into the proposal/experiment and carried out with adequate monitoring.

5.4. Monitoring and Enforcement

A mechanism for monitoring and inspection is a part of the risk management procedure of the national Biosafety system. It is usually carried out as post-release observations and is the responsibility of the user. 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.

Inspection is necessary to ensure compliance with the conditions set out in the decision documents or permits. This is the responsibility of the Ministry of Environment and can be carried out by the Sectoral Competent Authorities who conducted the risk assessments.

Generally, monitoring will focus on environmental impacts (both positive & negative) and impact on human health (e.g. farm workers). Depending on the GMO released, monitoring will have to focus on specific areas such as effect on endangered species, presence of super-weeds, build-up of insect resistance, impact on soil microorganisms and disruption of food chain.

Monitoring confirms the assumptions made in risk assessment and indicates where risk assessment assumptions were wrong. Monitoring will prove the effectiveness of risk management methods.

Currently, Maldives does not have necessary expertise, laboratory facilities, technology and techniques to undertake the tertiary risk assessment and risk management of GMOs and GMO products. Pending the development of in-country expertise, regular implementation of these procedures may require a mechanism to obtain the services of the recommended laboratories and institutions in Maldives as well as neighboring countries by nominating them as centers of excellence and providing them with necessary financial support.
CHAPTER VI

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 LMOs and to be informed of the results of the decision making process (Article 23).

6.2. Role of the NBC in Public participation, education and awareness

The NBC will act as the focal point for development of suitable education and awareness programmes on biosafety in the country.

The NBC must ensure the meaningful participation of the public in the process of making decisions concerning the import and domestic use of GMOs.

The NBC, in cooperation with the related authorities, must ensure public access to non-confidential information related to GMOs in general and in particular to their presence and use in Maldives.

The NBC, in cooperation with the related authorities, must develop and implement strategies, programmes and activities designed to increase public awareness of GMOs in general, and in particular of their presence and use in Maldives.

6.3. Importance of Public Participation, Education and Awareness

As biotechnology develops rapidly, GMOs can potentially revolutionize both the health and agriculture industries thereby improving the lives. However, there are growing concerns over the potential environmental and health risks associated with both medical and agricultural applications of biotechnology. Therefore a proper mechanism should be established to create awareness and enable the public to participate in implementation of the biosafety measures. Awareness and participation are important:

i. To promote sustainable development;
ii. To promote smooth implementation of the decisions;
iii. To build transparency and accountability;
iv. To provide balanced information
v. To harmonize institutions that provide awareness activities
6.4. Access to information

6.4.1. Right of access to information:

The right of the public and the relevant stakeholders to information about applications for handling, use, transport, transboundary movement, release and management, R&D of GMOs shall be respected. The NBC should subject to reasonable limitations, protect confidential information and should disclose all information on such applications in a prompt and timely manner.

6.4.2. Information on Biosafety Decisions

The public and relevant stakeholders should have access to all biosafety decisions approving or denying application for the handling, use, transport, transboundary movement, release and management, R&D of GMOs. Such decisions need to summarize the application, the results of the scientific risk assessment and the evaluation of socio-economic risks, the public participation process followed and the basis for approval or denial of the application.

6.4.3. Minimum Requirements

Public awareness and participation shall apply to all stages of the biosafety decision-making process from the time the application is received. In conducting these processes, the following minimum requirements should be followed:

i. Notice to all concerned stakeholders, in local language through media to which they have access. Such notice must be adequate, timely and effective.

ii. Adequate and reasonable time frames for public participation procedures.

iii. Public consultations, as a way to secure wide input into the decisions that are to be made. These could include public hearings in certain cases, particularly where there is public concern about the proposed measures. These consultations should encourage exchange of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders should be encouraged.

iv. Procedures for public participation should include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions.

Public opinion as gauged through the procedures for public participation must be taken into account in the decision. The public must be informed of the final decision promptly, have
access to the decision, and must be provided with the reasons and considerations resulting in the decision.

6.5. Methods

Methods that are used for public awareness, education and participation are inter-linked; a mix of tools and process will assist in achieving the goals. Following are the methods that will be used:

6.5.1. National Biosafety Clearing-House (NBCH)

The NBCH is an integral part of the Biosafety Clearing House mechanism which was established under Cartagena Protocol on Biosafety (Article 20) in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms, and to assist Parties to implement the Protocol. The system of BCH was design as decentralized system with NBCHs components organized by the parties of the Protocol and central portal (run by CBD Secretariat) to support and organize the information flows from national BCH.

In the Maldives the trend towards an information society is getting stronger, and web based government services are seen as very important developments in the future. Maldives chose the format of its NBCH to be web-based interlinked or interoperable with central portal.

The NBCH will play a key role on public awareness and participation in Biosafety in the Maldives and will serve as an information exchange mechanism providing the public with objective and accurate information. Further, it will also analyze the social and economic impact of GMOs and products thereof, so as to provide in-depth information for researchers, traders, consumers and the government.

The NBCH will have information of the users, information obtained from the users and information for the users.

Capacity building in this important area is urgently required.

6.5.2. Workshops and Seminars

Workshops and seminars targeted at particular stakeholders e.g. awareness workshops involving groups of consumers, farmers etc.

6.5.3. Capacity building for various stakeholders

Implementation of the NBF requires the building of biosafety capacities by NBC. Capacity building programs on biosafety are need for relevant stakeholders including policymakers, regulators, researchers, media, and the civil society.
6.5.4. Mass media: Using radio, newspapers and television

- Printed information on biosafety e.g., leaflets, brochures, fact-sheets, posters, newsletters in accessible format;
- Electronic communication technologies such as mail news-group.
- Auditorium art, such as public lectures and other performance to raise awareness and convey information in an accessible and engaging way.
- Information dissemination and advertising.