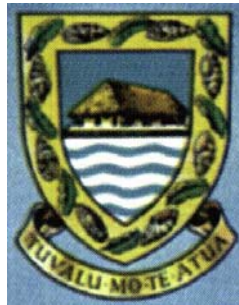


Draft National Biosafety Framework of Tuvalu



**Department of Environment
Ministry of Natural Resources & Environment
Government of Tuvalu
Funafuti**

September 2008

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Abbreviations

CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DOE	Department of Environment
EKT	Ekalesia Kerisiano Tuvalu
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
LMO	Living modified organism
MNRE	Ministry of Natural Resources and Environment
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Coordinating Committee
NEC	National Environment Committee
NPC	National Project Coordinator
SPS	Sanitary and Phytosanitary
TANGO	Tuvalu Association of NGOs
TAG	Technical Advisory Group
TBT	Technical Barriers to Trade
UNEP	United Nations Environment Programme
WTO	World Trade Organization

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Explanation of terms

Technical Terms

"Biodiversity" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Biosafety" means the management of risk to human health and safety, and to the conservation of the environment as a result of the use in research and commerce of genetically modified organisms or products of modern biotechnology.

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Conference of the Parties" means the Conference of the Parties to the Convention on Biological Diversity

"Contained use" means any operation such as importation, development, fermentation, or field test, undertaken within a 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;

"Food, Feed, and Processing" means GMOs intended for direct use as food or feed, or for processing that are agricultural commodities which are subject to a more simplified procedure than the AIA procedure. Under this procedure, A Party must inform other Parties through the Biosafety Clearing House, within 15 working days, of its decision regarding domestic use of GMOs that may be subject to transboundary movement.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"GMO products" mean products containing dead or non-living modified organisms or components including certain vaccines; drugs; food additives; and many processed, canned, and preserved foods. They can also include corn and soybean derivatives used in many foods and nonfoods, cornstarch used for cardboard and adhesives, fuel ethanol for gasoline, vitamins, vaccines and pharmaceuticals, and yeast-based foods such as beer and bread

"Genetic resources" means genetic material of actual or potential value.

"Genetically Modified Organisms" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. This term is used in this NBF except when specifically referring to the CPB, and has a corresponding meaning to "living modified organism".

"Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. This term is used when specifically referring to the CPB, and has a corresponding meaning to "genetically modified organism".

"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"Meeting of the Parties" refers to the meeting of Parties to the CPB under the CBD.

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"Risk assessment" measures the likelihood that an LMO or GMO will cause harm to the environment or human health if released into the environment. Risk assessments enable informed decisions to be

made about GMOs before they are introduced into Tuvalu.

“**Risk management**” means how risks identified by the risk assessment process are managed.

“**Sustainable use**” means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity and to ensure its potential to meet the needs and aspirations of present and future generations.

“**Transboundary movement**” means the movement of a living modified organism from one country to another country.

“**Transit**” means movement of GMO from and through a jurisdiction to another jurisdiction.

Tuvaluan Terms

“**Falekaupule**” means the traditional assembly in each island of Tuvalu (as defined in the Falekaupule Act, 1997).

“**Kaupule**” refers to the executive arm of the Falekaupule as defined in Section 5 of the Falekaupule Act, 1997.

“**Pulaka**” refers to the traditional giant taro variety favoured by the people of Tuvalu and grown in pits; it is a *Cyrtosperma* spp.

“**Te Kakeega**” – Tuvalu’s national strategy for sustainable development, 2005-2015.

1. Introduction

1.1. Tuvalu and its Environment

Tuvalu is a small and fragmented land that is made up of nine small islands, with a total land area of only 26 sq km. This makes Tuvalu the fourth smallest country in the world in terms of land area. The highest elevation is no greater than 4 metres and on average the land is less than 1 metre above sea level. It covers an ocean area of some 900,000 sq km. The island group is geologically very young, with most of its islands having poorly developed, infertile, sandy or gravel coralline soils.

Of the nine island groups that make up Tuvalu, five are considered true atolls (Nanumea, Nui, Nukufetau, Nukulaelae and Funafuti), three are table reef islands (Nanumaga, Niutao and Niulakita) while Vaitupu has a composite characteristics of an atoll and a table reef island. Total population of approximately 10, 000 people inhabit the nine islands of Tuvalu, which are all susceptible to damage caused by land degradation and the impacts of climate change.

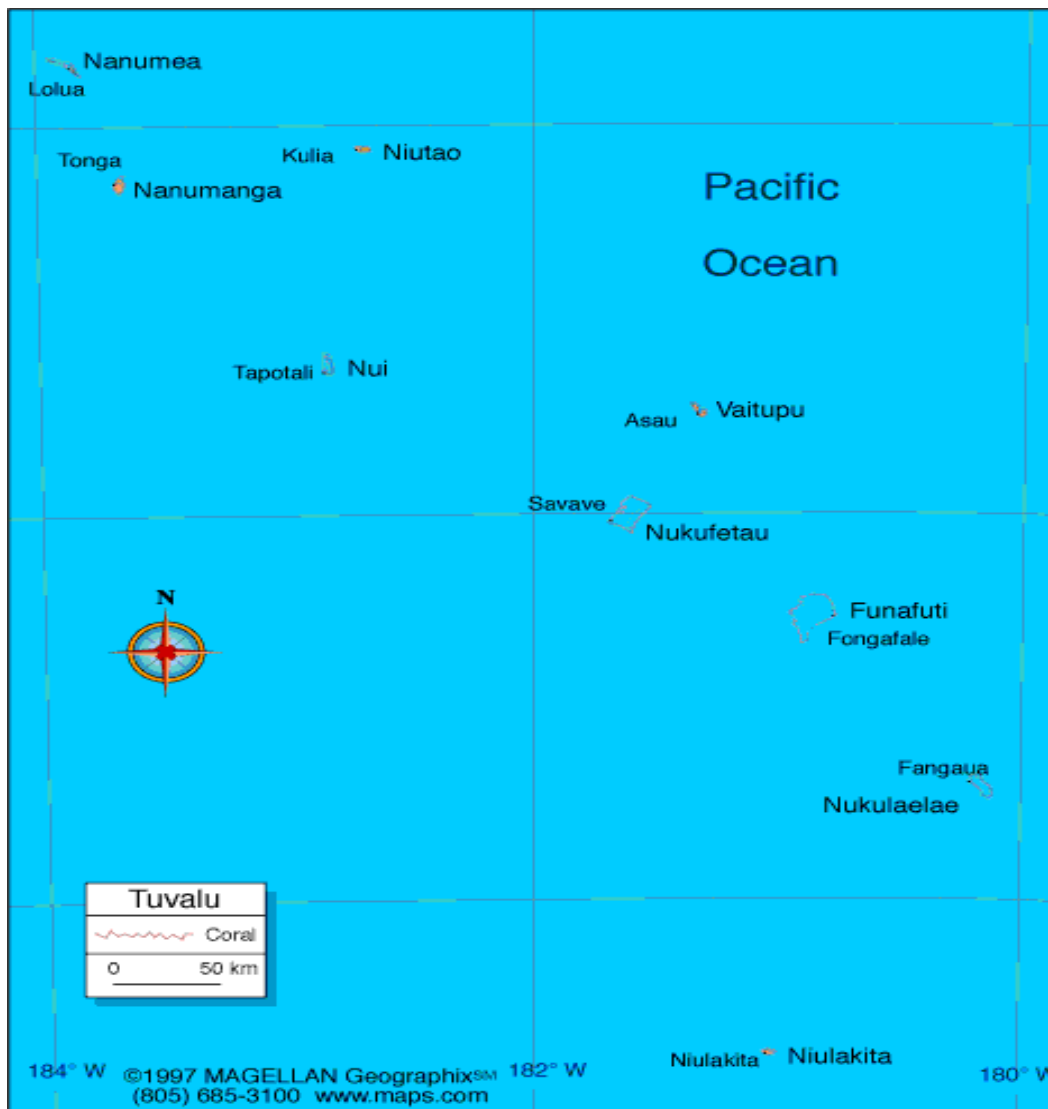


Figure 1: Map of Tuvalu

The marine environments of Tuvalu are comprised of six major ecosystem types (oceanic, outer reef, lagoonal back-reef, lagoon floor, bommies or patch reefs and natural channels between the ocean and lagoon). These ecosystems produce the sediment required for island building and maintenance and support communities of corals, other invertebrates, algae, plankton, fish and marine mammals and reptiles. For example, approximately 30 common species of corals and over 350 species of fish characterize the marine ecosystems of the country. On land, indigenous plants are rare because of habitat modifications such as the extensive planting of coconuts and other food plants. There are probably 200 plant species in Tuvalu, 50 of which are possibly indigenous and none of which are endemic. There are probably no indigenous land mammals, though there are indigenous birds (28 species), a few species of lizards, insects and land crabs.

1.2 Biotechnology and Tuvalu

Modern biotechnology tools can be used to transfer characteristics from one species to another by taking genes from one species and inserting them into the same or another species to produce new and desired characteristics. This may include resistance to biotic stresses such as diseases or pests, and abiotic stresses such as salt tolerance. The products of modern biotechnology are often referred to as Living Modified Organisms (LMOs) or Genetically Modified Organisms (GMOs).

Modern biotechnology and biosafety are relatively new concepts for Tuvalu as agricultural production in the country has focused primarily on subsistence farming. Although subsistence farming has been practised in Tuvalu since its settlement by humans over 3,000 years ago, the development of agriculture in Tuvalu faces many fundamental challenges, which include: poor soils and growing conditions; small land areas; declining outer island populations; increasing urbanisation; declining interest in traditional agriculture practices, distance to export markets, and poor local market access for those who do wish to produce cash crops. Nonetheless, there is still considerable scope for increasing production for local consumption and reversing the recent decline in production.

Tuvalu has a subsistence economy and crop plants such as taro, breadfruit, bananas and papaya are grown mainly for consumption within the families of the growers. In many of the islands, a constraint to the achievement of food security is the decline in yields of many of the major food crops as a result of increasing salinity. Two of the key policy objectives of Te Kakeega¹ (Chapter 11 on Natural resources) are to “reverse the decline in subsistence agricultural production” and to “mitigate climate change related agricultural impacts”. Biotechnology could contribute to these aims by helping to develop crop plant cultivars that are tolerant to salinity whilst retaining the agronomic, cultural and culinary qualities valued in Tuvalu. Biotechnology therefore offers the prospect of helping to increase food production in order to enhance import substitution by helping to improve production of traditional and new crops that are adapted to the growing conditions in the country.

Modern biotechnology can assist with the conservation and sustainable use of biodiversity in a time when species are quickly becoming extinct and natural resources are becoming exhausted. However, systems must be in place to ensure that maximum protection and caution is used. This can be done through regulatory and monitoring systems, safety procedures and protocols. It must also take into account the risks to human health and the environment, as well as social, cultural, ethical and spiritual considerations.

Biosafety is a way of reducing potential risks that result from modern biotechnology. It is a means of protecting a country's biodiversity, or its environment, ecosystems, plants, animals and micro-organisms, as well as human health. The key aim of biosafety protection is to safeguard human health and the environment from any possible adverse effects of LMOs or GMOs.

Therefore, Tuvalu has to be able to ensure that any transboundary movement of GMOs or any GMO related activity in the country is controlled and monitored adequately, whilst still being able to benefit from any potential benefits of biotechnology. Moreover, given the size of its population and the lack of any R&D infrastructure, it is likely that any transgenic crop plants introduced into the country for release into the environment will have been developed outside the country; hence the need for biosafety systems that will enable Tuvalu to control the introduction of GMOs into the country. The rationale for biosafety systems also includes the question of food safety: at present, under the Food Safety Act 2006, monitoring of food imports focuses on questions of quality, expiry dates, and contamination of food by potential pathogens, etc. The question of food safety would need to be addressed in the NBF; these are likely to be based on food safety tests carried out by countries in the

¹ Te Kakeega, 2004.

region such as Australia, Fiji and New Zealand as well as the countries of origin of the food products. All of these reasons support the need not only for Tuvalu to develop a National Biosafety Framework (NBF), but also to accede to the Cartagena Protocol on Biosafety (CPB).

1.3. The International context

With the advent of modern biotechnology, there have been a number of international instruments over the last two decades that seek to harness the benefits of modern biotechnology whilst ensuring that adequate safety systems are in place. The major instruments include:

Agenda 21 – states in Chapter 16 that “Biotechnology promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes.”

The Convention on Biological Diversity (1992) – Parties to this Convention are obliged to:

- “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 into account the risks to human health” **Article 8(g)**.
- “Consider the need and modalities of a protocol setting out appropriate procedures, including, in particular advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity” **Article 19.3**.

The Cartagena Protocol on Biosafety was negotiated in 2000 and came into force two years later states that:

- “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.” Article 1.

The Cartagena Protocol goes to some lengths to acknowledge the importance of the small island developing States in this context. Article 22 deals with capacity building and notes the particular needs of the developing country Parties, “in particular the least developed and small island developing States among them...”

1.4. The National context: developing Tuvalu’s NBF

Tuvalu’s national sustainable development strategy, Te Kakeega, identifies the sustainable utilisation of the country’s natural resources as a key priority:

“Natural Resources: Agriculture, Fisheries, Tourism and Environment. The traditional structure of Tuvalu society and its subsistence economy have been built on the sustainable use of the nation’s limited, but nevertheless valuable natural resources, and the conservation and careful exploitation of the fragile atoll ecosystems. These are now under threat from changing attitudes in society and from a continuously growing cash economy. With traditional subsistence production in decline, the challenge is to reconcile these conflicting factors to create sustainable growth and greater stability.”

Tuvalu became a Party to the Convention on Biological Diversity in December 2002 and joined the global UNEP-GEF Project on the Development of National Biosafety Frameworks in January 2004, after negotiations were completed on an MOU with UNEP. The NBF development project began its activities in 2004 when a national project coordinator (NPC) was appointed by the Department of Environment (DOE); some significant progress was achieved during the tenure of the NPC. This included:

- appointment of a National Coordinating Committee (NCC) – this included: Government representatives from DOE, Trade, Customs, Office of the Attorney General, Agriculture, and

- preliminary awareness-raising activities;
- the preparation of a draft policy on biosafety following a consultative workshop in 2007;
- the preparation of a draft regulation under the Environment Protection Act (2008) by a regional legal consultant; and
- a review of relevant national legislation and systems carried out in 2007.

The Government of Tuvalu has approved the country's accession to the CPB, but the necessary instruments of accession have not been lodged as yet with the UN Treaty office or with the Secretariat of the CBD.

This draft of the NBF contains the following sections, which comprise the five key elements of a National Biosafety Framework:

- **A national policy on biotechnology and biosafety** – as there is no Government policy that could apply to biosafety and biotechnology, it was decided to develop a new draft policy that covers both the potential benefits from the application of biotechnology to achieve the overall aims of Te Kakeega, and the importance of biosafety in order to ensure the safe use of biotechnology;
- **A regulatory regime** – this is a draft regulation under the Environment Protection Act, 2008;
- **A system to handle applications** (administrative, risk assessment, risk management and decision making processes);
- **Follow up actions** (monitoring, inspections and enforcement); and
- **Systems for public awareness and participation** in order to ensure that all stakeholders are able to take part effectively in decision-making on GMOs.

2. Draft National Policy on Biosafety and Biotechnology

2.1. Preamble

Tuvalu recognizes the importance of biotechnology in its sustainable development, and the contributions biotechnology can make towards a prosperous Tuvalu as envisaged in the vision of the Te Kakeega II: National Strategies for Sustainable Development: 2005 – 2015:

“By 2015, guided by strong spiritual values enshrined in its motto - ‘Tuvalu mo te Atua’ - we will have achieved a healthy, educated, peaceful and prosperous Tuvalu.”

Developments in biotechnology however, are undergoing rapid acceleration worldwide, as more powerful techniques are becoming available for studying data, and information technology enables knowledge to be used with increasing rapidity for a wide range of applications. Some applications of modern biotechnology, such as tissue culture and the use of molecular techniques as a means of selection in classical plant improvement, are uncontroversial and already used widely in the Pacific. Other applications however, such as genetic modification or ‘genetic engineering’, which uses a variety of methods to isolate single genes from one or more organisms (plants, animals or micro-organisms) and insert them into the genetic material of the cells of another, are subject to debate. On one hand, modern biotechnology “promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improve supply of portable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods for afforestation and reforestation, and detoxification of hazardous wastes” as stated in Agenda 21. On the other, there are serious concerns, ranging from ethical questions of whether modern biotechnology transcends that which humans should be doing, the possible negative impacts on cultures, traditions and beliefs, potential risks to human health and the environment, and encompass a number of socio-economic issues.

Recognizing that the debate on potential risks and benefits of genetic modification will continue for years to come, Tuvalu will adopt the precautionary approach in ensuring an adequate level of protection in the field of safe transfer, handling and use of the products, and applications of, modern biotechnology, and in making informed decisions on a case-by-case basis,

As a small island developing state in the Pacific, modern biotechnology is a relatively new phenomenon to Tuvalu. To realise the significant contributions that modern biotechnology promises it could make to the sustainable development of Tuvalu, capacity building in the area of modern biotechnology is crucial.

2.2. Overall Policy Goal

The overall goal of Tuvalu’s policy on biosafety and biotechnology, framed within the context of Te Kakeega, is to safeguard the health of the people of Tuvalu, protect their traditional culture and values, and protect the biodiversity and natural environment of the country from any potential adverse impacts of modern biotechnology. At the same time, the people of Tuvalu should be able to benefit from the safe use of biotechnology and the Government shall promote the safe and responsible use of modern biotechnology and its products in order to help achieve food security, sustainable livelihoods, improve health services and promote the development of alternative sources of renewable energy based on Tuvalu’s biodiversity resources.

2.3. Guiding Principles

The implementation of Tuvalu’s national policy on biosafety and biotechnology shall be guided by the following principles:

Socio-economic and Ethical considerations

In implementing the NBF, the social, economic, ethical, cultural and religious impacts, including its use, benefits and risks, of research, development and release of genetically modified organisms in the country, shall always be taken into account. In particular, decision-making on GMOs shall take full account of any impacts on small farmers and fisherfolk, women, small and medium enterprises and consumers.

Precautionary Approach

A precautionary approach shall be applied through the regulatory system proposed in the NBF, particularly through the procedure for scientific risk assessment to human health and the environment and evaluation of socio-economic risks.

Environmental Sustainability

The policy will promote environmental sustainability by helping Tuvalu to manage the risks posed by release of GMOs into the environment to marine and terrestrial biodiversity, and sustainable livelihoods. The policy will also promote the application of biotechnology to help resolve threats from increasing salinity due to climate change.

Transparency and Public Participation

Decisions taken under the regulatory system proposed in the NBF shall be arrived at in a transparent and participatory manner. Biosafety issues are best handled with the participation of all concerned citizens and organizations. All concerned stakeholders shall have appropriate access to information and the opportunity to participate in biosafety decision-making processes. Dissemination of information on biosafety issues will be a priority of all the concerned agencies.

Consensus Building

In making biosafety decisions, all government departments and agencies shall seek consensus among all relevant stakeholders using well-accepted methods such as negotiation, mediation, and other appropriate dispute resolution processes.

Principle of Subsidiarity

Decisions should be made at the lowest level to involve all affected citizens regardless of their status, wealth, power, ethnicity, or gender. While it may not be reasonable to expect that local institutions such as *Kaupule and Falekaupule* have the technical capacity to evaluate scientifically the risks associated with the release of genetically modified organisms, they should have a substantial influence on the final decision after being presented with all the relevant information regarding the risks and benefits of GMOs to be released into their local environment as they have a better knowledge of the local situation in their jurisdiction, and in particular the socio-economic, ethical, and cultural implications of a biosafety decision.

2.4. Priority areas for action

The following priority areas for action in implementing the draft policy on biosafety and biotechnology were identified during the consultation on the development of the NBF²; these priority areas would be guided by the principles listed in 2.3. The discussion below also identifies those strategic areas of Te Kakeega that are supported by the biosafety and biotechnology policy.

Promote Food Security

Food security is a major problem facing Tuvalu; one of the priorities identified in Te Kakeega is the need to improve food security by reversing the decline in subsistence agricultural production and increasing production of local produce. As environmental changes leading to increased salinity have been identified as a major constraint to the cultivation of the main staple crop, *pulaka* (giant taro) traditionally grown in pits, biotechnology offers a means of introducing salt-tolerance into the local variety, using either non-GM biotechnology to speed up more conventional breeding or through the introduction of transgenic plants containing GMOs. The research and development on these varieties would have to be carried out elsewhere in the region, using traditional varieties from Tuvalu as the base species and introducing the desired genes from other taro varieties or other plants from elsewhere in the Pacific. The new cultivars would then be brought to Tuvalu for field testing after undergoing the requisite stringent risk assessments in the case of transgenic plants. Varieties

² Based on the discussions at a national consultation workshop in May 2006 and a roundtable meeting of stakeholders in July 2008.

produced by non-GM technologies would only have to undergo pest risk analysis based on the biosecurity law as they would not contain GMOs.

The policy objective for this priority area would be to support Te Kakeega by promoting food security through research on both GM and non-GM biotechnology so as to develop crop plant cultivars that are tolerant to salinity whilst retaining the agronomic, cultural and culinary qualities valued in Tuvalu.

Protection of traditional customs, values and knowledge

The introduction of any products of biotechnology R&D, especially when they are intended for introduction into the environment, would have to be thoroughly assessed for their potential social, economic, cultural, and ethical impacts during the decision-making process. As one of the main objectives of Te Kakeega is to protect Tuvalu's cultural heritage and traditional knowledge, any initiatives at boosting food security through the application of biotechnology should also take these wider impacts into account in decision-making. Therefore, given the close relationship between traditional cultural practices, subsistence farming systems and the use of traditional cultivars of taro and other food crops such as breadfruit, any systems for decision-making on GMOs must include these considerations as part of the regulatory requirements.

The policy objective for this priority area would be to ensure that any introductions of GMOs into the environment in Tuvalu should take full account of any social, cultural, ethical or economic impacts, and that there must be a demonstrated benefit to the people of Tuvalu before any introduction is allowed.

To establish and strengthen systems for regulating and monitoring GMOs in Tuvalu

The development of the NBF is but a first step in setting up functional systems for risk assessment, management and decision-making for GMOs. The NBF therefore identifies the following components:

- ✓ A regulatory regime for biosafety based on a regulation under the EPA 2006.
- ✓ A system for handling applications for the development, contained use, release into the environment for use, export, or transit of GMOs³ with a key role for the MNRE as the National Competent Authority (NCA), and the DOE as the Secretariat for the NCA and as the National Focal Point (NFP).
- ✓ A system, for decision-making on GMOs based on the National Environment Committee (NEC) appointed under the EPA 2008.
- ✓ A system for monitoring and enforcement that makes use of existing structures that are part of the Central Government (e.g. DOE, Customs, Biosecurity officers, Department of Rural Development) as well as the Kaupule and Falekaupule systems.
- ✓ A system for public participation in decision-making on GMOs that is based on awareness raising in order to enable the public to be able to make informed decisions. The consultation process is based on traditional systems such as Falekaupule and will make use of NGO and local government networks in Funafuti and the outer islands.

The policy objective for this priority area would be ensure that Government agencies have in place systems for the control of importation of GMOs and their products, as well as for monitoring of any GMOs released into the environment.

Food safety with respect to GMOs

Tuvalu is heavily dependent on the importation of food, both fresh food products (vegetables, fruits, taro, cassava, etc) and processed foods (rice, canned foods, packaged food products. Food safety in the country is managed under the Food safety Act, 2006; border control is under the jurisdiction of Biosecurity and Customs Officers, whilst the Public Health Unit of the Ministry of Health is responsible

³ In accordance with Article 22 of the CPB which requires all Parties shall ensure that the development, handling, transport, use, transfer and release of any LMO are undertaken in a manner that prevents the risk to biological diversity, taking also into account risks to human health”

for monitoring of food safety in the country. However, none of these agencies have the facilities to carry out food safety assessments.

Therefore, the policy proposes that any risks to human health with regard to food safety would be assessed under the Food Safety Act 2006 and the proposed Biosafety regulation on the basis of existing risk assessment reports. These reports would be provided either by the country of origin of the food products or accessed by the NCA from reports published by countries in the region, for example risk assessment of GM food conducted by Food Standards Australia New Zealand (FSANZ). These reports would be assessed by the NCA prior to importation of the food products.

The policy objective for this priority area would be to ensure that the health and safety of the people of Tuvalu is protected by ensuring the effective implementation of the Regulations on Biosafety and the Food Safety Act, 2006.

Capacity building for the implementation of the NBF

Given Tuvalu's resource constraints, capacity building in biosafety issues is an important element of the implementation of the National Biosafety Framework. Capacity building activities should include:

- Strengthening and building the capacity of the administrative framework, including handling requests for GMO activities and developing technical expertise to undertake risk assessments and management;
- Strengthening national technical facilities and capacities for risk assessment and inspection purposes and facilities to store and dispose of GMOs; and
- Strengthening information systems, including links to the Biosafety Clearing House and a database of applications and information stored in Tuvalu ; and
- Building the capacity of key stakeholders, both government and non- government, to participate in and contribute to biosafety issues, including the administrative framework and decision-making processes.

The policy objective for this priority area would be for Tuvalu to seek further funding from the GEF under its resource allocation for biodiversity to implement its NBF, preferably through a regional project that supports national capacity building for the safe use of biotechnology.

Establish enabling mechanisms for public participation in decision-making on GMOs

The responsibility for decision-making on GMOs will lie with the NEC. This is a multi-stakeholder committee, established under the EPA 2008 that includes representatives Government agencies, the private sector, NGOs, local government and the Church. The NEC will have the mandate to ensure that socio-economic and ethical considerations are taken fully into account in decision-making on GMOs, and will be the final body that makes recommendations to Cabinet for the final decision.

In order for all stakeholders to participate fully in the deliberations of the NEC and to make informed decisions, all stakeholders will need to:

- Have access to the necessary information in a form that is accessible to all sectors of society.
- Be consulted on individual GMO applications. The NCA will organize, through the network of NGOs and the Kaupule and Falekaupule systems, consultations in all eight inhabited islands of Tuvalu.
- Participate in awareness raising activities as part of the capacity building programme for the NBF. These activities will include workshops, radio programmes, and distribution of written material such as posters and pamphlets. These materials will contain information that limits the use of scientific language, with key concepts translated into Tuvaluan so that it may be easily understood by all stakeholders.

The policy objective for this priority area would be to establish systems that promote public participation in decision-making on GMOs by ensuring that mechanisms are in place for public contribution to decision-making and for public awareness on the risks and benefits of biotechnology.

Promote regional and international cooperation

Regional cooperation will include information sharing on the movement of GMOs within the sub-region and collaboration on biotechnology R&D on important food crops in the Pacific. At the same time, Tuvalu will promote cooperation and collaboration at the international level in order to have access to biosafety information as well as information on biotechnology research in important areas such as drought tolerance and resistance to biotic stresses. This includes information sharing through the Biosafety Clearing House (BCH), participation in the activities of the COP-MOP and collaboration and coordination with multilateral organizations such as SPREP, Secretariat of the Pacific Community, the Forum Secretariat, FAO and other relevant bodies.

The policy objective for this priority area would be to support regional cooperation on biosafety within the Pacific sub-region with respect to research on food crops of regional importance, capacity building on the safe use of biotechnology, and sharing of information of information on biotechnology and biosafety including participation by Tuvalu in the BCH.

Ratification of the CPB

The Government of Tuvalu is committed to becoming a Party to the Cartagena Protocol and is developing its NBF in order to meet its obligations under the CPB. The Government therefore intends that the accession to the CPB is completed as soon as possible, and in parallel with the finalization of the NBF. The Tuvalu Cabinet has already approved the accession of Tuvalu to the CPB and the appropriate instrument of accession will be lodged with the UN Treaty Office and the Secretariat of the CPB as soon as possible.

The policy objective for this priority area is the Government's commitment to accede to the CPB as soon as possible.

3. Regulatory Regime for biosafety

3.1. Legislation survey⁴

A review of relevant legislation is a first step in the process of formulating a National Biosafety Framework. There is a need to take account of a great many important factors, including existing applications of biotechnology within a country, the extent and impact of releases of GMO's and systems aimed at assessing and managing risks. The review of legislation would assist in applying a proper focus on the key elements of the NBF. In this way the implementation of the NBF can be facilitated by the clear conceptualisation of practical and achievable administrative arrangements in Tuvalu applying under its laws.

For ease of reference, this review of Tuvalu's legislation includes both current laws, and those that are at an advanced stage of formulation and drafting, but which have not yet been enacted. Each current law is referred to as an "Act". Proposed laws are termed "Bills".

It is common that legislative reviews applying to particular areas of the law require a subjective determination as to their relevance, and therefore as to their inclusion in the review. In this case however, the fundamental concepts arising from the *CBD* and the *Cartagena Protocol* are easy to identify. These then form the basis of determining the relevance of any particular law to this review. The critical concepts are –

- A competent authority in Tuvalu
- Regulation, Management and Control
- Risk assessments based upon sound scientific analysis
- Effects on the environment and on the biological diversity
- Risks to human health
- Transboundary movements
- Public awareness and participation (including the involvement of the private sector)
- Preservation of cultural and traditional values
- Regional and international cooperation and harmonisation of arrangements

These are discussed as relevant under each of the Acts or Bills.

ENVIRONMENT PROTECTION Act 2008

This Act is administered by the Department of Environment.

The main objective is to make provision in relation to the protection and management of the environment in Tuvalu. This will become the principal law in Tuvalu relating to the protection and management of the environment. Specific provision shall be made in relation to the implementation of international environment related Conventions (including the *CBD* and the *Cartagena Protocol*).

Section 14 of the Act provides for the convening of a National Environment Forum to discuss environmental issues of national importance. It also provides for the appointment of a National Environment Council to provide advice to the Minister on matters related to environmental protection and sustainable development in Tuvalu.

Part II Deals with objectives, functions and powers

Section 4 The Objectives of the Act are stated to be -

- (a) to coordinate the role of government in relation to environmental protection and sustainable development;
- (b) provide a mechanism for the development of environmental policy and law;
- (c) to promote a clean and healthy environment for all Tuvaluans;
- (d) to prevent, control, monitor and respond to pollution;

⁴ This section provides a short summary of the comprehensive review carried out by a consultant, Graham Bruce Powell, for the NBF project in June 2007. "Review of Laws in Tuvalu relevant to GMOs and the implementation of the CPB".

- (e) to promote public awareness and involvement in environmental issues and the preservation of Iloga as it relates to the environment;
- (f) to facilitate compliance and implementation of obligations under any regional and international environmental or natural resource agreements or conventions to which the Government of Tuvalu has ratified or acceded to;
- (g) to facilitate sustainable development with respect to the management of the environment and natural resources;
- (h) to facilitate the assessment and regulation of environmental impacts of certain activities;
- (i) to promote the conservation and, where appropriate, sustainable use of biological diversity and the protection and conservation of natural resources, on the land, in air and in the sea;
- (j) to reduce the production of wastes, and to promote the environmentally sound management and disposal of all wastes.

Section 5 The powers of the Minister are provided for.

Section 7 The powers of the Director of Environment are provided for.

Part III Provides for powers of enforcement

Section 9 The Minister may appoint in writing any appropriately qualified person to be an Environment Officer, including employees of the Department of Environment, police officers, quarantine officers, fisheries officers and public health inspectors.

Section 11 The powers of environment officers are comprehensively provided for.

- (a) Section 12 An environment officer may serve a Precautionary Notice where an activity may be adversely affecting the environment.

Section 13 Environment Officer may serve a Notice to Cease Activity to require any activity which is adversely affecting the environment to stop.

Part IV Provides for the appointment of the National Environment Forum and Council.

Part V Makes provision in relation to environmental impact assessment.

Section 17 Monitoring of environmental impacts. The Director shall ensure that the Department monitors activities that are likely to have, or are having an environmental impact in any area of land or sea within the jurisdiction of Tuvalu.

Part IX Makes provision in relation to the protection of the biodiversity

Section 30 The Department shall formulate, apply and enforce policies and programs for the protection of the biodiversity in Tuvalu, and in particular for -

- (a) the control and eradication of invasive species;
- (b) the protection and conservation of Tuvalu's endemic species;
- (c) the recognition, protection and application of traditional knowledge, innovations and practices in relation to the management, protection and utilisation of Tuvalu's biological diversity;
- (d) the declaration and management of protected areas, and the implementation of special measures to conserve Tuvalu's biological diversity;
- (e) regulating access to genetic resources within Tuvalu, and the equitable sharing of benefits arising from the development and exploitation of such resources;
- (f) promoting access to and transfer of technologies relevant to Tuvalu's biological diversity;
- (g) implementing plans, strategies and measures for the rehabilitation and restoration of degraded eco-systems, and for the rehabilitation of degraded lands; and
- (h) implementing systems for the monitoring of and reporting on issues and matters relevant to or affecting Tuvalu's biological diversity.

Regulations may be made under this Act in relation to any of the matters relevant to Tuvalu's biodiversity as stated above.

BIOSECURITY BILL 2007

The main objective of this legislation is “To protect the health, environment and agriculture of Tuvalu and to facilitate trade in its animal and plant products.” This draft law seeks to make comprehensive provision for biosecurity related issues and processes, and to harmonise these in the region.

Section 3 The purposes of the law are stated to be –

- controlling the introduction and spread of new pests and diseases affecting plants and animals;
- controlling those pests and diseases affecting plants and animals that are already present in Tuvalu;
- providing for the safe import and export of animals and animal products and plants and plant products;
- facilitating cooperation in the prevention of the international movement of pests and diseases affecting plants and animals.

PLANTS ACT 1976

The main objective of this Act is “To provide for the protection of plants and the imposition of quarantine arrangements to control the importation of plants, and to prevent the introduction and spread of plant diseases.” As effective quarantine arrangements are important aspects of a nation’s environmental protection regime and are aimed at preventing the introduction of plant diseases and pests. This has particular relevance to the controls that may be exercised over trans-boundary movements into Tuvalu.

IMPORTATION OF ANIMALS ACT 1919

The main objective of this Act is “To regulate the importation of animals into Tuvalu.” The controls applied to the importation of animals are an important aspect of the nation’s environment protection regime and has particular relevance to the controls that may be placed on trans-boundary movements into Tuvalu.

IMPORTATION OF ANIMALS REGULATIONS, 1965

The main objective is “To place prohibitions and controls of the importation of animals, manure and fodder, litter, fittings and other things which have come into contact with animals.” As noted above the ability of a country to control the trans-boundary movement of animals into its jurisdiction is an important feature of its environment protection capacity.

QUARANTINE ACT 1929

The main objective is “To make comprehensive provision in relation to quarantine.” The effective imposition of quarantine arrangements and requirements are an important aspect of environment protection. It is also relevant in the context of trans-boundary movements.

MARINE RESOURCES ACT 2006

The main objective is “To ensure the long term conservation and sustainable use of the living marine resources for the benefit of the people of Tuvalu.” This is a modern and comprehensive law relating to the sustainability and effective conservation of the fisheries resources of Tuvalu, whilst regulating their exploitation and giving effect to international agreements permitting access to the resources. This Act also provides for the conservation, management and sustainable use of marine resources.

FOOD SAFETY ACT 2006

The main objective is “To promote public health and safety with regard to food, to regulate the preparation, sale and use of food, to assist consumers to make informed choices on food and to

promote fair trading practices in relation to food.” This law has important implications for human health and for the rights of consumers. The substance of the relevant provisions include:

Part II Makes general provision in relation to pure food, including –

- labelling requirements (section 3)
- registration of food premises (section 4)
- training of food handlers (section 5)
- Health of food handlers (section 6)
- Expiration and “best before” dates (section 7)
- Obtaining food from closed areas (section 8)

Part III Prescribes certain prohibition, including –

- Food that is not suitable for consumption (section 10)
- Misleading or deceptive food (section 11)
- Food not complying with standards (section 12)
- Insanitary conditions (section 15)

Part IV Makes provision for food inspection, including –

- Appointment of food inspectors (section 23)
- Sampling (section 27)
- Appointment of analysts (section 28)

FALEKAUPULE ACT 1997

The main objective is “To make provision for Falekaupule and Kaupule in each island of Tuvalu as the local government structure.” Many functions and powers of Falekaupule exercised through their Kaupule and officers relate to matter of environmental management.

THE CONSTITUTION OF TUVALU 1986 (CAP. 1)

The main objective is “To make provision for the constitutional framework of Tuvalu.”

The Constitution provides the basis for law-making in Tuvalu, it sets the limits of Tuvalu’s jurisdiction and has many other provisions which enable the management of the environment by the responsible Minister and officers of the Public Service.

(There are no specific references in Tuvalu’s Constitution to conservation of resources and sound environmental or resource management. The rights of future generations however are acknowledged in the *Principles of the Constitution*.)

3.2 Relevant International Obligations

Tuvalu is a Party (or intends to become one) to a number of international instruments that are relevant to biosafety. These were discuss in a review carried out by a consultant for the NBF project and are summarised here⁵.

The Cartagena Protocol on Biosafety

Background

The Protocol is based upon Article 19(3) of the CBD which provides –

“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 any LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity”.

⁵ Graham Bruce Powell, for the NBF project in June 2007. “Review of Laws in Tuvalu relevant to GMOs and the implementation of the CPB”.

Accordingly, the objective of the Protocol is said in Article 1 to be –“To contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMO’s, taking also into account risks to human health, and specifically focusing on transboundary movement”.

The Precautionary Approach

The precautionary approach provided for in Principle 15 of the *Rio Declaration* has particular application in this context. States are obliged to “widely apply” the precautionary approach in accordance with their capabilities.

The key aspect of the Precautionary Approach

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”. (Principle 15 – **Rio Declaration**)

This can be said to be a principal obligation applying in this context.

THE OTHER PRINCIPAL OBLIGATIONS

1. Designation of a competent authority (Article 19)

Tuvalu must designate one or more national competent authorities to be responsible for performing the administrative responsibilities of the Protocol. This authority must be authorised to act on behalf of the State in regard to these responsibilities.

2. Obligations arising under the Advanced Informed Agreement (AIA) Procedure (Article 7)

Tuvalu’s obligations relate to the following matters –

- (a) Notification must be given of any transboundary movement of a LMO from Tuvalu. Certain information must be provided in accordance with Annex 1, and this relates to the exporter, the LMO and the use for which the LMO is intended.
- (b) Within 90 days of Tuvalu receiving a notification of the transboundary movement of a LMO to Tuvalu, receipt of the notification must be acknowledged.
- (c) Within 270 days of receiving the notification of the transboundary movement of a LMO to Tuvalu, the decision in relation to the proposed import must be advised to the notifier and to the Biosafety Clearing-House established under the Protocol. The decision can be an approval of the import, a rejection of it, a request for further information or a deferral for a stated period of time. (A failure to communicate a decision within this time frame does not imply consent to the import).
- (d) Tuvalu’s decisions under paragraph (c) must be based on a risk assessment carried out in a scientifically sound manner. The risk assessment requirements are stated in Article 15 and Annex III. The impact on sustainable development and the risks to human health must be considered. The precautionary principle may be applied and socio-economic factors may be taken into account. The exporter may be required to carry out the risk assessment, and to meet the costs of it.
- (e) The exporter must be permitted to nominate any information provided under the AIA arrangements to be kept confidential. Justification for the confidential nature of the information may be requested. No commercial use may be made by Tuvalu of any confidential information provided in this way.
- (f) Given its circumstances it may be said that Tuvalu is under some obligation to consider bilateral, regional or multilateral agreements or arrangements regarding the transboundary movement of LMO’s. This is based upon the almost certain lack of scientific capacity that may be available to Tuvalu to undertake the necessary risk assessments.

Excluded LMO’s from the AIA arrangements

- LMO’s in transit
- LMO’s destined for contained use
- LMO’s intended for direct use for food, feed or for processing (LMO-FFP’s) (but prior consent may be provided for under Tuvalu’s laws)
- LMO’s identified by the meeting of the Parties as being unlikely to have adverse effects
- LMO’s that are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations

3. *Notification of LMO-FFP's*

If Tuvalu were to export any LMO-FFP then it must be accompanied by documentation indicating that it "may contain" an LMO, and that it is not intended for intentional introduction to the environment.

Tuvalu would be entitled to prescribe in its domestic laws that it requires advance notification and approval of any proposed transboundary movement of any LMO-FFP.

4. *Unintentional releases of LMO's*

In relation to any unintentional transboundary movements of LMO's, Tuvalu must –

- (a) comply with the Protocols notification and consultation requirements; and
- (b) provide to the Biosafety Clearing-House details of a contact point for receiving any such notifications given by other Parties.

5. *Illegal transboundary movements of LMO's*

Measures must be adopted within Tuvalu to prevent and penalise transboundary movements of LMO's that occur in contravention of Tuvalu's laws. Requests may be made to the party of origin to dispose of the LMO's by repatriation or destruction.

6. *Provision of information to the Bio-safety Clearing House*

The following are examples of the types of information that Tuvalu is obliged to provide to the Bio-safety Clearing House –

- (a) Decisions on import or release of LMO's, including those made under the AIA arrangements;
- (b) The existence of any domestic law, regulation or guideline for implementation of the Protocol, including any law requiring prior notification and approval of any transboundary movement of a LMO-FFP;
- (c) Any determination that a decision will be made on the first import of a particular LMO-FFP in accordance with a risk assessment;
- (d) Summaries of risk assessments or environment reviews of LMO's generated by Tuvalu's regulatory process;
- (e) Bilateral, regional and multilateral arrangements under Article 14; and
- (f) Any illegal movements of LMO's.

7. *Capacity Building*

Tuvalu must cooperate in the development and strengthening of human resources and institutional capacities within Tuvalu and in other developing countries. (However, it cannot expect any specific commitments from the developed countries in this regard).

The Convention on Biological Diversity

Article 8(g) of the CBD calls on Parties to – "*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 into account the risks to human health*".

Other relevant Conventions

Some of the international instruments that may be considered in the context of biosafety include the following:

- (a) **Codex Alimentarius** - The Codex Alimentarius Commission is the internationally recognised body for setting standards relating to food safety. The objectives of Codex standards are to protect the health of consumers and ensure fair practices in the trade of food.
- (b) **International Plant Protection Convention (IPPC)** - The IPPC seeks to prevent the spread (and introduction to new countries) of pests to plant and plant products around the world, and to promote appropriate measures to control these pests. Contracting parties are obliged to establish a regulatory regime to assure the safety of plants, plants products and other regulated products for import and export, surveillance of plants throughout their own territories and inspection of plants "moving in international traffic". They must institute only phytosanitary measures that are technically justified and consistent with the pest risk involved. These must be

the least restrictive measures available and result in the minimum impediment to the international movement of people, commodities and conveyances.

- (c) **World Organization for Animal Health (OIE)** - The OIE has the responsibility to promote the transparency of incidence of animal diseases throughout the world, and the member states are required to report diseases that are current in their territories. These include diseases that may be transferred to humans (e.g. mad cow disease). The OIE has the further responsibility to guarantee the sanitary safety of world trade by developing rules for trade in animals and animal products that are recognised by the World Trade Organization as reference standards.
- (d) **Agreements of the Application of Sanitary and Phytosanitary Measures** - The Sanitary and Phytosanitary Measures (SPS) Agreement provide the right of countries to take measures they consider necessary to protect plant, animal and human life or health. Such measures must be –
- (i) scientifically justified;
 - (ii) based on an assessment of risks (being no more than necessary); and
 - (iii) non discriminatory (which do not constitute a disguised restriction on trade).

The emphasis of the SPS agreement is on scientific justification, risk assessment and consistency of approach to the determination of national measures. Further, it must conform to the international standards, recommendations and guidelines in respect with the protection of human, animal or plant life or health unless there is a scientific justification. (Note: This is in contrast to the precautionary approach).

- (e) **Agreements on Technical Barriers to Trade** - The Technical Barriers to Trade (TBT) are relevant to biotechnology products because they apply to technical regulations and standards, including packaging, marking and labelling requirements. Member states are obliged to take appropriate measures to ensure the quality of its exports, so as to protect human, animal or plant life or health, and the environment. TBT's principal objectives include preventing deceptive trade practices and protecting human, animal or plant life and health, and the environment.
- (f) **International Treaty on Plant Genetic Resources** - This treaty provides for the establishment of an efficient, effective and transparent multilateral system to facilitate access to plant genetic resources for food and agriculture, and for the benefits to be shared in a fair and equitable way. It gives the Government the responsibility for implementing these rights.
- (g) **Agreement on Trade – Related Aspects of Intellectual Property Rights Measures (TRIPS)** - Those articles which relate to patents may have some impact on a regulatory system introduced for the safe use of living modified organisms.
- (h) **Union for the Protection of Plant (UPOV)** - The UPOV's objective is the protection of new varieties of plants through the recognition of intellectual property rights. These are applied to the process of plant breeding, and have been developed with the aim of encouraging the development of new plant varieties.

3.3. Draft Biosafety (Genetically Modified Organisms) Regulations

Tuvalu's proposed draft regulatory regime for biosafety is contained in Annex 1 of this draft NBF. These regulations would be made under the Environmental Protection Act, 2008. The draft regulations implement all operative provisions of the CPB and provide for:

- a regulatory and administrative framework for LMOs and GMOs;
- procedures relating to the importation and other activities involving LMOs and GMOs;
- other procedures for dealing with LMOs and GMOs such as export, transit, use for food, feed and processing, development, contained use and testing of GMOs and unintentional and illegal releases and transboundary movements; and
- enforcement and penalties.

Key provisions of the draft regulations include:

Objectives:

- (1) The Objectives of these Regulations are to -
 - (a) regulate all activities involving genetically modified organisms and the applications of modern biotechnology in Tuvalu so as to preserve the environment and protect human health;
 - (b) facilitate Tuvalu's economic development by ensuring that beneficial uses of genetically modified organisms and modern biotechnology may be applied after appropriate scientific assessments and analysis have been undertaken;
 - (c) protect the cultural values and heritage of Tuvalu as they may be affected by the applications of modern biotechnology; and
 - (d) ensure that the community of Tuvalu is made aware of matters relating to genetically modified organisms and modern biotechnology in Tuvalu, and is capable of meaningfully participating in the regulatory processes that are prescribed in this context.

The Precautionary Approach

All persons and agencies having responsibilities under these Regulations, or whose functions and powers may relate to any matter or thing involving the development, field testing, fermentation, release, processing, use, handling and transboundary movement of genetically modified organisms and the applications of modern biotechnology within Tuvalu, shall apply the precautionary approach as provided for in section 27 of the Principal Act.

Roles and Responsibilities

The Ministry of Natural Resources and Environment shall be the National Competent Authority.

The Department of Environment shall be the National Focal Point for all purpose associated with the Cartagena Protocol.

The National Environment Council shall be the decision-making body that will consider the results of the risk assessments as provided by the NCA, taking into account all relevant socio-economic, ethical and cultural considerations in making their recommendations to Cabinet on the importation of GMOs.

The regulation sets out the functions of the DOE and the powers of the Director of DOE.

Procedures for the importation of GMOs

The regulations set out provision for applications for transboundary movements, approval procedures for imports, scientific risk assessment and assessment of socio-economic, ethical and cultural impacts, confidential information, exemptions and review of decisions.

Other regulatory requirements

These include provisions for export, transit, use for food, feed and for processing, development, contained use and testing, as well as unintentional and illegal releases.

Other provisions

These include compliance and offences, as well as issues such as notification forms, fees and liability and redress.

4. Administrative System for handling applications for GMOs

The implementation of the regulatory regime is accompanied by an administrative system for handling applications, carrying out scientific risk assessment, and making decisions on individual GMO applications based on both the risk assessment and assessment of socio-economic, cultural and ethical consideration. This requires clear allocation of roles and responsibilities for the various agencies involved⁶.

4.1 Roles and Responsibilities

The draft regulations on biosafety for Tuvalu under the Environmental Protection Act, 2008 provide for the following roles and responsibilities of the various Government agencies involved in implementing the Regulation.

National Competent Authority

The draft Regulation designates the Ministry of Natural Resources and Environment as the national competent authority (NCA) for all purposes associated with the CPB (Article 19). The NCA would exercise its powers and carry out its functions in terms of handling applications for GMOs in accordance with the provisions of the Environmental Protection Act 2008. The NCA would be responsible for appointing ad hoc Technical Advisory Groups to assist with functions such as the evaluation of risk assessments provided by the country or party of export of the GMO.

The Department of Environment would provide the secretariat and support services for the NCA and any Technical Advisory Groups appointed by the NCA. These services would include: receive and process all applications for GM activities; carry out daily biosafety administrative activities; and coordinate public inputs, risk assessment, and decision-making activities under the NBF. The Technical Advisory Group will comprise appropriate experts from Government agencies and may also include experts from other countries in the region (including New Zealand and Australia) as necessary.

National Focal Point

The draft Regulation on biosafety designates the Department of Environment as the National Focal Point for Biosafety for all purposes associated with the CPB (Article 19) and shall be responsible for liaison with the Secretariat of the Protocol. The Department shall also serve as the national BCH focal point.

Decision-making body

The draft Biosafety Regulation nominates the National Environment Council (NEC, to be established under Article 14 of the EPA 2008, as the decision-making body for all GMO applications. The NEC will review and consider all data, information and assessments (scientific risk assessment and socio-economic, cultural and ethical assessments) on the proposed GMO activity, and will make its recommendations to Cabinet for ratification.

⁶ “Administrative systems for handling applications”, Phase 3 Toolkit module (ii), UNEP-GEF Project on the development of NBF.

4.2 Processing of Applications

The various steps involved in handling applications are set out in Part II of the draft regulations and summarized in Figure 2 below:

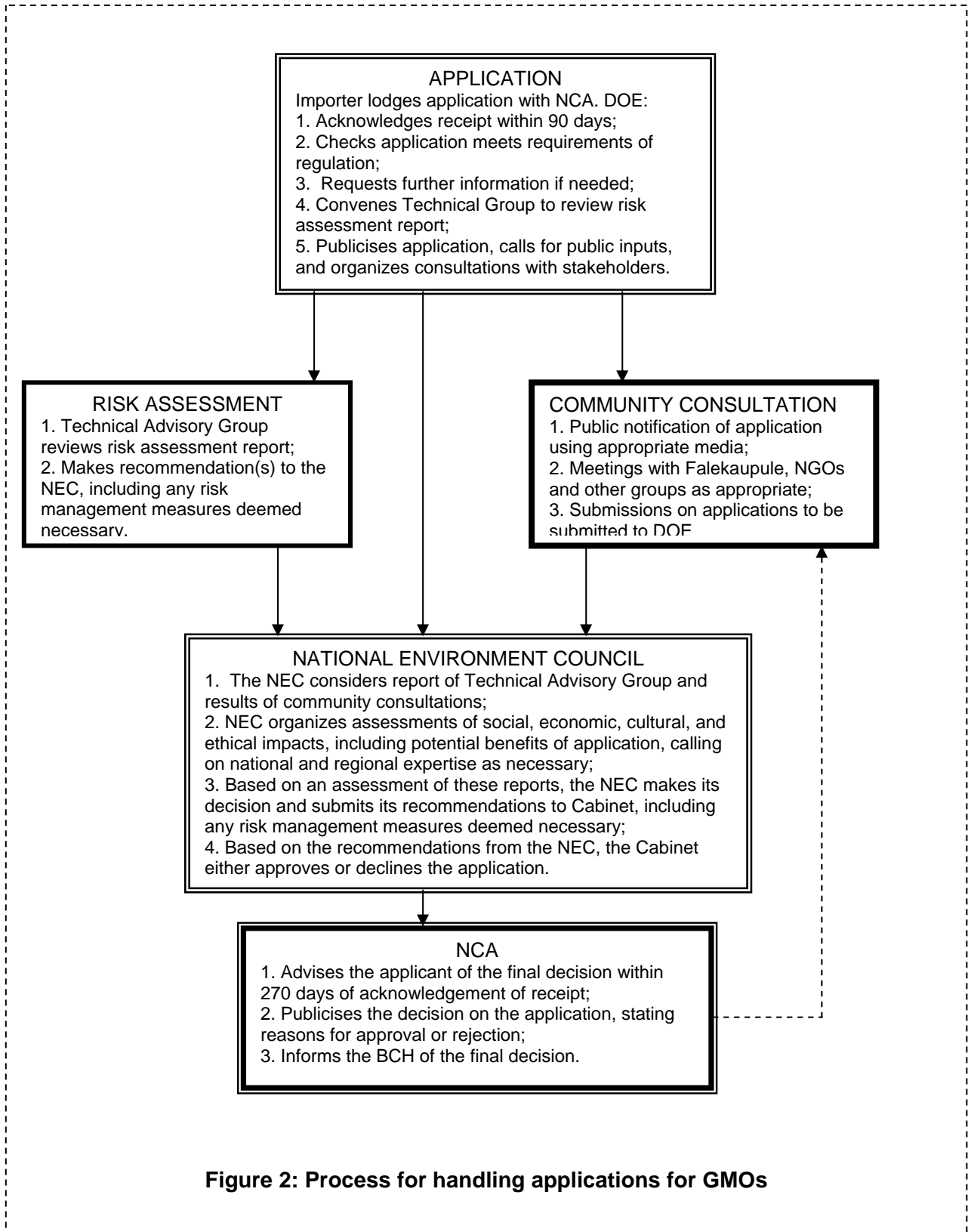


Figure 2: Process for handling applications for GMOs

Timeframe for Processing of Applications

The timeframe for dealing with applications in accordance with the CPB are in the table below. It is expected that the times noted are to be the maximum unless a time extension became necessary.

Table 1: Timeframes for processing of applications

	Activity	Timeframe
1	Acknowledgement of receipt	90 working days
2	Communication of decision	270 working days from the date of acknowledgement
3	Information of decision to the BCH	15 working days
4	Notify an applicant of a change in decision regarding a transboundary movement	30 working days
5	Party of imports' response to changed decision on transboundary movement	90 working days
6	Notification of unintentional transboundary movement likely to have significant adverse effect	Immediate

4.3 Risk Assessment

The risk assessment is a central part of the decision-making process and is used to make informed decisions about GMO activities. The objective of GMO risk assessment is to identify and evaluate the potential adverse effects of GMO activities on the conservation and sustainable use of biological diversity and human health in Tuvalu.

Risk assessments are based on a scientifically sound, transparent and logical approach. A Precautionary approach, as provided for in the Regulations and defined in the EPA 2008, means that a 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. Similarly, decisions should be able to be reviewed once new scientific information comes to light.

While risk assessments are based on the information initially given by the applicant, further background checks should be conducted. This may include seeking information from regional and international experts, including through the Biosafety Clearing House.

Risks associated with GMO activities should be considered in the context of the risks posed by the non-modified recipients or parental organisms in Tuvalu's environment. It includes consideration of:

- ✓ Any hidden costs, including the costs of long-term maintenance of surveillance and monitoring of LMO activities;
- ✓ The current status of biodiversity and the effects on biodiversity of introduction of GMOs, GMO products and derivatives.

Risk assessments should 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 particular GMO activities and potential impact on Tuvalu. Previous risk assessments done elsewhere in relation to the same GMO, GMO product or derivative may be considered. However, such previous risk assessments should be evaluated in light of Tuvaluan conditions. Testing under local conditions may be conducted. However, this should only be done under carefully contained or isolated conditions and where the consensus of scientific opinion is that the GMO, GMO product or derivative is low-medium risk.

As illustrated in Figure 2, the NCA will be responsible for convening a Technical Advisory Group (TAG) to carry out the review and assessment of the risk assessment report provided by the applicant, either from the country of export, or from other countries in the Pacific. The TAG will consist of local experts drawn from the relevant Government agencies such as Agriculture, Environment, Health, Biosecurity, etc, and may include experts from outside Government where necessary. The TAG (and/or the NCA) may also draw on the services of experts from other countries in the Pacific for advice on particular GMO activities.

4.4 Risk Management

Risk management refers to appropriate strategies to manage, regulate, monitor, control and eliminate any risks that have been identified in risk assessments. The aim of risk management is to prevent adverse effects of GMO activities on Tuvalu's biodiversity, environment and human health, in accordance with the objectives of the Biosafety Regulation.

The TAG and the NCA should consider placing any risk management requirements on permits. These risk management requirements should also be included in recommendations to the NEC and to Cabinet so that they may be included as conditions on any Permits issued.

Examples of risk management include:

- ✓ Safe handling requirements for the transport and use of GMOs;
- ✓ Labelling or marking requirements for any products that contain GMOs, GMO products or derivatives;
- ✓ Restrictions on where or when GMO activities may be conducted; and
- ✓ Ensuring that any GMO, GMO product or derivative has undergone an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use.

Any risk management requirements must be complied with by the person or company authorised to carry out LMO activities, and compliance with these conditions should be monitored (see Chapter 5 below).

Labelling requirements may utilise schemes in place in other countries, particularly in relation to GMO products and derivatives. For example, GM foods may rely on labels that are produced for compliance with New Zealand market requirements.

4.5 Decision-making

Decisions on GMOs need to be taken on a case-by-case basis. Each GMO may have a different impact on the release environment or on human health. GMOs may also differ on their potential benefits offered and their contribution to national development priorities such as food security, as well as their impact on different communities. Consultation with the wider community is part of the decision-making process in order to ensure that all views and potential impacts are taken into consideration in the decision-making.

The Biosafety Regulation provides for the NEC to be the main decision-making body on GMO activities; the NEC will carry out an assessment of:

- ✓ The report of the TAG on the risk assessment provided by the applicant, as well as any additional assessments carried out by the TAG and any additional assessments from other countries in the Pacific;
- ✓ The potential social, cultural, ethical and economic impacts of the GMO activity, including any potential benefits for Tuvalu. These will be carried out by national and regional experts, including those from the non-Government sector at the request of the NEC;
- ✓ Any written or oral submissions from the public consultation on the GMO application.

After considering all of these assessments, the NEC will make recommendations on whether to approve or decline the application; the recommendations will include any conditions to be placed on the GMO activity, such as time limits, geographical location of releases into the environment, distances from other crops, and other specific requirements.

A key criterion for the decision will be the extent to which the GMO activity will provide tangible benefits to the country, particularly towards achieving food security and adapting to climate change. The NEC will submit this decision to Cabinet for the final decision on the application.

Communication of Decisions

The communication of the NEC's and Cabinets' decision on the proposed GMO activity is an important contribution to transparency, both with respect to the applicant and the general public in Tuvalu. The decision document that communicates the decision to stakeholders, whether approval or rejection, will include the following information:

- ✓ A summary of the process used for the review, including risk assessment, the evaluation of other impacts, as well as the identification of potential benefits;
- ✓ A summary of the application, including information about the GMO and its perceived benefits and the reasons for the application;
- ✓ A summary of the scientific risk assessment review by the TAG and any additional assessments carried out by them;
- ✓ A summary of the discussions by the NEC in arriving at their decision, including an assessment of social, cultural, ethical and economic impacts, as well as the benefits identified;
- ✓ The biosafety recommendation, including conditions for managing risks in the case of approvals and the reasons for declining the application in case of rejections;
- ✓ A summary of the written and oral submissions received from the public, indicating how they influenced the decision.

Biosafety Clearing House (BCH)

The CPB has specific obligations regarding information sharing through the BCH; when Tuvalu becomes a Party to the Protocol, it will be obliged to provide information to the BCH. Initially, the type of information that Tuvalu will be obliged to lodge with the BCH will include details of their contact points, the NCA, a copy of the biosafety regulations and any relevant guidelines for forms. Later, when Tuvalu has made decisions on GMO activities including transboundary movement, it will be required to place these decisions on the BCH.

However, Tuvalu will also benefit from access to the information available on the BCH as it has been established to facilitate information exchange. Thus Tuvalu will have access via the BCH to information from other countries on: intentional releases of GMOs; placing on the market of GMOs and their products; direct use of GMOs for food, feed and processing; and their decisions on transboundary movement of GMOs. The BCH will therefore provide the NCA in Tuvalu with information on how other countries are dealing with transboundary movement of GMOs, and which GMOs are likely to occur in food imports, as well as the results of risk assessments carried out before these products were placed on the market.

In Tuvalu, the DOE as the Focal Point, will be responsible for updating information from Tuvalu for the BCH. In addition, the DOE could also serve as a local clearing house by alerting other Government agencies and stakeholders about biosafety information relevant to Tuvalu that is available on the BCH.

In order for Tuvalu to access and update biosafety information on the BCH, the country will need access to both the necessary equipment (computers, printers, modems, etc) as well as capacity building. The global BCH capacity building project will provide assistance for this through GEF funding; Tuvalu will have access to this funding once it has completed the ratification of the CPB.

5. Monitoring and Enforcement

5.1 Monitoring

Monitoring is a critical part of any biosafety regulatory system. Monitoring has been defined as the systematic measurement of the effects of GMOs on the environment over time⁷. The overall aim of GMO monitoring is to identify direct, indirect, immediate, delayed, or unforeseen effects that GMOs and their applications might cause to the environment and human health. This can be achieved through:

- ✓ **Evaluating** or verifying results and assumptions arising from the previous assessments of environmental and health risk, as well as social, cultural, ethical and economic impacts;
- ✓ **Gathering information** so as to be able to assist with future assessments;
- ✓ **Surveying for any unintended impacts** on the environment, human health, society, and the economy.

The data collected by such monitoring measures would be used by the NCA to ensure that:

- (i) Any approved environmental releases of GMOs comply with the conditions imposed by the biosafety decision; these conditions would be made on the basis of the assessments carried out during the risk assessment and decision-making process;
- (ii) There are no unforeseen environmental or other impacts resulting from the environmental release of the GMO
- (iii) Appropriate remedial action is taken if unforeseen negative impacts occur or the conditions imposed by permits are not complied with.

For Tuvalu, the MNRE, as the NCA, would be responsible for overseeing the monitoring of the GMO activity in order to ensure compliance with the permit conditions for the reliance of a GMO into the environment. The responsibility for monitoring would rest in the first instance with environmental officers as defined in Part III of the Environmental Protection Act, 2008; these officers could include (as defined in the Act, Clause 9): employees of DOE, quarantine officers, fisheries officers, public health officers and the police. The NCA would also ensure that monitoring activities are coordinated, both between the Government's agencies responsible for oversight, and with monitoring activities carried out in the field.

The permit holder would carry out the actual monitoring activities in the field; the permit holder could be a Government agency, an individual, or an organization such as an NGO and/or a private sector company. Moreover, it is also important that all releases of GMOs into the environment also involve the local Kaupule and Falekaupule in carrying out monitoring activities.

5.2 Border Control

Given the very limited capacity to develop GMOs and GMO products in Tuvalu, imports will be the main source of GMO activities. Therefore border control is critical for enforcing the Biosafety Regulations. The types of imports could include:

- (i) Live organisms containing GMOs that have been approved under the NBF for release into the environment; these will be subject to the conditions imposed by the biosafety assessment process. These imports should be accompanied by the necessary documentation giving biosafety clearance, but would also be subject to Biosecurity clearance in order to ensure the absence of any pests and diseases.
- (ii) Fresh produce (such as vegetables and fruits) intended for release on the market as food for human consumption; these would be subject to Biosecurity and food safety clearance under the appropriate acts.
- (iii) Processed foods intended for human consumption and animal feed intended for feeding chickens or pigs. These would also be subject to Biosecurity and food safety clearance under the appropriate acts.

⁷ EU Guidance notes on monitoring.

Standard border control methods that are required under the Biosecurity Bill (2008) and the Food Safety Act 2006 would also apply to GMO activities. This includes activities such as checking documentation accompanying the imports for the relevant permits, as well as searching of containers arriving by sea, air freight and passenger baggage.

As proposed in the draft biotechnology and biosafety policy (Chapter 2), any risks to human health with regard to food safety would be assessed under the Food Safety Act 2006 and the proposed Biosafety regulation on the basis of existing risk assessment reports. These reports would be provided either by the country of origin of the food products or accessed by the NCA from reports published by countries in the region, for example risk assessment of GM food conducted by Food Standards Australia New Zealand (FSANZ). These reports would be assessed by the NCA prior to importation of the food products.

5.3 Enforcement

The enforcement of the Biosafety Regulations with regard to monitoring GMO activities and border control will require coordination between a number of Government agencies that are responsible for border control: Customs, Biosecurity (Agriculture), Immigration and Police. In addition, given that Tuvalu is a small country consisting of nine islands scattered over a wide area, local government has a critical role to play in border control and monitoring the informal or illegal transboundary movement of GMOs, as well as for monitoring compliance with conditions required by permits issued under the biosafety regulations. Therefore, the role of Kaupule and Falekaupule is critical for effective monitoring and enforcement of the Biosafety Regulations.

The Biosafety Regulations (Part V) and the Environmental Protection Act, 2008 (Part III), provide the legal authority for enforcement of the Biosafety Regulations for GMO activities. The responsibility for enforcement lies primarily with the MNRE as the NCA for biosafety regulation; this arrangement would facilitate administration of enforcement activities as the three departments with the applicable responsibilities: agriculture (biosecurity), marine resources and environment are part of this Ministry and report to the same Minister.

6. Public Participation

The Cartagena Protocol provides for public awareness and participation in decision-making on GMOs under Article 23, which states that:

“1. *The Parties shall:*

(a) *Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;*

(b) *Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.*

2. *The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.*

3. *Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.”*

Tuvalu's policy for biotechnology and biosafety gives effect to this Article of the CPB by stating that the policy objective for public participation and awareness is to “*establish systems that promote public participation in decision-making on GMOs by ensuring that mechanisms are in place for public contribution to decision-making and for public awareness on the risks and benefits of biotechnology*”. This will require actions in three related areas:

- ✓ **Awareness raising on biotechnology and biosafety** in order to promote public awareness and understanding of the costs and benefits of biotechnology, and the importance of biosafety.
- ✓ **Mechanisms for public participation in decision-making on GMOs** are necessary so that the Tuvalu public are able to take part in decision-making on individual GMO applications as well as helping to set policies for biotechnology and biosafety.
- ✓ **Access to information:** in order to be able to make an effective contribution to decision-making, the public should have access to the necessary information in a form that is accessible to all sectors of society.

These three areas can be considered to be the three pillars for effective public participation in decision-making on GMOs. This is supported by the draft biosafety regulation that in clause 6 (d) also requires the DOE to “conduct programs of public awareness and education in relation to genetically modified organisms and applications of modern biotechnology, and facilitating public participation in relation to the processes prescribed by these Regulations and envisaged by the *Cartagena Protocol* in relation to their use and development within Tuvalu”.

Therefore, public participation is one of the key components of the NBF, and all three pillars: awareness, mechanisms and information have to be addressed in order to get effective public participation in decision-making on GMOs.

6.1 Awareness Raising

The first priority for the NBF development project has been to promote an awareness of biotechnology and biosafety amongst all stakeholders, including awareness of the potential risks and benefits of biotechnology. The aim was to help stakeholders to make a contribution to the development and implementation of the NBF through their active and informed participation in the decision-making structure(s) proposed in the NBF, as well as enabling them in the future to make informed contributions to decisions on individual applications for importation of GMOs.

In order to build on these awareness raising activities carried out during development of the NBF, the DOE, as the Secretariat for the NCA is required by the biosafety regulations to provide further ongoing awareness raising on biotechnology and biosafety for the public. These awareness-raising activities

would target stakeholders in Funafuti as well as all inhabited outer islands of Tuvalu. These awareness-raising activities would require a partnership between:

- (i) The MNRE, and in particular the DOE;
- (ii) The Ministry of Home Affairs and Rural Development;
- (iii) The Kaupule and Falekaupule in each island; and
- (iv) NGOs with a proven track record of working with communities in similar awareness activities such as health, agriculture, or environment.

Some of the key activities for awareness raising would include:

- ✓ Translation of some key concepts on biotechnology and biosafety into Tuvaluan;
- ✓ Preparation of awareness raising materials on biotechnology and biosafety most appropriate to the situation in Funafuti and in the outer islands. These could include pamphlets, posters, booklets, radio programme, a video or DVD, etc;
- ✓ Ensuring that key documents and materials on any new applications are translated into Tuvaluan and are made available to all stakeholders throughout the country using appropriate media.

6.2 Mechanisms for Participation

Effective participation by the public in biotechnology and biosafety matters will require two types of mechanisms for participation:

- (i) **Representation on the decision-making body.** Policy advice on biotechnology and biosafety would be best achieved by representation by a range of stakeholders on the NEC as the main biosafety decision-making body as provided for in the Environmental Protection Act, 2008. The groups that should be represented on the NEC include the Church, private sector, and NGOs; this would follow the precedent was set by the NCC. Presence of a range of stakeholders on the NEC would also enable these representatives to make a contribution to decision-making on individual applications for GMO activities.
- (ii) **Consultation with the general public** - on individual applications for GMO activities as provided for in the Biosafety Regulations Clause 6. Consultation with the wider community should part of the decision-making process in order to ensure that all views and potential impacts are taken into consideration in the decision-making. The NCA would be responsible for ensuring that all non-confidential information on each GMO application are made available to the general public in a form that is readily accessible to all. These would include written materials, radio programmes, and public meetings arranged through the Falekaupule in each island community. The NEC, in arriving at its decision, would consider any written or oral submissions from the public consultation on the GMO application. In order to ensure transparency, a summary of the written and oral submissions received from the public would be published by the NCA, indicating how they influenced the final decision on the application.

6.3 Access to Information

Effective participation by the public in decision-making will require access to information in a readily understandable form (for example translated into Tuvaluan) and using media that are accessible to all stakeholders throughout the country (for example public meetings arranged through the Kaupule and Falekaupule). Although some sectors of the population, especially their organizations have access to the Internet, for example some Funafuti based NGOs, most groups do not have access to the Internet and therefore they will have to depend on the NCA to provide them with access information on GMO applications and their implications.

In addition, Government agencies, such as the NCA (MNRE) responsible for handling applications on GMOs and the Ministry of Health, responsible for food safety, will need access to information on GMOs available on the Biosafety Clearing House (BCH). Thus it is important that Tuvalu takes an active role in the BCH as this would give the NCA access to information on many aspects of GMOs.

Annex 1: Draft Environment Protection (Biosafety and Genetically Modified Organisms) Regulations 2008⁸

TUVALU

Made under the Environment Protection Act 2008

Arrangement of Regulations

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⁸ *Note: the proposed draft regulations for Biosafety in this NBF are a working proposal that provide a skeleton for further elaboration; these will be refined through consultation and a stocktaking exercise before the draft Regulations are finalized and promulgated by the Minister.*

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PURSUANT to section 39(2)(j) of the *Environment Protection Act 2008*, **I, TAVAU TEII**, Deputy Prime Minister and Minister for Natural Resources and Environment, acting with the consent of Cabinet, **HEREBY MAKE** the following Regulations:

DATED at Funafuti this day of 2008

.....
TAVAU TEII
DEPUTY PRIME MINISTER AND
MINISTER FOR NATURAL RESOURCES
AND ENVIRONMENT

REGULATIONS

PART I PRELIMINARY

1. Title and commencement

(1) These Regulations may be cited as the Environment Protection (Biosafety and Genetically Modified Organisms) Regulations 2008, and shall come into operation upon their publication in accordance with the *Interpretation and General Provisions Act (Cap. 1A)*.

2. Interpretation

(1) In these Regulations, unless the context otherwise requires –

“Advanced Informed Agreement Procedure” means the procedure prescribed in Article 7 of the *Cartagena Protocol* relating to the notification requirements for transboundary movements of genetically modified organisms;

“Applicant” means a 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 Tuvalu. “Applicant as used in this Rules and Regulations has the same meaning as “notifier” as that term is used in the Cartagena Protocol on Biosafety.

“Application” means the documentation that must be submitted to request prior approval of any activity involving GMOs and GMO products. “Application” as used in this Rules and Regulations includes “notification” as that term is used in the Cartagena Protocol on Biosafety.

“Biological diversity” has the same meanings and applications as under the Convention on Biological Diversity;

“Biosafety” means the avoidance of risk to human health and safety, and to the conservation of the environment as a result of the use for research and commerce of infectious or genetically modified organisms

“Biosafety Clearing-House” means the Biosafety Clearing-House established under Article 20 of the *Cartagena Protocol*;

“*Cartagena Protocol*” means the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* adopted at Montreal in January 2000;

“Contained use” means any operation, including import into containment, development, fermentation, 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.;

“*Convention on Biological Diversity*” means the *1992 Convention on Biological Diversity* adopted at Nairobi in May 1992;

“Council” means the National Environment Council convened from time to time under section 14 of the Principal Act;

“Department” means the Department of Environment;

“Director” means the Director of Environment;

“Environment Officer” includes all environment officers appointed under the Principal Act, and all other appropriate public officers appointed by the Minister for the purposes of enforcing these Regulations;

“Export” and “exportation” mean intentional transboundary movement from Tuvalu to another Party or from another Party to Tuvalu, as the case may be;

“Exporter” means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a genetically modified organism to be exported;

“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 and includes both living and non-living modified organisms, and has a corresponding meaning to “living modified organism”;

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

“Import” and “importation” mean intentional transboundary movement into Tuvalu from another Party;

“Importer” means any legal or natural person within Tuvalu who arranges for any genetically modified organism to be imported;

“Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, and has a corresponding meaning to “genetically modified organism”;

“Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

“Minister” means the Minister responsible for the environment;

“Ministry” means the Ministry of Natural Resources and Environment;

“Modern biotechnology” means the application of –

- (a) *In vitro* nucleic acid techniques, including recombinant nucleic acid and direct injection of nucleic acid into cells or organelles;
- (b) fusion of cells beyond taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

“National Competent Authority” and “Authority” means the Ministry of Natural Resources and Environment designated as the National Competent Authority under regulation 5;

“Party” means a Party to the *Cartagena Protocol*;

Precautionary approach means the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

Protocol means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

“The Principal Act” means the *Environment Protection Act 2008*;

“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;

“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;

“Transboundary movement” means the movement of a genetically modified organism from Tuvalu to another Party, or from another party to Tuvalu, and where indicated in these Regulations it may include the movement to or from non-Parties.

“Transit” means movement of GMO from and through a jurisdiction to another jurisdiction.

“Working day” means a day other than a Saturday, Sunday, or a public holiday.

(2) Words used in these Regulations, shall have the same meaning as is given to them in the *Convention on Biological Diversity* and the *Cartagena Protocol*, unless a contrary intention appears.

3. Objectives of these Regulations

(1) The Objectives of these Regulations are to -

- (a) regulate all activities involving genetically modified organisms and the applications of modern biotechnology in Tuvalu, including transboundary movements so as to protect the environment and human health;
- (b) facilitate Tuvalu's economic development by ensuring that beneficial uses of genetically modified organisms and modern biotechnology may be applied after appropriate scientific assessments and analysis have been undertaken;
- (c) protect the cultural values and heritage of Tuvalu as they may be affected by the applications of modern biotechnology; and
- (d) ensure that the community of Tuvalu is made aware of matters relating to genetically modified organisms and modern biotechnology in Tuvalu, and is capable of meaningfully participating in the regulatory processes that are prescribed in this context.

4. The Precautionary Approach

(1) All persons and agencies having responsibilities under these Regulations, or whose functions and powers may relate to any matter or thing involving the development, field testing, fermentation, release, processing, use, handling and transboundary movement of genetically modified organisms and the applications of modern biotechnology within Tuvalu, shall apply the precautionary approach as provided for in section 27 of the Principal Act.

PART II
REGULATORY FRAMEWORK FOR
GENETICALLY MODIFIED ORGANISMS

5. National Competent Authority, Decision-making and National Focal Point

- (1) The Ministry of Natural Resources and Environment shall be the National Competent Authority for all purposes associated with the *Cartagena Protocol*.
- (2) The Department of Environment shall be the National Focal Point for all purposes associated with the *Cartagena Protocol*, and shall discharge all its functions in this regard in accordance with these Regulations
- (3) The Council shall be the decision-making body that will consider the results of the risk assessments as provided by the NCA, and will take into account all relevant socio-economic, ethical and cultural considerations in making their recommendations to Cabinet on all activities involving GMOs, including development, import, field testing, contained use, transit, fermentation, release or processing.
- (4) All functions and powers of the Ministry acting as the National Competent Authority, the Council in decision-making, and of the Director in relation to the meetings and procedures of the Authority, shall be exercised in accordance with the provisions of the *Environment Protection Act 2008*.
- (5) The NCA may appoint one or more Technical Advisory Groups in accordance with the *Environment Protection Act 2008* for the purposes of implementing the *Cartagena Protocol*.
- (6) In addition to its role as focal point, the Department shall perform the functions and exercise the powers provided for in regulation 6.

6. Functions of the Department

- (1) For matters relating to the *Cartagena Protocol* the Department shall be responsible for –
 - (a) providing secretariat and support services to the National Competent Authority and any Technical Advisory Group;
 - (b) dealing with requests for the review of decisions in accordance with Article 12, and referring such matters to the National Competent Authority with such reports and additional information as is required for a decision to be effectively reviewed;
 - (c) arranging for certain information to be treated as confidential in accordance with these Regulations and the *Cartagena Protocol*;
 - (d) conducting programs of public awareness and education in relation to genetically modified organisms and applications of modern biotechnology, and facilitating public participation in relation to the processes prescribed by these Regulations and envisaged by the *Cartagena Protocol* in relation to their use and development within Tuvalu;
 - (e) liaising with other Departments and agencies, and working collaboratively with them to -
 - (i) establish and maintain appropriate mechanisms, measures and strategies for the regulation, management and control of risks associated with all aspects of genetically modified organisms including development, import, field testing, contained use, transit, fermentation, release or processing of genetically modified organisms and the application of modern biotechnology within Tuvalu;
 - (ii) implement measures to control and prevent unintentional and illegal transboundary movements of genetically modified organisms, and to respond to such movements, including the taking of necessary emergency responses;
 - (iii) ensure that genetically modified organisms which are subject to transboundary movement are handled, packaged and transported under conditions of safety, and that relevant international standards and rules are applied in this regard;
 - (iv) ensure that genetically modified organisms within Tuvalu, or proposed to be imported into Tuvalu, are packaged and labelled so as to disclose their genetically modified organism

content, and otherwise identified as being or containing genetically modified organisms as required by any law and by the *Cartagena Protocol*; and

- (v) facilitate the development and strengthening of human resources and institutional capacities within Tuvalu in the field of biosafety; and
- (f) facilitating appropriate bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of genetically modified organisms, and for the sharing of information and the enhancement of institutional capacities for the purposes of applying the provisions of the *Cartagena Protocol*.

7. Powers of the Director

(1) For the purposes of implementing these Regulations, and to meet the obligations and to exercise the rights of Tuvalu under the *Cartagena Protocol*, the Director shall have the power to –

- (a) approve the provision of assistance and support to the National Competent Authority and Technical Advisory Groups;
- (b) require that further information be provided under the Advanced Informed Agreement Procedure, and in relation to any other matter associated with meeting the obligations and exercising the rights of Tuvalu under the *Cartagena Protocol*;
- (c) make arrangements for the keeping of certain information confidential in accordance with the provisions of these Regulations and the *Cartagena Protocol*;
- (d) prepare information and reports required by the *Cartagena Protocol*;
- (e) arrange for the monitoring and reporting of the effects to the environment and on human health arising from genetically modified organisms and the application of modern biotechnology within Tuvalu;
- (f) approve and implement any appropriate program of public information and education concerning genetically modified organisms and the implementation of the *Cartagena Protocol*; and
- (g) do any other act or thing necessary to manage the risks and maximise the benefits associated with genetically modified organisms and the application of modern biotechnology within Tuvalu.

(2) Where the National Competent Authority has exercised a power which concerns a matter specified in sub-regulation (1), the Director shall exercise the power specified in sub-regulation (1) in a manner which is consistent with the decision or determination of the National Competent Authority.

8. Other statutory powers not to be affected

(1) No power or requirement provided for in any other Act is to be affected by or derogated from, by any provision of these Regulations, and all approvals, permits and licences required to be obtained in relation to the importation, exportation, development, testing, release, use, storage, handling or movement of any genetically modified organism must be obtained under any applicable Act, notwithstanding that additional provision is made under these Regulations.

(2) Without limiting the generality of sub-regulation (1), any person seeking to import, export, develop, test, release, use, store or handle a genetically modified organism in Tuvalu must comply with all statutory requirements applying to the particular genetically modified organism under laws relating to –

- (a) plant and animal quarantine and disease control;
- (b) the protection of human health;
- (c) the assessment of impacts on the environment;
- (d) the use of pesticides;
- (e) the importation and exportation of fish and the development of aquaculture;
- (f) the carriage of goods by air or sea; and
- (g) the development and use of medicinal drugs;
- (h) the establishment and undertaking of business activities; and
- (i) consumer protection and the provision of product information to consumers.

PART III
PROCEDURES RELATING TO ACTIVITIES INVOLVING
GENETICALLY MODIFIED ORGANISMS (GMOs)

9. Applications for GMO activities, including transboundary movements

(1) Every person intending to import, develop, export, use in containment, use or release any GMO shall obtain approval from the Authority before importation, development, exportation, use in containment, use or release.

(2) A application given under sub-regulation (1) shall –

- (a) be in the form of the Schedule;
- (b) be accompanied by the fee set in regulation 24; and
- (c) be delivered to the Director.

(3) The Director shall acknowledge receipt of the application within 90 working days of its receipt, and the acknowledgement shall state –

- (a) the date of receipt of the application;
- (b) whether the application appears to be in compliance with sub-regulation (2)(a); and
- (c) whether an approval is required from the National Competent Authority, or that the National Competent Authority has determined that the approvals required by other applicable laws in Tuvalu shall be sufficient authorisation for the intended GMO activity, including transboundary movement.

(4) An applicant may be required to provide further information –

- (a) Where the Authority considers that an applicant is able to provide further relevant information, the Authority may, by written notice given to the applicant not later than 20 working days after the receipt of the application, require the applicant to supply such further information relating to the application as is specified in the notice;
- (b) The Authority may seek prior consent from the applicant to seek further information on the application from a source other than the applicant and charge the cost of this to the applicant;
- (c) Where the applicant fails to comply with any request made in accordance with subsection (a) of this section within 1 year after the date of the request, the application shall lapse.

(5) Any failure to acknowledge receipt in accordance with sub-regulation (3) may not be deemed to be consent to the importation of the genetically modified organism.

(6) For all GMO applications deemed by the Authority to require public input, the Authority will direct the Director to arrange for public notification of all such applications within 30 working days of receipt. The public notification will include all relevant and non-confidential information on the application and will:

- (a) be sent to each Kaupule and Falekaupule in Tuvalu to be made available at the Kaupule office in every community;
- (b) be made available at the national library in Funafuti.

(7) Within 60 days of the public notification, the Authority will direct the Director to organize a public consultation on the application. The process of public consultation will include:

- (a) A public hearing in each island of Tuvalu under the auspices of the Falekaupule and with the participation of the DOE; and/or
- (b) Written submissions on the application to be submitted within 60 days of the public notification.

10. Approvals for GMO activities

(1) Subject to regulation 13, this regulation shall apply to all GMO activities, including importation, development, exportation, use in containment, use or release, notified under regulation 9, unless the Director has given notice under regulation 9(3)(c) that the National Competent Authority, with the approval of the Council and Cabinet, has determined that other applicable laws shall constitute sufficient authorisation.

(2) Subject to sub-regulation (1), no GMO activities, including importation, development, exportation, use in containment, use or release, may be carried out Tuvalu unless approval for the activity has been given under this regulation.

(3) An approval shall only be given if there has been a demonstrable benefit to Tuvalu, and no adverse socio-economic, ethical or cultural impacts have been identified during the assessments undertaken in relation to the GMO activity.

(4) After consideration of the intended GMO activity as set out in regulation 11, the National Competent Authority shall, within 270 working days of the receipt of the notification for the proposed activity, unless a time extension has been agreed, make a decision to-

- (a) approve the GMO activity, with or without conditions;
- (b) prohibit the GMO activity;
- (c) request additional information from the applicant;
- (d) advise the applicant that the time required for the determination of the matter is to be extended by a stated period; or
- (e) defer a decision until the costs associated with the required risk assessment have been paid.

(5) No decision made by the National Competent Authority to approve an activity involving GMOs shall be effective until it is approved by the Council as the decision-making body and ratified by Cabinet. Upon ratification a permit may be issued by the Director for the GMO activity, including importation, development, exportation, use in containment, use or release.

(6) Notification of all decisions made under this regulation shall be given to the Council and to Cabinet.

(7) Reasons for any decision shall be provided to the applicant, unless the decision is an unconditional approval for the GMO activity, but a failure to give reasons shall not affect the validity of the decision.

(8) Any failure to communicate a decision in accordance with sub-regulation (4) may not be deemed to be consent to the GMO activity, including importation, development, exportation, use in containment, use or release.

11. Scientific risk assessments and socio-economic considerations

(1) Applying the precautionary principle, decisions made under regulation 10 shall be based upon risk assessments, which shall –

- (a) comply with any general requirements imposed by the National Competent Authority;
- (b) be undertaken in a scientifically sound manner taking into account internationally recognised risk assessment methodologies and techniques;
- (c) be based upon the information supplied in the application given under regulation 9, and other available scientific evidence to identify and evaluate possible adverse effects on biological diversity and risks to human health;
- (d) identify all risks and benefits relevant to the GMO activity; and
- (e) be reviewed and assessed by a Risk Assessment Review Panel appointed by the Minister, on the recommendation of the Authority.

(2) Subject to requirements imposed by the Authority, the arrangement of all risk assessments shall be the responsibility of the applicant for the GMO activity, and the costs associated with them shall be borne by the said applicant.

(3) Nothing in these Regulations prevents a risk assessment being undertaken in conjunction with any assessment required under any other Act applying to the GMO activity.

(4) The Council will consider all potential socio-economic, ethical and cultural impacts of activities involving GMOs before making any recommendations to Cabinet on the GMO activity.

12. Confidential information

(1) When giving notification under regulation 9 or providing any additional information that is required, the applicant may indicate that certain information is of a confidential nature, if it is information other than -

- (a) the name and address of the notifier;
- (b) a general description of the genetically modified organism or organisms;
- (c) a summary of the risk assessment undertaken; and
- (d) any proposed methods and plans for emergency response.

(2) If the Director is satisfied that the nature of the information justifies it being kept confidential, the information may only be provided to members of the National Competent Authority, a Technical Advisory Group, a Risk Assessment Review Panel, persons undertaking the relevant risk assessment and Environment Officers.

(3) No person to whom the information has been provided under sub-regulation (2) may disclose it to any other person, and it may not be used for any commercial purpose within Tuvalu, except with the written consent of the applicant.

(4) If the Director is not satisfied that the nature of the information justifies it being kept confidential –

- (a) the applicant shall be advised of the Director's decision;
- (b) reasons for the decision shall be provided if requested by the applicant;
- (c) the Director shall consult with the applicant if requested; and
- (d) the decision may be reviewed under regulation 14.

(5) Upon receipt of an advice under sub-regulation (4)(a) the applicant may advise the Director of the withdrawal of the application and in that event all information, documents and reports provided in support of the application shall be returned to the applicant.

13. Exemptions from the procedure

(1) The National Competent Authority may exempt any GMO activity, including importation, development, exportation, use in containment, use or release, from the need to comply with regulations 10 and 11 if the notification given under regulation 10 indicates that the genetically modified organism is –

- (a) to be in transit through Tuvalu;
- (b) to be the subject of contained use within Tuvalu;
- (c) is for direct use as food, feed or for processing;
- (d) of a type that the Parties to the *Cartagena Protocol* have agreed is unlikely to have adverse effects on biological diversity or pose a risk to human health or the environment;
- (e) of a type that the National Competent Authority, with the approval of Cabinet, has determined falls under the scope of any notification given under Article 13 of the *Cartagena Protocol*, and if all requirements of other laws are met in relation to its import into Tuvalu; or
- (f) a pharmaceutical for human consumption that is addressed by other relevant laws or agreements and subject to the control of other international organizations.

(2) The Director of Health may seek the approval of Cabinet for the importation of any pharmaceutical containing a genetically modified organism without an approval being given under these Regulations on the grounds of a medical emergency.

(3) When granting an exemption under this regulation, the National Competent Authority may impose any conditions or requirements relating to the use, storage, handling or movement of the genetically

modified organism to minimise any impact on biological diversity or risk to human health or the environment.

(4) When granting an exemption for genetically modified organisms intended for direct use as food, feed or for processing, the National Competent Authority may require that the first import of such an organism shall be subject to a risk assessment in accordance with Annex III of the *Cartagena Protocol* and approval by the National Competent Authority, and any decision in relation to that import shall be given not later than 270 working days after notification has been given –

PROVIDED THAT the failure to make or communicate a decision within 270 working days may not be deemed to be consent to the importation of the genetically modified organism.

(5) All decisions to grant exemptions under this regulation shall be referred to Cabinet, and will take effect only if ratified by Cabinet.

14. Review of Decisions

(1) An exporter or person who has given notification under regulation 9 may request the Department for the review of any decision made under these Regulations, on the grounds that –

- (a) a change in circumstances has occurred that may influence the outcome of the risk assessment upon which a decision has been based;
- (b) additional relevant scientific or technical information has become available since the decision was made; or
- (c) any other grounds that the National Competent Authority considers justify a review of the decision.

(2) Upon receipt of a request under sub-regulation (1), the Department shall respond in writing to the request within 30 days of its receipt, and shall –

- (a) provide the reasons given for the decision that is the subject of the request for review;
- (b) indicate whether a further risk assessment is to be undertaken; and
- (c) refer the matter, together with all relevant information that has been provided in support of the request, to the National Competent Authority.

(3) The National Competent Authority may review and change any decision made under these Regulations on the grounds stated in sub-regulation (1) on its own motion, and in that event the notifier shall be informed of the change of decision within 30 working days.

(4) No change of decision made under this regulation shall avoid the requirement to give notifications under regulation 11 for subsequent imports of the genetically modified organism to which the change of decision relates, or prevent the National Competent Authority from requiring that risk assessments be undertaken in relation to the subsequent imports.

(5) All decisions made by the National Competent Authority under this regulation shall be referred to the Council and to Cabinet, and will take effect only if endorsed by the Council and ratified by Cabinet.

PART IV
OTHER REGULATORY REQUIREMENTS RELATING TO
MODIFIED ORGANISMS

15. Monitoring

(1) The Authority shall, in cooperation with the relevant agencies monitor all in-country operations involving GMOs and GMO products. The Authority, in consultation with the relevant agencies shall issue guidelines for this purpose.

(2) The Authority, in consultation and coordination with the relevant agencies, Kaupule and Falekaupule,, shall coordinate to monitor the impact of GMOs and GMO products on human health and on the environment generally and on biological resources and biodiversity in particular. The Authority shall issue guidelines for this purpose.

16. Inspections

(1) An Environment Officer, as authorized under the Environmental Protection Act 2008, may, at any time, enter and inspect the facilities where any activities or operations involving GMOs and/or GMO products are being, or have been, carried out.

(2) An Environment Officer, as authorized under the Environmental Protection Act 2008, may stop and search any means of transportation (motor vehicles, boat, etc) in which any GMO and/or GMO product is being or is suspected of being treated, packed, stored, transported, or handled or in which any other operation or activity in connection with GMOs and/or GMO products is being or is suspected of being carried out.

(3) During an inspection, the owner or person in-charge of the premises or means of transportation:

(a) may accompany the Environment Officer;

(b) shall supply any information or documents requested by the Environment Officer relevant to any inspection object;

(c) shall permit the taking of samples and evidence such as photographs.

(4) Where the Authority has reasonable grounds to believe that any condition of a permit issued under this Regulation has been breached, the Authority may serve an order on the holder of the permit in question:

(a) requiring that person to remedy the breach within a specified period at his/her own cost; or

(b) suspending the permit with immediate effect if this is considered necessary to prevent or mitigate an immediate risk of significant adverse effects to the environment or to human health.

(5) Where there is a clear and present danger for human health or the environment, an Environment Officer may immediately destroy or order the destruction of GMOs and/or GMO products at the owner's cost.

(6) The Authority will coordinate with the Biosecurity Service, Department of Customs, Department of Rural Development and the Ministry of Health to prepare and issue guidelines for biosafety inspections in compliance with the Biosafety Regulations.

17. Emergency response

(1) The Authority shall, in coordination with the relevant agencies, form an emergency response team to deal with emergencies involving GMOs or for the use of GMOs in an emergency within Tuvalu. The Authority shall issue guidelines for these purposes.

(2) In the event of an emergency involving a GMO or GMO product, any person with knowledge of the emergency must immediately inform the Authority, or Kaupule and/or Falekaupule authorities who must immediately notify the Authority.

(3) In the event that an emergency may lead to an unintentional transboundary movement of a GMO that is likely to have significant adverse effects on the environment, on the conservation and sustainable use of biological resources or on human health, the Authority shall immediately notify the BCH, the potentially affected States, and any relevant international organizations.

18. Exportation of genetically modified organisms

(1) Any Applicant or Operator who intends to export GMOs and/or GMO products from Tuvalu for any purpose must first apply to the Competent National Authority of the proposed importing country according to the laws and regulations of that country. With the permission from the Competent National Authority of the proposed importing country, the Applicant must then apply to the MNRE, as the NCA for tc, for prior approval for the export, before applying to the Ministry of Finance for a trade license.

(2) All decisions made by the National Competent Authority under this regulation shall be referred to Cabinet, and will take effect only if ratified by Cabinet.

19. Transit of genetically modified organisms

(1) For GMOs in transit through Tuvalu, Operators shall apply to the Authority ninety (90) working days in advance of the beginning of the transit period, providing the following information:

- (a) name, address, and telephone contact information of the Operator;
- (b) name, address, telephone contact information of the carrier, if different from the Operator;
- (c) origin and destination of the shipment;
- (d) the identity and relevant traits and/or characteristics of the GMOs in transit;
- (e) any requirements for their safe handling, storage, transport and use; and
- (f) any other information that BAFRA may require at the time of receiving the application.

20. Direct use for food, feed or for processing

(1) 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 Authority.

(2) The Applicant must notify the Authority of the intent to import and apply for prior approval. 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 this Regulation.

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

- (a) Indicating the date of receipt of the application;
- (b) Stating whether the application for prior approval is 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.

(3) Failure by the Authority to acknowledge receipt of an application within ninety (90) working days does not constitute acknowledgement or approval of the application.

(4) Within two hundred and seventy (270) working days of the date of receipt of the application for prior approval, the Authority 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 GMO; or
- (b) Denying approval of the proposed import.

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

(6) When the Authority approves a GMO or GMO product for direct use as food or feed or for processing, it must notify the BCH within fifteen (15) working days of approval.

(7) Approval to import a GMO or GMO product for direct use as food or feed or for processing is valid for a period of one (1) year from the date of approval, unless revoked on any of the grounds set out in this regulation. Approval may be renewed for successive one-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. The Applicant must include the original approval with the application for a trade license.

PART V

OFFENCES ETC.

21. Offences

(1) Any person who –

- (a) imports a genetically modified organism into Tuvalu or is responsible for any activity in relation to genetically modified organisms including development, field testing, contained use, transit, fermentation, release or processing of GMOs in respect of which no application has been made as required by regulation 9;
- (b) fails to give any notification required by regulation 9;
- (c) fails to fully disclose all information known to be relevant to genetically modified organism in a notification or application relating to it;
- (d) carries out any activity involving GMOs in Tuvalu without having an approval required under regulation 10 or regulation 13(3);
- (e) fails to comply with any condition or requirement imposed under regulation 13(2);
- (f) fabricates any risk assessment, or misrepresents any matter associated with a risk assessment undertaken in accordance with regulation 11 or regulation 13(3);
- (g) fabricates or misrepresents any scientific or technical information relied upon for the purposes of requesting a review of any decision under regulation 14;
- (h) exports a genetically modified organism from Tuvalu in respect of which no notification has been given as required by regulation 15;
- (i) exports a genetically modified organism from Tuvalu without having an approval required under regulation 15(3) and (4);
- (j) provides any false or misleading information in relation to a notification of export given in accordance with regulation 15;
- (k) fails to obtain an approval for an activity related to the development, contained use, field testing, fermentation or processing of a genetically modified organism in accordance with regulation 18;
- (l) fails to comply with any condition, requirement or restriction applying to the development, contained use, field testing, fermentation or processing of a genetically modified organism under regulation 18;
- (m) undertakes any activity relating to a genetically modified organism when the approval required under these Regulations is suspended or has been withdrawn;
- (n) breaches regulation 19(1) in relation to an unintentional release or transboundary movement of a genetically modified organism;
- (o) breaches regulation 20 in relation to an illegal release or transboundary movement of a genetically modified organism; or
- (p) fails to comply with any other obligation or requirement imposed under these Regulations -
commits an offence and shall be liable upon conviction to a fine not exceeding \$25,000 or to imprisonment for a term not exceeding 3 years.

(2) Any person who provides false information in or for any notification given under these Regulations or when required under these Regulations to provide any information, commits an offence and shall be liable upon conviction to a fine not exceeding \$5,000.

(3) Any person who divulges or deals with confidential information contrary to regulation 12 (2) or (3) commits an offence and shall be liable upon conviction to a fine not exceeding \$500.

(4) In addition to any penalty imposed under this Regulation, an offender may be ordered to pay to or reimburse the Government the costs of any remedial action taken or needed to rectify the consequences of any breach.

22. Dealing with organisms contravening these Regulations

(1) For the purposes of enforcing the provisions of these Regulations, all Environment Officers may exercise the powers relating to investigating, monitoring, prosecuting and preventing the continuation of any breach that are vested in them in any law.

(2) In relation to any modified organism which has been imported into Tuvalu, or developed, tested, used, released, fermented or processed in contravention of these Regulations, or which is or remains in Tuvalu in breach of these Regulations or any condition applying to the organism under these Regulations, an Environment Officer may –

- (a) seize the organism;
- (b) destroy the organism as determined by the National Competent Authority or the Director; or
- (c) deliver up the organism to an officer of another Department to be dealt with in accordance with law.

(3) The cost of destroying any seized organism, and of rectifying any adverse effects from a genetically modified organism which has breached these regulations may be recovered as civil debt from any person making use of the organism in contravention of these Regulations.

(4) Nothing in these Regulations shall affect the powers to search, seize and deal with items under laws relating to plant and animal quarantine, customs and excise and any other law that has application to the development, use, handling, storage or movement of genetically modified organisms.

PART VI

MISCELLANEOUS PROVISIONS

23. Form of Notifications etc

(1) All applications for the notification of transboundary movements of genetically modified organisms into the Tuvalu required by regulation 9 shall be in the form specified in the Schedule.

(2) The National Competent Authority may require the verification by statutory declaration or any other means determined by the Authority, of any information provided in accordance with these Regulations.

24. Fees for Notifications and Applications

(1) The fee to accompany every notification or application made for an approval under these Regulations shall be as prescribed by Minister NCA subject to approval by Cabinet, which shall be additional to any other obligation under these Regulations to pay or reimburse any costs or fees.

(2) Other fees for any matter relevant to these Regulations may be set by the National Competent Authority, but shall be subject to approval by Cabinet.

25. Liability and redress

(1) No authorized official of the Government of Tuvalu shall be jointly or severally liable in respect of anything done in good faith in the exercise of a power or duty under this Regulation unless the act or omission contravenes any of the provisions of this Regulation or any direction or order made pursuant to it. The relevant agency shall be liable for paying the appropriate compensation.

(2) Any person who intentionally or negligently commits any act or is responsible for an omission involving GMOs and/or GMO products which causes damage or threatens potential harm to human health and the environment shall be liable for the costs of restoration and remediation.

(3) Issues of liability and redress arising under the Cartagena Protocol shall be applied as directed by Cabinet, taking account of the rules and procedures agreed to by the Parties.

SCHEDULE

NOTIFICATION OF TRANBOUNDARY MOVEMENT OF A GENETICALLY MODIFIED ORGANISM TO TUVALU

Annex 1 of Cartagena Protocol

1. Name, address, telephone and facsimile numbers and email address of -
 - (a) notifier or applicant
 - (b) exporter
 - (c) importer(s)(state the nature of the relationship between the notifier and the exporter or importer)
2. Name and identity of the genetically modified organism –
 - (a) Domestic classification
 - (b) Biosafety Level of genetically modified organism in the state of export
3. Purpose of the transboundary movement to Tuvalu –
 - (a) import for release
 - (b) import for contained use
 - (c) transit through the Tuvalu (if so, give full details of destination and other relevant approvals)
 - (d) direct use for food, feed or for processing(Give full details of proposed purpose and means of release, contained use, transit or use as food, feed or for processing.)
4. Intended date/s and means of transboundary movement -
5. Taxonomic status –
 - (a) Common name
 - (b) Point of collection
 - (c) Characteristics recipient organism/or parental organism
6. Centres of origin -
(Describe the habitats where the organisms may persist)
7. Describe the nucleic acid or the modification introduced -
 - (a) What was the modification technique used for the development of the organism?
 - (b) What are the resulting characteristics of the genetically modified organism?
8. Give full details of the intended use of the genetically modified organism.
9. Give full details of the quantity and volume of genetically modified organism to be transferred.
10. Has your organisation undertaken a risk assessment of the transferred genetically modified organism? (Attach any available report and all supporting information and data)
11. Give full details of proposed method(s) for –
 - (a) safe handling
 - (b) storage

- (c) transport and use
 - (d) packaging and labeling
 - (f) monitoring and reporting on effects
 - (g) disposal and emergency procedures
12. Regulatory status of genetically modified organism within the country of export –
(State any reason for any previous rejection of approval or ban of the genetically modified organism, and give full details of any breaches of any relevant law in another jurisdiction, or any criminal prosecution under such law)
13. Purpose, status and outcome of any notification by the exporter to any other country.
14. State or provide any other information known to the notifier, importer or exporter that is relevant to this application.

Ideclare that all the above information is correct.

.....
Signature

.....
Date