
# BIODIVERSITY ENABLING ACTIVITIES - DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORK PROJECT

## TONGA NATIONAL BIOSAFETY FRAMEWORK

## NOVEMBER 2004

## (DRAFT)

GEF

UNEP

Kingdom of Tonga

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Edition:

November 2004

## FOREWORD

The completion of this National Biosafety Framework (NBF) for Tonga has marked the first Enabling Activity to be successfully completed by the newly established Department of Environment. This was a coordinated effort among the National Coordinating Committee (NCC), National Executing Agency (Department of Environment), National Project Coordinator, Community Leaders and all who have contributed throughout the consultation phases.

The development of the NBF was based on the National Strategic Development Plan 7 (SDP7) of the Kingdom of Tonga which stated among the objectives to be pursued during SDP7, to prevent and minimize the degradation of the environment and misuse of resources. Therefore it is important that the NBF, Biosafety Bill and Regulations 2004 is now completed and being processed for approval prior to implementation which will ensure adequate level of protection in the field of the safe transfer, handling and use of Living Modified Organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The modern biotechnology, is not yet a practice in Tonga but it is timely to establish an NBF to ensure adequate level of protection from imported LMOs and to empower the consumer the right of choice with regards to LMOs.

This document serves as a basic guide to the implementation of the biosafety system which was prepared with input from the different ministries and several stakeholders. I would like to acknowledge the kind contribution of UNEP/GEF which has enabled the development of this NBF.

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Uilou Samani,
Director of Environment

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# INTRODUCTION

## Project Initiation

The Government of Tonga initiated the development of the National Biosafety Framework (NBF) as part of its commitment and obligations to the Convention on Biological Diversity and the Cartagena Protocol, which is in accordance with existing government policy for sustainable utilization of natural resources as stated in its current Development Plan.

The NBF project in Tonga started in January 2003 after the recruitment of Mrs Suliana Vi, National Project Coordinator and the signing of the National Project Document by Hon. J. Cecil Cocker, the Hon. Minister of Environment on behalf of the government of Tonga on 8th August 2002. The project was completed in November 2004. The National Executing Agency for the United Nation Environment Programme-Global Environment Facility (UNEP-GEF) project was the Department of Environment with the contact person as Mr Uilou Samani, Director of Environment, P.O. Box 917, Nuku'alofa, Tonga, email: uilousamani@hotmail.com, fax (676) 25 051, phone (676) 25 050. The institutions and people represented in the National Coordination Committee are listed in Annex 1.

The NBF aims to establish an enabling environment to address 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.

## NBF Components

The NBF consisted of biosafety policy and strategies, regulatory regime, system to handle notifications or requests for authorizations, monitoring and enforcement, mechanisms for promoting and facilitating public awareness, education and participation. These components were developed through 3 phases of the project: the inventory and assessment, analysis and consultation, and the drafting of the NBF.

## Project Coordination

The Cabinet established the National Coordinating Committee (NCC) in January 2003 to provide advise and guide the preparation of the National Biosafety Framework with membership from Department of Environment, Ministry of Agriculture, Forestry and Food, Ministry of Health, Ministry of Finance (Customs), Ministry of Civil Aviation, Ministry of Labour Commerce and Industries, Ministry of Fisheries, Crown Law Department and Tonga Association of Non-Government Organizations.

The NCC was tasked to develop a Tonga National Biosafety Framework to address regulatory implementation and capacity-building needs of Tonga as party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD). The Department of Environment and NCC coordinated the drafting of Framework for implementing national biosafety systems.

**Inventory & Assessment**

National Consultants conducted the biosafety inventory and assessment which is now being published by the Department of Environment. A brief summary of the findings are as follows:

- There has been a marked development in the biotechnology industry in Tonga in the past years including tissue culture;
- The practice of modern biotechnology is yet to be in Tonga;
- It is difficult to detect transboundary movements of LMOs due to limited capabilities, lack of labeling and documentation;
- There is a lack of legislation pertaining to LMOs as specified in the Cartagena Protocol; and
- Lack of general awareness on modern biotechnology and LMOs.

**Analysis & Consultations**

The analysis and consultations were conducted through national workshops conducted at Tongatapu, Vava'u and Ha'apai. The representatives from 'Eua attended the workshop conducted at Tongatapu and representatives from Niua Toputapu and Niua Fo'ou attended the workshop conducted at Vava'u. The reports of the workshops are now available from the Department of Environment. The main concerns from the workshops were capacity building and genetically modified food. The issue of capacity was addressed through the drafting of NBF, to ensure that capacity exist for the implementation, otherwise a strategy for capacity building is to be proposed in order to fulfill obligations under the Cartagena Protocol. The issue of genetically modified food is addressed by the National Codex and Alimentarius Committee hence the NBF focus only on LMOs.

**Computerisation**

An LMO database was developed under the project which can be used to register LMOs. The database will be updated by the Department of Environment. A website was also developed under the project, providing biosafety information which can be accessed as http://www.environment.gov.to/biosafety. Access to the Biosafety Clearing House (BCH) was also established, as well as supporting the BCH project. The rosters of experts was deferred to be completed during the BCH project phase as advised by the Assistant Regional Coordinator.

**Drafting of NBF**

The drafting of the NBF was conducted by national consultants which made up the Technical Working Group 3 (TWG3) of the project. The TWG3 drafted the "Follow-up Actions for Implementation of the National Biosafety Framework for Tonga" which provides the basis for the 5 components of the NBF compiled by the NPC. The NBF components were biosafety policies, regulatory regime, system to handle notifications or requests for authorisations, monitoring and enforcement, mechanisms for promoting and facilitating public awareness, education and participation. The draft NBF then provided the basis for the Biosafety Legislation, which an international consultant, Mr Graham Powell was hired to draft the Biosafety Bill and Regulations 2004. The translation, key stakeholder's consultations, technical review of the Draft NBF and Biosafety Bill and Regulations 2004 as well as development of a medium size project for the implementation of the NBF were also covered by the project.

**Project Funding**

UNEP-GEF and the Government of Tonga funded this project. Progress reports were provided on a quarterly basis for NCC and UNEP. Funds were disbursed for the project as follows:

| **Date** | **US$** |
|---|---|
| 9th August 2002 | 14,850 |
| 6th June 2003 | 25,000 |
| 7th October 2003 | 30,000 |
| 18th May 2004 | 10,000 |
| 25th August 2004 | 13,150 |
| 30 November 2004 | 6,000 |
| **TOTAL** | **99,000** |

The total amount of US$ 99,000 was received for the project which is 100% of the amount allocated for the national project. There were other assistance from UNEP/GEF such as funding of 4 participants from Tonga to attend the SIDs Sub-regional workshops in Risk Assessment/Management and Public Participation that was held in Nadi, Fiji from 18-22 February 2003, 4 participants to attend SIDs Sub-regional workshops on Regulatory Regime and Administrative System for NBF held in Trinidad from 11-14 May 2004. The consultancy fees of the Technical Adviser to review the NBF and Draft Biosafety Bill and Regulations 2004 was funded by the Global Project. Assistance were also received from the CBD Secretariat through capacity building by funding the NPC to attend to workshops on BCH held in Malaysia in February 2004 and Article 18 of the Cartagena Protocol that was held in Germany in November 2004.

# 1. BIOSAFETY POLICY

## 1.1 NATIONAL POLICY

The existing national policy is documented in the National Strategic Development Plan Seven (SDP7) which is for the period 2001-2004, which stated that one of the basic values/dimensions for the socio-economic development structure envisaged for Tonga in the near future is the:

"*Clean healthy environment and sustainable natural resources".*

This signifies the need to maintain a clean, healthy and unpolluted environment and sustainable management of the natural resources for the present and future generations is essential. In view of the fragile nature of Tonga's ecosystems: its limited land, fresh water, natural resources, and vulnerability to natural disasters. Future development must be consistent with the conservation of the environment and sustainable utilization of natural resources. The educational awareness and legislative means are to be integrated where appropriate.

One of the eleven Government Strategic Result Areas (SRA) for SDP7, states

"*Sustainable Utilization and Management of Natural Resources and the Environment" (SRA 8)*

with the following policy guidelines:

- Tonga's economic and social development policies and investments are required to be environmentally responsible. The central policy guideline is to promote environmentally sustainable development that is consistent with the priority economic and social needs of Tonga.
- Implement procedures for assessing and monitoring the environment impact of development activities
- Support environment management institutions to strengthen their capacity to anticipate, identify, assess and resolve issues of environmental protection, natural resources management and nature conservation
- Effectively integrate environmental protection into the policy and investment programmes
- Cooperate with the communities, private sector, NGOs and other stakeholders involved in utilizing the environment and natural resources to ensure that their actions facilitate environmentally sustainable forms of economic and social development,
- Ensure that local Governments give high priority to ensuring a clean healthy environment.
- To have Emergency Plans to minimize the effects of natural and manmade disasters

## 1.2 PRIORITIES

The NBF priorities developed from the 3 phases of the project are as follows:

1. **Development of Regulatory Regime**. Enforcement of the Cartagena Protocol at the national level, hence the need to develop Biosafety legislations as well as amending related existing Acts which can be incorporated at the development of NBF project.

2. **Capacity Building**. Building capacity at all levels in order to fulfill the country's obligation under the Cartagena Protocol is the priority for the implementation phase of the NBF.

3. **Interlinkages**. Linking to Biosafety Clearing House (BCH) for exchange of information with the international community should be strengthened during the add-on phase of the project through the procurement of appropriate infrastructure and training of users.

## 1.3 TARGETS

The country targets are specified in the following policies which were developed during the drafting of the NBF to be implemented during the NBF implementation phase. The details for the implementation are in the "*Follow-up Actions as Appropriate for the Implementation of the National Biosafety Framework*".

1. Protect the natural plants and animals of Tonga from accidental escape of the LMO's novel engineered gene into the wild or domesticated relative.

2. Minimise risk to biodiversity and human health from LMOs in trade.

3. Develop effective and efficient pest risk assessment for LMOs.

4. Facilitate trade while protecting the interest of the country pertaining to LMOs through effective boarder management.

5. Minimize the incidence of food borne diseases due to LMO-FFP.

6. Monitor aquatic LMOs to minimize effect on biodiversity from aquaculture practices.

7. Monitor LMOs to minimize effect on biodiversity.

8. Promote public awareness and participation through the media, and village meeting such as *faikava* and *fono*.

9. Develop, implement and enforce Biosafety regulatory regime.

## 1.4 STATUS OF RATIFICATION

Tonga acceded to the Convention on Biological Diversity (CBD) on 19th May 1998, and to the Cartagena Protocol on the 18th September 2003 which therefore entered into force on 17th December 2003 in Tonga.

## 1.5 CAPACITY BUILDING

The capacity building need pertaining to biosafety policy is mainly for training of relevant staff on biosafety policy evaluation and formulation during the implementation phase. This is particularly important as the biosafety policies are action oriented and the need to be integrated into the corporate plan of key stakeholders at the national level.

Since biosafety is a newly introduced programme, it is important to conduct meetings so that key stakeholders can share experiences and to discuss any issues that arise during the implementation phase.

# 2. REGULATORY REGIME

## 2.1 RELATED EXISTING LEGISLATION

There is no separate or independent Act that directly addressing biosafety issues, which prompts the need to incorporate the Protocol into national law either by statute or regulation. However, it is an essential task that prior implementation of the Protocol, potential and actual overlaps between obligations inherent thereto and existing laws are eliminated.

The following are the related existing legislation:

Aquaculture Management Act 2003
Fisheries Act 1989
Public Health Act 1992
Health Services Act 1991
Therapeutic Goods Act 2001
Pharmacy Act 2001
Consumer Protection Act 2000
Business Licenses Act 2002
Plant Quarantine Act 1995
Pesticides Act 2003 (Amendments)
Animal (Importation) Diseases Act 2003 (Amendments)
Noxious Weeds Act 1967
Industrial Property Act 1994
Custom and Excise Act 1994
Civil Aviation Regulation 1992

Related existing legislation pertaining to pharmaceuticals were assessed and identified as containing no provisions that overlaps or conflicts with the Protocol:

Health Services Act 1991
Pharmacy Act 2001[1]

[1] Note: Article 5 of the Protocol, states that it does not apply to pharmaceuticals that are addressed by other relevant international agreements or organizations.

The following statutory Acts have been identified as containing provisions that overlaps with articles of the Protocol[2]. They are discussed under the relevant Ministry responsible for administration of that particular Act[3].

**(1) Ministry of Fisheries**

*(a) Aquaculture Management Act 2003*

The long title of Aquaculture Management Act 2003 (hereinafter referred to as "the Aquaculture Act") states that it provides for the management and development of aquaculture in Tonga and other matters incidental thereto. Overlap between the Aquaculture Act and the Protocol are identified and discussed below.

The Aquaculture Act is limited in scope to the management and control of aquaculture[4], aquaculture products[5], and fish[6], some of which may qualify as an LMO pursuant to the definition of that term in article 3 of the Protocol.

Accordingly, there is potential overlap in the scope of the Aquaculture Act and the Protocol, should an aquaculture product or fish qualify as an LMO. The statutory power of Minister of Fisheries to manage and develop aquaculture under the Aquaculture Act, and the proposed authority of the Competent Authority to supervise the transboundary movement, handling, and transfer of LMOs will clash.

This possible clash should be eliminated to ensure that the envisaged Competent Authority will have the power to apply the Advanced Informed Agreement Procedure (hereinafter referred to as "the AIAP") pursuant to article 7, and other requirements of the Protocol to ensure its effective enforcement.

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[2] This discussion does not provide an exhaustive list of all actual and potential overlaps due to the limited time allocated for compiling this report.

[3] These are considered line Ministries that should be members of the Expert Group advising the proposed Competent Authority.

[4] Section 2(1): defines "aquaculture" as any operation involving the husbandry, cultivation, propagation or farming of fish, during the whole or part of its life cycle.

[5] Section 2(1): defines "aquaculture products" as live or dead fish which have been reared or raised or otherwise cultivated as a result of aquaculture or related activity.

[6] Section 2(1): defines fish" as any fish and includes any aquatic animal or plant, mollusc, crustacean, coral (living or dead) and other coelenterates, sponge, holothurian (beche-de-mer) or other echinoderm, and turtle, and their young and eggs

Section 29 of the Aquaculture Act is a separate provision in the Act that deals with genetically modified fish[7] (hereinafter referred to as "GMFs"). Subsection (1) prohibits the importation, possession, sale or cultivation of any GMFs without the written authorization of the Secretary for Fisheries. Subsection (2) authorizes an aquaculture officer to seize and destroy GMFs or take possession of any GMFs to determine if it is a GMF, and the cost shall be borne by the person in possession of such GMF contrary to subsection (1).

It is submitted that the possible clash between the Aquaculture Act and the Protocol discussed earlier should be reconciled by amending the Aquaculture Act. A new and separate section should be inserted to deal with LMOs in a manner similar to section 29. It would be appropriate to insert the new section immediately after section 29, possibly as section 29A.

It is essential that the proposed Competent Authority should give their written authorization, in addition to the written authorization of the Secretary for Fisheries, before the importation, sale, possession, or cultivation of an aquaculture product or fish that is an LMO. Upon an application to the Competent Authority pursuant to the proposed section 29A, the AIAP and other requirements of the Protocol could be imposed on the applicant without the need to expressly state that in the new provision.

It is recommended that the new section 29A of the Aquaculture Act should read:

| | |
|---|---|
| Section 29A | No person shall import, possess, sell or culture any living modified fish in aquaculture or related activity without the written authorization of the Secretary and the Competent Authority. |

Section 2(1) of the Aquaculture Act should also be amended inserting definitions for the terms LMOs and Competent Authority. The former should adopt its definition in article 3(g) of the Protocol, and the latter should be defined according with the definition of the same in the Biosafety Act or Biosafety Regulations that is proposed to implement the Protocol.

*(b) Fisheries Act 1989*

The long title of the Fisheries Act 1989 (hereinafter referred to as "the Fisheries Act") state that it is an Act that provides for the management and development of fisheries in Tonga and other matters incidental thereto.

[7] Section 2(1): defines "genetically modified organism" as an organism in which the genetic material has been altered.

Section 26(1) of the Fisheries Act states that it is an offence to import or export or attempt to export or import any live fish[8] into Tonga without the permission of the Secretary for Fisheries. It effectively regulates the transboundary movement of live fish, which overlaps with the Protocol where it is LMO fish being imported into or exported from Tonga[9].

The power of the Secretary for Fisheries to permit fish to be imported into or exported from Tonga pursuant to section 26(1) can be used to control the transboundary movement of LMO fish in accordance with the Protocol.

However, the Protocl is concerned not only with the transboundary movement of LMO, but also with its use and transit. Apart from section 26(1), there is nothing in the Fisheries Act that would extend the scope of the Fishereis Act to LMO fish.

However, there is a need to amend the Fisheries Act to extend its scope to LMO fish, which will enable the use of powers inherent in the Fisheries Act to the use of LMO fish once it passes the transboundary stage. Further, the term "LMO fish" should be defined in the Fisheries Act by inserting it in section 2.

**(2) Ministry of Labour, Commerce, and Industries**

(a) Consumer Protection Act 2000

The long title of the Consumer Protection Act 2000 (hereinafter referred to as "the Consumer Act") states that it is an Act that provides for the protection of the consumer[10] and for the establishment of fair trade practices and other matters incidental thereto.

The Consumer Act provides protection for consumers by setting up the Consumer Affairs Division to set approved standards with which goods[11] and services[12] must comply. Evidently, the scope of the Consumer Act is limited only to the protection of the consumer, and compliance with approved standards is required only from

[8] Section 2: defines "fish" as any aquatic animal, whether piscine or not and includes any mollusc, crustacean, coral (living or dead), sponge, holothurian (beche-de-mer) or other echinoderm, and turtle, and their young and eggs.

[9] Note: Section 27(1) of the Fisheries Act gives the Minister of Fisheries power to make regulations prohibiting or restricting the export from Tonga of any prescribed species where necessary.

[10] Section 2: defines "consumer" as a person who acquires goods or services from a manufacturer or trader.

[11] Section 2: defines "goods" as any consumer goods of whatever nature sold for valuable consideration and includes, the sale of gas, electricity, water and communications.

[12] Section 2: defines "services" to include any rights, benefits, privileges and facilities that are, or are to be provided, granted or conferred under a contract for or in relation to the performance of work etc.

manufacturers[13] and traders[14]. Any person that is not a consumer is not afforded protection under this Act.

There is potential overlap between the Consumer Act and the Protocol where an item that qualifies as a good or service under the Act is an LMO pursuant to the definition of LMOs under article 3(g) of the Protocol. Goods may be an LMO, or it may contain LMOs. On the other hand, services may be rendered that facilitates the production of LMOs. The scope of the Consumer Act extends to both cases.

There is a need to ensure that the Consumer Act recognizes and adheres to the requirements of the Protocol with respect to goods and services that are LMOs, but the Act does not contain provisions that requires this of the Consumer Affairs Division, or of manufacturers and traders. Accordingly, goods and services that qualify as such under the definitions of those terms in the Consumer Act would be subject to that Act, and the proposed Competent Authority would not have jurisdiction or authority over those goods and services.

Section 12(2) of the Consumer Act lists some of the requirements that may be imposed for purposes of setting approved standards for goods. These requirements are listed in paragraph (a) to (g) of section 12(2).

It is submitted that section 12(2) should be amended to include a requirement that if a good is an LMO, that in addition to complying with approved standards, that good must also comply with standards set by the proposed Competent Authority in accordance with the Protocol.

It is further submitted that the amendment should be done by way of a proviso, which means that all the requirements or any standards set in accordance with paragraphs (a) to (g) pursuant to section 12(2) shall be subject to the proviso, which is the requirement to comply with standards set by the Competent Authority.

*Section 12(2) as amended by insertion of the proviso should read:*

*Section 12 (2) Approved standards for goods may include requirements as to –*

*(a) performance, composition, contents, manufacture, processing, design, construction, finish or packaging of the goods;*
*(b) the testing of the goods during, or after the completion of, manufacture or processing;*
*(c) the form and content of markings, labels, warnings or instructions to accompany the goods;*

[13] Section 2: defines "manufacturers" as any person, who makes any goods, assembles or joins any goods, or adapts for sale or repairs any goods.
[14] Section 2: defines "traders" as any person carrying on business as an importer of goods for purposes of sale or supply, or an exporter of goods in pursuance of a contract of sale or supply.

*(d) equipment or accessories to be supplied with the goods;*
*(e) minimum quality or grade;*
*(f) measures that manufacturers or traders should take to ensure safe and proper handling or storage; and*
*(g) such other safety standards, measures or specifications, as are reasonably necessary to prevent or reduce risk of injury to person or damage to property or equipment.*

*Provided that if a good contains or is an LMO it must also comply with standards set by the Competent Authority.*

*The terms LMO and Competent Authority should also be defined in section 2 of the Consumer Act. This will effectively require an amendment to section 2 similar to that recommended in the discussion in* 2.2.1.

*It is submitted that a further amendment to the Consumer Act is required because section 12(2) only applies to goods, whereas the scope of the Act extends to both goods and services.*

*Section 26 of the Consumer Act imposes a warranty on provision of services by a trader to a consumer that it is shall be rendered with due care and skill and that materials supplied shall be fit for purpose supplied for, and other requirements. The provision of such services may relate to LMOs.*

*Accordingly, section 26 should be amended to ensure that where LMOs are involved in any manner in the provision of services, that the Competent Authority should have authority to deal with those LMOs.*

*It is submitted that section 26 should be amended by inserting a proviso at the end of that section.*

*Section 26 as amended should read:*

*Section 26* *(1) In every contract for supply of services by a trader to a consumer there shall be an implied warranty that the services shall be rendered with due care and skill and that any materials used or supplied in connection with those services shall be reasonably fit for the purpose for which they are used or supplied.*

*(2)Where a trader supplies services to a consumer in the course of a business and the consumer, expressly or by implication, makes known to the trader any particular*

*purpose for which the services are required or the results he desires the services to achieve, there is an implied warranty that the services supplied under the contract for the supply of the services and any materials supplied in connection with those services shall be reasonably fit for that purpose or are of such nature and quality that they might reasonably be expected to achieve that result, except where circumstances show the consumer does not rely, or that it is unreasonable for him to rely, on the trader's skill or judgment.*

*(3) In this section, services include services by way of -*

*(a) the construction, maintenance, repair, treatment, processing, cleaning or alteration of goods; or*

*(b) the distribution of goods; or*

*(c) the transportation of goods.*

*Provided that where a service involves LMOs that the approval of the Competent Authority is obtained before that service is rendered.*

*The amendments to the Consumer Act purposely ensures that the Competent Authority will be able conduct the AIAP and comply with other requirements of the Protocol in respect of goods and services that are LMOs, or contain LMOs.*

(b) Business Licenses Act 2002

*The long title of the Business Licenses Act 2002 (hereinafter referred to as "the Licenses Act") states that it is an Act providing for the licensing of business activities.*

*Section 4 of the Licenses Act states that every person carrying on a business shall hold a valid license. Hence, it is in contravention of this Act to operate or exercise a business without a license.*

*The proposed Competent Authority could use section 4 by taking advantage of the line Ministry of Labor, Commerce, and Industries' power to administer the Act. It could monitor the transboundary movement of LMOs to and from, and the use of LMOs within Tonga by these businesses. When an application is lodged for a business license, the line Ministry can assess whether or not the nature of that particular business involves LMOs, and issues surrounding the Protocol.*

*Accordingly, section 4 should be amended giving the licensing authority the power to monitor the transboundary movement and use of LMOs by licensed businesses. The proposed amendment could include a requirement that the onus lies on the applicant to prove that their business does not involve the transboundary movement and use of LMO. If it does, then it must prove that it has complied with relevant requirements of the Protocol.*

**(3) Ministry of Health**

(a) Public Health Act 1992

*The long title of the Public Health Act 1992 (hereinafter referred to as "the Public Health Act) states that it deals with public health services in Tonga.*

*Neither the term "public health" nor "services" are defined in the Public Health Act, which effectively widens its scope. Arguably, the powers inherent in the Public Health Act are limited to matters expressly stated therein. The Public Health Act is divided into several parts each dealing with a specific aspect of public health, namely food[15], food premises, food hygiene, water supply, waste disposal, sanitary facilities, air pollution, noise pollution, port health, notifiable diseases, health and safety at work, hairdressers and beauticians, and cemeteries (hereinafter referred to as "public health matters").*

*There is potential overlap between the Public Health Act and the Protocol where public health matters relate to LMOs. For example, certain types of food contain LMOs, which bring that specific food item under the provisions of the Public Health Act.*

*However, as evident from Part III (A) of the Public Health Act, which deals with food, its concern is limited to hygiene and quality. It is concerned with types of food that is injurious to health, but not all food that contains LMO is injurious to health. The concerns of the Protocol may be more extensive. Accordingly, there is a need to amend the Public Health Act to ensure that the concerns of the Protocol are addressed where public health matters relate to LMOs.*

*It is recommended that the Public Health Act is amended by inserting a new and separate Part that deals specifically with LMOs where it overlaps with public health matters. This would be appropriate given the format of the Public Health Act. The new Part may be inserted as Part XIII (A) immediately after Part XIII dealing with cemeteries and before the Part XIV that deals with repeal and savings.*

*Accordingly, if a public health matter also deals with LMO issues, it will be dealt with under the new Part. The requirements of the Protocol should be incorporated to that Part of the Public Health Act.*

[15] Section 3: defines "food" as any article manufactured, sold or represented for human consumption, and includes drink, chewing substances, and any ingredient, food additive or other substance that enters into or is capable of entering into or is used in the composition or preparation of food.

(b) Therapeutic Goods Act 2001

The long title of the Therapeutic Goods Act 2001 (hereinafter referred to as " the Therapeutic Goods Act") states that it establishes a system to regulate therapeutic goods as well as a national drugs and medical supplies committee, and regulates the import, quality, availability and use of registered therapeutic goods.

The scope of the Therapeutic Goods Act extends only to therapeutic goods[16], which are registered in the Tongan Registered List of Medicinal Drugs. The importation, distribution, prescription and sale of a medicinal drug are prohibited unless it is listed in the said list.

There is possible overlap between the Therapeutic Goods Act and the Protocol if therapeutic goods listed in the Tongan Registered List of Medicinal Drugs (or others that the Act applies to) are LMOs or contain LMOs.

Specific sections of the Therapeutic Goods Act conflicts with articles and requirements in the Protocol. For example, section 8 of the Therapeutic Goods Act sets out the procedure for application to include a drug in the Tonga Registered List of Medicinal Drugs allowing that particular drug to be imported into Tonga. This procedure is similar to an application under the Protocol for intended transboundary introduction of an LMO. However, section 8(6) of the Therapeutic Goods Act states that a decision of the Committee[17] on an application pursuant to section 8 shall be final. On the other hand, article 12 of the Protocol allows the review of decisions subject to specific requirements.

Some sections of the Therapeutic Goods Act contain similar requirements with those contained in the Protocol. For example, section 23 of the Therapeutic Goods Act contains labeling requirements, which are essential before therapeutic goods or medicinal drugs are dispensed to any person. This is similar to article 18 of the Protocol, which deals with the safe handling, transport, packaging, and identification of LMOs.

Accordingly, whilst some sections of the Therapeutic Goods Act conflicts with article or requirements of the Protocol, there are some sections of that Act that contain similar requirements to those contained in the Protocol.

It is recommended that the Therapeutic Goods Act should be amended by inserting a new and separate Part in that Act to deal with therapeutic goods that are LMOs or contain LMOs. This Part should be inserted just before Part VII, preferably as Part VI (A). It

[16] Section 2: defines "therapeutic goods" as including medicinal drugs and products, herbal medicines other than those prepared by traditional Tongan healers, therapeutic devices, goods for use as an ingredient in the manufacturer of medicinal products and therapeutic devices, and goods for use as container or part of a container for goods, but not goods the principal use of which is cosmetic.

[17] Section 4(1) of the Therapeutic Goods Act establishes the National Drugs and Medical Supplies Committee to be responsible for the administration of this Act.

should effectively ensure that where there is overlap between the Therapeutic Goods Act and the Protocol, requirements in the Protocol must be complied with as requirements additional to those contained in the Act.

It is further recommended that section 8(6) of the Therapeutic Goods Act, which states that decisions of the Committee shall be final, should be amended. This requirement directly conflicts with article 12 of the Protocol, which allows for decisions by the party of import regarding LMOs to be reviewed. Section 8(6) should be amended by inserting a proviso at the end of that section imposing a requirement that decision regarding medicinal drugs or therapeutic goods that are LMOs or contain LMOs, could be reviewed.

*Section 8(6) of the Therapeutic Goods Act, as amended should read:*

> *Section 8(6) The decision of the Committee under this section should be final.*
>
> *Provided that where the medicinal drug is an LMO, or contain LMOs, the decision may be reviewed in accordance with Part VI (A) of this Act*[18].

**(4) Ministry of Agriculture, Forestry and Food**

Plant Quarantine Act provides that ***inter alia*** –

- all person entering Tonga must make a declaration in the form prescribed by the Minister;
- any plant, plant material or other regulated articles importing to Tonga must require a prior written permit issued by the Minister; and
- all importations of living plants and plant material must be accompanied by a phytosanitary certificate.

**Proposed amendment**

*A provision(s) on LMOs which demand compliance with the Biosafety Bill*

Pesticides Act provides that ***inter alia –***

- prior manufacturing in, importation into or used, offered for sale, sold or distributed of pesticides, the same must be registered ; and
- all containers containing pesticides must be clearly and durably labeled including "the nature and formulation of the pesticide" and the brand name and percentage by weight of all active chemical ingredients.

**Proposed amendment**

*A provision(s) on LMOs which demand compliance with the Biosafety Bill*

Animal Diseases Act provides that ***inter alia*** –

- the control of animal diseases;
- the quarantine grounds for the detention of imported animals;
- the restrictions on importation of specific animals; and

[18] Part VI (A) should contain the procedure for review as set out in article 12 of the Protocol.

- the prohibition on importation or liberation of certain animals with prescribed conditions.

**Proposed amendment**

*A provision(s) on LMOs which demand compliance with the Biosafety Bill*

**(5) Ministry of Civil Aviation**

**Civil Aviation Regulations 1992.** It provides the procedures for the carriage of dangerous goods. Dangerous goods is defined as any article or substance which capable of posing significant risk to health, safety or property when carried by air and which classified in the Technical Instructions.

**Proposed amendment**

*It is recommended that under Regulations made under Biosafety Bill, a provision on Transportation be inserted to address that the procedures for the transboundry of LMO must comply with the same procedures on carriage of dangerous.*

**(6) Customs and Excise Department**

It is suggested that an agreement on cooperation in the field of GMO between the Competent Authority and Customs in providing a clear and simple guidelines on the procedures and documentation needed under the Protocol concerning GMO import and export

## 2.2 *PROPOSED STATUTORY AMENDMENTS*

The following lists a summary of statutory amendments proposed in the discussion of relevant existing laws in 2.1:

**1. Aquaculture Management Act 2003**

- Insert section 29A as separate section to deal with LMOs
- Insert definition of "LMOs" in article 3(g) of Protocol in section 2(1) of Act
- Insert definition of "Competent Authority" in section 2(1) of Act

**2. Fisheries Act 1989**

- Amend Act to extend scope to LMO fish.
- Insert definition of "LMOs" in article 3(g) of Protocol in section 2(1) of Act
- Insert definition of "LMO fish" in section 2 of Act
- Insert definition of "Competent Authority" in section 2(1) of Act

**3. Consumer Protection Act 2000**

- Insert proviso in section 12(2) to incorporate requirements of the Protocol
- Insert definition of "LMOs" in article 3(g) of Protocol in section 2 of Act
- Insert definition of "Competent Authority" in section 2 of Act
- Insert proviso in section 26 to empower Competent Authority to deal with goods and services that are LMOs

**4. Business Licenses Act 2002**

- Amend section 4 to give power to licensing authority to ensure applicant comply with the Protocol
- Insert definition of "LMOs" in article 3(g) of Protocol in section 2 of Act
- Insert definition of "Competent Authority" in section 2 of Act

**5. Public Health Act 1992**

- Insert Part XIII (A) to deal with LMOs where there is overlap between the Protocol and Act
- Insert definition of "LMOs" in article 3(g) of Protocol in section 3 of Act
- Insert definition of "Competent Authority" in section 3 of Act

**6. Therapeutic Goods Act 2001**

- Insert Part VI (A) to deal with LMOs where there is overlap between the Protocol and the Act
- Insert proviso in section 8(6) allowing for decisions regarding LMOs to be subject to review
- Insert definition of "LMOs" in article 3(g) of Protocol in section 2 of Act
- Insert definition of "Competent Authority" in section 2 of Act

## 2.3 DRAFTING BIOSAFETY LEGISLATION

Based on the assessment of related existing legislation, drafting a biosafety legislation was identified as a priority and this project has enabled the drafting of a Biosafety Bill with regulations to regulate the transboundary movements of LMOs.

The Bill is expected to be tabled in the 2005 session of parliament. Once the Bill is approved, the regulations will then be processed for approval then the next phase will be the implementation. This will be made available through the BCH and project web-site once approved.

## 2.4 INTERNATIONAL OBLIGATIONS

In the international law and in principle, Tonga as a contracting State to the Cartagena Protocol, must consider continuously its international obligations in other international conventions and protocols related to biosafety to avoid any infringements and contradictions. Therefore these are some of the international instruments that requires some attentions to:

**(a) Codex Alimentarius**

The Codex Alimentarius Commission is the internationally recognized standards setting body for food safety. The objective of Codex standards is to protect the health of consumers and ensure fair practices in food trade. It is as much concerned about protecting the health of consumers as in protecting them from deceptive trade practices

**(b) International Plant Protection Convention (IPPC)***

The IPPC seeks to prevent the spread (and introduction to new countries) of pests of 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 and represent 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 guarantee the transparency of animal diseases throughout the world and the member states are required to report diseases that are current in their territories, including diseases that may be transferred to humans (mad cow disease). Further the OIE has the responsibility to guarantee the sanitary safety of world trade by developing rules for trade in animals and animal products that are recognized 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 provides the right of countries to take measures that consider necessary to protect plant, animal and human life and death. Such measures must be:

(i) scientifically justified;
(ii) based on an assessment of risks and no more than necessary; and
(iii) non discriminatory and do not constitute a disguised restriction on trade.

The SPS's emphasis is on scientific justification, risk assessment and consistency of approach to the determination of national measures. Further it must conform with 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.

**(e) Agreements on Technical Barriers to Trade**

The Technical Barriers to Trade (TBT) is relevant to biotechnology products because it applies to technical regulations and standards, including packaging, marking and labeling requirements. Member states are obliged to take appropriate measures to ensure the quality of its exports; to protect human, animal or plant life or health, of the environment. TBT's legitimate objectives include preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or 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 to share the benefits 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 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 the new varieties of plants by an intellectual property rights, specially adapted for the process of plant breeding and has been developed with the aim of encouraging to develop new varieties of plants.

**(i) World Trade Organisation (WTO)***

Given that Tonga is intended to be a member of the WTO in the future and the trade related nature of the Protocol, as Party to the Protocol there is a need to take into account aspects of both regimes when regulating the transboundary movement of LMOs.

**(j) Convention on Biological Diversity (CBD)**

It addresses biodiversity issues. It provides a comprehensive approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of generic resources. One of the issues addressed by the Convention is Biosafety. Biosafety refers to :

(i) the need to protect human health; and

(ii) the environment from the possible adverse effects of the products of modern biotechnology.

**Cartagena Protocol (CP)**

It provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry. Further it creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to

offer, while minimizing the possible risks to the environment and to human health.

In the Protocol, Modern biotechnology is defined as *the application of vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

Tonga has ratified both the CBD and CP and therefore is bound by those international obligations laid down under the same. In principle, Tonga must honour the provisions of the Convention and the Protocol by implementing the same at the national level, by enacting the appropriate regulatory regime to have the jurisdiction to apply and enforce those provisions of the same. It is important to note that when the regulatory regime is drafted, it must take into consideration those international legal instruments* that Tonga is yet a Party to them.

## 2.5 CAPACITY BUILDING

The capacity building during the drafting stage of the National Biosafety Framework contributed greatly towards the successful completion of a biosafety legislation in Tonga. It is important that such support will be strengthened during the implementation phase in order to upgrade legal capabilities and to share experiences on the implementation of the Biosafety legislation.

# 3. SYSTEM TO HANDLE NOTIFICATIONS OR REQUESTS FOR AUTHORISATION

## 3.1 EXISTING SYSTEM

There is an existing system for importation of aquatic GMOs but not specifically for LMOs. However, to handle notification and requests for permit on living organisms, the following departments: MAFF, Ministry of Fisheries, Ministry of Labour, Commerce and Industries, and Customs Department are responsible for all importation/exportation of living plants and animals.

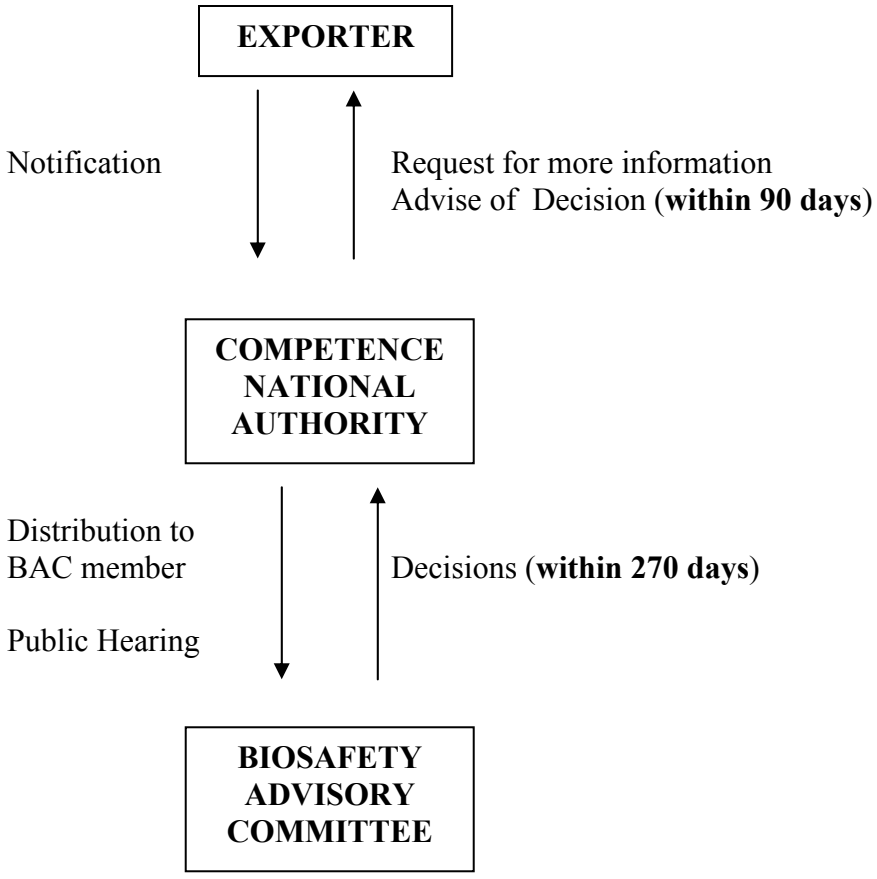
The Ministry of Fisheries have regulate the import of Aquatic GMOs under its Aquaculture Management Act 2003 which authorised the Secretary for Fisheries to issue the permit for import prior to shipment of aquatic GMOs. The Aquaculture Advisory Committee (AAC) provide the advise to the Secretary for Fisheries. The AAC membership consisted of Ministry of Fisheries, Department of Environment, Ministry of Labour, Commerce and Industries, Ministry of Marine & Ports and 3 representatives from the aquaculture industry.

## 3.2 PROPOSED SYSTEM

Department of Environment is the Competent National Authority (CNA), and the Director of Environment is the Focal Point. The NCC will form a Biosafety Advisory Committee (BAC) to provide advise on issues concerning prior notification for transboundary movements of LMOs.

The procedures for handling notification and requests for permits have been developed based on the first 2 phases of the project, as well as consultations during the drafting stage. Therefore, the proposed system complements the current notification system. It is recommended that the proposed system be reviewed in every five years since any change(s) in the notification system will have an impact on the proposed system for notifications and request for permits.

**Fig.1 System for Handling Notifications and requests for permits**




The exporter is to complete the application form (Annex 2) and submit it to the CNA. The CNA will check the completion of information required for decision making and get back to the Exporter for more information if needed, within 90 days. Once the information required is completed, the CNA will refer the application to BAC to process recommendation(s). Public consultations on the application will be conducted prior to recommendation of BAC to CNA. The CNA will then pass on its decision to the appropriate authority that issue the permit to convey to exporter within 270 days.

The membership of the BAC is to be selected from Department of Environment (Chair & Secretariat), Ministry of Agriculture, Forestry and Food, Ministry of Fisheries, Ministry of Health, Ministry of Labour, Commerce and Industries, Ministry of Finance (Customs), Tonga Association of Non Government Organisation, Chamber of Commerce and District Officer (alternate). The following are to be co-opted members: Ministry Marine & Ports, Crown Law Department, Ministry of Foreign Affairs and Ministry of Lands & Survey.

## 3.3 CAPACITY BUILDING

In implementing the system to request for permit, it is important to conduct: meetings to share experiences, trainings at all levels to upgrade knowledge and skills of relevant staff who contributed towards decision making of the National Competence Authority, and to procure relevant equipments.

# 4. MONITORING AND ENFORCEMENT

The use of monitoring in this report refers to evaluating of actual impacts on the environment and human health whereas enforcement typically focuses on compliance with the regulatory regime.

## 4.1 EXISTING MONITORING & ENFORCEMENT

The existing system for monitoring of any live organism that was imported from overseas is to be carried out by the line ministries as follows:

### 4.1.1 Department of Environment

The Technical and Sustainable Development Division is responsible for all aspects of environmental management. One of its key responsibilities is to conduct research and assessment of potential environmental impacts.

### 4.1.2 Ministry of Health

The Ministry is responsible for food safety through inspection services such as food inspection, food premises inspection, condemn of food that is not fit for human consumption, investigate food borne diseases and food related complaint.

### 4.1.3 MAFF

Tonga Quarantine & Quality Management Division (QQMD) of the Ministry of Agriculture, Forestry and Food (MAFF) is the national competent authority and or contracting member of the FAO for the IPPC, OIE and CODEX. All policies and working procedures of the MAF QQMD are in compliance with the IPPC, OIE (International Office of Animal Health & Diseases) and FAO/WHO Codex (Food Safety Guidelines).

### 4.1.4 Ministry of Fisheries

Ministry of Fisheries is collaborating with MAFF QQMD in implementation of the FAO guidelines and international standards for the living marine organisms.

### 4.1.5 Ministry of Labour, Commerce and Industries

Tonga Trade of MLCI will continue to monitor impact on trade related impact of the introduced LMOs

### 4.1.6 Ministry of Finance (Customs)

There is no existing proceeding for unintentional transboundary movements of LMOs. Customs collaborate with other agencies like Quarantine Division of the Ministry of Agriculture for clearance of living plants and animals to enter the country.

The existing proceedings for emergency with regards to importation of illegal goods, the custom department of the reporting country notified the Head of Customs in Tonga who will then give direction to appropriate custom's officer for action. Other authorities such as Police Department are brought in after the illegal goods is seized. The process is based on which authority is doing the notification from the reporting country. The Police Department will report to the Police Department in the importing country and likewise if it is the Customs Department.

To ensure that all incoming goods comply with Customs & Excise Act 1984, the Custom departments are at the port of entry namely the airport and wharf to conduct the following proceedings:

(1) **Passenger processing**. This is conducted in collaboration with the MAFF - Quarantine at the airport luggage claim lounge prior to passenger from international flight exiting. This service is only provided at Fua'amotu Airport.

(2) **Cargo Inspection**. This is conducted in collaboration with the MAFF Quarantine in Customs Shed at the Wharf prior to clearance of overseas cargo. This service is provided at Queen Salote Wharf at Tongatapu and Neiafu Wharf of Vava'u.

(3) **Yacht Clearance**. All incoming yachts contact the Customs Boarding Officer and they are directed to a landing place where the officer will come onboard the ship for clearance. That is inspecting his papers from his last port of call and searching for any prohibited/restricted goods carried by the vessel. This service is provided at Queen Salote Wharf at Tongatapu and Neiafu Wharf of Vava'u. The Sub-Treasurer of Ha'apai, 'Eua, Niua Toputapu and Niua Fo'ou are responsible for yacht clearance in absence of Custom Officers.

(4) **Alert System**. An Alert system can set up under existing harmonization programme to provide signal on suspected LMOs which can then be verified later.

## 4.2 PROPOSED MONITORING AND ENFORCEMENT SYSTEM

As a result of the first 2 phases of the project, it was concluded that the line ministries involved in the existing system is to provide monitoring and enforcement of LMOs under their existing jurisdiction. This involves the Department of Environment, Ministry of Fisheries, MAFF, Ministry of Labour, Commerce and Industries, and Ministry of Health. Since this is a new extension for the existing services, there is a need for capacity building both at the technological capability and training.

In the case where the Biosafety Clearing House is aware of any unintentional transboundary movement of LMOs to Tonga without any approval, the BCH can contact directly to the Customs Department and copied to CNA who will handle the matter in accordance with specified guidelines.

## 4.3 CAPACITY BUILDING

There is a need to conduct: meetings to share experiences during the implementation phase, specific trainings at all levels to upgrade skills and knowledge of relevant staff for monitoring and enforcement, and to procure relevant equipments in order to fulfill Tonga's obligations under the Cartagena Protocol.

# 5. MECHANISMS FOR PROMOTING AND FACILITATING PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

## 5.1 EXISTING PROGRAMMES

There are no existing public awareness programmes apart from that currently implemented since the beginning of the NBF project including TV/Radio programme, brochures, newsletters etc. However, because of the existence of the NBF project and the capacity building that it has provided to members of the key stakeholder groups, the biosafety public awareness programmes were integrated to existing programmes of other sectors.

## 5.2 PROPOSED MECHANISMS

The following proposed mechanisms for promoting and facilitating public awareness, education and participation is to complement the other components of the framework.

### 5.2.1 Public Participation in Collaboration with NGOs

The NGO have been very active in community environmental programme which involve awareness through the village meeting including *faikava* and *fono*. NGO will continue to play this important role during the implementation of the framework.

### 5.2.2 Consultations

Relevant communities will be consulted prior to decision making regarding the import of any LMOs

### 5.2.3 National BCH

Data will be entered into the national BCH then transferred to the international BCH. This is more cost effective.

### 5.2.4 LMO Register

At present, there are no known LMO in Tonga due to lack of documentation of imported goods as well as capacity for detection. However, as the Cartagena Protocol have entered into force, Once a new LMO is approved, the LMO register will be updated by the Department of Environment and a list will be distributed to all key stakeholders and made available to the public through the media for information.

### 5.2.5 Website

The Biosafety website designed during the development of the NBF phase will be updated by the Department of Environment, keeping the international stakeholders informed of Biosafety related developments. The Biosafety website can be viewed at http://www.environment.gov.to/biosafety .

## 5.3 CAPACITY BUILDING

The capacity building during the drafting stage of the NBF contributed a lot in upgrading knowledge and skills. It is important that such support continue, especially in training at all level on how to access information in the BCH, training on the use of media to share biosafety information and to procurement relevant IT for public awareness and communication.

**Annex 1**

**Institutions and People Represented in the National Coordination Committee**

| | | |
|---|---|---|
| Department of Environment | - | Mr Uilou Samani<br>Director of Environment |
| | - | Mrs Suliana Vi<br>National Project Coordinator |
| Ministry of Agriculture, Forestry & Food | - | Mr Sione Foliaki<br>Deputy Director of Agriculture (Quarantine) |
| | - | Dr Viliami Manu<br>Deputy Director of Agriculture (Food) |
| Ministry of Labour Commerce & Industries | - | Dr Ha'unga Petelo<br>Deputy Secretary for Labour (Tonga Trade) |
| Ministry of Finance | - | Mr Sione Likiliki<br>Deputy Commissioner of Revenue (Customs) |
| Ministry of Fisheries | - | Mr 'Ulunga Fa'anunu<br>Deputy Secretary for Fisheries |
| Ministry of Civil Aviation | - | Mr Tevita Havea<br>Principal Legal Adviser |
| Ministry of Health | - | Mr Niutupuivaha Fakakovi<br>A/Supervising Public Health Inspector |
| Tonga Association of Non-Government Organisation | - | Mr Simione Silapelu<br>The President |

**Annex 2**

## NOTIFICATION OF TRANBOUNDARY MOVEMENT OF A LIVING MODIFIED ORGANISM TO THE KINGDOM OF TONGA

*From Annex 1 of Cartagena Protocol*

1. Name and address of -
   a. notifier
   b. exporter
   c. importer

   (state the relationship between the notifier and exporter, if applicable)

2. Name and identity of the LMO -
   a. Domestic classification:
   b. Biosafety Level of LMO in the state of export:

3. Purpose of the transboundary movement to the Kingdom of Tonga –
   a. import for release
   b. import for contained use
   c. transit through the Kingdom of Tonga (if so, give full details of destination and other relevant approvals)
   d. direct use for food, feed or for processing

4. Intended date/s 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 technique used for the modification?
   b. What is the resulting characteristics of the living modified organisms?

8. The intended use of the Living Modified Organism -

9. Quantity and volume of LMO to be transferred -

10. Has your organisation undertaken a risk assessment of transferred LMO? (Attach any available report and supporting information and data)

11. What are your proposed method/s for –
    a. safe handling

b. storage
c. transport and use
d. packaging
e. labeling
f. documentation
g. disposal and contingency procedures

12. Regulatory status of LMO within the country of export –
(State any reason for the banning of the LMO is applicable)

13. Purpose, status and outcome of any notification by the exporter to other countries -

14. Any other information known to the notifier or exporter that is relevant to this application -

I ……declare that all the above information is correct.

…… ……..
Signature Date